Optimising the care and treatment pathways of older patients facing major gastrointestinal surgery

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Date of submission: September 2021

A thesis submitted for the degree of Doctor of Medicine

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Declaration

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Acknowledgements

This project would not have been possible without the dedicated support and encouragement of a number of people. In particular, Professor Lynda Wyld, my primary supervisor, has supported me at every step of this project and never wavered in her belief that I could see it through to completion. I would also like to thank my second supervisor, Professor Steve Brown, for his expertise, guidance and for introducing me to a number of collaborators.

I am grateful to all the healthcare professionals who took the time out of their busy schedules to participate in the interviews and respond to the questionnaires. Their open and honest responses have enabled a thorough exploration of what current practice is.

I would also like to thank all the patients who have participated in the observational study so far. Giving up their time to fill in questionnaires and answer questions will hopefully enable us to improve practice for future patients in their situations.

I must also thank my funders, Bowel Research UK and BASO, for supporting me in this project. The work in this thesis would not have been possible without their support. In addition, I would like to thank the NIHR clinical research network.

In particular, I would also like to thank:

- Professor Susan Moug for sharing her knowledge and enthusiasm for this area of surgical research
- Caroline Steele for her brilliant work with patient recruitment and Debby Hawkins for guiding me through the ethics applications and regulatory aspects
- Matt Lee for methodological support and constant encouragement
- Jenna Morgan for her mixed methods knowledge and guidance

Finally, to my partner, Jamie and son, Benji for their support, patience and for highlighting the important things in life.

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Funding

This project has been supported by two educational grants:

Bowel Research UK grant (formerly Bowel Disease Research Foundation (BDRF))

- Title: Optimising the care and treatment pathways for older patients facing major gastrointestinal surgery (OCTAGON)
- £8,647 awarded February 2019
- Co-investigators on grant: Prof Steve Brown, Prof Lynda Wyld, Dr Caroline Mitchell, Dr Maria Burton, Mr Matt Lee
- The grant application, award letter and re-submitted grant application can be found in Appendices A, B and C respectively

British Association for Surgical Oncology~the Association of Cancer Surgeons (BASO~ACS) grant

- Title: Optimising the Care and Treatment Pathways for Older Patients with colorectal cancer
- £2000 awarded February 2019
- Co-investigators on grant: Prof Lynda Wyld, Prof Steve Brown, Dr Caroline Mitchell, Dr Maria Burton
- The grant application and award letter can be found in Appendices D and E.

Salary costs were provided by appointment to a Clinical Research Fellow role at Sheffield Teaching Hospitals NHS Foundation Trust.

Acknowledgement of the role of others in this work

The project steering group and co-authors have been involved in the design, planning, analysis and dissemination of this work. Co-authors have been involved in the preparation of manuscripts and grant applications.

The research co-ordinator at Sheffield Teaching Hospitals, Dr Debby Hawkins, has been involved in the IRAS applications, study set-up, monitoring and reporting.

The clinical trials assistant at Sheffield Teaching Hospitals, Miss Caroline Steele, was involved in the recruitment of patients to the OCTAGON study and inputting data into the Research Electronic Data Capture (RedCap) system.

Publications arising directly from this thesis

1. **Daniels SL**, Lee MJ, George J, Kerr K, Moug S, Wilson TR, Brown SR, Wyld L. Prehabilitation in elective abdominal cancer surgery in older patients: a systematic review and meta-analysis. 22/9/20 BJS Open DOI:10.1002/bjs5.50347
2. **Daniels SL,** Lee MJ, Moug S, Wilson TR, Burton M, George J, Brown SR, Wyld L. Protocol for a multi-centre observational and mixed methods pilot study to identify factors predictive of poor functional recovery after major gastrointestinal surgery and strategies to enhance uptake of peri-operative optimisation: Optimising the Care and Treatment pAthways for older patients facing major GastrOiNtestinal surgery (OCTAGON). Colorectal diseases DOI:10.1111/CODI.15603
3. **Daniels SL,** Burton M, Lee MJ, Moug S, Kerr K, Wilson TR, Brown SR, Wyld L. Healthcare professional preferences in the health and fitness assessment and optimisation of older patients facing colorectal cancer surgery. Colorectal Disease 2021;00:1-10. DOI: 10.1111/codi.15758

Published abstracts arising directly from this thesis

1. **Daniels SL,** Lee ML, Burton M, Moug S, Morgan J, Wilson T, Brown S, Wyld L. National survey of surgeon practice in the assessment and optimisation of older adults facing major gastrointestinal surgery. Published abstract. EJSO Supplement 2020
2. **Daniels SL**, Lee ML, Burton M, Moug S, Wilson T, Brown S, Wyld L. Semi-structured healthcare professional interviews to explore their preferences for the treatment and optimisation of older adults facing major gastrointestinal surgery. Published abstract. EJSO Supplement 2020.

Presentations arising directly from this thesis

1. **Daniels SL,** Lee ML, Burton M, Moug S, Morgan J, Wilson T, Brown S, Wyld L. National survey of surgeon practice in the assessment and optimisation of older adults facing major gastrointestinal surgery. Poster presentation at BASO conference November 2020
2. **Daniels SL,** Lee ML, Burton M, Moug S, Wilson T, Brown S, Wyld L. Semi-structured healthcare professional interviews to explore their preferences for the treatment and optimisation of older adults facing major gastrointestinal surgery. Poster presentation at BASO conference 2020

Publications arising indirectly from this thesis

1. Pearson I, Blackwell S, Fish R, **Daniels S,** West M, Mutrie N, Kelly P, Knight S, Fearnhead NS, Moug S. Defining Standards in Colorectal Optimisation (DiSCO): a Delphi study protocol to achieve international consensus on key standards for colorectal surgery prehabilitation. BMJ Open 2021; 11:e047235. Doi:10.1136/bmjopen-2020-047235
2. **Daniels S,** Elanko A, Court S, O'Flynn P, Wyld L. RCS Senior Clinical Fellowship Survey: motivations, outcomes and cost of senior surgical fellowships. Bulletin of the Royal College of Surgeons of England. DOI: 10.1308/rcsbull.2020.1

Abbreviation list

ADL	Activity of daily living
ASA	American College of Anaesthesiologists
AHP	Allied Health Professional
AT	Anaerobic Threshold
AUGIS	Associated of Upper GastroIntestinal Surgeons
BASO	British Association for Surgical Oncologists
BDRF	Bowel Disease Research Foundation
BMI	Body Mass Index
BPT	Best Practice Tariff
CCT	Certificate of completion of training
CD	Clavien Dindo classification
CFS	Clinical Frailty Scale
CGA	Comprehensive Geriatric Assessment,
CI	Chief Investigator
CNS	Clinical Nurse Specialist
COREQ	Consolidated criteria for reporting qualitative research
CPET	Cardiopulmonary exercise testing
CPOC	Centre for Perioperative Care
CQC	Care Quality Commission
DCE	Discrete Choice Experiment
DSS	Disease Specific Survival
ECOG	Eastern Cooperative Oncology Group
ERAS	Enhanced Recovery After Surgery
ERB	Enhanced Recovery Bed
ESMO	European Society for Medical Oncology
EORTC QLQ-C30	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire
GDPR	General Data Protection Regulations
GI	Gastrointestinal
GIQLI	Gastrointestinal Quality of Life Index.

GIRFT	Getting It Right First Time
GIST	Gastrointestinal stromal tumour
GFI	Groningham Frailty Index
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale
HCP	Health Care professional
HDU	High Dependency Unit
HPB	Hepato Pancreatico Biliary
HRA	Health Research Authority
HR	Hazard Ratio
IADL	Instrumental activity of daily living
IQR	Interquartile range
IRAS	Integrated Research Application System
ITU	Intensive therapy unit
LBO	Large Bowel Obstruction
LOS	Length of hospital Stay
MDT	Multi-Disciplinary Team
MESH	Medical Subject Heading
METs	Metabolic equivalents
mFI	Modified Frailty Index
MM	Mixed methods
MNA	Mini Nutritional Assessment
MUST	Malnutrition Universal Screening Tool
NBOCA	National Bowel Cancer Audit
NCEPOD	National Confidential Enquiry into Patient Outcome and Deaths
NELA	National Emergency Laparotomy Audit
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NOAC	Novel oral anticoagulants
OG	Oesophagogastric
ONS	Oral Nutritional Supplement
OR	Odds Ratio

OS	Overall survival
OT	Occupational Therapist
Peak VO_2	Peak oxygen consumption
Peak OP	Peak value of oxygen pulse
Peak VE	Peak minute ventilation
PEC	Percutaneous Endoscopic Colostomy
Peri-op	Peri-operative
PI	Primary Investigator
PICO	Population Intervention Comparator Outcome
PIS	Participant Information Sheet
pre-op	pre-operative
PRO	Patient Reported Outcome
PROM	Patient Reported Outcome Measure
post-op	Post-operative
P-POSSUM	Portsmouth Physiological and Operative Severity Score for the enumeration of Mortality and Morbidity
PS	Performance Status
RCS	Royal College of Surgeons
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
REDCap	Research Electronic Data Capture
RFA	Radio frequency ablation
ROBINS-I	Risk of Bias In Non-randomised Studies of Interventions
RR	Relative Risk
R&D	Research and Development
SD	Standard Deviation
SE	Standard Effect
SF-36 PCS	Short Form-36 Physical Component Score
SIOG	International Society for Surgical Oncology
SORT	Surgical Outcome Risk Tool
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
STH	Sheffield Teaching Hospitals

TUG	Timed Up and Go
UGI	Upper GastroIntestinal
UK	United Kingdom
VES	Vulnerable Elders Survey,
2WW	2 week wait
6MWT	6-minute walk test

Abstract

Background

The population of patients presenting with gastrointestinal pathology amenable to surgery is becoming increasingly complex; patients are older, often with co-morbidities and functional or cognitive impairments that make treatment decision-making challenging. Lack of evidence-based guidelines mean that the assessment of an older patient for suitability for surgery, and subsequent optimisation to improve outcomes, is variable.

Methods

This mixed-methods study has looked at the evidence for pre-operative optimisation in older adults, explored what clinicians and healthcare professionals think about assessment and optimisation of older adults, assessed decision-making in hypothetical scenarios and studied current practice with functional outcomes. This has been achieved through a systematic review, semi-structured interviews, a national survey of practice with discrete choice experiment and an observational cohort study.

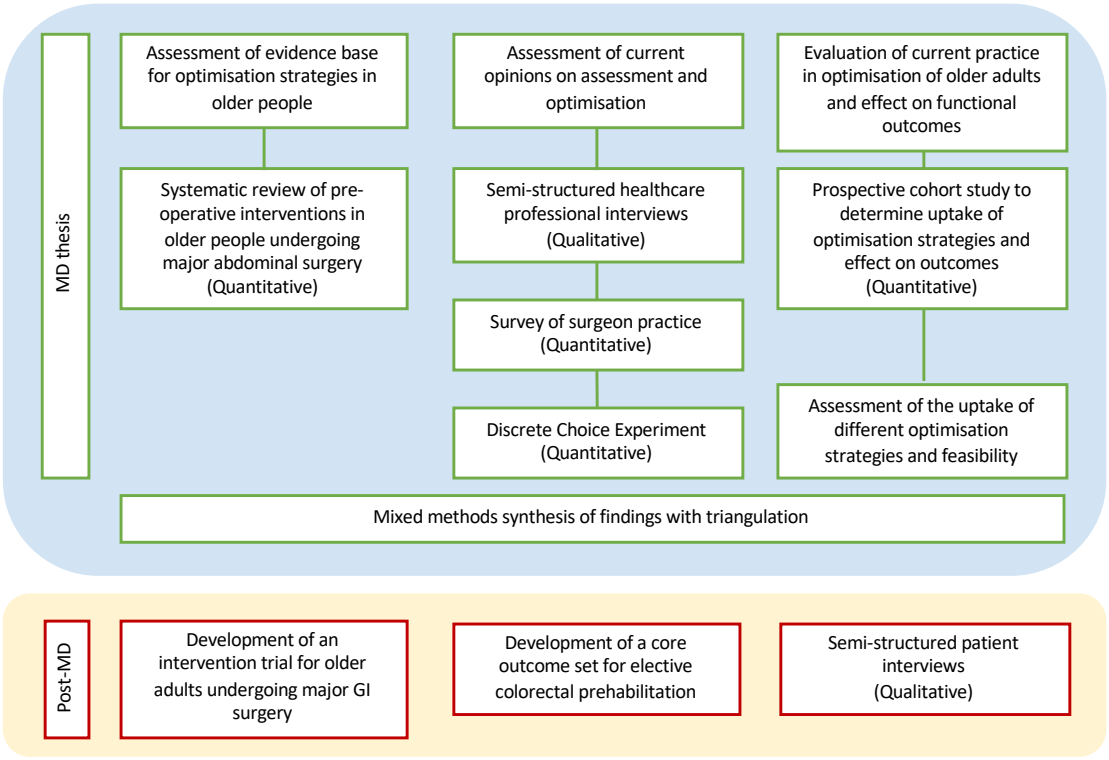
Results

A number of different interventions were identified in the pre-operative period with evidence that they may improve post-operative surgical outcomes. There were a limited number of studies focusing on the older population and heterogeneity of interventions and outcomes measures limited comparison of studies. Semi-structured interviews explored the barriers and facilitators to assessing and optimising older patients; these included lack of time in the surgical pathways, lack of resources and time in job plans and lack of high-quality evidence and guidelines to guide practice. The survey of practice demonstrated that current practice varies considerably; from use of objective testing, involvement of specialists in geriatric medicine and allied health professionals to the use of screening questionnaires. The Discrete Choice Experiment revealed the importance of key variables in treatment decision-making in older patients, with co-morbidities and cognitive impairment particularly important on binomial analysis. The observational cohort study demonstrated heterogeneity in the health and fitness status of older adults who underwent elective or emergency major gastrointestinal surgery and those who underwent non-resectional

management pathways. Low provision of peri-operative optimisation strategies in practice was observed. Functional impairments after surgery were common.

Conclusions

Robust methods of assessing all patients are needed to ensure that those at risk of poor post-operative outcomes are identified early and interventions put in place. Lack of national guidelines and research evidence in older surgical patients limits the development of surgical pathways with interventions to improve outcomes. Variation in attitudes towards surgery in older adults, methods of assessment of fitness and optimisation practice amongst surgeons likely contributes towards variation in outcomes.



1 Introduction

1.1 Population ageing

The UK population continues to age, with life expectancy currently 79.3 and 82.9 years for men and women respectively[1]. This trend is predicted to continue with 1 in 20 of the population aged 85 years or more by the year 2041[2]. Increasing age is associated with increased rates of co-morbidity, polypharmacy, cognitive impairment, physical dependency and frailty, all of which increase the risk of all-cause mortality.

1.1.1 Surgery in the ageing population

Advancing age is an independent predictor of poor outcomes after surgery. Numerous reports over the last 10 years have highlighted outcomes in older people undergoing abdominal surgery as an area requiring major improvement[3–7]. This is due to the high overall rates of mortality and morbidity compared to similar populations in the United States and Western Europe[8,9], but also due to large variation in outcomes between different units within the UK[4].

1.1.2 The high-risk patient

The 'high-risk' surgical patient is defined as having a predicted hospital mortality of 5% or higher[10]. This group of patients account for over 80% of postoperative deaths after general surgical procedures; they consist predominantly of older patients with co-existing medical disease undergoing major surgery, often as an emergency[11]. Identification of this high-risk group and interventions to reduce complications is a priority.

1.1.3 Physiological and pathological changes of ageing

There are a number of physiological changes associated with ageing which predispose to post-operative complications and death[12,13]. The impact of ageing on normal body physiology is called 'senescence', with the majority of organs affected to varying degrees. Cardiac reserve decreases due to loss myocytes and pacemaker cells, and maximal heart rate declines with age. Renal reserve is reduced due to loss of nephrons and reduced renal blood flow. Consequently, tolerance to dehydration and fluid overload are impaired. Cognitive function, balance and co-ordination are reduced which promote acute post-operative confusion and falls[6,7].

1.1.3.1 Frailty

Frailty is defined as the accumulation of deficits in multiple physiological systems which collectively result in increased vulnerability to minor stressors resulting in sudden health state changes[14]. The neuromuscular, neuroendocrine and immunological systems are the main systems affected and changes act cumulatively resulting in a decline in physiological function and reserve[14]. The phenotype of frailty includes sarcopenia (loss of muscle mass and strength), anorexia, osteoporosis, fatigue, risk of falls and poor physical health[15]. Figure 1 illustrates how even a minor illness in a frail person may lead to a major decompensation in their health state resulting in dependency[14]. Major surgery is a much greater insult than a minor illness, meaning that a patient initially much further away from the theoretical line of decompensation may become dependent following major surgery and may not fully recover their independence[16]. Frailty is a 'cycle' whereby increasing frailty predisposes to further decline[14]. Whilst frailty is not synonymous with age, the incidence does increase with age.

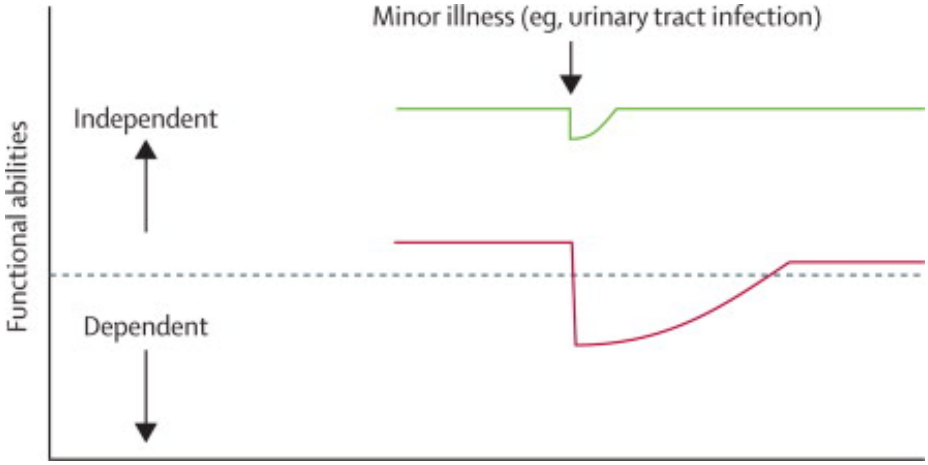


Figure 1. Effect of frailty on the impact of minor illness on functional ability

The diagram illustrates the effect of a minor illness on the functional abilities of a fit adult (green line) compared to a frail adult (red line) over time. The dotted line represents a theoretical line of decompensation, below which the individual will need support from others. © Clegg et al 2013[14]. Permission for use in this thesis granted 12/2/19

1.1.3.2 Sarcopenia

Sarcopenia is characterised by a progressive loss of skeletal muscle mass and strength[17]. It is part of the frailty phenotype and results from physiological changes in the neuromuscular system. Sarcopenia contributes towards falls, functional

impairments and mortality. Sarcopenia increases with age but it is also influenced by genetic and lifestyle factors across the life-span of an individual[18].

1.1.3.3 Co-morbidities

The prevalence of co-morbidities increases with age. Population ageing means that there are now more people living longer with poor health in their later years, which is attributed to premature illness in older people[1,19]. Co-morbidities reduce life expectancy and treatment tolerance[20]. Many diseases that are associated with ageing, such as diabetes, cardiovascular disease and dementia, often cluster in individuals, suggesting common patterns of causation. Multi-morbidity, the occurrence of two or more long-term health conditions, increases with age, with 64.9% of individuals aged 65-84 years and 81.5% of individuals aged 85 years and older being classified as multi-morbid (Figure 2)[21]. Co-morbidity is often cited as a reason why older people are excluded from clinical trials[22]. The James Lind Alliance has identified the management of patients with multiple conditions in later life as a research priority[23]. Multi-morbidity is also closely related to socioeconomic deprivation.

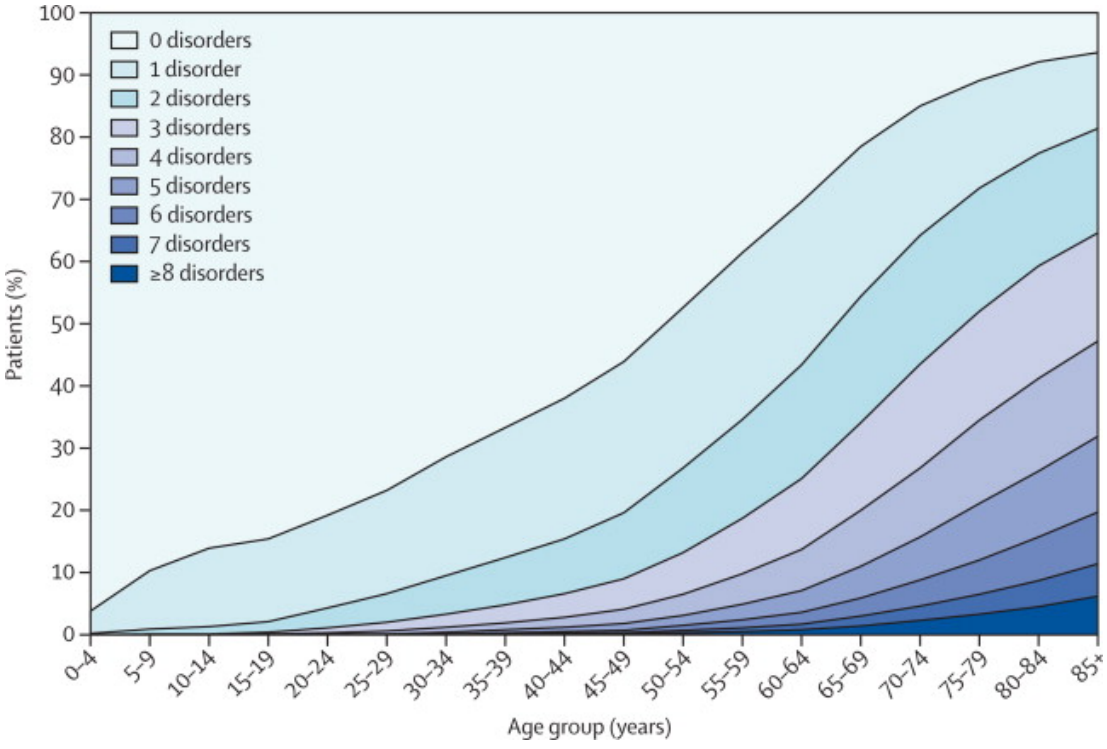


Figure 2. Prevalence of co-morbidities by age

This demonstrates increasing prevalence of co-morbidities with age, with a steep rise after 60 years.

Permission for use in thesis granted 08/10/20 © Barnett et al 2012[21].

1.1.3.4 Polypharmacy

Polypharmacy is the simultaneous use of multiple medications, commonly five or more[24]. Co-morbidities increase the risk of an individual being exposed to polypharmacy, in particular hypertension, diabetes and cardiovascular disease. Polypharmacy is associated with adverse drug reactions, drug-drug interactions and increased risk of hospitalisation[22]. Anti-coagulants and Novel Oral Anti-Coagulants (NOACs) in particular may be complicating factors for patients undergoing surgery and may also pre-dispose patients to develop acute surgical conditions, for example, lower gastrointestinal haemorrhage.

1.1.3.5 Functional impairments

The ability to perform everyday tasks, such as attending to personal hygiene, eating and mobilising around the home (Activities of Daily Living; ADL) and handling finances, transportation outside the home and shopping (Instrumental Activities of Daily Living; IADL) are essential to independent living. The presence of functional impairments may impact on whether a patient is offered major GI surgery due to concerns about post-operative rehabilitation. The risk of post-operative functional decline may also impact on a patient's decision-making regarding whether to undergo surgery or not[25].

1.1.3.6 Cognitive impairments

Cognitive impairments are common in the older surgical population. Dementia, a chronic cognitive disorder resulting from brain disease or encephalopathy, is estimated to have a prevalence of 6.4% in the general population aged 65 years and over[26]. There is emerging evidence that patients with a diagnosis of dementia are less likely to undergo a colorectal cancer resection than patients without dementia, are twice as likely to undergo palliative stenting of tumours rather than resection and have poorer survival outcomes[27]. Delirium, a transient mental condition characterised by global disorders of cognition and attention, is a common condition in older patients presenting with acute illness[28] and has an estimated incidence of 37% in post-operative patients[29] rising to 50% of those who are admitted to intensive care post-operatively[30]. It is associated with significant healthcare costs[31]. Both dementia and delirium may impair an older person's ability to make decisions regarding their treatment and may also impact on the treatment options that are considered for a patient.

1.1.3.7 Physical inactivity

Physical inactivity is a major global public health concern, increasing the risk of death from non-communicable diseases such as cardiovascular disease and cancer[32]. Physical activity levels generally decline with age with the Eurostat project finding that only 6.7% of people aged 65 years or older in the UK engage in health-enhancing aerobic and muscle-strengthening physical activities in a typical week[33]. Physical inactivity and physical deconditioning contribute towards post-operative complications, increased treatment costs due to prolonged hospital stays and poor tolerance of medical treatments such as chemotherapy. Physical deconditioning, even in the absence of significant co-morbidities, may result in patients being advised against major surgery[34].

1.2 Gastrointestinal pathology in older patients

1.2.1 Malignant GI pathology

1.2.1.1 Rising incidence in older people

The surgical oncology population is becoming increasingly complex as the UK population ages. Gastrointestinal cancers form a diverse group of cancers, the commonest being colorectal, oesophageal and pancreatic, with 44%, 41% and 47% respectively diagnosed in patients aged 75 years and above[35]. Major surgical resection remains the mainstay of curative treatment for gastrointestinal cancers, although there is an increasing role for the use of neo-adjuvant chemotherapy and radiotherapy to improve resectability, as well as local and distant disease control. Older patients are more likely to have advanced disease at diagnosis, present as an emergency with complications of their cancer and to have metastatic disease at diagnosis [36–39]. Reasons for this are multifactorial and may include the upper age limit of screening programmes (such as the bowel cancer screening programme), lack of established screening programmes (oesophagogastric and pancreatic cancer) and normalisation of common symptoms as a part of ageing (e.g. tiredness, change in bowel habit, weight loss).

1.2.1.2 Survival in older people with GI cancers

Recent reports demonstrate a widening survival gap for older versus younger patients with cancer[3]. Despite recent improvements in cancer survival rates across all cancer types, older patients continue to have inferior cancer-specific survival than their younger counterparts[3,4,40] Causes for this are multi-factorial but timeliness of diagnosis, upper age limits of screening programmes, poor treatment tolerance and reduced resection rates are implicated[41]. Patients are more likely to experience treatment complications if they suffer from weight loss, malnutrition, sarcopenia and cognitive impairment, all of which are more common in older patients with cancer[42], leading to concerns regarding overtreatment[43,44].

As people age, the risk of death from non-cancer causes increases (attributed to co-existent co-morbidities), however, this is highly dependent on the type and grade of cancer[45]. Pancreatic and oesophageal cancers have some of the worst overall cancer

survival rates with 10-year survival 5 and 12% respectively[46]. However, a small slow growing colonic cancer may not cause problems in a patient with a limited survival from other co-morbidities. It is likely that undertreatment of older patients with GI cancers represents a greater problem than overtreatment, as the risk of dying from cancer exceeds the risk of dying from other causes up to five years after resection[47].

Age-related treatment variation is acknowledged in all areas of surgical oncology and has been most extensively studied in the field of breast cancer[48,49]. However, the difference with GI surgery is that curative surgery is a risk factor for long-term disability, reduced quality of life and death. Therefore, it is important to determine who will benefit from surgery, who is at risk of poor outcomes, what can be done to mitigate identified risks and what outcomes are important for patients.

1.2.1.3 Surgical resection in older people with GI cancer

National cancer registration data from England demonstrate that GI cancer resection rates fall with age, this is most pronounced for cancers of the pancreas, oesophagus, liver and biliary tree and stomach (Figure 3)[46]. Whilst these rates are not adjusted for co-morbidity or stage of diagnosis, they do suggest variation in surgical treatment practice by patient age[46,50]. Many factors are important, including variable levels of patient cardiorespiratory fitness and co-morbidity[51], lack of age-specific evidence-based guidelines[52] and attitudes of surgeons and members of the multi-disciplinary team (MDT) towards older patients. These factors, combined with higher rates of adverse post-operative outcomes in older patients, likely contribute towards undertreatment in older adults[46,51,53]. The concern is that patients in centres with low elective surgery rates may be inappropriately denied curative surgical resection, leading to disease progression and potentially resulting in higher rates of salvage and emergency surgery[54,55]. There is also concern that risk-adapted surgical strategies, such as limited lymphadenectomy or limited resection, are more commonly performed in older patients.

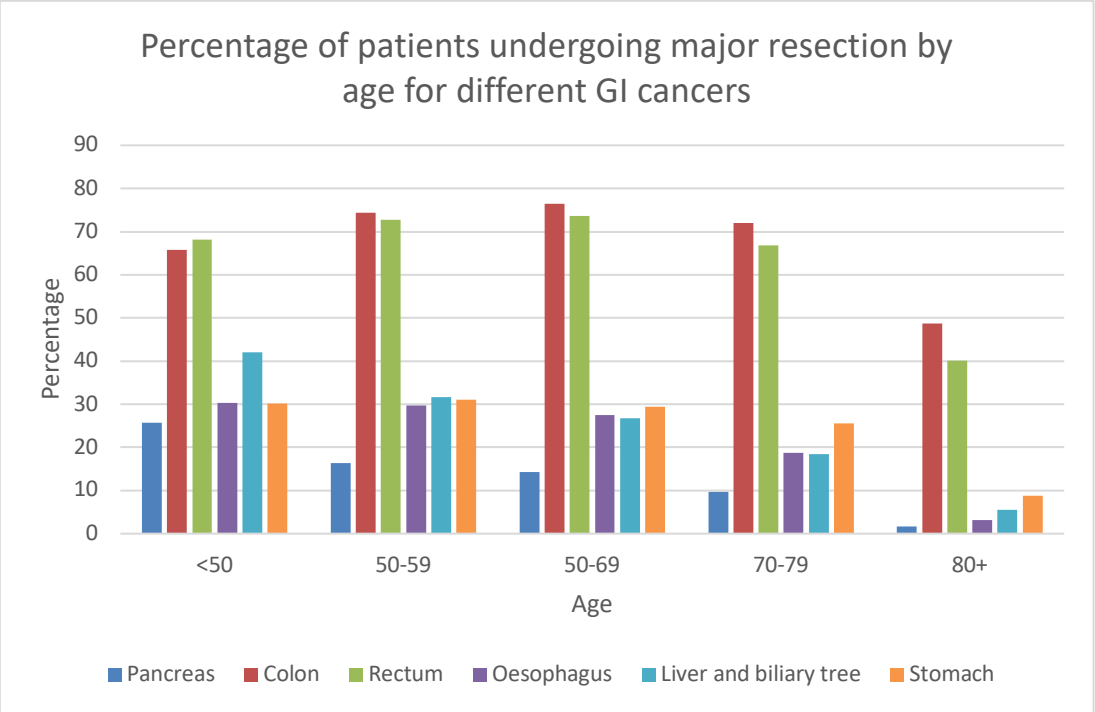


Figure 3. GI cancer resection rates by age

Percentage of patients in each age group who underwent surgical resection as part of their treatment by cancer type. Data from the NCRAS-CRUK database www.cancerdata.nhs.uk/treatments accessed 7/10/20.

1.2.1.4 Oncological treatment in older patients

Older people are less likely to receive adjuvant chemotherapy and radiotherapy[3,46,56–58]. Again, there are many potential causes for this, with concerns about increased toxicity and lower survival benefit frequently cited in the older population[59,60]. Older patients are also less likely to complete intended adjuvant therapy due to post-operative complications and prolonged post-operative recovery, which contribute towards reduced disease-free and overall survival[61]. Older patients are under-represented in clinical trials, resulting in a lack of high-level evidence on which to base age- or fitness-stratified treatment protocols[62,63].

1.2.1.5 Emergency management of GI cancers

Emergency surgery for GI cancers accounts for less than 10% of emergency operations. The most common presentations are malignant large bowel obstruction and obstructive jaundice, caused by colonic and pancreatic cancers respectively[64]. These are commonly treated by combined endoscopic and radiological management in the emergency situation with planned elective surgery if amenable to curative

resection and the patient is fit enough. Bowel obstruction secondary to peritoneal spread of advanced malignancies is also a frequent emergency presentation. Oesophageal cancer commonly presents with dysphagia via cancer referral pathways and patients may require endoluminal stenting on an urgent basis to relieve symptoms. Non-resectional management options for emergency presentations of colon, oesophagus and pancreas cancer are summarised below.

Colon cancer

Current guidelines state that endoluminal colonic stents should only be used as a 'bridge to surgery' in patients who are fit for surgical resection in malignant large bowel obstruction (LBO)[65]. However, the recent European Society for Medical Oncology (ESMO) guidelines suggest that colonic stenting as a bridge to elective surgery should be used particularly in patients with higher rates of postoperative complication after emergency surgery (>70 years old and/or ASA>II; level II evidence)[63]. A recent NICE evidence review[66] and the UK ColoRectal Endoscopic Stenting Trial (CREST)[67] suggest that stenting compared to emergency surgical resection may help to reduce stoma rate without impacting survival. If a patient is not fit for resection, stenting may be used as a palliative procedure. Recent data from the National Bowel Cancer Audit (NBOCA) report suggests that older patients and those with dementia are more likely to have a palliative stent rather than as a bridge to surgical resection in the management of obstructing colonic tumours[27].

'Defunctioning' refers to when a stoma is formed without resection of the tumour or when they are performed proximal to an anastomosis. These may be performed under local or regional anaesthetic and are associated with a short intraoperative time so are better tolerated in 'unfit' patients. They may help to relieve distressing symptoms caused by rectal tumours or prevent or relieve colonic obstruction caused by stenosing cancers. They also have a role prior to neoadjuvant therapy.

Oesophageal cancer

Endoluminal stenting is commonly performed in symptomatic patients with oesophageal cancer, both those undergoing neoadjuvant therapy and palliative

pathways. Stenting is usually well tolerated and associated with a low incidence of complications. Stenting improves tolerance of oral diet but does not affect disease progression.

Pancreatic cancer

Patients with pancreatic cancer often present with obstructive jaundice which may require stenting before any treatments can commence. Many older patients with localised 'resectable' disease are considered 'unfit' for major resection or may choose not to undergo resection. For these patients a permanent biliary stent is used as a palliative procedure. An intestinal bypass procedure or duodenal stenting may also be required if pancreatic cancers cause intestinal obstruction and the patient chooses or is unable to undergo curative resection[68].

1.2.1.6 Alternative treatment strategies

When a patient is considered to be at 'high-risk' of adverse outcome following major cancer resection or 'unfit' they may be offered palliative risk-adapted surgery or a procedure to help control the disease, alleviate symptoms or prevent complications (e.g. defunctioning stoma, colonic stenting, oesophageal stenting, biliary stenting, radiofrequency ablation (RFA) or palliative radiotherapy (see Table 1 for examples)). These procedures are generally well tolerated but tend to have higher rates of failure and disease progression[27]. With the exception of RFA, these procedures are often reserved for if/when the patient develops symptoms, so are commonly performed on an urgent or semi-urgent basis.

Colorectal liver metastases

Radiofrequency ablation (RFA) of colorectal liver metastases may be performed by percutaneous, laparoscopic or open approaches. Guidelines state that only patients who are medically 'unfit' for surgery should be considered for ablative therapy[69]. However, there is increasing recognition that for patients who are considered high-risk (advanced age or with significant co-morbidities), the lower morbidity associated with ablation could justify its use over resection, provided patients accept the trade-off of potentially inferior long-term results[70]. The LAVA trial aimed to compare RFA

with resection in high-risk patients but closed early due to poor recruitment[71]. Lack of surgeon equipoise regarding the two treatment options with unconscious bias towards surgery was cited as one of the reasons for poor recruitment[71].

	Standard care	**Risk adapted/ palliative**
Malignant diagnoses		
Oesophageal cancer	Oesophagectomy	Stenting
Gastric cancer	Gastrectomy	Stenting, intestinal bypass
Pancreatic cancer	Pancreatic resection	Intestinal bypass/stenting
Liver cancer (primary or secondary)	Liver resection (hepatectomy)	Radiofrequency ablation
Colorectal cancer	Resection +/- anastomosis	Defunctioning stoma/ intestinal bypass/ stenting
Non-malignant diagnoses		
Complicated diverticular disease	Hartmann's procedure or sigmoid colectomy	Laparoscopic peritoneal lavage or defunctioning colostomy
Sigmoid volvulus (recurrent)	Hartmann's procedure or sigmoid colectomy	Percutaneous Endoscopic Colostomy (PEC)
Adhesion related small bowel obstruction	Trial of conservative management. Laparoscopic or open adhesiolysis	
Cholecystitis	Laparoscopic cholecystectomy	Percutaneous drainage
Perforated peptic ulcer disease	Laparoscopic or open washout and repair	Radiological drainage of abscess
Obstructed hernias	Laparoscopic or open repair	

Table 1 Examples of malignant and non-malignant GI diagnoses and their potential management strategies.

1.2.2 Non-malignant GI pathology

There are a number of non-malignant conditions that increase in incidence with age and span the emergency (unplanned) and elective (planned) settings where surgery is the major modality of treatment. These include complicated diverticular disease, bowel ischaemia, intestinal volvulus, adhesion related small bowel obstruction, biliary pathology and complicated hernias. In the emergency setting, some of these conditions may be immediately life-threatening, with surgery being the only potential option for survival. In the presence of generalised peritonitis, suspected bowel ischaemia or failure to respond to conservative measures, surgery is the only curative option, however it is associated with high morbidity and mortality rates[11]. Many non-malignant pathologies can cause severe symptoms which, whilst not immediately life-threatening, can significantly impact on a person's quality of life. The main non-malignant surgical gastrointestinal diagnoses, with the standard care and risk-adapted alternatives, are summarised in Table 1.

In patients with non-malignant conditions, failure to refer for surgical management and lower rates of elective surgery in older patients contributes to higher rates of emergency surgery and readmission, particularly in the over eighty age group[50,72]. Conversely, in regions with high rates of surgery, patients may be inappropriately subjected to the morbidity or even mortality of major surgery with limited or no benefit. Older patients often present with non-specific symptoms and may be admitted under medical rather than surgical teams, leading to delays in diagnosis[73]. Two non-malignant GI conditions common in the older population are detailed below, with standard and risk-adapted management strategies.

<u>Complicated diverticular disease</u>

This includes a number of different problems including fistulation (bowel, bladder, uterus), obstruction and perforation. Definitive treatment is resection of the affected segment of bowel (sigmoid colectomy) and either an end colostomy (Hartmann's procedure) or a primary anastomosis. In a patient considered unfit for resection, alternative options may be explored such as a 'defunctioning' stoma, stenting of a

stricture or percutaneous drainage of an abscess. These are generally associated with poorer symptom control, treatment failure and the need for rescue surgery[74].

Sigmoid volvulus

Sigmoid volvulus is condition where the bowel twists on its mesentery causing luminal obstruction. First line management is usually endoscopic decompression to untwist the affected segment. If the bowel subsequently re-twists then the options are to perform a colostomy with or without resection (curative) or to perform a Percutaneous Endoscopic Colostomy (PEC) (risk-adapted). These are usually reserved for patients for whom surgery is not possible due to high peri-operative risk[75].

1.3 Outcomes in the older adult

1.3.1 Surgical outcomes

Age is a risk factor for poor post-operative outcomes, however even amongst the older surgical population outcomes vary substantially[76–78]. Surgical outcomes that are routinely recorded after GI surgical procedures include mortality (in hospital, 30-day or 90-day), length of hospital stay, complication and readmission rates. However, surgical conditions that fall outside of national audits, such as elective resections for benign disease or emergency hernia repairs, often do not have outcomes routinely collected[79]. Lack of recognised definitions or standards for measuring surgical outcomes results in significant heterogeneity in outcome reporting in surgical trials[80].

1.3.2 Functional outcomes

Disuse atrophy of muscles occurs rapidly in older patients, especially when compounded by a post-operative catabolic state and reduced food intake. Early mobilisation after surgery, such as sitting out of bed, standing and walking, decreases the risk of complications and length of hospital stay[81,82]. However, the majority of patients in hospital for acute medical or surgical conditions spend most of their time inactive[83]. Older patients are particularly at risk of functional decline following major surgery, which contributes towards prolonged length of hospital stay and increased care needs on discharge[84]. Many older patients never regain their previous level of functioning after major surgery[84]. Increasing age alone is a risk factor for discharge to a rehabilitation facility rather than home post-operatively, even in people who were functionally independent prior to their procedure and who have an uneventful postoperative course[85]. Other outcomes of importance to patients' functional recovery include fatigue, sleep disturbances, cognitive decline and low mood[86,87].

1.3.3 Quality of life outcomes

Quality of life is an important outcome after major GI surgery due to the potential significant detrimental effects that GI conditions and their treatments can have on multiple aspects of life. This includes the impact of the diagnosis and treatment on emotional, financial and social aspects of life, alongside the impact of surgical treatment on long-term illnesses. Patient Reported Outcome measures (PROs) are frequently collected using validated questionnaires that assess different aspects of

quality of life and in particular aspects that are directly important to the patient[88]. PROs are not routinely collected in most areas of GI surgery, however, a recent feasibility study combining national PRO survey results with NBOCA bowel cancer data demonstrated the value of combining clinical outcomes with patient perspectives[89,90]. This has led on to the development of the PROMS study, collecting PROs in patients with bowel cancer, which is currently underway. Multiple studies suggest that older people are more likely to prioritise quality of life rather than length of life when deciding on cancer treatment and that those with poorer baseline quality of life are more likely to prioritise quality over length of life[91,92].

1.3.4 Outcomes in the older adult

The International Society for Surgical Oncology (SIOG) has published a position paper with guidelines on end points in oncology trials in older patients[93]. These state that overall survival (OS) is a critical endpoint in trials in older adults with cancer, but that disease-specific survival (DSS) should also be reported due to the risk of death from non-oncological causes (i.e. other diseases, treatment toxicity) increasing in frequency in the older population[93]. However, many trials do not follow these guidelines or report outcomes identified as important for understanding the effects of disease and treatment on older patients, such as functional recovery, PROs and the effect of treatment on cognitive function[94].

1.4 Assessment of fitness for surgery in the older adult

Deciding whether an older patient will benefit from major resection is complex and there is a paucity of national guidelines to guide clinicians[52]. The ability to tailor management decisions to baseline health, cardiorespiratory fitness and frailty status relies on accurate and timely assessments, which is often lacking[50,72,95].

No standard definition of 'fitness for surgery' exists, contributing to practice variation[34]. 'Fitness' relates to patient factors rather than disease related or technical factors, such as whether the disease is operable. Traditionally, patients were considered 'fit' if they could perform four metabolic equivalents of activity without symptoms[96] based on subjective assessment by clinicians. Increasingly, objective tests such as cardiopulmonary exercise testing (CPET) are being used[34]. Whilst these give detailed information on cardiorespiratory function, they may not take into account other potentially modifiable risk factors in the older adult that may impact on peri-operative outcomes.

1.4.1 Baseline assessment

1.4.1.1 Elective assessment in primary care

Whether an older patient with suspected GI pathology is referred from primary care is variable[97]. The NICE guidelines for suspected cancer diagnosis advocate referral of all patients regardless of age, with no consideration of frailty, quality of life or comorbidities[98]. The suspected cancer referral pathway in the UK (two week wait (2WW)) requires an appreciation of the patient's performance status (PS) and whether they would be able to tolerate the proposed investigations. Older people are less likely to be referred via this system and yet are more likely to be diagnosed with cancer when a referral is sent[99]. There is a lack of robust evidence to help General Practitioners (GPs) with these complex decisions. This may lead to inappropriate, invasive and potentially risky investigations in an older patient who might not be 'fit' for intervention and under-referral of 'fit' older patients[100].

1.4.1.2 Elective assessment in secondary care

A thorough history and examination remains the cornerstone of elective surgical assessment. This includes an assessment of co-morbidities, functional capabilities and

social circumstances to determine whether a patient will tolerate and benefit from the proposed procedure. In the majority of cases the patient will then proceed to pre-operative assessment with the intention to undergo surgical management.

At pre-operative assessment, patients are initially assessed by a pre-operative assessment nurse who will assess for the presence of co-morbidities, lifestyle factors and risk according to the American Society of Anesthesiologists (ASA) scoring. They may also perform nutritional screening, cognitive assessment and frailty screening, although this is not universal. Those considered to be at increased peri-operative risk either due to the extent of the procedure or due to patient characteristics may be reviewed by an anaesthetist and/or undergo formal exercise testing (e.g. cardio pulmonary exercise testing (CPET)[101], six-minute walk test (6MWT), incremental shuttle test). Rarely, a Comprehensive Geriatric Assessment (CGA) (including functional status, comorbidities, polypharmacy, cognition, nutritional status, emotional status and social support in older adults[102]) is performed. The different domains of the CGA and some of their associated tests are listed in Table 2 below.

There is evidence that a CGA incorporated into the care of older cancer patients can help to determine baseline function and identify potential factors that could be optimised before initiation of treatment[3,103–105]. However, a full CGA is time consuming, costly to administer, requires specialist geriatric skills and therefore may not be feasible in many hospitals and settings. Other simpler tests have been validated as having prognostic and predictive functions such as the Timed Up and Go (TUG)[106] and the Eastern Cooperative Oncology Group (ECOG) performance status (PS)[54]. It is important to note that the role of these tests should not simply be to calculate risk and guide decision-making and counselling but should also be used to identify reversible pathology to enhance reserve and resilience by pre-operative intervention if possible. This is often not done in practice.

Domain	Example tests
Functional status – Activities of daily living	Barthel's Activities of Daily Living (ADL) index Instrumental Activities of Daily Living (IADL) index
Functional status – objective physical performance measures	6-Minute Walk Test (6MWT) Gait speed Timed Up and Go Hand grip strength
Co-morbidity	Charlson's comorbidity index
Polypharmacy	Number of different medications
Cognitive function	Montreal Cognitive Assessment (MoCA) Mini Mental State Examination (MMSE) Mini-COG©
Nutritional status	Nutritional risk score (NRS) Malnutrition Universal Screening Tool (MUST)
Emotional status	Geriatric depression scale (GDS)

Table 2. Summarises the different domains of a CGA and some of the tests associated with each.

1.4.1.3 Emergency assessment

In the emergency setting, there is often insufficient time for detailed baseline assessments, there may not be access to previous medical records, patients may present without their relatives or usual caregivers and they may have delirium or altered conscious level that precludes detailed information gathering. The balance of operative risk versus quality of life may be difficult, particularly when considering multiple co-morbidities and frailty[76]. Geriatricians are infrequently involved in the pre-operative decision-making or assessment of an older patient facing emergency GI surgery[73,107].

1.4.1.4 Risk assessment

There are a number of risk calculators that may be used in the elective and emergency settings to give an estimation of the risk of mortality and morbidity of a particular procedure in a patient with certain characteristics. Commonly used risk calculators in UK practice include; National Emergency Laparotomy Audit (NELA) risk calculator[55], Portsmouth Physiological and Operative Severity Score for the enumeration of

mortality (P-POSSUM)[108] and the Surgical Outcome Risk Tool (SORT)[109]. These may help in the consent process to quantify individual risk to a patient and facilitate shared decision-making. They may also be used to target peri-operative resources, such as planned admission to HDU post-operatively, use of invasive monitoring (arterial and central lines) and consultant involvement.

1.4.2 Guidelines for assessment in secondary care

The majority of surgical and oncological guidelines focus on the investigation, staging and optimal management of patients who are considered 'fit' for standard treatment. However, the assessment of 'fitness' is often left to the treating clinician with little guidance on how patients should be assessed in practice[110–112]. Where there are evidence-based guidelines, these are often based on low quality evidence due to lack of research studies in the older population. Lack of auditing of practice means that little is known about which guidelines surgeons follow in practice.

1.4.2.1 Guidelines for the assessment of older patients with cancer

The tables below summarise the available surgical guidelines for the elective assessment of patients with the main gastrointestinal cancer types (colorectal (Table 3), oesophagogastric (Table 4) and pancreatic (Table 5)). Guidelines for the assessment of patients with colorectal liver metastases (Table 6) is included as the most frequent malignant pathology requiring liver resection. Of note there is very little mention of how patients' rehabilitation needs should be assessed. In general, the guidelines for the management of patients with colorectal cancer are the most comprehensive in terms of recommending assessment of all of the domains of relevance to the older adult. In particular, colorectal cancer was the only cancer type where guidelines were found stating that frailty should be routinely assessed in all patients[113,114]. Anaesthetic guidelines for peri-operative assessment are not included here as these will often not impact on surgical decision-making and planning

Colorectal cancer
Fitness for surgery • If an older patient is fit they should be treated with algorithms developed for younger patients: SIOG guidelines 2018[114] • No mention of how fitness should be determined: NICE guidelines NG151[111] • Older individuals may require adapted care and prioritisation of health issues: ECCO review 2017[113] • Management decisions for an elderly patient with rectal cancer should consider physiological age, life expectancy, risk versus benefit of treatment versus nontreatment, treatment tolerance, patient wishes/ goals and possible treatment barriers: SIOG guidelines 2018[114] • Clinical examination and laboratory tests to provide a correct assessment of patient status and characteristics before decisions on the definitive treatment approach (level of evidence III, Grade A). Performance status and severe co-morbidities should be taken into account: ESMO clinical guidelines 2020[63]
Cardiorespiratory • Cardiopulmonary exercise testing should be considered for stratification of high-risk cases and can help predict morbidity: ACPGBI 2017[115], SIOG guidelines 2018[114] • 6-minute walk test correlates with postoperative outcomes: SIOG guidelines 2018[114]
Functional • Assessment of older patients' for suitability of treatment should be assessed on co-morbidity and performance status rather than age alone (recommendation grade C): ACPGBI 2017[115]
Nutritional • Regular screening should be performed: ECCO review 2017 • In cases of malnutrition a structured assessment should be performed: ECCO review 2017[113]
Psychological • Assessment of psychological distress should be considered: ESMO clinical guidelines 2020[63] • Psychosocial distress, psychological disorders and psychosocial needs should be identified by screening and considered by the MDT: ECCO review 2017[113]
Frailty and geriatric • Older patients should be screened for frailty and should have routine geriatrician involvement: ECCO review 2017[113], SIOG guidelines 2018[114] • The 'geriatric oncology team' must be available for all frail patients and their evaluation discussed in MDT meeting to offer personalised treatment: ECCO review 2017[113]
Co-existing medical conditions/ risk calculators/ pre-operative assessment • Robust risk stratification tools are needed to help MDTs and patients make informed decisions, particularly in an older and frailer population, use of scoring systems e.g. ASA and POSSUM is encouraged: ACPGBI guidelines 2017[115]

Table 3. Summary of guidelines for assessment of patients with colorectal cancer

Oesophagogastric cancer
Fitness for surgery • Offer surgical resection "if they are fit enough": NICE guidelines NG83[110] • Treatment decision-making should take into account patient co-morbidities, nutritional status, patient preferences and staging information: AUGIS/ BSG/ BASO guidelines 2011[116]
Cardiorespiratory • Exercise testing for UGI cancer surgery patients should not be used as a sole criterion for denying someone an operation: AUGIS/ BSG/ BASO guidelines 2011[116] • Incremental shuttle is a sensitive indicator of operative risk in oesophageal cancer patients: Murray et al 2017[117] • CPET has limited value in predicting post-operative morbidity following oesphagectomy: Forshaw et al 2008[118] • Evidence is currently limited for the use of exercise derived parameters in risk stratification: Oesophagectomy ERAS guidelines 2019[119] Gastrectomy ERAS guidelines 2014[120]
Nutritional • Offer nutritional assessment and tailored specialist dietetic support before, during and after radical treatments: NICE guidelines NG83[110], Oesophagectomy ERAS guidelines 2019[119], Gastrectomy ERAS guidelines 2014[120] • Assessment of nutritional status at presentation and before surgery recommended: AUGIS/ BSG/ BASO guidelines 2011[116], ESMO guidelines 2016 (Level of evidence III, Grade A)[121]
Co-existing medical conditions/ risk calculators/ pre-operative assessment • No consensus on risk predictors for gastric or oesophageal cancer: AUGIS/ BSG/ BASO guidelines 2011[116] • Medical risk assessment should comprise a differential blood count as well as liver, pulmonary, cardiac and renal function tests: ESMO guidelines 2016[121]

Table 4. Summary of guidelines for assessment of patients with oesophagogastric cancer

Pancreatic cancer
Fitness for surgery • Performance and nutritional status, as well as medical comorbidities, are important considerations for all patients with pancreatic cancer who are being considered for surgery, chemotherapy or radiation. Advanced age is not a contraindication to any of those treatments: ESMO guidelines 2015[122] • Surgical treatment may be considered in elderly patients (>80) if they wish to undergo surgery and their general condition allows it (weak, level D): Japan Pancreas Society guidelines 2019[123]
Nutritional • Assessment of nutritional status and body composition recommended as they have been shown to predict long-term prognosis and post-operative complications in patients who undergo surgery (weak, level C): Japan Pancreas Society guidelines 2019[123]
Psychological • Throughout the cancer care pathway the psychological impact of fatigue, pain, GI symptoms, nutrition, anxiety and depression should be assessed: NICE guidelines NG85[112]
Co-existing medical conditions/ risk calculators/ pre-operative assessment • Surgical outcomes and research (SOAR) pancreatectomy score for perioperative mortality (IV, C): ESMO 2015[122]

Table 5. Summary of guidelines for assessment of patients with pancreatic cancer

Colorectal liver metastases
Fitness for surgery • Liver surgeon and anaesthetist should take the clinical decision regarding fitness for surgery (category III evidence, strength C): Gut guidelines 2006[69] • No mention of how patients' suitability for surgery should be assessed: NICE guidelines NG 151[111] • Accurate assessment of a patient's general health condition (comorbidities, performance status and liver function): Colorectal liver metastases. An update on multidisciplinary approach 2019[70]
Functional • General condition and performance status are strong prognostic and predictive factors: ESMO guidelines for advanced colorectal cancer 2014[124]
Co-existing medical conditions/ risk calculators/ pre-operative assessment • Evaluation of the general condition, organ function and concomitant non-malignant diseases determines therapeutic strategy: ESMO guidelines for advanced colorectal cancer 2014[124] • Laboratory prognostic factors – albumin, bilirubin, alkaline phosphatase level: ESMO guidelines for advanced colorectal cancer 2014[124]

Table 6. Summary of guidelines for assessment of patients with colorectal liver metastases

1.4.2.2 Guidelines for the elective assessment of patients with non-malignant conditions

Guidelines regarding the assessment of patients with non-malignant GI conditions are even more scarce. Regarding elective surgery for diverticular disease, the RCS guidelines state that age should not be used as a criteria when considering whether to offer elective surgery[74]. The Danish diverticular guidelines state that it needs to be considered whether the patient's co-morbidities represent a contraindication to surgery, however they also note that patients with certain co-morbidities may benefit from elective resection as they are more at risk of relapses and complications[125].

1.4.2.3 Guidelines for the assessment of older patients with emergency GI conditions

The assessment of older patients with emergency GI conditions has received increased attention over the last decade, due to the poor outcomes in the older population highlighted in a number of reports [65,73,126,127]. The National Emergency Laparotomy Audit (NELA)[73] has driven improvements by highlighting variation in practice and has recently resulted in the introduction of a Best Practice Tariff (BPT) for emergency laparotomy patients. One aspect of the BPT requires patients to be risk assessed prior to surgery. The ELF study (Emergency Laparotomy Frailty study) has also highlighted the need to assess frailty in older individuals[128]. Table 7 summarises the main guidelines and UK reports regarding the assessment of patients prior to emergency GI surgery.

Emergency GI surgery
Fitness for surgery • Patients and their families should be involved in shared decision-making: ASGBI Surgery in the older frail patient document 2020[129]
Nutritional • Nutrition should be assessed in all patients undergoing high risk emergency general surgical procedures: RCS the higher risk general surgical patient report 2011, ASGBI Surgery in the older frail patient document 2020[129] • Patients with bowel obstruction should have their nutritional status assessed before and after surgery: NCEPOD Bowel obstruction report 2020[65]
Psychological • Patients with bowel obstruction should have their pain assessed, ideally by a pain team: NCEPOD Bowel obstruction report 2020[65]
Frailty and geriatric • Frailty and mental state should be assessed in all patients undergoing high-risk emergency general surgical procedures: RCS the higher risk general surgical patient report 2011[126], NCEPOD Bowel obstruction report 2020[65], ASGBI Surgery in the older frail patient document 2020[129]
Co-existing medical conditions/ risk calculators/ pre-operative assessment • Patients should have a risk assessment performed and documented, anaesthetic and critical care reviews and outcomes should be audited: NCEPOD Bowel obstruction report 2020[65], EGS commissioning guide RCS 2017[130], RCS the higher risk general surgical patient report 2011[126] • Patients should be assessed for acute kidney injury: NASBO 2019[127]
Post-operative and rehabilitation • Prompt assessment for the development of complications: RCS the higher risk general surgical patient report 2011[126] • Location of post-operative care should be determined by risk and staff competence: RCS the higher risk general surgical patient report 2011[126] • All emergency surgery patients should be assessed early on in their admission to ensure an appropriate ongoing care, discharge and rehabilitation package is in place: Emergency surgery RCS Standards for unscheduled surgical care 2011[131] • Discharge planning teams should be involved for patients with acute bowel obstruction and this ideally should include specialist nutritionists or dieticians: NCEPOD Bowel obstruction report 2020[65] • Therapy decisions should be tailored to the holistic needs of the patient: NCEPOD Bowel obstruction report 2020[65]

Table 7. Summary of guidelines for assessment of patients with GI conditions requiring emergency surgery

1.5 Interventions to improve outcomes

There are a number of different interventions in the pre-, peri- and post-operative periods that may be used in an individual to help prepare them for surgery, minimise the surgical stress response and help them to recover and regain their independence afterwards. Not all patients will require all aspects, which highlights the importance of thorough baseline assessments and targeted interventions based on these assessments to provide individualised care. There is limited evidence of how these interventions are applied in current clinical practice, particularly in older populations. Some of the interventions that may be implemented are summarised (Table 8). Patients with complex co-morbidities and frailty often require input from multiple different health and social care professionals, requiring co-ordination of this care to achieve good outcomes and efficiency[132].

	Pre-operative	Peri-operative	Post-operative
Cardiorespiratory fitness	Exercise programmes (low/moderate/high intensity, strengthening) Physical activity promotion Respiratory physiotherapy Inspiratory muscle training	Inspiratory muscle training	ERAS protocols (early mobilisation) Physiotherapy Rehabilitation programmes
Nutrition	Nutritional optimisation Supplementation	ERAS protocols (reduced fasting time, carbohydrate loading)	Early re-introduction of diet (ERAS) Dietician input
Psychological	Tailored information Anxiety reduction Skills training (stoma, wound care) Cognitive behavioural therapy	Anxiety reduction Skills training (stoma, wound care)	Skills training (stoma, wound care) Referral to appropriate support
Multimodal	"Prehabilitation" involving exercise, nutritional optimisation and psychological preparation		
Geriatric	Comprehensive Geriatric Assessment and optimisation	Medication reviews Avoidance of certain anaesthetic agents	Delirium prevention strategies Multi-disciplinary input Early discharge planning
Co-morbidities	Iron infusion Optimisation of medical co-morbidities	Medication reviews	Iron infusion
Lifestyle	Smoking cessation and alcohol reduction advice	Nicotine replacement, alcohol detoxification regimes	Referral to appropriate support

Table 8 Summary of potential interventions in the pre-, peri- and post-operative periods

1.5.1 Pre-operative

1.5.1.1 Cardiorespiratory fitness

There are multiple different types of intervention to try to improve cardiorespiratory fitness prior to surgery. These range from simple advice to walk more through to intensive supervised exercise programmes. Exercise interventions may include many different types of exercise, such as interval training, stretching and strengthening, as well as the use of fitness trackers to try to encourage physical activity. Interventions in the form of respiratory muscle training may also be included. There is controversy regarding which type of exercise training is most effective prior to surgery and what is most effective in the older population.

1.5.1.2 Nutritional optimisation

Interventions to improve the nutritional status of patients prior to surgery include nutritional advice, food enrichment and dietary supplements[133]. Screening and replacement of micronutrient deficiencies may also have a role. In severe cases it may be necessary to arrange for a period of nutritional optimisation in hospital prior to surgery with intensive enteral or parenteral nutrition.

1.5.1.3 Psychological interventions

Psychological distress caused by a surgical diagnosis or pre-existing mental health problems may limit a patient's ability to engage with pre-operative optimisation strategies and also post-operative rehabilitation. The introduction of ERAS programmes with structured pre-operative information and Clinical Nurse Specialists (CNS) into routine cancer care in the UK likely reduces psychological distress. Interventions such as pre-operative stoma education and counselling may help to reduce anxiety and length of hospital stay[134]. Pre-operative cognitive training may also help to reduce the incidence of post-operative delirium[135]. Comparison of studies looking at psychological interventions in GI surgical patients is difficult because studies include a diverse range of interventions and outcomes measures.

1.5.1.4 Multi-modal

It may be possible to modify multiple adverse factors simultaneously and improve patients' resilience to both major surgery and adverse events by implementing

tailored 'prehabilitation' programmes[5]. 'Prehabilitation' is defined as 'the process of enhancing one's functional and mental capacity to buffer against the potential deleterious effects of a significant stressor'[5]. Prehabilitation programmes commonly involve one or more of the following: exercise programmes, nutritional optimisation or psychological interventions. Prehabilitation in the context of optimising the older adult for surgery may also include pre-operative geriatric assessment and optimisation. It is also advised that more general health advice and behavioural support should also be given including smoking and alcohol cessation, as well as optimisation of underlying health conditions, in particular anaemia. There is acceptance that prehabilitation should encompass all of the above, referred to as 'multimodal' prehabilitation[136]. There is evidence to support many of the aspects of prehabilitation programmes in elective GI surgery, however significant heterogeneity of studies including interventions tested, goals of treatment and outcomes measured limit the comparison of studies[137,138]. Many studies focus on only one aspect of prehabilitation, most frequently exercise interventions, whereas there is an argument, particularly in the elderly, for the role of simultaneously addressing multiple adverse factors with the aim of aggregating marginal gains[139]. There is a need to determine what combination of prehabilitation interventions is required in older people, how to facilitate engagement in those who are most likely to benefit and also the cost effectiveness of such interventions.

1.5.1.5 Comprehensive geriatric assessment with interventions

Care of older patients in high volume cancer centres with integrated geriatric assessments and risk stratification has been shown to improve outcomes in the US[56]. In the UK, geriatric involvement in peri-operative care of elective older patients can help to reduce length of hospital stay[140]. In addition, undergoing a geriatric assessment, as part of multidisciplinary management, may lead to a less aggressive treatment regimen in over one third of patients[141]. In the field of orthopaedic surgery, integration of geriatrician-led teams into the routine peri-operative care of older patients and the introduction of a BPT has led to substantial improvements in outcomes[142].

1.5.1.6 Medical optimisation

Correction of anaemia, optimisation of hypertension and diabetes control are all beneficial pre-operative interventions in both the elective and emergency settings. There is evidence that iron infusions may be more effective at reducing pre-operative anaemia than oral iron supplementation in the elective colorectal cancer setting[143]. Obesity is a global public health crisis that affects all ages. Obesity is associated with many other co-morbidities such as diabetes and obstructive sleep apnoea. Patients are often advised to lose weight prior to elective surgery for non-malignant conditions but support to enable them to do this is often lacking.

1.5.1.7 Lifestyle interventions

There is mounting evidence that surgery is a 'teachable moment' when patients are more receptive to behaviour change[144–146]. This includes lifestyle changes such as physical activity and dietary modifications (Prehabilitation section 1.5.1.1 above) as well as smoking cessation and alcohol reduction. It has been suggested that surgeons should do more to encourage behaviour change around the time of surgery as this could have long lasting effects on health behaviours and quality of life[147].

1.5.2 Peri-operative

1.5.2.1 Enhanced Recovery After Surgery protocols

Enhanced Recovery After Surgery (ERAS) protocols are multi-disciplinary peri-operative packages of care to promote recovery after surgery[148]. They were originally developed following the recognition that a small number of elective colorectal procedures contributed disproportionately to surgical morbidity, length of stay and unplanned readmissions[149,150]. ERAS protocols encompass pre-, peri- and post-operative components to improve patient education, reduce the stress response to major surgery and promote faster recovery. Peri-operative aspects of ERAS include anaesthetic techniques such as avoidance of certain anaesthetic agents, use of regional anaesthesia, use of agents to prevent post-operative nausea and vomiting, laparoscopic surgery and avoidance of routine abdominal drains. Post-operative aspects include early mobilisation, resumption of oral diet and early removal of catheters and drains. ERAS protocols have now been successfully implemented in the

majority of cancer surgery disciplines and demonstrated to reduce length of hospital stay and costs[151]. They have also been shown to be safe and effective in older populations[152–154]. Some aspects of ERAS protocols may be applied in the emergency setting, although implementation may be challenging[155,156].

1.5.2.2 Peri-operative quality improvement initiatives

Implementation of pathway quality improvement care bundles have been shown to reduce mortality after emergency laparotomy in a number of studies by standardising peri-operative care[155,157,158]. However, a large UK multi-centre study of a quality improvement bundle for patients undergoing emergency abdominal surgery failed to demonstrate any difference in outcomes, attributed to challenges in pathway adherence[156].

1.5.3 Post-operative

1.5.3.1 Rehabilitation programmes

Post-operative rehabilitation programmes aim to reduce hospital length of stay, promote return to function and prevent complications following major surgery. They are typically delivered by physiotherapists and ward staff and may be encompassed within ERAS protocols whilst patients remain in hospital following their surgery[159]. However, there is interest in whether progressive strength training and higher intensity post-discharge rehabilitation programmes that are part of the prehabilitation continuum may improve long-term outcomes[160].

1.5.3.2 Geriatrician input

The integration of specialist geriatric teams into the post-operative care of older patients undergoing major surgery, such as the Proactive care of Older Persons undergoing Surgery (POPS) initiative in the UK, has shown improvements in length of stay and cost savings[161]. However, national surveys and reports indicate that the majority of older patients undergoing major abdominal surgery still do not have input from a geriatrician-led team[73,162]. Interventions may include medication review, optimisation of co-morbidities, early engagement with social services to facilitate discharge planning and delirium prevention strategies, for example.

1.5.4 Guidelines for optimisation of older patients

The surgical guidelines for optimisation of older patients prior to major GI surgery are variable. No guideline covers all aspects of relevance to the older patient, but they do appear to be more comprehensive in colorectal cancer surgery (Table 9) than oesophagogastric (Table 10) or pancreatic cancer surgery (Table 11). An exhaustive review of the anaesthetic guidelines for optimisation of patients prior to major GI surgery was beyond the scope of this thesis.

Colorectal cancer
Cardiorespiratory • Multidimensional prehabilitation should be utilised, required elements including exercise, nutrition, treatment of anxiety/ depression: SIOG guidelines 2018[114]
Nutritional • Advice should be given to minimise side-effects after surgery: ECCO review 2017[113] • Patients should be encouraged to make dietary changes to reduce risk of recurrence: ACPGBI 2017[115]
Psychological • Patients should be encouraged to take part in ostomy management programmes and psychological distress management programmes: ESMO clinical guidelines 2020[63] • Psychosocial care should be provided to all patients: ECCO review 2017[113] • The CNS has an important role in providing psychological support and to develop positive coping strategies, particularly regarding stomas: ACPGBI 2017[115] • Pre-operative preparation in stoma education can reduce length of stay: ACPGBI 2017[115]
Frailty, functional and geriatric • Geriatric oncologists must ensure the early integration of palliative care plans or 'geriatric interventions' especially for frail patients: ECCO review 2017[113] • If identified as frail, patients should have a geriatrician routinely involved: SIOG guidelines 2018[114], ASGBI Surgery in the older frail patient 2020[129]
Co-existing medical conditions and lifestyle • Preoperative optimisation should be initiated in the community (e.g. correction of anaemia, control of hypertension and diabetes, smoking and alcohol cessation). Further optimisation should take place at anaesthetic pre-operative assessment: ACPGBI 2017[115]
Peri-operative • If enhanced recovery protocols are used it should be explained to the patient why they are used and their value in improving recovery after surgery: NICE guidelines NG151[111] • Perioperative care in elective surgery should be based on ERAS principles (recommendation grade A) as it improves length of stay: ACPGBI 2017[115] • Laparoscopic surgery is safe and may have advantages over open surgery in the elderly: ACPGBI 2017[115] • Laparoscopic, robotic, open and transanal techniques should all be considered in elderly patients: SIOG guidelines 2018[114]
Rehabilitation • Activity levels should be maintained during recovery, dietary changes may be necessary and healthy lifestyle choices should be encouraged, such as weight management and physical activity: NICE guidelines NG151[111], ESMO clinical guidelines 2020[63] • Every professional should anticipate rehabilitation needs before treatment and offer appropriate care to prevent, restore, support or palliate: ECCO review 2017[113] • Patients should be advised on physical activity, weight management and diet should be available for cancer survivors (recommendation grade C): ACPGBI 2017[115]

Table 9. Summary of guidelines on the optimisation of patients with colorectal cancer

Oesophagogastric cancer
Cardiorespiratory • Oesophagectomy patients may benefit from prehabilitation programmes but the evidence-base is currently limited: Oesophagectomy ERAS guidelines 2019[119]
Nutritional • Preoperative nutritional support for 10-14 days should be considered in those identified as malnourished: AUGIS/ BSG/ BASO guidelines 2011[116], Oesophagectomy ERAS guidelines 2019[119] • Nutritional support is an integral part of medical care of patients with oesophageal cancer: ESMO guidelines 2016[121] • Early enteral feeding should be strongly considered using either feeding jejenostomy or nasojejenal/nasoduodenal tubes: Oesophagectomy ERAS guidelines 2019[119] • Offer immediate enteral or parenteral nutrition after surgery to people having radical surgery: NICE guidelines NG83[110]
Psychological • An upper GI specialist nurse should be allocated to each patient to give psychological support, help co-ordinate the pathway and act as an advocate: AUGIS/ BSG/ BASO guidelines 2011[116] • Patients should receive pre-operative counselling with emphasis on perioperative and post-operative targets and goals: Oesophagectomy ERAS guidelines 2019[119]
Co-existing medical conditions and lifestyle • Smoking should be stopped and high alcohol users should abstain for 4 weeks before surgery: Oesophagectomy ERAS guidelines 2019[119]
Peri-operative • Minimally invasive techniques may have some beneficial outcomes without clear disadvantages: Oesophagectomy ERAS guidelines 2019[119] • Careful peri-operative management of fluids is recommended: Oesophagectomy ERAS guidelines 2019[119]l • Thoracic epidurals should be considered first line: Oesophagectomy ERAS guidelines 2019[119] • Early mobilisation should be encouraged with daily targets: Oesophagectomy ERAS guidelines 2019[119]
Rehabilitation • Rehabilitation should focus on symptoms, nutrition and psychological support: ESMO guidelines 2016[121]

Table 10. Summary of guidelines on the optimisation of patients with oesophagogastric cancer

Pancreatic cancer
Nutritional • Offer enteric coated pancreatin before and after pancreatic resection: NICE guidelines NG85[112] • Offer early enteral feeding after pancreatoduodenectomy rather than parenteral: NICE guidelines NG85[112] • Enteral nutrition therapy is not recommended after surgical resection for pancreatic cancer (weak, level C): Japan guidelines 2019[123] • Routine use of pre-operative artificial nutrition is not warranted but significantly malnourished patients should be optimised with oral supplements or enteral nutrition pre-operatively: Pancreaticoduodenectomy ERAS society recommendations 2012[163] • Immunonutrition should be considered for 5-7 days peri-operatively: Pancreaticoduodenectomy ERAS society recommendations 2012[163]
Psychological • Preoperative counselling involving leaflets, personal counselling or multimedia information may help to reduce fear and anxiety: Pancreaticoduodenectomy ERAS society recommendations 2012[163]
Co-existing medical conditions and lifestyle • 1-month abstinence before surgery should be attempted in alcohol abusers and daily smokers: Perioperative care for pancreaticoduodenectomy patients, ERAS society recommendations 2012[163]
Peri-operative • Patients should be given tasks to improve post-operative feeding, early mobilisation, pain control and respiratory physiotherapy: Pancreaticoduodenectomy ERAS society recommendations 2012[163] • Short (2 hrs) preoperative fasting and mid-thoracic epidurals are recommended. There is some evidence to support the use of patient controlled analgesia (PCA), wound catheters or TAP blocks: Pancreaticoduodenectomy ERAS society recommendations 2012[163] • Patients should be mobilised actively from the morning of their first postoperative day and encouraged to meet daily targets: Pancreaticoduodenectomy ERAS society recommendations 2012[163]
Rehabilitation • Exercise therapy is recommended after surgery in patients with pancreatic cancer (weak, level C): Japan guidelines 2019[123]

Table 11. Summary of guidelines on the optimisation of patients with pancreatic cancer

1.6 Variation in practice

Regionally, variation in outcomes may be explained in part by deprivation levels. Deprivation levels are linked to higher burdens of chronic disease, rates of smoking and lower uptake of cancer screening programmes. These factors may contribute to patients presenting at a later stage in their disease and being less able to undergo safe surgery[50]. Regional differences in clinical commissioning and referral practice of individual primary care doctors may also account for some of the differences in both elective and emergency surgery rates.

Clinician preference may also form a substantial aspect of practice variance as clinician recommendation is known to be an important determinant of treatment choice in older adults[164]. Anecdotal evidence in cancer surgery indicates that some surgeons have a very strong preference for surgery and others feel that palliative procedures (e.g. stenting), chemotherapy, radiotherapy or best supportive care are more appropriate for older patients, particularly those with co-morbidities or dementia[165]. In emergency surgery for non-malignant pathologies, some surgeons may place more value on chance of survival, whilst others consider likelihood of survival to discharge, quality of life and functional outcomes to be more important[10,166]. The causes of this varying opinion are not known but may include personal experience, interpretation of the literature or unit protocols. It may also be affected by anaesthetic staff attitudes to anaesthesia in older patients and critical care bed availability and admission criteria[11,167]. The publication of individual surgeon's outcomes for cancer resections may also affect treatment decision-making behaviour, particularly in 'high-risk' patients[168].

The development of pathways and optimisation strategies in practice often relies on motivated individuals from surgery, anaesthesia, nursing or allied health professions. Healthcare professional opinions regarding methods of assessment and optimisation may therefore contribute towards variation in practice and uptake by patients. It is also possible that optimisation strategies, such as prehabilitation, may actually increase health inequalities if they do not manage to engage the full spectrum of surgical patients[169]. Patients from disadvantaged backgrounds are known to be less

likely to engage with lifestyle modification interventions and older patients may have difficulty engaging with interventions delivered using digital technologies, for example.

1.7 Summary

The patient population undergoing elective and emergency GI surgery is ageing with increasing prevalence of underlying health problems, frailty, cognitive and functional impairments. Improvements in surgical and anaesthetic technique means that more complex procedures are possible whilst innovations in interventional radiology and endoluminal practice present alternatives to surgery in some situations. Deciding on the right course of treatment for a particular patient is therefore complex and depends on how a patient is assessed, what the treatment options are and the wishes of the patient. Opportunities for optimisation of patient pathways are diverse but are dependent on how patients are assessed, availability of different resources and co-ordination of professionals across different disciplines.

2 Aims and significance

2.1 Research questions

- What are the effective strategies to optimise the care and treatment pathways of older patients facing major GI surgery?
- What is the impact of clinician preference on variation in the management of older patients facing major GI surgery?

2.2 Hypothesis

Lack of evidence-based guidelines for clinicians on the assessment and optimisation of older patients for major gastrointestinal (GI) surgery contributes to variation in practice. Healthcare professional preferences for assessment, treatment and optimisation may account for some of this variation.

2.3 Aim

The aim of this thesis is to determine the evidence for and current practice in the assessment and optimisation of older patients facing major GI surgery and to explore whether healthcare professional preferences influence this.

2.4 Objectives

- To determine the evidence-base for optimisation strategies of relevance to the older patient undergoing major abdominal surgery
- To explore the views of healthcare professionals involved in the management of older patients facing major GI surgery with regards to assessment of fitness for surgery, optimisation strategies and treatment allocation
- To identify current practice in the process of assessment and optimisation amongst GI surgeons to identify whether there is variation in practice
- To identify factors underlying treatment decisions amongst GI surgeons
- To determine the uptake of optimisation strategies in clinical practice

2.5 Significance

The majority of older people are not frail, have minimal co-morbidities, remain fit and active and therefore should be offered standard surgical treatment options for their condition. However, when patients are at the extremes of age, are considered unfit or frail, particularly if they have a diagnosis of dementia, they often receive non-standard care[50]. Non-guideline based management practices are more prevalent with

increasing patient age and levels of co-morbidity, however there is a paucity of evidence on which to base fitness-based thresholds[170,171]. It is hoped that this research will contribute towards the development of guidelines for optimised, individualised care of older patients with malignant and non-malignant GI conditions.

2.6 MD Schematic

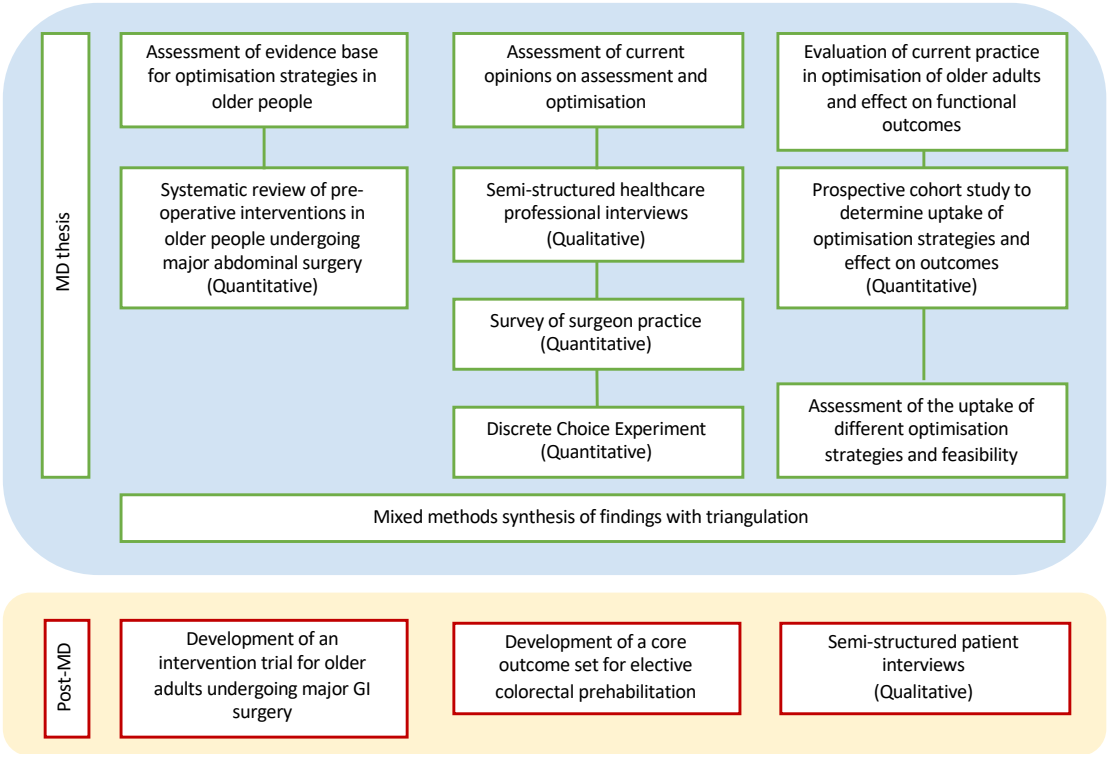


Figure 4 Summary of MD work and planned future work

3 Methodology

3.1 Study components

This study has been carried out using a mixed methods (MM) approach to look at strategies to optimise the treatment pathways of older patients facing major GI surgery, what current practice is and to determine the effects of clinician preferences on practice.

The different study components are summarised below:

- Systematic review and meta-analysis of the optimisation strategies that may be used pre-operatively in the older patient (quantitative)
- Semi-structured interviews to explore current preferences for assessment and optimisation of older patients (qualitative)
- Survey of clinician practice (quantitative)
- Discrete choice experiment (DCE) (quantitative)
- Prospective observational study of current practice (quantitative) with patient reported outcomes

This chapter will review each of the different research methodologies of relevance to this thesis and also explain why these methodologies were chosen.

3.2 Mixed methods research methodology

Mixed methods research is generally defined as a type of research where elements of qualitative and quantitative research approaches are combined for the broad purposes of breadth and depth of understanding and corroboration[172]. It was chosen for this project to enable an exploration of different aspects of the research question with methodologies that were relevant to the type of question being posed. Quantitative methodologies are often used to answer "what" questions whereas qualitative are more suited to address "why"[173]. In this study, the questions "what is the evidence base for pre-operative optimisation interventions in older patients", "what are the optimisation strategies used in practice" and "what is the effect of different optimisation strategies" were best addressed with quantitative methodologies; systematic literature review, survey and cohort study respectively. The question of "why is there variation" was best addressed with a qualitative methodology, in this case semi-structured interviews.

A sequential exploratory mixed methods approach was chosen for this project. It started with a review of the literature and systematic literature review to establish the evidence base and to identify gaps in the literature. This then informed the design of the semi-structured healthcare professional interviews to explore clinician preferences for management and the feasibility cohort study to explore variation in practice. The interviews informed the design of the survey to quantify the themes identified in the interviews, DCE to establish surgeon preference and also the cohort study. The study advisory group were used to refine and validate the survey and DCE.

A mixed methods approach also meant that the results could be analysed together to give a deeper understanding[174]. Integration of data obtained from qualitative and quantitative research strands is an important aspect of mixed methods research and is considered to be essential in some definitions[175]. Figure 5 illustrates how different aspects of the study informed the design of other aspects (black arrows) and how the data will be integrated (orange arrows) using a mixed methods approach.

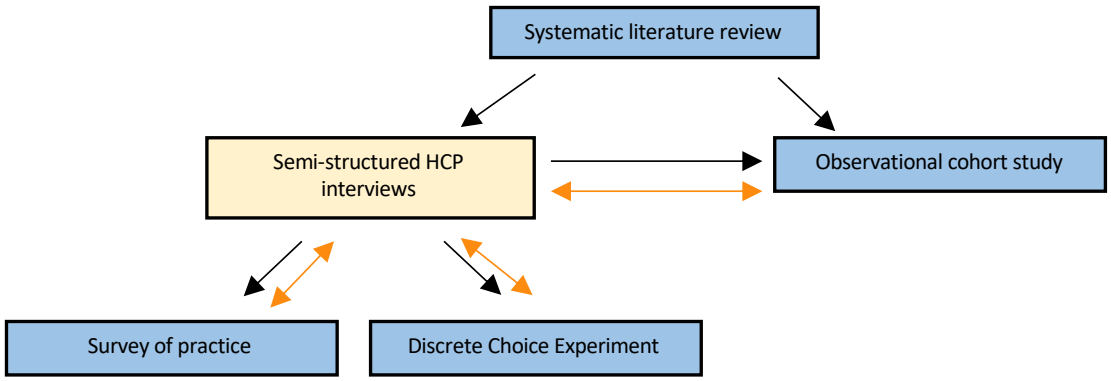


Figure 5. Study schematic

This illustrates the main aspects of the project, how the different aspects informed the design of other aspects (black arrows) and how the data will be integrated (orange arrows). Quantitative methodologies are shown in blue, the qualitative methodology is shown in yellow.

Integration of data

Various techniques for integrating data have been described[176], triangulation is one of the main methods and will be discussed in more detail here. Triangulation in mixed methods studies is generally defined as the process of studying a problem using different methods to gain a more complete picture[176]. Two or more methodologies are used to examine different aspects of an overall research question. The data is collected and analysed separately to give two sets of findings which are then combined together in the interpretation stage. There are several techniques described for triangulation but they generally look for where the findings agree (converge), offer complementary information on the same topic (converge) or appear to contradict (discrepancy or divergence).

- Triangulation protocol. This is where a 'convergence coding matrix' is produced by displaying all the emerging findings from the studies together. They are then analysed to look for agreement (convergence), partial agreement, silence (where a theme is present in one data set but not another) or disagreement (divergence) between the different components. This then results in the development of 'meta-themes' which cross the boundaries between the different methods[177].
- Following a thread. This takes place at the analysis stage. An initial analysis is carried out of the two separate components to identify key themes or questions

requiring additional exploration. One of these is then chosen from one methodology data set and 'followed' across to the other data set[178]

- Mixed methods matrix. This is where both qualitative and quantitative data is available on some of the same cases. All the data for one single case is analysed in detail and then surprises or paradoxes identified are examined in all cases[176].

3.3 Quantitative research methodologies

Quantitative research methodologies are widely used in healthcare research. They involve the generation of a hypothesis from previous knowledge which is then tested by collecting and analysing numerical data. These data are then used to identify patterns, relationships and make predictions using statistical processes that can then be generalisable to the wider population of interest[179]. There are clear guidelines and procedures for implementation of quantitative research studies. There are two main types of quantitative research:

1. Experimental – under controlled conditions the effect of changing an independent variable on a dependent variable is studied.
2. Non-experimental – observations, surveys and other methods of collecting numerical data that does not involve experimental conditions. This may include secondary research, such as a systematic review, where data that has been collected for other purposes is reviewed and collated. They are useful for observing current practice and opinions.

Non-experimental study designs were chosen for the quantitative aspects of this project and will be discussed in more detail here. The DCE could be classed as experimental.

3.3.1 Cohort study

Cohort studies compare outcomes in groups that did or did not receive an intervention, with the allocation of individuals to different interventions usually by clinician or patient choice rather than by chance. They are a type of observational study and are particularly helpful in situations where an experimental method (primarily a randomised controlled trial) would not be possible, necessary, appropriate or adequate[180]. They are therefore suited to studying practice in realistic settings. It was felt that a cohort study would be able to address the questions "what is the variation in practice in optimisation strategies" and "what are the effects of optimisation on post-operative outcomes".

Observational studies are particularly suited to areas where the intervention depends on the subject's active participation, as the patient's own beliefs and preferences will

impact on the effectiveness[181]. In addition, if the clinician has a preference or belief (for example, that post-operative physiotherapy reduces pulmonary complications) then they would be unable to agree to randomisation. Similarly, observational studies are useful to test interventions that would be unethical to randomise patients to, for example in this setting, post-operative high dependency care for a patient identified as needing high level care by their clinicians[182]. Questions of how to organise and deliver care are often suited to observational study designs because these types of interventions cannot be allocated on a random basis[183]. In addition, the vast number of interventions that could be used to optimise the peri-operative care of older patients would be too many to evaluate using an experimental design[184].

Interventions such as peri-operative care, physiotherapy, psychotherapy and rehabilitation programmes are highly dependent on the provider, environment and the patients themselves. A cohort study conducted across multiple hospitals within a geographical region was felt to be able to observe variation in provision of different services, with the qualitative interviews performed with healthcare professionals at those same hospitals helping to explain why there were differences. It is likely that patients who participate in experimental trials are also more likely to engage in optimisation strategies that are suggested to them, resulting in difficulty in generalisability of results. In contrast, this study was purely observational and so its effect on uptake of interventions should be minimal.

A cohort study design also meant that a wide range of patients were eligible for inclusion, far wider than if an experimental design had been used. Patients undergoing a diverse range of surgical procedures for both malignant and non-malignant pathologies were able to be observed, rather than restricting the study to a single cancer type or even type of procedure. Optimisation strategies are considered complex interventions as they commonly have a number of different interacting components, require new behaviours in those receiving the intervention and have a variety of outcomes[185], all of which are difficult to test using traditional trial designs. Observational studies are suited to identifying clinical uncertainty, generating hypotheses, identifying structures and processes, as well as outcomes that could be

tested in a trial[180]. They are useful for studying 'real world' situations where there may be interactions from multiple different variables.

Limitations

The main limitation of non-experimental approaches is internal validity. Previously unrecognised confounding factors may not be evenly distributed between intervention groups, therefore any comparison between groups may be biased. In addition, the use of patient report outcomes (PROs) risks recall bias, particularly where patients are asked about previous discussions or experiences in the past.

Feasibility study

A feasibility study is a study that can help investigators to determine whether an intervention is appropriate for further testing[186]. They generally help researchers to refine research methods or protocols prior to conducting a larger study. They can help to determine feasibility of multiple aspects of study design. For this study, we were interested in whether older patients were willing to be recruited, whether the questionnaire-based design was acceptable and whether the outcome measures and timings were appropriate. Feasibility and pilot studies are not meant to be used for hypothesis testing.

Choice of methodology

There are a number of RCTs already in the field of prehabilitation and two large, multi-centre studies are currently underway (PREPARE ABC (Identifier: ISRCTN8223315)[187] and Wesfit (Identifier: NCT03509428)). This has led to a number of hospitals and surgical units to develop their own prehabilitation programmes according to their own resources and expertise. Whilst these large RCTs will hopefully answer the question of whether prehabilitation is effective in improving post-operative outcomes, we felt that we needed to determine what current practice was across the range of optimisation strategies of relevance to the older adult rather than just prehabilitation. It still remains to be determined what strategies are considered 'standard practice', what are the most effective and acceptable to older patients and the best way to

implement these in practice. An observational cohort study as part of a mixed methods approach was felt to address these exploratory aims.

Clarity of reporting

It is now becoming commonplace for study protocols to be published prior to commencement of recruitment. This is felt to improve research quality by ensuring that researchers are open about their study objectives, methods and outcomes. It is also hoped that the publication of study protocols will help to improve visibility of studies with negative results or those that do not reach publication to avoid duplication of research efforts and promote sharing of negative findings. The SPIRIT checklist (Standard Protocol Items: Recommendations for Interventional Trials) is frequently required by journals to ensure that sufficient information is included in study protocols (https://www.spirit-statement.org). Journals often require the STROBE statement (STrengthening the Reporting of OBservational studies in Epidemiology) to be included in reports of cohort studies (https://www.strobe-statement.org), again to improve clarity of reporting.

3.3.2 Surveys

Surveys are a systematic method of gathering quantitative information from a sample of a population of interest[188]. They can be self-administered questionnaires, structured interviews, record reviews or observations[179]. In surveys, the same questions are delivered to each participant without any deviation, although some degree of tailoring is possible based on answers received. They allow the collection of quantitative data from a large number of respondents. They are used extensively in healthcare settings to collect data from healthcare professionals and patients[165,189] Self-administered questionnaire studies are the most common type of survey performed in healthcare and was chosen for this study.

Design of surveys

The initial content of a survey may be determined by review of existing literature, expert opinion or a qualitative exploration of a topic. Initial topics or domains for questions are developed and then transformed or 'operationalised' into question

format[190]. If previously validated questions are available, then they can be used as they have already been tested for reliability and validity. If no validated questions are available then the researcher must develop their own, termed 'bespoke'[188]. These questions must then undergo piloting and psychometric evaluation to ensure it is a valid instrument for the purpose. Questions must be constructed in a manner that is clear to the respondent, uses appropriate language including defining any specific terminology, are neutral and avoid long or complicated questions.

Surveys are a series of questions. Different types of questions are used including:

- Closed questions – where respondents are asked to pick from a number of options. They are valuable for defining the strength of opinion or effect, when options are well established. They are easy to analyse and interpret.
- Open questions – where respondents are given the freedom to write their opinions or views. They are more useful when the options are unclear, in a more exploratory setting and may be a pre-empt to a further survey later once key options are better defined. Open questions are more difficult to analyse.

Validity

Internal validity is the extent to which a question measures what the researcher is aiming to assess (face validity) and whether the domains within a question are relevant to the research question (content validity)[188]. It is assessed by members of the research team, experts in the field or participants. This can be through focus groups or individual discussion. Feedback can then be used to modify the proposed questions. Piloting is carried out in a small sample of the target population and can be used to further develop questions, particularly with reference to wording and length.

External validity is the extent to which the research findings from a sample of individuals are generalisable to the larger population from which they are selected or similar populations in terms of context, individuals, times and settings[191]. This relies on the survey being administered to an adequate and representative sample of the population under study without recruitment bias. Mechanisms need to be put in place

to ensure there is representative sampling and an adequate sample size. Data should be collected to ensure that population demography covers the spread required.

Reliability

Reliability is an important aspect of questionnaire design and refers to how 'dependable' a measure is. It refers to whether the results to particular questions will be reproducible across different samples of the population or on repeat testing. There are four main types of reliability[188];

- test-retest (test consistency) – that an individual will give the same response on repeat testing
- internal consistency – the extent to which items within the same instrument that measure the same viewpoint or construct will generate the same response
- equivalent form (parallel forms) – if different instruments are used to test the same question, whether the results will be the same within a short time frame
- split-half reliability – where questions for a single topic are divided into two and the responses from both halves correlated

Error

Errors in survey data can arise from the study design or collection, processing and analysis of study data. The cumulative effect of errors in different aspects of the study design and execution are referred to as 'total study error'[188]. Sampling errors are the where the population who complete the survey may not be representative of the population being studied. This may be due to many factors, including the method of survey dissemination, language of the survey or due to differences between those who choose to complete the survey ('respond') and those who do not (non-responders). 'Non-sampling errors' are related to the measurement items and their delivery. Responder bias relates to whether a respondent decides to complete a survey based on good or bad experiences of the subject area or a prior interest in the field.

Response accuracy refers to whether the participant was able to select a response that represented their opinion. If no suitable option is available the respondent may choose not to answer that individual question, termed 'non-response'. This is commonly due to poor wording of questions or overly long instruments leading to questionnaire fatigue. Non-response can limit the interpretation of findings. It can also arise when a respondent feels uncomfortable disclosing potentially sensitive or controversial information and is more common in an interview survey or when responses are not anonymised. There is also potential for error in survey data management and analysis. In interview surveys this may be due to the interviewer recording the wrong response or in self-complete questionnaires due to the respondent selecting too many or too few options. This may mean that the researcher has to make a subjective decision about coding the final response.

Sample size estimation

A statistical sample size estimation is required to ensure that a survey has adequate power to detect a meaningful answer. It is calculated based on the anticipated population size, the accepted confidence interval, margin of error and response distribution. There are a number of online sample size calculators that can be used (http://www.raosoft.com/samplesize.html). For this study a 10% margin of error, 95% confidence interval with a response distribution of 50% were set. The population of UK GI surgeons was estimated to be around 1500, therefore using these parameters at least 91 responses were required.

Response rate

The response rate is the number of participants who complete a survey compared to the total number who received it. This is difficult to determine for surveys that are distributed through email or social media platforms as you cannot be certain who has received the invitation. One accepted method is to use a proxy URL that can count the number of times the link was clicked. This can then be compared to the number of participants who completed the questionnaire. Based on similar surveys of clinicians, a response rate of 40% was expected[165,189]

Delivery of surveys

Questionnaire surveys are commonly delivered online, by post or in person (e.g. to attendees at a relevant conference). Delivery by post or in person are associated with highest levels of completion, particularly when the researcher is known to the respondent. However, they are associated with significant cost in terms of postage but also in handling the questionnaires and inputting results. There are also issues in terms of how the contact details of potential respondents are obtained, particularly in light of GDPR 2008. In contrast, online surveys are very cheap or free to design and distribute, are often easy for the user to complete and the results may be downloaded as a spreadsheet to facilitate analysis. However, for these reasons, significant numbers of online surveys are now distributed to healthcare professionals which has led to questionnaire fatigue and low response rates.

Choice of methodology

A survey was chosen as a quantitative aspect of the mixed methods study design to determine whether themes developed in the semi-structured interviews were generalisable to a wider population of UK GI surgeons. Again, the aim of the survey was to observe variation in practice. An online questionnaire survey was chosen as a relatively simple way of collecting data from a large sample within the resources of this study.

Clarity of reporting

Similar to other research types, standard checklists for the reporting of survey research are available and may help to improve the quality of survey research reporting[192].

3.3.3 Discrete choice experiment methodology

The discrete choice experiment (DCE) methodology is a robust survey methodology widely used in healthcare research[193]. It is capable of eliciting individuals' preferences in controlled experimental conditions through responses to hypothetical scenarios. The DCE approach is based on the idea that a patient, service or intervention can be

described by a number of different attributes and that these attributes can take different levels. It is useful for studying decision-making by an individual and specifically for studying 'stated preferences', which is what individuals say they would do rather than what they are observed to do[194]. They are useful for eliciting trade-offs that individuals make when there are a number of different factors to consider. It has the advantage over conjoint analysis, another stated preference technique, in that the scenarios are more realistic and resemble clinical practice, therefore is likely to be more acceptable to HCPs[195]. They have been used in a wide range of clinical situations such as patients' preferences for services[196], healthcare professionals' preferences for treatment[197] and economic evaluations[194]. They are felt to be particularly useful for situations where there is uncertainty about best practice and where clinician or patient preference is likely to be important in decision-making.

Design

The choice of attributes is determined by literature review, expert opinion or exploratory qualitative work. In this study, the semi-structured interviews with healthcare professionals were used to refine the attributes and levels identified in the literature with input from the study steering group (which included researchers experienced in the methodology). There is no limit to the number of attributes in a DCE but most studies contain less than 10 to prevent the questionnaire from becoming unmanageable[195]. Attribute levels are set to reflect the range of situations that are expected whilst being realistic. Levels must be mutually exclusive for the analysis to be meaningful. For example; functional independence, mild dependence, moderate dependence or severe dependence.

DCE are most commonly a pairwise choice design where respondents are asked to give their preference for one treatment or another or treatment versus no treatment. This is easier to analyse than scenarios where three or more options are given, as particularly if there is a middle option (e.g. no preference), respondents are more likely to pick this rather than state a preference[197].

Once the attributes are set, the hypothetical scenarios are generated. A full factorial design lists all possible combinations of attributes, so for five attributes with four possible levels each will produce 1024 possible scenarios. A selection of scenarios is subsequently produced using an orthogonal factorial design which aims to select statistically independent (orthogonal) and balanced scenarios with minimal overlap[198]. The number of scenarios in the final questionnaire is decided based on the complexity of the setting and the characteristics of the target population but is usually around 25[199,200]. The scenarios are checked for plausibility once they have been selected so this may result in the exclusion of some scenarios. Piloting is carried out to ensure that the participant instructions are clear and that the question style is acceptable and understandable to participants.

Sample size

There are various methods described to calculate sample size for DCE, however many studies do not report what kind of sample size method is used[201]. It has been suggested that sample sizes over 100 for DCE are able to provide a basis for modelling preference data[202]. This is because each participant will state their preference for each question, resulting in a large number of scenarios if taken independently. Formal estimation of the minimum sample size for a DCE requires the significance level, statistical power level and estimation of preference[201].

Statistical analysis

Logistical regression is used to identify associations between the outcome variable (treatment preference) and the various attributes levels given in the scenarios. When only two treatment choices are given binomial logistic regression may be used. Regression coefficient estimates are used to calculate confidence intervals and significance levels given the clustered nature of the data (each participant answers all of the questions so responses are clustered by participant).

Choice of methodology

This methodology was chosen as a robust way of eliciting clinician preference. By performing it alongside the survey and as part of a mixed methods study it enabled

triangulation of the two different types of quantitative data with qualitative interview data. It also enabled a comparison of what surgeons stated is their standard practice compared to how they responded in hypothetical scenarios.

3.3.4 Systematic review and meta-analysis methodology

Systematic review is a type of secondary research methodology because it analyses data collected in other studies. It is a rigorous methodology that allows the evidence base for a particular question to be examined, combined, analysed and synthesised to answer the original question and for any gaps in the literature to be identified. Unlike a non-systematic review, it allows a full and unbiased assessment of all known literature and therefore is less subject to bias. For example, a non-systematic review by a researcher with a special interest in a particular intervention might selectively report only on trials that support its use, giving a biased view of the intervention's effect. A systematic review, by collecting all data, positive or negative, and by transparently reporting its methods, should be reproducible and largely free from bias.

Methodology of systematic review

The methodology of a systematic review has been refined by the Cochrane collaboration in their methodological handbook[203]. It is expected that all systematic reviews will be conducted with reference to this handbook. Systematic reviews may include a meta-analysis, qualitative synthesis and/or critical review[204].

Formulation of the research question

The research question for a systematic review is formulated using the Population Intervention Comparator Outcome (PICO) framework. The question must be broad enough that there are relevant research studies for inclusion whilst focused enough that the number of studies will be manageable. At this stage it is useful to perform a preliminary review of the literature to see what systematic reviews are already published on the topic of interest as well as those in progress.

Defining inclusion and exclusion criteria

This is an important step in the design of a systematic review. They may be related to the study design (e.g. RCTs, cohort studies, qualitative), history of the intervention (this may require the date of publication to be restricted) or resources of the study (there may not be resources for translation of articles into English), for example. Restricting the inclusion and exclusion criteria may introduce bias, so the rationale and justification for these must be explicit.

Development of a search strategy

The search strategy for systematic reviews also tends to be standardised according to research subject. Reviews of medical interventions tend to search standard electronic databases including PUBMed, EMBASE, CINAHL and the Cochrane Collaboration. Medical Subject Heading (MeSH) terms and operators are used to perform searches in the different databases. Efforts are also made to search 'grey' literature, such as the published conference abstracts of relevant societies. The reference list of relevant systematic reviews and articles may also be searched to identify additional papers. Clinical trials websites can be searched for relevant studies that are registered but not published.

Registration of protocol

The registration of a systematic review protocol prior to commencement of searches is becoming more commonplace and may help to drive improvements. Registration means that the researcher must consider all aspects of the review including plans for analysis. This helps to prevent duplication of research work as researchers are expected to check that there are not similar studies registered already. It also helps to prevent 'research drift' and reporting bias by having the protocol clearly defined before commencing searches. Many journals require that a review protocol is published prospectively for them to publish the finished review. There is also some evidence that reviews that are registered before starting are more likely to report more of the domains identified in reporting guidelines[205]. PROSPERO, an international register of systematic reviews in health and social care funded by the National

Institute for Health Research (NIHR), is commonly used in UK practice. (https://www.crd.york.ac.uk/PROSPERO/).

Study selection

After initial searches, a list of potential studies with their abstracts is generated. This list is screened by two independent reviewers for relevant studies. The results from the two reviewers are compared and a third reviewer consulted if there is any disagreement[203]. The process is then repeated for the full text versions of the articles identified in the last stage resulting in a list of articles that fulfil all of the inclusion and exclusion criteria. Details of all studies excluded, and reasons are recorded.

Data extraction

The full text articles are systematically searched for data relevant to the study. Examples of data include type of trial, number of participants receiving each intervention, age of participants and institutional setting. All data are recorded in a pre-prepared data collection form by both reviewers independently. Again, results are compared, and any discrepancies checked by a third reviewer if needed.

Bias and quality assessment

The quality of the included studies and any bias is assessed by both reviewers independently. This is performed using a recognised tool, such as the Cochrane risk of bias tool for randomised studies[206] or the ROBINS-2 for non-randomised studies[207]. It involves systematically checking the studies for reporting of key quality details.

Qualitative synthesis of data

The extracted data is grouped into outcomes or study types of interest. This allows the researcher to qualitatively compare studies that are similar (e.g. those that studied the impact of a particular intervention) or those in which the population is similar (e.g. patients with the same cancer type).

Meta-analysis

Meta-analysis is a methodology that enables the pooling of data from different studies to estimate event rates across a larger population. Pooling is only possible if heterogeneity is not high. Two different models of pooling are available, the fixed and random effects models, which are based on whether the individual-specific effects are assumed to be correlated with the independent variable (fixed) or not (random). Adjustment is made based on sample size of the included studies. Data from meta-analysis may be presented as Odds Ratios (OR) or Relative Risk (RR) with 95% confidence intervals. The data may be displayed graphically as Forrest plots.

Meta-analysis is only possible when there are a sufficient number of studies (usually four or more) and the study outcomes are consistently reported (e.g. post-operative complications reported using the same classification system). The quality of a meta-analysis is determined by the quality of the included studies, therefore studies may need to be excluded from an analysis if they are significantly different from the other included studies or if there is concern about the quality of the data[208].

Publication bias

Publication bias is where studies that report positive results are more likely to be reported than studies that report negative results. Systematic reviews may therefore amplify publication bias as they are more likely to include trials that are published. Researchers performing systematic reviews must be mindful of this by searching trial registries and 'grey' literature for studies that have been performed but not published due to negative results.

Clarity of reporting

Systematic reviews must be reported according to agreed standards to ensure that all relevant details are included. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines are used in healthcare research[209]. Many journals require that the PRISMA guidelines be followed for an article to be considered for publication and also that the PRISMA diagram be included to clearly show how many articles were screened and excluded at each stage with reasons.

Choice of methodology

As already stated, a systematic review is a robust methodology to establish the evidence base for a particular intervention. The systematic review for this thesis focused on the pre-operative strategies to optimise older patients prior to elective surgery as preliminary searches revealed that the evidence base for optimisation strategies for emergency patients and post-operative interventions was limited and would not be sufficient for a systematic review. An understanding of the current literature informed the design of subsequent aspects of the study.

3.4 Qualitative research methodologies

Qualitative research is focused on exploring 'why' and 'how' questions to develop a deeper understanding of a concept or phenomenon. This involves exploring with study participants their views, reasonings and opinions relating to a topic. It is useful for understanding why individuals act as they do within their own environment[210].

Theoretical perspectives

The data generated in qualitative research is complex and there are many different theoretical approaches that can be used. Constructivism and pragmatism are two theoretical perspectives of relevance to this project. Constructivism is theory generating. This approach acknowledges that the information shared through an interview is the result of an exchange between the researcher and the participant rather than 'fact'. Pragmatism is more problem centred and aims to understand the consequences of actions.

Types of qualitative data collection

There are numerous types of qualitative data collection, the three predominant types are:

- Observational – where the researcher observes the actions, discussions and interactions of a group of people in a particular situation or context. They usually make notes or recordings of what they observe.
- Interviews – usually involve the researcher and participant on a one-to-one basis but sometimes may include the partner or care giver for the participant. They are usually digitally recorded and transcribed verbatim to enable analysis of the data at a later time. They allow in depth exploration of an individual's views[211,212]
- Focus groups – are where several participants are asked to discuss a particular topic with a facilitator (who is often the researcher). They enable ideas to be developed and views explored with input from the different participants. They also tend to be digitally recorded and transcribed

Qualitative interviews were chosen as one of the methods for this thesis, so qualitative research methodology with relevance to interviews will be discussed in more detail here.

3.4.1 Interview methodology

Sampling

Sampling strategies vary in interview research and depend on the aims of the study[213,214]. They do not aim to identify a statistically representative set of respondents. The main types are:

- Convenience sampling is where participants are selected based on a particular characteristic e.g. attendance at a clinic on a particular day
- Purposive sampling is where the researcher decides on certain characteristics that they want to be present in their sample and invites participants on the basis of those characteristics e.g. employment status
- Snowball sampling is where participants are asked to recruit subsequent participants. This is particularly useful for hard to access groups
- Theoretical sampling is where participants are selected to test theories developed in other research[215]

Structure

Interviews can be structured, semi-structured or unstructured:

- In a structured interview the researcher asks exactly the same set of questions in the same order to all participants and is actually a quantitative technique used to administer questionnaires.
- A semi-structured interview is when a prompt sheet or interview schedule is used to guide discussions, but the researcher has the freedom to explore new topics or themes as they emerge. The questions may be open or closed, can be delivered in any order and do not all have to be covered. The interview tends to be started with an introduction where the researcher introduces the reason for the interview, followed by open questions that may become more focused as the interview progresses and then rounding off where the participant is invited to mention anything they feel has not been covered already.

- An unstructured interview involves the researcher thinking of questions as the interview is conducted and is more conversational in nature. Unstructured interviews are more time consuming than structured interviews. Semi-structured and unstructured interviews allow the researcher to explore participants responses in more depth and to generate new ideas and theories.

Data

Recordings from interviews or focus groups are usually transcribed verbatim to enable the researcher to analyse the data in more depth. Qualitative research data also includes "field notes" which are the researcher's reflections on the discussion. Transcribed recordings and field notes are the raw data which must then be interpreted by the researcher.

Analysis

Analysis of qualitative data often takes place alongside collection so that the ideas generated can be used to inform future interviews. This is partly because the researcher is "in the field" whilst collecting the data and therefore it is difficult for one interview to not inform the conduct of the next[210]. It also means that the researcher is able to refine questions, develop hypotheses and explore emerging themes in depth, that might not have been considered at the start of the study.

Different analytical categories are used to describe and explain social phenomena. There are two different ways in which these categories are derived:

- Inductive – obtained gradually from the data. Grounded theory is a term used to describe analytical theories that are developed as they emerge from the data[216]
- Deductive – where the categories are either decided at the start of the analysis or part way though as a way of approaching the data. The "framework approach" is often performed in a deductive manner.

There are several ways of interpreting qualitative data to develop theories and hypotheses, two that are of relevance to this thesis are:

- Analytic induction – where theoretical ideas are tested and retested using the data[217]
- A priori – the analytic process is usually decided before starting the study

The transcripts, alongside any fieldnotes, are initially read to immerse the researcher in the data. The data is then sorted into themes and categories. This then means that the data in each category can by analysed and interpreted together, informed by the analytical and theoretical ideas developed during the research. A variety of methods for sorting and organising the data are available including spreadsheets and computer software. The use of more than one analyst can help to improve the consistency and reliability of analyses termed 'inter-rater reliability', however, others have contested its appropriateness in qualitative research[218].

The framework approach is commonly used in qualitative healthcare research. The objectives and aims are usually set in advance (*a priori*) and the data collection and analysis tend to be more structured than for other qualitative approaches. There are five stages of data analysis in the framework approach[219220]:

- Familiarisation – a list of key ideas and themes is generated by immersion in the data; either listening to recordings or reading the transcripts and making detailed notes
- Identifying a thematic framework – all key issues, themes and concepts in the data are identified. The interview schedule, *a priori* themes and the aims and objectives of the study are used to develop themes, alongside the data. This results in labels or 'codes' that can be used to separate the data into manageable chunks for exploration.
- Indexing – the thematic framework is applied to all the data by annotating the transcripts. Some passages of text may contain multiple themes which will all need to be indexed.
- Charting – the data is arranged according to the thematic framework. A chart for each key theme will contain data from different participants. The data will include some quotations taken directly from the text if they illustrate a

particular idea or view but distilled summaries created by the researcher are important for analysis.

- Mapping and interpretation – the charts are used to explore the data and find associations between the themes to draw conclusions. Both the original research objectives and the themes that emerge from the data influence the mapping and interpretation.

Sample size

The sample size in qualitative research is directed by the research question and analytical requirements of the study, commonly data saturation. Data saturation is defined at the point at which no new themes emerge from the data[221].

Validity of qualitative research

There are various methods of improving the validity of qualitative research

- Triangulation – where the results of two or more methods of data collection or two or more sources are compared. This assumes that any weakness in one method will be compensated by the other. It is seen as a way to ensure comprehensiveness and encourage reflexive analysis. This has already been discussed in the

- Mixed methods research methodology section above.
- Respondent validation – this is where the transcript and analyses are checked by the participant to ensure that they agree[222]. The reactions of the participants to the analyses may then also be incorporated into the analysis.
- Clear disclosure of the methods of data collection and analysis. The final report of the research should contain sufficient data for the reader to judge whether it supports the interpretation presented
- Reflexivity – this refers to the acknowledgement by the researcher of their role in shaping the research data and outcomes of the study through their involvement[212]. This can be due to their professional status, personal characteristics or the "distance" between the researcher and participants (whether they have a relationship with the participant already established).
- Negative cases – this is where participants or elements of the data that seem to contradict the main body of data are sought out and explored to help refine the analysis.
- Fair dealing – ensuring that the research design incorporates diverse perspectives

Quality of qualitative research

There is ongoing debate about the assessment of quality in qualitative research[223]. Traditional markers of quality in quantitative research, validity, generalisability and reliability, cannot be applied to quantitative research. There are a number of different checklists that have been developed to improve the quality of reporting of qualitative research, such as the COnsolidated criteria for Reporting Qualitative research (COREQ) checklist (www.equator-network.org) for interviews and focus groups[224]. Journal requirements for checklists to be included when submitting articles for publication will likely drive the more widespread use of these checklists.

Relevance

Relevance is related to whether the research adds to knowledge or increases confidence in existing research[223]. Another aspect is whether the findings can be generalised beyond the setting in which they were generated. This requires that the

research be reported in sufficient detail that a reader can judge whether or not the findings apply to similar settings.

Limitations

Interviews are time consuming and can be expensive, particularly in terms of researcher time to conduct the interview, transcription costs and time required to analyse the data. As already mentioned, there are often concerns about the quality of qualitative research, particularly from quantitative researchers. Ensuring that study protocols are followed and that data is collected, analysed and reported in a robust manner will hopefully help to allay these criticisms.

Choice of methodology

Semi-structured interviews were chosen to ensure that rich and diverse data were collected across the subject area. It enabled the context and reasoning for responses to be explored. It also meant that the interviews could be guided by the skills and the experience of the participants. For example, some allied health professionals (AHPs) are only involved in the post-operative care of patients, therefore asking questions about their practice in the pre-operative setting or decision-making for surgery would not be relevant. A combination of purposive and snowball sampling was used to identify participants. Purposive sampling ensured that core professionals involved in all aspects of the pathway were interviewed at each site (a surgeon plus either an anaesthetist or nurse specialist). Snowball sampling, whereby a participant was asked to recruit other participants, was particularly useful for engaging AHPs and CNSs in the study as they may be reluctant to participate in a study run by a surgeon due to interprofessional barriers. The framework approach was chosen as it fitted with the aims and objectives of the study. The study is pragmatic and phenomenological, aiming to understand what the range of current practice is and the barriers and facilitators healthcare professionals face in optimising older patients.

3.5 Ethics and research governance

3.5.1 Ethical approval

The mixed methods study protocol "Clinician Preferences for the treatment of older people facing major gastrointestinal surgery" (Appendix F) was approved by the University of Sheffield Medical School's Ethics Review committee (Ref. 180255328) (Appendix G). It was subsequently approved by the Health Research Authority (HRA) (IRAS ID 272619, REC ref. 19/HRA/5964); IRAS application (Appendix H) and letter of approval (Appendix I). This included the qualitative healthcare professional interviews, quantitative survey and DCE. It is referred to as the 'clinician preferences' study here. Details of all non-substantial amendments approved by the HRA are included in Appendix J.

The mixed methods protocol "Optimising the care and treatment pathways for older patients facing major gastrointestinal surgery (OCTAGON)" (Appendix K) was approved by the Health Research Authority (IRAS ID 277161, REC ref. 20/SC/0076); IRAS application (Appendix L) and letter of approval (Appendix M). This included both the quantitative cohort study and qualitative patient interviews (which will be completed in the post-doctoral phase). It is referred to as the 'OCTAGON' study. Amendments to the study protocols were submitted to the HRA for approval and circulated to participating sites. Details of all non-substantial amendments approved by the HRA are included in Appendix N.

3.5.2 Research and development approval (R&D)

Local research and development approvals for the clinician preferences study were obtained at five NHS trusts (Table 12). Separate approval was not required for the questionnaire. Approvals for the OCTAGON study have been obtained at five NHS trusts so far, with one further trust awaited (Table 12). Huddersfield Royal Infirmary was not involved in the clinician preferences study but included as a site for the OCTAGON study.

Trust	Local PI	Date of R&D approval 'clinician preferences' study and local ref.	Date of R&D approval 'OCTAGON' study and local ref.
Sheffield Teaching hospitals NHS Foundation Trust	Steve Brown	13/01/20 STH20693	9/9/20 STH20694
Doncaster and Bassetlaw NHS Foundation Trust	Tim Wilson	20/11/19 1016/2019/NCT	22/9/20 1070/2020/NCT
Barnsley District General Hospital	Michael Shanaghey	18/11/19 B127235	17/9/20 B129592
Chesterfield Royal Infirmary	Harjeet Narula	19/12/19 2020/09	Awaited
Rotherham District General Hospital	Richard Slater	16/06/20 20-02-04	12/04/2021 20-08-03
Huddersfield Royal Infirmary	Tamsyn Grey	N/A	30/04/2021 1527

Table 12 Summary of the different Trust's R&D approvals and local PIs.

3.5.3 Consent

Written informed consent was obtained prior to commencement of the interviews and enrolment in the cohort study. Consent was implied in the questionnaire and DCE by participation. Copies of the consent form, participant letter of invitation and participant information sheet (PIS) for the Clinician Preferences study can be found in Appendix O, P and Q respectively. Copies of the consent form, participant letter of invitation and participant information sheet (PIS) for the OCTAGON study can be found in Appendix R, S and T respectively.

3.5.4 Confidentiality

All data was be handled in accordance with the GDPR 2018 principles.

- All HCP interviews were digitally recorded and transcribed verbatim. Transcripts were pseudo-anonymised to protect participant identity. The original recordings were destroyed after data analysis.
- All responses to the questionnaire and DCE were anonymous. No names, professional registration numbers or e-mail addresses were gathered that might be able to identify participants. A structured, web-based (Google Forms, Google, Palo Alto, CA) questionnaire delivered via the University of Sheffield was chosen due to its compliance with the GDPR regulations 2018.

- All patient participants in the OCTAGON study were given a unique ID number which was used in the database rather than their NHS number i.e. pseudoanonymised. The key detailing NHS number and study ID has been retained by each site in the Investigator Site File (ISF) to enable data collection at different timepoints. Data was collected and recorded by hospital staff or members of the hospital research team on paper-based CRFs which was then entered into a secure server running the Research Electronic Data Capture (REDCap) web application[225]. REDCap allows collaborators to enter and store data in a secure system.

3.6 Funding

This study was funded by research grants from Bowel Research UK (formerly Bowel Disease Research Foundation) and the British Association for Surgical Oncologists (BASO~ACS).

The study was supported by the NIHR Clinical Trials Network, therefore anonymised details of all participants recruited were uploaded onto EDGE (www.edge.nhs.uk).

4 Systematic review

Data from this chapter has been published following peer review:

Daniels SL, Lee MJ, George J, Kerr K, Moug S, Wilson TR, Brown SR, Wyld L. Prehabilitation in elective abdominal cancer surgery in older patients: a systematic review and meta-analysis. 22/9/20 BJS Open DOI:10.1002/bjs5.50347 https://bjssjournals.onlinelibrary.wiley.com/doi/epdf/10.1002/bjs5.50347

Permission from the publisher (Appendix U) and the co-authors (Appendix V) have been obtained for reproduction in this thesis.

My role in this study was in formulating the review question, registering it on PROSPERO, performing the searches, collating and analysing the data and writing the manuscript for publication.

4.1 Abstract

Background

Prehabilitation has emerged as a strategy to prepare patients for elective abdominal cancer surgery with documented improvements in postoperative outcomes. The aim of this study was to assess the evidence for prehabilitation interventions of relevance to the older adult.

Methods

Systematic searches were conducted using MEDLINE, Web of Science, Scopus, CINAHL and PsychINFO. Studies of preoperative intervention (prehabilitation) in patients undergoing abdominal cancer surgery reporting postoperative outcomes were included. Age limits were not set as preliminary searches revealed this would be too restrictive. Articles were screened and selected based on PRISMA guidelines, and assessment of bias was performed. Qualitative, quantitative and meta-analyses of data were conducted as appropriate.

Results

Thirty-three studies (3,962 patients) were included. Interventions included exercise, nutrition, psychological input, comprehensive geriatric assessment and optimisation, smoking cessation and multimodal (two or more interventions). Nine studies purposely selected high-risk, frail or older patients. Thirty studies were at moderate or high risk of bias. Ten studies individually reported benefits in complication rates, with meta-analyses for overall complications demonstrating significant benefit: multimodal (risk difference−0·1 (95% CI −0·18 to −0·02); P = 0·01, I^2 = 18%) and nutrition (risk difference−0·18 (−0·26 to −0·10); P <0·001, I^2 = 0%). Seven studies reported reductions in length of hospital stay, with no differences on meta-analysis.

Conclusion

The conclusions of this review are limited by the quality of the included studies, and the heterogeneity of interventions and outcome measures reported. Exercise, nutritional and multimodal prehabilitation may reduce morbidity after abdominal surgery, but data specific to older patients are sparse.

4.2 Introduction

As outlined in Chapter 1, the majority of cancers in the UK are diagnosed in the older adult population (aged 65 years and above), with this population predicted to increase exponentially[226]. The pathogenesis and treatment of cancer can lead to a decline in cardiorespiratory fitness, weight loss and psychological morbidity[227]. Surgery remains the mainstay of curative treatment for many gastrointestinal, gynaecological and urological cancers, but outcomes are poorer in the older adult, making strategies to optimise this complex group increasingly important.

This review evaluates the entire of spectrum of prehabilitation interventions in elective abdominal cancer surgery with particular relevance to the older patient (summarised in Figure 6).

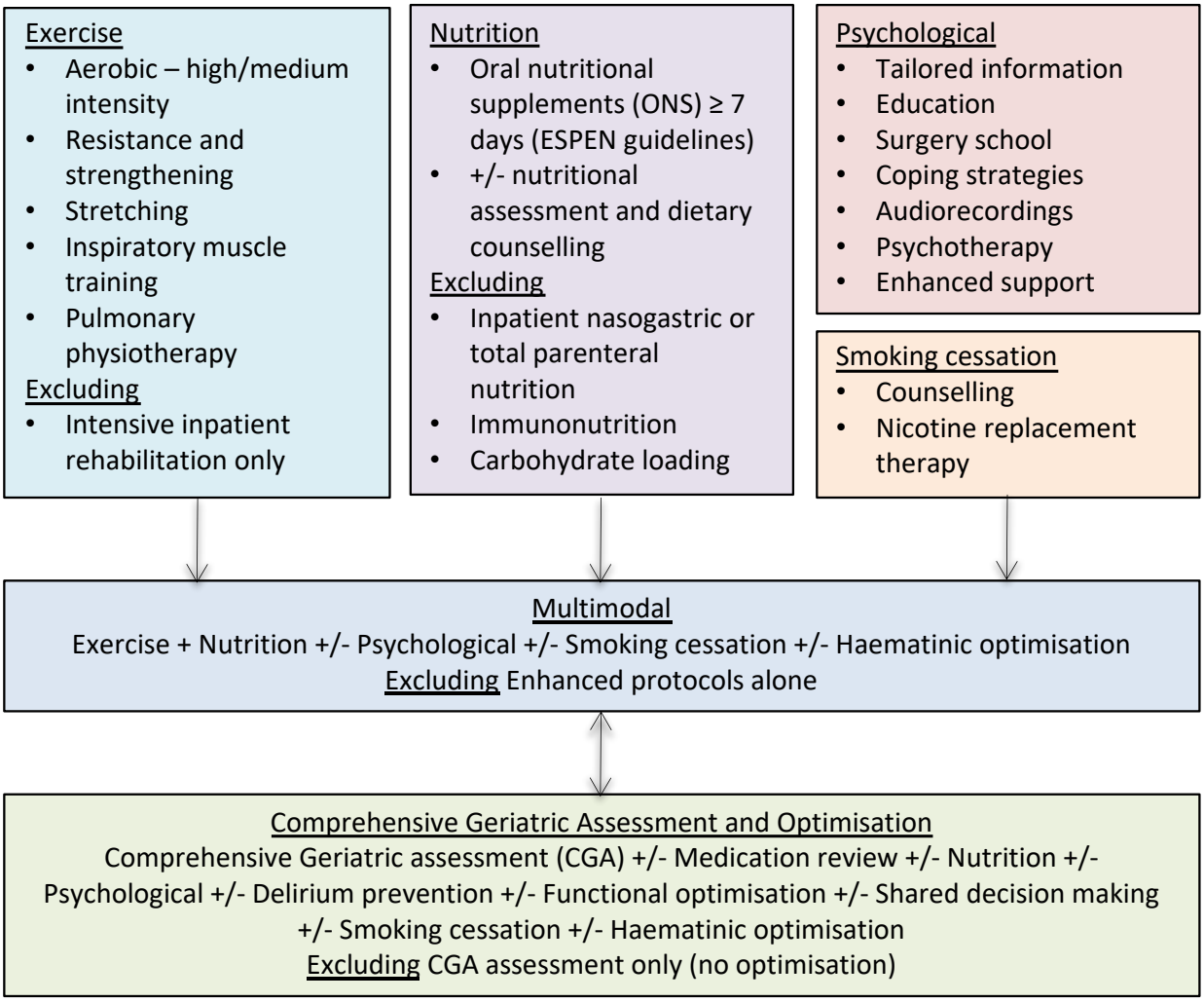


Figure 6. Summary of prehabilitation components and exclusions

4.3 Methods

This systematic review and meta-analysis was conducted with reference to the Cochrane Handbook and is reported using the PRISMA guidelines[209]. The protocol was registered with PROSPERO (CRD42019120381). The primary objective was to determine whether any modality of prehabilitation (alone or in combination) before elective abdominal surgery leads to a reduction in either length of hospital stay (LOS) or complications (overall, pulmonary, wound infection rate, delirium, severe complications) compared with a control arm that does not include prehabilitation. This was undertaken with particular reference to older adults. The secondary objectives were to determine any effect on functional outcome measures (physical activity or walking capacity, weight loss, discharge independence) and psychological outcome measures (quality of life, QoL).

4.3.1 Search strategy

Systematic searches were performed of the MEDLINE, Web of Science, Scopus, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsychINFO and the Cochrane databases for papers published from database inception to January 2019. Preliminary searches revealed that limiting the searches to studies performed in older adults would be too restrictive and result in the exclusion of potentially relevant studies, therefore no age limits were set. Searches were limited to those studies published in the English language as resources were not available to support translation. The search was conducted according to the patient-intervention-comparison-outcome (PICO) framework; patient (adults undergoing abdominal cancer surgery), intervention (prehabilitation or pre-operative optimisation), comparison (standard care or rehabilitation only) and outcome (Primary; length of stay or complication rates). Clinical trials.gov was also searched for trials that have been completed but not published. (Sample search strategy; Appendix W)

4.3.1.1 *Inclusion and exclusion criteria*

Randomized, case–control, cohort or retrospective studies reporting on adults (aged 18 years or above) undergoing surgery with curative intent for any gastrointestinal or intra-abdominal cancer were included. Studies including mixed surgical populations were included if they reported the cancer and non-malignant results separately or if

>50% of the population were cancer patients. Studies could test any prehabilitation intervention or pre-operative optimisation strategy, alone or in combination (multi-modal), and had to report outcomes in a control group. Control groups could include standard care, placebo, post-operative rehabilitation programme only, information leaflet or verbal advice on preparing for surgery and positive behaviour change (for example, smoking cessation or alcohol reduction) in line with current peri-operative care guidelines. Studies of post-operative interventions only were excluded, as were studies that did not report on either of the primary outcomes. Studies only published in abstract form without full text were excluded. Reference lists of primary studies and relevant systematic reviews were also hand searched for additional studies.

Screening of all titles and abstracts was undertaken independently by two reviewers. Articles were considered for full-text review if they met the study inclusion criteria or could not be excluded on the basis of the abstract alone. Full-text articles were retrieved and assessed by the same two reviewers. Disagreements were addressed by discussion and consensus and, if required the opinion of a third reviewer was sought.

4.3.1.2 *Definitions of eligible interventions*

Eligible interventions included exercise interventions (either alone or in combination with pulmonary exercises), nutritional assessment and supplementation, psychological interventions, CGA and optimization, smoking cessation and multimodal (two or more modalities) (summarised in Figure 6).

4.3.2 **Assessment of study quality**

Risk-of-bias assessment was performed using the Cochrane risk-of-bias tool[228] for randomized trials and the Risk of Bias In Non-randomized Studies of Interventions (ROBINS-I) [207] for non-randomized trials. Randomised studies were graded for risk of bias ('low risk' (+), 'high risk' (-) or unclear (?)) in each of the following domains: sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other source of bias. Non-randomised studies were assessed on bias due to confounding, selection, classification of interventions, deviations from intended interventions, missing data, outcome measurement and

reporting. Quality assessment was undertaken independently by two reviewers, and disagreements were resolved by consensus.

4.3.3 Data extraction

Data were extracted according to a predesigned pro forma, which included study characteristics, baseline data, intervention characteristics, adherence and outcomes. Studies were divided into modality; exercise (alone or including pulmonary training), multimodal, nutrition, psychological, smoking and comprehensive geriatric assessment (CGA) with optimisation.

The primary outcomes, LOS and complication rates, were recorded as mean (s.d.) values and proportions respectively. Where the mean was not reported, an approximation was calculated from the median and range[228]. Complication rates were recorded as total, severe (Clavien–Dindo grade III or above) or pulmonary complications, wound infections and delirium within 30 days of surgery. Secondary outcomes were extracted where reported; change in functional outcome measures (pre-operative change in 6-Minute Walk Test (6MWT) or CardioPulmonary Exercise Test (CPET) variables of physiological fitness, percentage pre-operative weight loss or discharge independence) or psychological outcomes (post-operative Hospital Anxiety and Depression Scale (HADS), Short Form-36 Health Survey (SF-36) or European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 29 and 30 (EORTC QLQ-C29/C30) score)).

4.3.4 Statistical analysis

Qualitative analyses were performed for all studies that met the inclusion criteria. Studies were analysed according to the type of prehabilitation intervention. Meta-analysis was performed using RevMan software (Review Manager version 5.3, 2014; The Cochrane Collaboration, The Nordic Cochrane Centre, Copenhagen, Denmark) where the number (greater than 3) and quality of studies permitted, if the 95% confidence interval overlapped and effect sizes were similar[229]. Meta-analysis was performed using random-effects models, assessing risk difference for both dichotomous and continuous outcomes. Heterogeneity was assessed using the I^2 statistic. Significance was set at an alpha of 0.05.

4.4 Results

4.4.1 Search results

Searches were performed on 6 January 2019. Some 130 papers were identified for full text review; 79 were excluded, leaving 33 studies for inclusion. The reasons for exclusion were manuscript availability (n=13), study design (n=1), intervention (n=30), re-analysis of an earlier trial (n=8), population (n=29), language (n=5) and post-operative outcomes not reported (n=11). (Figure 7).

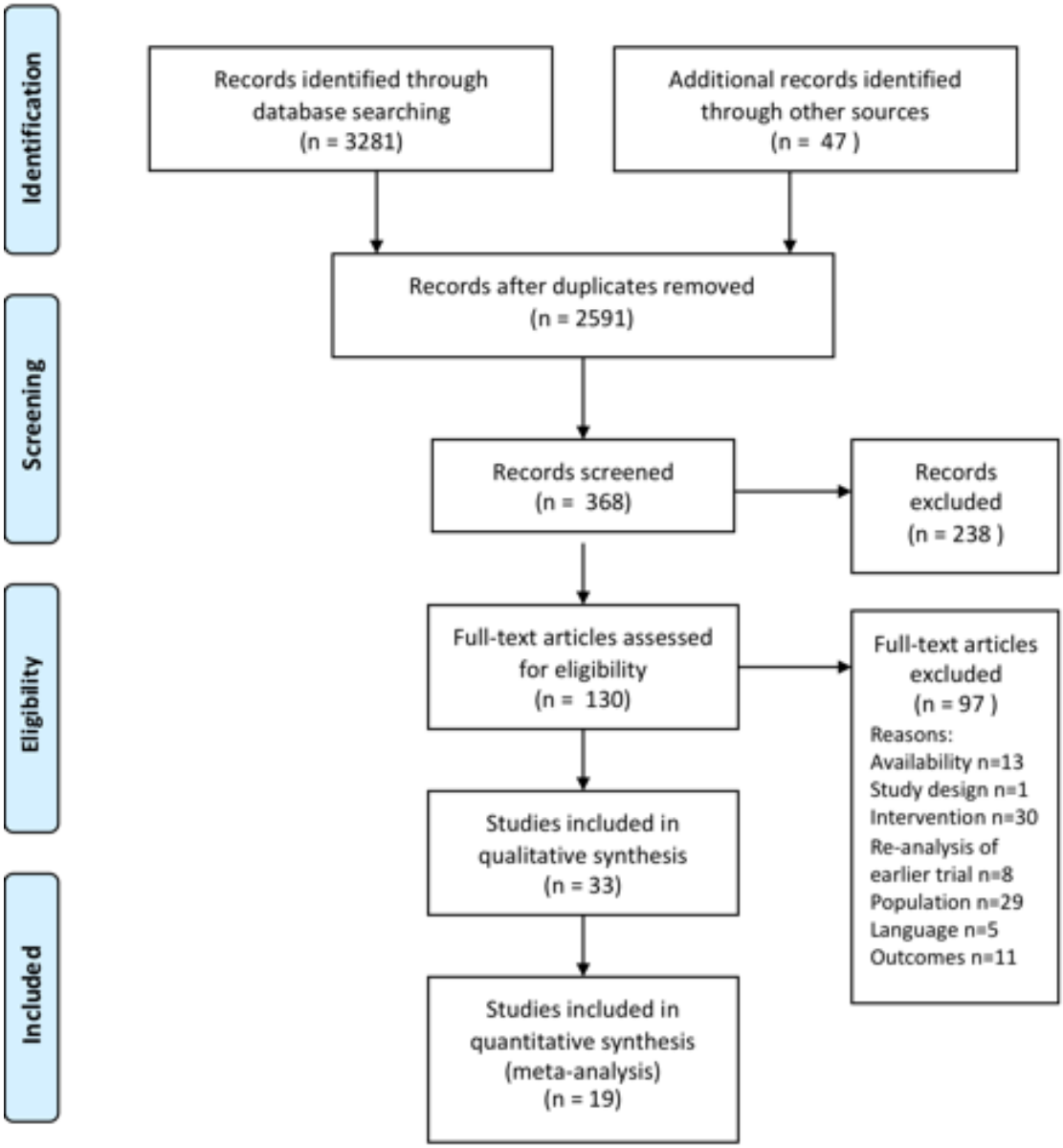


Figure 7. PRISMA diagram

Of those studies included, twenty-five studies were RCTs (including pilot and feasibility studies)[134,230–253], seven were prospective cohort studies (with either contemporary or historical controls)[254–260] and one was a retrospective study[261]. Three studies[238–240] reported two separate intervention groups, resulting in a total of 36 interventions for comparison (Table 13).

Table 13. General characteristics of the included studies

a. Exercise

Study	Study design and location	Population	Study groups	Sample size	Age in years intervention (control)
Banerjee 2018	Feasibility RCT, single centre, UK	Bladder cancer including neoadjuvant	Supervised high-intensity, aerobic interval training on cycle ergometer, Individual at University exercise facility; 30 minutes per session, twice weekly for 3-6 weeks. Compared to standard care	Intervention 30; control 30	Mean 71.6 (72.5)
Barberan-Garcia 2018	RCT, single centre, Spain	Abdominal surgery (75% oncological) Age >70 ± ASA 3/4 and Duke Activity Status index score ≤46	Supervised, personalised high-intensity endurance exercise programme plus programme to promote physical activity. Predominantly home-based. Physiotherapist led. 47 minutes 1-3 times a week, 6 weeks. Compared to standard care which included screening for iron deficiency and correcting and nutritional screening	Intervention 63, control 62	Mean 71 (71)
Boden 2018	RCT, multi-centre Australasia	Upper GI surgery (68% oncological)	Supervised pulmonary physiotherapy education and training session for 30 minutes plus educational booklet. Delivered in hospital. Compared to educational booklet provision only.	Intervention 218, control 214	Median 63.4 (67.5)
Carli 2010	RCT, single, Canada	Colorectal surgery (62% oncological)	Home based aerobic (cycle) and strengthening programme based on % maximal heart rate. 20-45 minute sessions daily for 4 weeks. Compared to encouragement to walk more and breathing exercises. Both groups at least one home visit and weekly telephone calls	Intervention 58, control 54	Mean 61(50)
Dronkers 2010	Feasibility RCT, single centre Netherlands	Colon cancer Age >60 years	Supervised resistance, moderate intensity aerobic exercise, inspiratory muscle training and training in functional activities in hospital twice a week for 60 minutes for 2-4 weeks plus advice to walk or cycle for 30 minutes a day. Compared to home exercise advice.	Intervention 22, control 20	Mean 71.1 (68.8)
Dunne 2016	RCT, single centre, UK	Colorectal liver metastases	Supervised, high-intensity cycle, interval training programme, 45 minutes, three times a week for 4 weeks. Compared to standard care.	Intervention 20, control 18	Median 61 (62)
Santa Mina 2018	Feasibility RCT, multi-centre Canada	Prostate cancer	Home-based, unsupervised, moderate intensity exercise for 60 minutes 3-4 times a week plus daily pelvic floor muscle exercises (including booklet). Compared to booklet plus pelvic floor exercises only. Both groups weekly monitoring	Intervention 44, control 42	Mean 61.2 (62.2)

Soares 2013	RCT, multi-centre, Brazil	Upper GI surgery (78% oncological), open surgery only	Supervised hospital based physical therapy sessions including aerobic, stretching and respiratory muscle training for 50 minutes twice a week for 2-3 weeks plus daily self-directed respiratory exercises. Compared to standard care.	Intervention 16, control 16	Median 58.5 (55)
Yamana 2015	RCT, single centre Japan	Oesophageal cancer, including neoadjuvant	Supervised pulmonary rehabilitation programme including aerobic exercises on bike in hospital for 60 minutes, daily, for at least 7 days. Compared to standard care	Intervention 30, control 30	Mean 68.33 (65.9)

b. Multi-modal

Study	**Study design and location**	**Population**	**Study groups**	**Sample size**	**Age in years intervention (control)**
Bousquet-Dion 2018	RCT, single centre, Canada	Colorectal cancer	Home and hospital based aerobic and resistance exercise, Dietician assessment of nutritional status and prescription of supplements to achieve 1.2g protein/day, 60 minute psychological consultation regarding anxiety reduction. Exercise 30-45 minutes/ session, 3-4 times a week for 4 weeks. Compared to post-operative rehabilitation only.	Intervention 37, control 26	Median 74 (71)
Chia 2016	Prospective cohort with historical control, single centre, Singapore	Colorectal cancer, >65 years, frail	Education, cardiovascular strengthening, attention to nutrition, post-operative rehabilitation. Twice per week, duration not stated. Compared to pre-intervention standard care	Intervention 57, control 60	Median 79 (81)
Gillis 2014	RCT, single centre, Canada	Colorectal cancer	Home-based aerobic and resistance training, dietician assessment and prescription of protein supplementation (1.2g protein/kg), psychological assessment, exercises and DVD. 40 minutes/ session, 3 times a week for 4 weeks. Compared to post-operative rehabilitation only	Intervention 38, control 39	Mean 66 (66)
Jensen 2016	RCT, single centre, Netherlands	Bladder cancer	Strengthening and endurance (supervised instruction session then self-directed at home) using step trainer. 30-60 minutes daily for 2 weeks. Also included post-operative rehabilitation programme. Nutritional screening and supplementation and lifestyle advice on smoking and alcohol were part of standard care. Compared to standard care	Intervention 50, control 57	Mean 69 (71)

Kaibori 2013	RCT, single centre, Japan	Hepatocellular carcinoma with chronic liver injury Childs Pugh A or B	Personalised aerobic exercise programme plus specific diet recommended for liver disease. 60 minutes per session, 3 times a week for 4 weeks. Compared to diet recommendation alone.	Intervention 26, control 25	Mean 68 (71)
Li 2013	Prospective, non randomised, single centre, Canada	Colorectal cancer	Personalised programme, home-based; Moderate aerobic exercise plus resistance for 30 minutes per session, three times a week, dietician assessment, modification of alcohol or fat intake, whey protein supplementation 1.2g/kg/day and psychological advice focusing on anxiety reduction through breathing exercises and relaxation exercises. Compared to historical control	Intervention 42, control 45	Mean 67 (66)
Mazzola 2017	Prospective with historical control, single centre, Italy	Upper GI and pancreatic malignancies, neoadjuvant, frail patients mFI ≥ 2	Encouraged to exercise by moderate intensity walking for 30 minutes, three times per week. Respiratory exercises using incentive exerciser. Malnourished patients received ONS for 2 weeks prior to surgery, non-malnourished patients for 5-7 days. Smoking cessation advice. Compared to historical control	Intervention 41, control 35	Mean 75 (75)
Minnella 2018	RCT, single centre, Canada	Oesophageal cancer including neoadjuvant	Individualised home-based moderate intensity aerobic and resistance exercise for 30 minutes 3 times a week for 5 weeks plus strengthening exercises for 30 minutes once a week, dietician assessment and prescription of whey ONS 1.2g/kg ideal body weight. Compared to standard care.	Intervention 26, control 25	Mean 67 (68)
Nakajima 2018	Prospective cohort historical control, single centre Japan	HPB malignancies, open surgery only, excluding neoadjuvant	Home-based unsupervised moderate aerobic exercise and resistance training for 60 minutes, three times a week. Nutritional therapy involved taking an amino acid supplement after exercise. Compared to historical control (propensity matched)	Intervention 76, control 76	Median 69 (69)
Souwer 2018	Prospective cohort with historical controls, single centre, Netherlands	Colorectal cancer ≥ 75 years, including neoadjuvant	Supervised aerobic and resistance exercise 30-45minutes per session twice a week for 4-6 weeks, geriatric screening and intervention, dietician assessment and prescription of protein supplementation, Colorectal nurse specialist psychosocial support, referral for cardiac or pulmonary optimisation if indicated. Compared to historical control.	Intervention 86, control 63	Median 81 (81)

c. Nutrition

Study	Study design and location	Population	Study groups	Sample size	Age in years intervention (control)
Burden 2017	RCT, multi-centre UK	Colorectal cancer, malnourished	≥10day preoperative ONS 400ml/d between meals plus dietary advice leaflet to increase energy and protein. Compared to dietary advice alone	Intervention 54, control 62	Mean 65 (65)
Gillis 2016	RCT, single centre, Canada	Colorectal cancer	4 weeks preoperative individualised ONS prescription 1.2g/kg protein/day plus dietary counselling. Compared to dietary counselling plus placebo.	Intervention 22, control 21	Mean 68 (69)
Kabata 2015	RCT, single centre, Poland	GI and abdominal cancers, non malnourished	≥14 days preoperative ONS 400ml/day. Compared to standard care	Intervention 54, control 48	Median 60 (67)
Kong 2018	RCT, single centre, Korea	Gastric cancer, malnourished	14 days preoperative ONS 500kcal/day. Compared to standard care	Intervention 65, control 62	Mean 61.9 (62.3)
Macfie 2000	RCT, single centre, UK	Major GI surgery ('majority' oncological)	Group 1: ≥10 days preoperative ONS 400ml/day	Intervention 1 24	Mean 62 (64)
			Group 2: ≥10 days preoperative ONS 400ml/day plus 7 days post-operative ONS Compared to standard care	Intervention 2 24, control 25	63 (64)
Manasek 2016	Prospective cohort, multicentre, Czech Republic	Colorectal cancer, including neoadjuvant	≥10 days preoperative ONS 400ml/day between meals plus dietary advice. Compared to dietary advice alone	Intervention 52, control 105	Mean 64
Smedley 2004	RCT, multi-centre, UK	Colorectal surgery (62% oncological)	Group 1: ≥7 days preoperative ONS – advised to take small frequent doses between meals.	Intervention 1 41	Mean 61 (63)
			Group 2: ≥7 days preoperative ONS – advised to take small frequent doses between meals plus post-operative ONS Compared to standard care	Intervention 2 32, control 44	Mean 55 (63)

d. Psychological

Study	Study design and location	Population	Study groups	Sample size	Age in years intervention (control)
Chaudhri 2005	RCT, single centre, UK	Colorectal requiring stoma >69% oncological	Community stoma education; two 45-minute home visits preoperative with a community colorectal nurse specialist. Compared to standard care	Intervention 21, control 21	Median 69 (62)
Haase 2005	RCT, single centre, Germany	Colorectal cancer	Group 1: Guided imagery audio recording with music to be played three times a day 2 days preoperatively and for 30 days post-operatively. Group 2: Relaxation audio recording with music to be played three times a day 2 days preoperatively and for 30 days post-operatively. Compared to standard care	Intervention 1 20, intervention 2 22, control 18	Mean 65 (66)

e. Comprehensive Geriatric Assessment with Optimisation

Study	Study design and location	Population	Study groups	Sample size	Age in years intervention (control)
Hempenius 2013	RCT, multi-centre, Netherlands	Abdominal, GI, breast, ENT, lung cancers (52% major surgery) >65 years, frail GFI >3	CGA, best supportive care and prevention of delirium post-operative by geriatrician led team. Including medication optimisation, co-morbidity review, nutrition, visual/hearing loss, mobility, depression, preventative pharmacological measures. One pre-operative consultation plus daily post-operative geriatric nurse reviews. Compared to standard care	Intervention 127, control 133	Mean 77 (78)
Indrakusuma 2015	Retrospective single centre Netherlands	Colorectal cancer, >70 years	CGA and medical optimisation, nursing interventions, blood transfusion and nutritional supplementation by geriatric specialists. Compared to pre-intervention standard care	Intervention 221, control 222	Median 77 (77)
McDonald 2018	Case control study, single centre, USA	Major abdominal surgery, >65 years with risk factors or >85 without	CGA and optimisation of medications, nutrition, cognition, advanced care planning and risk reducing strategies by geriatric led team plus daily post-operative review. Compared to pre-intervention standard care	Intervention 183, control 143	Mean 76 (72)
Ommundsen 2017	RCT, multi-centre, Norway	Colorectal cancer, >65 years, frail VES plus clinical criteria	CGA and optimisation of medications, dietary advice, vitamin and iron supplementation by geriatric doctor. Plus post-operative physiotherapy for COPD. Compared to standard care	Intervention 57, control 65	Mean 78 (79)

f. Smoking cessation

Study	Study design and location	Population	Study groups	Sample size	Age in years intervention (control)
Sorensen 2003	RCT, single centre, Denmark	Colorectal disease (70% oncological)	Counselling and pharmacotherapy with nicotine replacement therapy, one visit plus telephone call. Compared to maintenance of daily smoking habits	Intervention 30, control 27	Median 65 (66)

4.4.2 Baseline characteristics

The studies, published between 2000 and 2019, included 2,028 patients undergoing prehabilitation and 1,934 controls. Interventions comprised: exercise only (9 studies)[230,241,247–253], multi-modal (10 studies)[231–235,254–258], nutrition only (7 studies)[236–239,245,246,259], psychological only (2 studies)[134,240], CGA with optimisation only (4 studies)[242,243,260,261] and smoking cessation only (1 study)[244]. Sample sizes ranged from 32 to 443 patients, with most having fewer than 100 patients in each arm; only four studies had more than this and they were mostly non-randomised studies[247,260–262]. The wide range of sample sizes reflects the diverse primary outcomes on which power calculations were based and also the fact that a small number were pilot or feasibility studies. Studies were predominantly single centre, with only eight studies conducted across multiple centres[239,242,243,245,247,251,252,259]. Studies were conducted in North America, Europe, Australasia, South East Asia and Brazil. A range of surgical populations were studied, including colorectal (16 studies), upper gastrointestinal, hepatobiliary and pancreatic (9 studies), urological (3 studies), and mixed populations (5 studies) (Table 13).

Twenty-four studies involved cancer patients exclusively, with a range of 52-78% of patients with cancer in the remaining studies. Six studies included patients receiving neoadjuvant therapy. Although the average age range was 55–81 years, it was less than 70 years in the majority of studies. Three of the ten multimodal studies[254,256,258] and the four CGA studies[242,243,260,261] had populations with an average age over 75 years. Nine studies selected patients who were either assessed as frail (using a recognised frailty screen or criteria) or over a certain age cut-off [230,242,243,249,254,256,258,260,261].

4.4.3 Methodological quality assessment

The assessment of methodological quality is summarised in Table 14 and Table 15. Only three randomized studies blinded both participants and researchers; one by using a placebo oral nutritional supplement[236], the second by having all patients attend a pre-operative physiotherapy appointment in which the control arm would only receive an information booklet whereas the intervention arm would learn

breathing exercises[247] and the last by using a double-informed consent model where the control and intervention arms were not aware of each other[230]. The absence of blinding of either participants or study personnel was the most common reason for high risk of bias assessment. The majority of RCTs adequately described randomisation, but allocation concealment was not as robustly reported. Half of studies adequately described blinding of outcome assessment [134,230,232,235,236,240,241,243–245,247,249,250]. Only two studies did not adequately report their outcome data[134,233] (Table 14). Seven of the eight non-randomised studies were graded as moderate risk of bias due to bias in outcome measurements and due to confounding factors as they mainly used historical controls[255,256,258–261,263] (Table 15). One study was judged to be at high risk of bias as they chose to include a wider age range in their intervention group compared to controls[254].

Reference	Randomisation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other sources of bias (other bias)
Exercise alone							
Banerjee 2018	+	+	-	+	+	?	?
Barberan-Garcia 2018	+	+	+	+	+	+	?
Boden 2018	+	+	+	+	+	?	?
Carli 2010	+	?	-	?	+	?	?
Dronkers 2010	+	?	-	+	+	?	?
Dunne 2016	+	+	-	+	+	?	?
Santa Mina 2018	?	?	-	?	+	+	?
Soares 2013	?	?	-	-	+	+	?
Yamana 2015	?	?	-	-	+	?	?
Multimodal							
Bousquet-Dion 2018	+	+	-	-	+	?	?
Gillis 2014	+	+	-	+	+	?	?
Jensen 2016	+	+	-	-	?	+	?
Kaibori 2013	?	?	-	?	+	?	?
Minnella 2018	+	+	-	+	+	+	?
Nutrition							
Burden 2017	+	+	-	+	+	+	?
Gillis 2016	+	+	+	+	+	?	?
Kabata 2015	+	+	-	?	+	?	?
Kong 2018	+	?	-	-	+	?	?
Macfie 2000	?	?	-	?	+	?	?
Smedley 2004	?	?	-	?	+	?	?
Psychological							
Chaudhri 2005	?	?	-	+	?	?	?
Haase 2005	?	?	-	+	+	?	?
CGA and optimisation							
Hempenius 2013	+	+	-	?	+	?	?
Ommundsen 2017	+	+	-	+	+	?	?
Smoking							
Sorensen 2003	+	+	-	+	+	?	?

Table 14. Randomised studies - Cochrane risk of Bias tool

Reference	Type of study	Bias due to confounding	Bias in selection of participants	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result
Multimodal								
Chia 2016	Prospective pre and post intervention	moderate	high	low	low	low	moderate	low
Li 2013	Prospective pre and post intervention	moderate	low	low	low	low	moderate	low
Mazzola 2017	Prospective cohort retrospective control	moderate	low	low	low	low	moderate	low
Nakajima 2018	Prospective cohort, retrospective control	moderate	moderate	low	low	low	moderate	low
Souwer 2018	Prospective pre and post intervention	moderate	low	low	low	low	moderate	low
Nutrition								
Manasek 2016	Prospective cohort, retrospective control	moderate	moderate	low	low	low	moderate	low
CGA and optimisation								
Indrakusuma 2015	Retrospective cohort	moderate	moderate	moderate	low	low	moderate	low
McDonald 2018	Case-control (matched)	moderate	low	low	low	low	moderate	low

Table 15. Non-randomised studies (ROBINS-I tool)

4.4.4 Interventions

4.4.4.1 *Exercise-based interventions*

Unimodal exercise interventions were most commonly based in hospital and conducted under supervision[247,249,250,252,253]; four studies included specific pulmonary exercises or training[247,249,252,253]. Exercise prehabilitation programmes varied in intensity from a single preoperative session[247] to one to three times per week, and ranged from 1 to 6 weeks in duration.

4.4.4.2 *Multimodal interventions*

Multimodal interventions were more likely to be home-based[232,235,255–257]; all included exercise and nutrition, with four also including psychological interventions[231,232,255,258]. The nutritional component of multimodal interventions commonly involved dietician assessment and supplementation if required. Two studies did not mention supplementation[234,254]. Two multimodal programmes specifically mentioned other behavioural modifications: alcohol reduction[255] and smoking cessation[256].

4.4.4.3 *Nutrition-based interventions*

Nutrition-only prehabilitation studies all included oral nutritional supplementation (ONS) but the prescriptions varied from 'ad libitum' between meals to 400 ml three times a day, with duration varying from 1 to 4 weeks [236–239,245,246,259]. Two studies included separate intervention groups that received supplements both pre- and post-operatively[238,239].

4.4.4.4 *Psychology-based interventions*

The two psychological prehabilitation studies had different interventions; the study by Chaudhri and colleagues looked at the impact of a community-based stoma education intervention[134], whereas the study by Haase and colleagues involved giving patients audio recordings with either guided imagery or relaxation techniques to listen to pre-operatively[240].

4.4.4.5 *Comprehensive geriatric assessment with optimisation*

The CGA prehabilitation studies all involved pre-operative CGA performed by a geriatrician led multi-disciplinary team, nutritional optimisation and medication reviews[242,243,260,261], two studies included post-operative daily reviews by a specialist nurse in geriatric medicine[242,260]. Two studies specified that they corrected anaemia with either blood transfusion[261] or supplementation[243].

4.4.4.6 *Smoking cessation*

One study of a smoking cessation intervention met the inclusion criteria; the intervention involved a single smoking cessation counselling session combined with nicotine replacement therapy[244].

4.4.5 Adherence

Adherence was reported in eight of the nine studies of exercise [230,241,247–251,253], five of the ten multimodal studies[231–233,235,255], and four of the seven nutrition prehabilitation studies[236,238,245,246], with percentages varying from 69 to 100 per cent, 59 to 98 per cent, and 75 to 99 per cent respectively. Adherence was not stated in studies of psychological, CGA and optimisation or smoking cessation interventions, which is likely because these were typically single pre-operative interventions, so adherence would not have been an issue.

4.4.6 Primary outcome

Twenty different primary outcomes were reported; 12 of the 33 studies (36%) reported more than one primary outcome measure (Table 16). Postoperative complications were the most common postoperative outcome measures, and were reported in all except one study[134]. LOS was reported in all except two studies[237,253].

4.4.7 Postoperative, functional and psychological outcomes

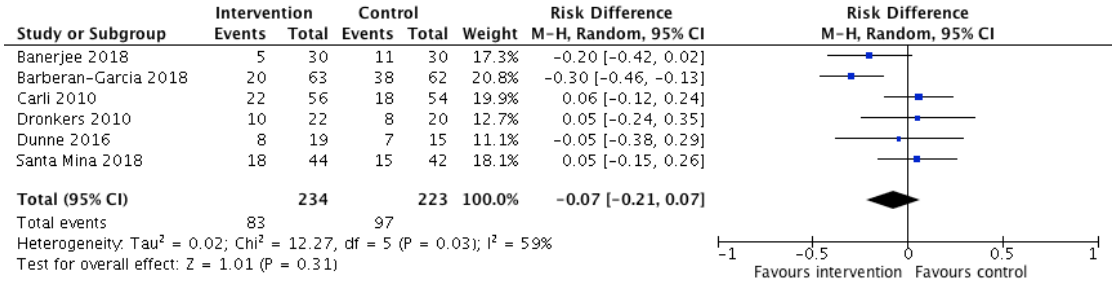
4.4.7.1 *Exercise studies*

One study reported a significant reduction in overall complications (19/62 intervention vs. 39/63 control; p=0.001, RR 0.5 95%CI, 0.3-0.8)[230]. One study found a non-significant higher complication rate in their intervention arm (22/56 intervention vs. 18/54 control, (p not reported)), which was attributed to poor compliance in the intervention group and an increase in physical activity in the control group[248]. A meta-analysis showed no significant differences in overall complications, however heterogeneity was high (mean difference -0.07 (95% CI -0.21 to 0.07); p=0.31, I^2 = 59%) (Figure 8a). Two studies reported lower rates of pulmonary complications in the intervention group; Boden and colleagues (27/218 vs. 58/214 (adj HR 0.48, 95%CI 0.3-0.75, p=0.001) and Soares and colleagues (5/16 vs. 11/16, p=0.03)[247,252]. Yamana also found a lower Clavien Dindo grade of pulmonary complication with intervention (Mann-Whitney U test, p=0.014)[253]. Meta-analysis of five studies (the study by Boden and colleagues was excluded due to significantly different intervention) for pulmonary

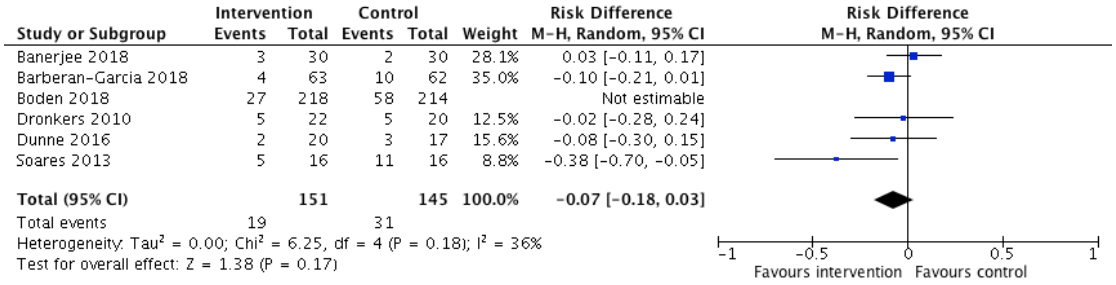
complications revealed a non-significant trend in favour of the intervention (mean difference -0.07 (-0.18 to 0.03); p=0.17; I^2 = 36%) (Figure 8b). A non-significant trend towards lower LOS was observed on meta-analysis (mean difference -0.18 (-2.29-0.14); p=0.08; I^2 = 31%) (Figure 8c, Table 16a).

Two studies that assessed pre-operative change in CPET variables before and after intervention both demonstrated significant improvements in peak oxygen uptake and peak work rate (Table 16a)[241,250]. Four studies that assessed functional walking ability using the 6MWT demonstrated no differences between intervention and control in the pre-operative period[230,248,251,252]. Of the five studies that reported psychological outcomes, only Dunne found an improvement in overall quality of life score measured using the SF-36 (+11 95%CI 1 to 21; p=0.028) and overall mental health score (+11 95%CI 1 to 22; p=0.037)[250](Table 16a).

a.



b.



c.

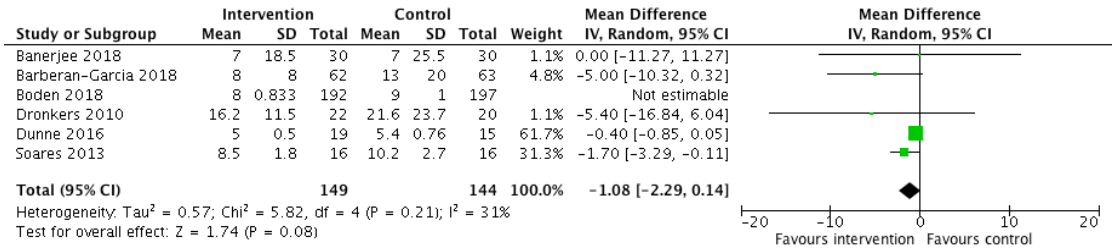


Figure 8. Forest plots showing the effect of exercise prehabilitation on overall complications (a), pulmonary complications (b), and length of hospital stay (c)

a. Meta-analysis of 6 studies for the effect of exercise prehabilitation on overall complications revealed no significant differences between intervention and control (mean difference -0.07 (95% CI -0.21 to 0.07); p=0.31, I^2 = 59%).

b. Meta-analysis of 5 studies for the effect of exercise prehabilitation on pulmonary complications revealed a non-significant trend in favour of the intervention (mean difference -0.07 (-0.18 to 0.03); p=0.17; I^2 = 36%).

c. Meta-analysis of 6 studies for the effect of exercise prehabilitation on length of hospital stay revealed a non-significant trend in favour of the intervention (mean difference -0.18 (-2.29-0.14); p=0.08; I^2 = 31%).

4.4.7.2 *Multimodal studies*

One study found a reduction in overall complications (17/41 vs. 26/35; p=0.005)[256]. A meta-analysis showed a significant reduction in overall complications after multi-modal prehabilitation (risk difference -0.1 (95%CI -0.18 to -0.02); p=0.01, I^2 = 18%)(Figure 9). Mazzola and colleagues (Grade CD≥3 7/41 vs. 15/35, p=0.02) and Souwer and colleagues (Grade CD≥3 14/86 vs. 24/75 (OR 0.4 95% CI 0.2-0.9; p=0.03)), both showed a reduction in severe complications with multi-modal prehabilitation[252,256]. No other studies demonstrated a reduction in severe complications, delirium, pulmonary or wound infections. Three studies reported a significant reduction in length of stay; Chia and colleagues (8.4 vs. 11days, p=0.029)[254], Nakajima and colleagues (median (IQR): 23 (16-34) vs. 30 days (21-40), p=0.045)[263] and Souwer and colleagues (patients with length of stay ≥14 days 5/86 vs. 17/63 OR 0.2 95% CI 0.1-0.5, p=0.001)[258]. A meta-analysis for length of stay including six studies was not significant, however there were high levels of heterogeneity (risk difference -0.7 (95% CI -1.76 to 0.37); p=0.2, I^2 = 68%) (Figure 9; Table 16b).

Four multi-modal studies demonstrated significant pre-operative improvements in functional walking ability using the 6MWT following intervention (mean difference range 24 to 62 metres; all p<0.01) (Table 16b) [232,235,255,263]. However, in two studies walking ability was only tested in the intervention group[255,263]. No difference in psychological outcomes were observed in multi-modal studies [231,232,255] (Table 16b).

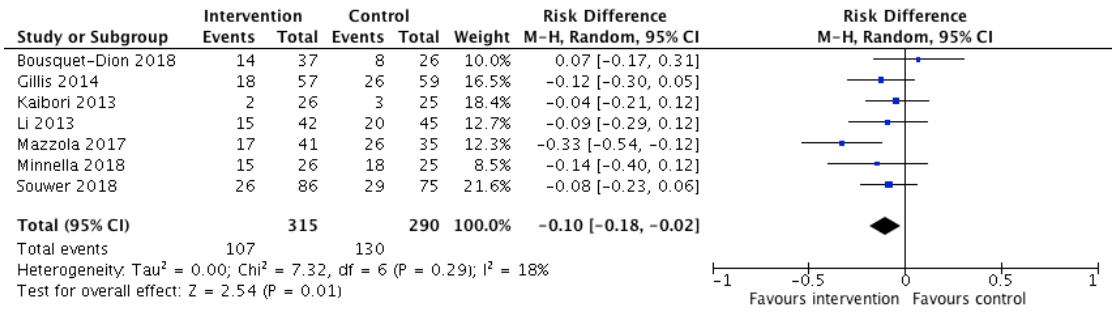


Figure 9. Forest plot showing the effect of multimodal prehabilitation on overall complications.

Meta-analysis of 7 studies for the effect of multimodal prehabilitation on overall complications revealed a significant reduction in the intervention group (risk difference -0.1 (95%CI -0.18 to -0.02); p=0.01, I^2 = 18%).

4.4.7.3 *Nutrition studies*

Two studies reported a reduction in overall complications; Kabata (8/54 vs. 17/48; p=0.04)[237] and Smedley(Group 2 15/32 vs. 34/44; p<0.05 Bonferroni test)[239]. A meta-analysis demonstrated significantly fewer overall complications with intervention (Macfie paper excluded from meta-analysis as historic) (Risk difference -0.18 (95% CI -0.26 to -0.10); p<0.001, I^2 = 0%)(Figure 10). Kabata also reported a reduction in severe complications (Grade CD≥3: 5/54 vs. 11/48; p<0.001)[237] and Burden found a reduction in surgical site infections (11/55 vs. 17/45, OR 0.41 95% CI 0.16-1.0; p=0.044)[245]. Only one study reported a reduction in length of stay with intervention (mean (SD) 9.4(4.97) vs. 12 (6.4); p=0.002)[259], with no difference in length of stay on meta-analysis (data not shown)(Table 16c).

Burden (median percentage weight loss 4.1 (IQR 1.7-7) vs. 6.7 (2.6-10.8); p=0.016)[245] and Smedley (Group 2; less weight loss p=0.05)[239] were able to demonstrate a reduction in pre-operative weight loss with their interventions, that was not seen in other studies[237,238,246]. No differences in functional walking ability [236] or psychological outcomes were found[236,238,239,246].

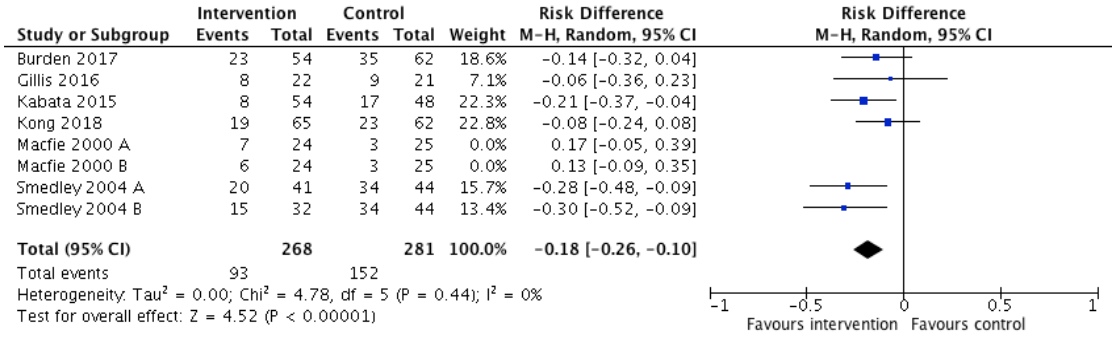


Figure 10. Forest plot showing the effect of nutrition prehabilitation on overall complications.

Meta-analysis of 8 interventions from 6 studies for the effect of nutrition prehabilitation on overall complications revealed a significant reduction in the intervention group (Risk difference -0.18 (95% CI -0.26 to -0.10); p<0.001, I^2 = 0%).

4.4.7.4 *Psychological studies*

Chaudhri reported a reduction in LOS in the intervention group (8 versus 10 days in the control group; P = 0.029), which was attributed to fewer delayed discharges owing to stoma proficiency (Table 16d) [134]. Haase et al. found no difference in overall complications between either of their interventions and the control[240]. Neither psychological intervention had any effect on the measured psychological outcomes[134,240] (Table 16d)

4.4.7.5 *Comprehensive geriatric assessment with optimization*

McDonald demonstrated a reduction in mean number of complications per patient (0.9 vs. 1.4, 95%CI -0.13 to -0.89; p<0.001) despite a higher incidence of delirium in their intervention group (52/183 vs. 8/143 CI 3.06-14.65; p<0.001)[260]. Two studies demonstrated a significant reduction in length of stay with intervention; McDonald (median 4 vs. 6 days, 95%CI -1.06 to -4.21, p<0.001)[260] and Indrakusuma (median (range); 7 (5-12) vs. 9 (7-14) days; p=0.001)[261]. McDonald demonstrated an improvement in discharge independence with intervention (114/183 vs. 73/143; p=0.04; 95% CI 1.02-2.47)[260]. Hempenius found an improvement in psychological outcome (SF-36 bodily pain scores) with intervention (same or better 57/127 vs. 41/133; OR 0.49 (0.29-0.82))[242] (Table 16e).

4.4.7.6 *Smoking studies*

The smoking cessation trial did not find a reduction in either complications or LOS with intervention (Table 16f) [244].

Table 16. Summary of outcomes and results.

Abbreviations: n.s; non-significant, CD; Clavien Dindo, LOS; length of stay, SF36 PCS; Short form 36 Physical Component Summary, MCS; Mental Component Summary, HADS; Hospital Anxiety and Depression Scale, 6MWT; 6 minute walk test, AT; Anaerobic Threshold, OP; Oxygen Pulse, VE; Ventilatory Equivalent, VO2; Oxygen uptake.

a. Exercise

Study	Adherence	Study primary outcome	Post-operative outcomes	Functional outcomes	Psychological outcomes
Banerjee 2018	92%	Feasibility	Complications all: 4/30 vs. 10/30 p=0.075 CD≥3 1/30 vs. 4/30 Pneumonia 3/30 vs. 2/30 LOS median:7 (4-78) vs. 7 (5-107) days	Peak OP +1.36ml/beat ((95% CI 0.63-2.1) ANCOVA p=0.001), Peak VE +7.49L/min ((95% CI 2.86-12.12) p=0.02), Peak power output +19W ((95% CI 10-27) p<0.001)	
Barberan-Garcia 2018	87%	Any complications	Complications all: 19/62 vs. 39/63 (p=0.001, RR 0.5 95%CI, 0.3-0.8) Pulmonary 4/63 vs. 10/62 p=0.155, wound 1/63 vs. 1/62 LOS mean /””?(SD):8 (8) vs. 13 (20) p=0.078	6MWT no difference	SF36 PCS n.s. HADS anxiety or depression no change either group
Boden 2018	98%	Pulmonary complications within 14 days	Complications: Any within 6/52 74/192 vs. 79/197, Pulmonary 27/218 vs. 58/214 (adj HR 0.48, 95%CI 0.3-0.75, p=0.001) Wound 36/192 vs. 40/197 LOS median: 8(6-11) vs. 9(7-13)		
Carli 2010	79%	Change in 6MWT pre-operative and post-operative	Complications all: 22/56 vs. 18/54 CD ≥3 6/56 vs. 3/54 LOS mean (SE): 11.9 (34.6) vs. 6.6 (3.6)	6MWT baseline to pre-op -10.6 (7.3) vs. +8.7 (6.8) Mean peak VO2 +134ml/min vs. +112ml/min	HADS anxiety Baseline to post-op FU -1.8 (0.7) vs. -2.0 (0.5) n.s. HADS depression -0.8 (0.6) vs. -0.4 (0.5) n.s.
Dronkers 2010	97%	Feasibility	Complications all: 9/22 vs. 8/20 Pulmonary 5/22 vs. 5/20 LOS mean(SD):16.2 (11.5) vs. 21.6 (23.7)		EORTC QLQ-C30 n.s
Dunne 2016	92%	Oxygen uptake at AT	Complications all: 8/19 vs 7/15, grade CD≥3 3/19 vs. 1/15 Pneumonia 2/20 vs. 3/17, Wound 3/20 vs. 0/17 LOS median (range): 5 (4-6) vs. 5 (4.5-7)	VO2 at AT Intervention vs control +1.5ml/kg/min 95%CI 0.2 to 2.9; p=0.023 Peak work rate +13W 95%CI 4 to 22, p=0.005	SF36 – overall QoL score +11 95%CI 1 to 21 p=0.028 Overall mental health score +11 95%CI 1 to 22 p=0.037
Santa Mina 2018	69%	Feasibility	Complications all: 18/44 vs. 14/42, CD≥3 1/44 vs. 1/42 LOS mean (SD): 1.7 (0.9) vs 1.76 (1)	6MWT preop +14.6±14.5 95% CI -13.87 to 43.05 p=0.313	Post op HADS Anxiety –difference estimate +0.47±0.68 p=0.49
Soares 2013		Pulmonary function change and 6MWT	Pulmonary complications 5/16 vs. 11/16, p=0.03 LOS median (range): 8.5 (4.8-12.3) vs. 8.5 (6.5-17.3)	6MWT preop 514.4 (460-557.5) vs. 441.5 (412.3-505.9) p=0.105	
Yamana 2015	100%	Pulmonary complications	Pulmonary complications (CD Grade ≥3 3/30 vs. 5/30. CD grade intervention vs. control lower Mann-Whitney U test (p=0.014)		

b. Multi-modal

Study	Adherence	Study primary outcome	Post-operative outcomes	Functional outcomes	Psychological outcomes
Bousquet-Dion 2018	98%	Exercise capacity 6MWT	Complications all: 14/37 vs. 8/26 Wound 5/37 vs 3/26 Grade CD≥2 5/37 vs. 4/26, Grade CD≥3 2/41 vs. 0/39 LOS median 3 (IQR3-4) vs 3 (IQR2-4) p=0.122	6MWT mean difference (SD); +21m (SD 47) vs. +10 (30), p=n.s	HADS anxiety >7 35% vs. 23% HADS depression >7 11% vs 19%
Chia 2016		Length of stay, complications	Complications CD grade ≥3 3/57 vs.5/60 p=0.511 LOS 8.4 vs 11days, p=0.029		
Gillis 2014	78%	6MWT at 8 weeks	Complications all: 12/38 vs. 17/39 p=0.277 Wound 3/38 vs. 3/39, Grade CD ≥3 4/38 vs. 6/39, Pulmonary 1/38 vs. 0/39 LOS 4 (IQR3-5) vs 4 (IQR3-7) p=0.812	6MWT pre-op +25.2 (SD 50.2) vs -16.4m (SD 46) mean diff 41.7m (95% CI 19.8 to 63.6) adjusted p<0.001	SF36/ HADS n.s
Jensen 2016	59%	Feasibility	Complications all: 30/50 vs. 34/57 LOS median 8 (3-30) vs. 8 (4-55) p=0.68		
Kaibori 2013		Whole body mass and fat mass	Complications all: 2/23 vs. 3/23 p=0.671 LOS mean (SD): 13.7 (4) vs 17.5 (11.3) p=0.12		
Li 2013	70% partial	6MWT at 8 weeks	Complications all: 15/42 vs. 20/45 Grade CD≥3 2/42 vs. 1/45 LOS median (IQR): 4 (3-6) vs. 4 (3-6) days	Pre-op 6MWT 464±92m vs. 402±57m baseline (prehab group only), p<0.01	SF36 n.s.
Mazzola 2017		Mortality, complications	Complications all: 17/41 vs. 26/35 p=0.005 Grade CD≥3 7/41 vs. 15/35 p=0.02, pulmonary 2/41 vs. 1/35 LOS median (range) 17 (7-76) vs. 27 (8-146) days p=0.08		
Minnella 2018	63%	6MWT pre-operative and post-operative	Complications all: 14/24 vs. 18/25 Grade CD≥2 12/24 vs. 16/25, Grade CD≥3 6/24 vs. 10/25 LOS: median 8 (IQR 5.75-11.75) vs. 7 (5.5-12.5) p=0.44	6MWT mean (SD) change preop +36.9 (51.4) vs -22.8(52.5)m, p<0.001	
Nakajima 2018		Pre-operative nutritional status and post-operative course	Complications CD≥3 32/76 vs 38/76, pneumonia 1/76 vs 1/76, wound 2/76 vs. 3/76 LOS median (IQR): 23 (16-34) vs. 30 days (21-40), p=0.045	Prehab (no control) 6MWT Median (IQR); baseline 530 (470-571) to pre-op 554m (499-620), p<0.001	
Souwer 2018		1-year mortality	Complications all: 24/86 vs. 26/63 Grade CD≥3 14/86 vs. 24/75 (OR 0.4 95% CI 0.2-0.9 p=0.03) Pulmonary p=0.3 LOS ≥14 days 5/86 vs. 17/63 OR 0.2 95% CI 0.1-0.5 p=0.001		

c. Nutrition

Study	Adherence	Study primary outcome	Post-operative outcomes	Functional outcomes	Psychological outcomes
Burden 2017	est. 75%	Surgical site infection or chest infection	Complications all: 23/54 vs 35/62 p=0.114, pneumonia 5/54 vs. 4/62, Grade CD≥3 9/54 vs. 10/62, SSI: 11/55 vs. 17/45 OR 0.41 CI 0.16-1.0 p=0.044 LOS median 7 (IQR 4-10.5) vs 7days (IQR 4-10 p=0.63)	% weight loss pre-op median 4.1 (IQR 1.7-7) vs 6.7 (2.6-10.8) p=0.016	
Gillis 2016	93.7-96.6%	6MWT pre-operative and post-operative	Complications all: 8/22 vs. 9/21 Grade CD≥3 2/22 vs. 2/21, Pneumonia 0/22 vs. 1/21 LOS median 5 (3-13) vs. 4 (3-10)	6MWT +20.8m (SD42.6) vs. +1.2m (65.5) p=0.27	SF36 post op: PCS 41.3 (34.2-46.5) vs. 36.5 (34.5-42.8), MCS 47.7(38.1-53.8) vs. 41.3 (35.6-55.8)
Kabata 2015	-	Complications within 30 days	Complications all: 8/54 vs. 17/48 p=0.04, Grade CD≥3: 5/54 vs. 11/48 p<0.001 wound 1/54 vs. 7/48, pneumonia 1/54 vs. 0/48	median % weight loss pre-op 7.4 vs. 6.3% n.s.	
Kong 2018	99% partial	Post-operative complications CD≥2	Complications: Grade CD ≥3 9/65 vs. 12/62, wound 7/65 vs. 3/62, pulmonary 6/65 vs. 4/62 LOS mean (SD) 9.3 (3.6) vs. 9.7(5.9)	% body weight change pre-op -0.37% vs -0.97% p=0.173	EORTC QLQ – no difference
Macfie 2000		Weight change and clinical outcomes			
Group 1	89.3		Complications all: 7/24 vs. 3/25 LOS mean 12 vs. 13	Pre-op weight loss n.s	HADs post-op: anxiety or Depression n.s
Group 2	80.7		Complications all: 6/24 vs. 3/25, LOS mean 11 vs. 13		HADs post-op: Anxiety or Depression n.s
Manasek 2016		Complications	Complications wound: 3/52 vs. 13/105 (RR 2.2) LOS mean (SD): 9.4(4.97) vs. 12 (6.4) p=0.002	% weight loss post-op 2.6 vs. 6.4% n.s.	
Smedley 2004	-	Post-operative change in body weight	Complication all: 20/41 vs. 34/44, Buzby def. minor 17/41 vs. 30/44, major 3/41 vs. 4/44	-	SF36 – no difference
Group 1			LOS mean 12.8 (4.5) vs 14.1 (6.6)		
Group 2	-		Complications all: 15/32 vs. 34/44 p<0.05 Bonferroni test, minor 10/32 vs. 30/44, major 5/32 vs. 4/44 LOS mean 11.7 (5.1) vs. 14.1 (6.6)	Only group to gain wt pre-op and lost less wt over course of study p=0.05	SF36 - no difference

d. Psychological

Study	Adherence	Study primary outcome	Post-operative outcomes	Functional outcomes	Psychological outcomes
Chaudhri 2005		Time to stoma proficiency, length of stay	Length of stay 8 vs. 10 days, p=0.029		HADS score post-op. anxiety 33% vs 32% Depression 17% vs. 24%
Haase 2005 Group 1 Group 2		Systemic analgesic consumption via Patient Controlled Analgesia	Complications wound 3/20 vs. 3/18, delirium 0/20 vs. 0/18 LOS median (range) overall 12.5days (11-14) Complications: Wound infection 4/22 vs. 3/18, Delirium 1/22 vs. 0/18, LOS median (range) 12.5 (11-14)		EORTC QLQ and GIQLI n.s

e. Comprehensive Geriatric Assessment with optimisation

Study	Adherence	Study primary outcome	Post-operative outcomes	Functional outcomes	Psychological outcomes
Hempenius 2013		Post-operative delirium	Complications >1 42/127 vs. 38/133 OR 1.24 (0.73-2.1) Pulmonary 31/127 vs. 27/133, Wound 13 vs. 12 p=0.37, delirium 12/127 vs. 19/133 OR 0.63 (0.29-1.35) LOS 8 vs. 8 days	Discharge independence 76/127 vs. 87/133 OR 1.84 CI 1.01-3.37	SF-36 bodily pain same/better 57/127 vs. 41/133 OR 0.49 (0.29-0.82)
Indrakusuma 2015		30 day mortality, delirium, length of stay	Complications: pneumonia 37/221 vs. 31/222, wound 18/221 vs. 26/222, Delirium 22/221 vs. 27/222 LOS: 7 (range 5-12) vs 9 (7-14) p=0.001		
McDonald 2018		Length of stay, readmissions and level of care at discharge	Complications: mean no. 0.9 vs. 1.4 95%CI -0.13 to -0.89, p<0.001, Delirium 52/183 vs. 8/143 CI 3.06-14.65 p<0.001, pulmonary 18/183 vs 25/143, wound 4/183 vs. 8/143. LOS Median 4 vs 6 days, 95%CI -1.06 to-4.21, p<0.001	Discharge home with self care 114/183 vs 73/143 p=0.04 CI 1.02-2.47	
Ommundsen 2017		Complications CD≥2	Complications: Any 40/52 vs. 55/62, grade CD≥2 36/52 vs. 47/62 LOS: 8 vs. 8 days	Discharged directly home 38/57 vs. 38/65 p=0.2	

f. Smoking cessation

Study	Adherence	Study primary outcome	Post-operative outcomes	Functional outcomes	Psychological outcomes
Sorensen 2003		Post-operative wound and tissue complications within 30 days	Complications: Any 11/27 vs. 13/30, pneumonia 3/27 vs. 4/30, wound 3/27 vs. 4/30 LOS median (IQR): 11(10-13) vs. 11 (8-14) days		

4.5 Discussion

This systematic review has found evidence from a number of trials that exercise, multi-modal, nutrition and CGA with optimisation prehabilitation programmes may reduce post-operative complications following elective gastrointestinal and urological cancer surgery. It has shown evidence that multi-modal, nutritional, psychological and CGA interventions, but not exercise interventions or smoking cessation alone may reduce length of hospital stay. In particular, the small number of studies that selected high risk, frail or older patients were more likely to report improvements in either complications or LOS compared to studies that included all patients. Equally, studies conducted in oesophageal and upper gastrointestinal surgery, known to be associated with high levels of post-operative morbidity and mortality, were more likely to demonstrate reductions in pulmonary complications. However, conclusions are limited by the methodological quality of included studies, in particular the lack of blinding of participants in all except three studies. Significant heterogeneity of interventions also limits comparison. Adherence to exercise, multi-modal and nutritional interventions was generally high, however, it is possible that participant selection bias and lack of blinding may have resulted in more motivated patients being recruited.

National and international guidelines recommend that a comprehensive geriatric assessment should be performed in all patients over the age of 70 with a diagnosis of cancer to try to predict treatment toxicities, post-operative complications and to aid in shared decision-making[264–266]. However, there remain very few studies of CGA in surgical cancer populations and the majority of these are limited to its role in risk prediction and prognostication[7,267]. This systematic review only identified two RCTs evaluating CGA and tailored optimisation[242,243]. It is worth noting that the median age of patients in studies included in our review was only 68 years, with the median age of patients in the exercise alone interventions 63 years. Only seven of the thirty-three studies in this review had a median age greater than 75 years. This suggests that many prehabilitation studies to date have either failed to recruit older patients due to the location or nature of the interventions or they have excluded older patients due to

perceived risk of the interventions, despite mounting evidence that exercise-based interventions are safe in older individuals[268,269].

This review has also demonstrated that improvements in pre-operative functional measures can be made with exercise prehabilitation (measured by CPET testing), multi-modal interventions (measured using 6MWT) and nutritional prehabilitation (reduction in pre-operative weight loss). However, the link between small statistically significant improvements in these variables and clinical outcomes is not clear.

A number of previous systematic reviews have examined individual components of prehabilitation in varying surgical populations; exercise[137,270–274], exercise in frail individuals[275], multimodal interventions[138,276,277], multimodal interventions in frail individuals[278], nutrition with and without exercise[279] and psychological interventions[280]. All of these reviews, including our own, have been limited by the quality of the underlying evidence. This is the first review that we are aware of that has included all modalities of prehabilitation of relevance to the older adult.

Prehabilitation programmes, regardless of the individual components they comprise, are complex, multi-component interventions and thus should be evaluated as such. The Medical Research Council (MRC) have published a clear framework regarding how to evaluate and conduct trials involving complex interventions[185]. Two of the potential reasons for negative findings in prehabilitation studies are that either the interventions are made too standardised to enable reproducible delivery or in efforts to provide truly personalised programmes no two individuals receive the same intervention. Equally, whilst there is accumulating evidence that multi-modal prehabilitation is likely to be more beneficial than single modality, future trials that use methodologies designed for evaluating complex interventions will be able to determine which components are most beneficial for different patients and why.

This review is limited by the heterogeneity of outcomes reported; length of stay and complications were selected as primary outcomes for this review. However, a number of studies were powered to detect changes in other primary outcomes and therefore

may have been inadequately powered for the primary outcomes of this review. The majority of trials in prehabilitation are relatively small which may contribute towards reporting bias of trials with statistically significant outcomes. Heterogeneity of studies may have also contributed to some analyses reaching statistical significance inappropriately. The wide date range of included studies may have added to the heterogeneity, as perioperative care has evolved over the last twenty years with the introduction of enhanced recovery pathways and laparoscopic surgery. Another potential limitation is that we have compared diverse surgical procedures with a range of complication rates. This may have resulted in some analyses not reaching significance and will have contributed towards heterogeneity on meta-analysis. For the purpose of this review, a large number of studies were excluded at full text review due to lack of reporting of LOS or complications, which are considered core outcomes for surgical trials[281,282]. In particular, a number of trials of psychological interventions were excluded for this reason[283–288]. Of note, only one pre-operative smoking cessation trial and no studies in gynaecological cancer surgery met the inclusion criteria. The main strength of this review is the comprehensive nature in which we have included all current prehabilitation modalities in GI and abdominal surgery. This means that it is of relevance to a wide range of surgical specialties, identifies gaps in the current evidence-base and will be of interest to commissioners looking to fund prehabilitation services.

Clearly, reporting of outcomes presents a challenge in this review due to the range of outcome measures used which reflects complex interventions and the inability to directly compare them. This raises an important issue for researchers. The evidence base for prehabilitation might be stronger if a core outcome set could be used in all trials, irrespective of modality of prehabilitation or surgical population, to facilitate comparison of interventions. The COMPAC-stEP group have already made progress in this regard in peri-operative medicine[289–292]. Initiatives such as the DiSCO (Defining Standards in Colorectal Optimisation) project[293], which aims to create key sets of standards for prehabilitation in collaboration with patients, their caregivers and the public will be vital to ensure that results are relevant to service users as well as clinicians, and that we are successful in promoting patient-centred care. Future

studies also need to evaluate strategies for implementation and the associated costs to enable adequate investment at a time of increasing healthcare costs.

4.6 Conclusion

Multi-modal prehabilitation may reduce the number and severity of complications after major abdominal cancer surgery. Integration into practice should be considered, although may be best offered to targeted high-risk groups. Future studies should focus on high-risk groups, particularly older populations, aiming to establish optimal methods of delivering and evaluating multi-modal prehabilitation and should report using a core outcome set and patient reported outcomes.

5 Qualitative semi-structured interviews with healthcare professionals

Data from chapters 5 and 6 have been published as a mixed methods paper:

Daniels SL, Burton M, Lee MJ, Moug S, Kerr K, Wilson TR, Brown SR, Wyld L. Healthcare professional preferences in the health and fitness assessment and optimisation of older patients facing colorectal cancer surgery. Colorectal Disease 2021;00:1-10. DOI: 10.1111/codi.15758

My role in this study was in writing the study protocol, submitting applications for funding and ethical approval, conducting and analysing the interviews and writing the paper for publication.

Permission from the publisher (Appendix U) and the co-authors (Appendix V) have been obtained for reproduction in this thesis.

5.1 Abstract

Introduction

There are few age and fitness specific, evidence-based guidelines for major gastrointestinal surgery. Rates of major gastrointestinal surgery decline with age, clinician opinion may be a factor in this. The uptake of different assessment and optimisation strategies is variable. The aim of this study was to explore healthcare professional opinion about surgery in the older patient, methods of assessment and optimisation via semi-structured interviews.

Methods

Semi-structured qualitative interviews were undertaken with healthcare professionals from a single UK region involved in the treatment, assessment and optimisation of gastrointestinal surgery patients. Interviews were analysed using the Framework approach.

Results

Thirty-seven healthcare professionals out of 42 approached (response rate 88%) were interviewed across 5 hospitals in the South Yorkshire region. Participants included surgeons, anaesthetists, specialist nurses, oncologists, Allied health professionals (dieticians, physiotherapists, occupational therapists), general practitioners and a geriatrician. Three broad themes were developed: attitudes towards treatment of the older patient, methods of assessment of suitability and experience of optimisation. Assessment was not standardised. Access to optimisation strategies was limited. Optimisation of patients presenting as emergencies was viewed as particularly challenging.

Conclusions

There is wide variation in the process of assessment and provision of optimisation strategies in UK practice. Lack of evidence-based guidelines, cost and time constraints restrict the development of services and pathways. Difference in opinion between healthcare professionals may account for some of the UK variation in gastrointestinal surgery outcomes.

5.2 Introduction

As already covered in Chapter 2, variation in practice is common in gastrointestinal (GI) surgery, particularly in the older population (>65 years)[50,294]. The health status of older adults varies considerably, which makes determining optimal treatment strategies challenging. This may require tailoring of treatment to individual patients rather than applying simplistic chronological age cut-offs to standard care. Deciding whether an older patient is suitable or 'fit' for major GI surgery is complex and involves balancing the potential benefits of surgery against the risks of post-operative morbidity, functional decline and poor quality of life[84,295]. There is little published data on healthcare professionals' opinions regarding performing major GI surgery in older patients, how they determine suitability for surgery and how they optimise them to improve outcomes[165,166].

Clinician preference heavily influences patient decision-making and may account for some of the differences in rates of major surgery in the older population[296–298]. The causes of this varying opinion are not known but may include personal experience, interpretation of the literature or unit protocols. It may also be affected by anaesthetic staff attitudes to anaesthesia in older patients and critical care bed availability and admission criteria[11,167]. Regarding optimising patient surgical pathways, again, there is variation in opinion regarding the value of prehabilitation, nutritional optimisation, smoking cessation and geriatric assessment, for example, which affects the advice given to patients as well as the commissioning of services.

Lack of evidence of efficacy on surgical outcomes and cost effectiveness, limits implementation of optimisation strategies in practice[299]. There are also questions regarding which patients should be targeted for interventions, timing, funding, how to measure the success of interventions and whether planned surgery should be delayed to enable optimisation[169]. Differences in healthcare professional (HCP) opinion regarding all of these factors may influence patient uptake of interventions.

This chapter explores the practices and attitudes of a wide range of HCPs involved in the referral, assessment, optimisation and rehabilitation of older patients undergoing major GI surgery to delineate barriers and facilitators to improving care.

5.3 Aims

The aims of this study were to explore HCP preferences for the treatment of older adults with operable major GI pathology and to explore how older patients are currently assessed and optimised in one geographical region. It also investigated some of the barriers and facilitators to introducing new assessment and optimisation measures in practice.

5.4 Objectives

Through semi-structured interviews:

- To explore HCP's attitudes towards major GI surgery in older patients and factors that they take into account when advising regarding treatment options
- To describe healthcare professional experiences and preferences related to the assessment and optimisation of older patients with GI pathology amenable to major surgery

5.5 Methods

5.5.1 Study design

Qualitative, semi-structured interviews were conducted with a range of healthcare professionals involved in the pre-, peri- or post-operative management of patients with GI conditions requiring elective or emergency surgery. This approach allows theories to be generated on a rich dataset from a small sample.

5.5.2 Sample and setting

5.5.2.1 *Sampling*

This study was carried out at all NHS trusts providing both emergency and planned GI surgery within the South Yorkshire region. This was to enable a comprehensive study of regional variation in practice. The five hospitals included one tertiary referral centre, one large Teaching Hospital and three District General Hospitals. General Practitioners were recruited via contacts of the study team and included one from a

rural practice, one from an inner-city practice and one from a mixed urban town all referring into these hospitals.

Healthcare professionals were selected through a combination of purposive and 'snowball' sampling across the spectrum of pre-, peri- and post-operative care and across the main gastrointestinal subspecialities. This included surgeons, clinical nurse specialists (CNS), anaesthetists, oncologists, dieticians, physiotherapists, occupational therapists, general practitioners (GPs) and a geriatrician. Participants were purposely selected to include at least one surgeon and one other healthcare professional at each unit (Table 17). Efforts were made to recruit clinical nurse specialists and anaesthetists at all hospitals, but this was not always possible due to availability of participants, no response from some participants and a delay in receiving regulatory approval for one site. Surgeons, oncologists and specialist nurses were selected to gather responses from colorectal, HPB and OG subspecialities. GPs were selected to represent the varied population of South Yorkshire, including urban, mixed and rural practices. GPs have been grouped together here as one 'trust'; however, they are all GP partners at independent practices. The local Principal Investigator (PI) or lead CNS were used to identify and approach potential participants. 'Snowball' sampling was used to recruit Allied Health Professionals (AHPs) who might not have been as confident to reply to a request for an interview from a surgical trainee that they did not know.

Trust ID	Number recruited							Total
	Surgeon	CNS	Anaesthetist	Oncologist	Geriatrician	GP	Allied HCP	
A	2	3	3	3	1	0	0	12
B	1	2	2	0	0	0	3	8
C	2	1	1	0	0	0	0	4
D	3	3	0	0	0	0	2	8
E	0	0	0	0	0	3	0	3
F	1	0	1	0	0	0	0	2
Total	9	9	7	3	1	3	5	37

Table 17. Participant recruitment per site

5.5.2.2 *Saturation of themes*

Recruitment continued until there had been saturation of themes. Saturation is defined as the point at which no new themes emerge from the data[300–302]. This is usually found to occur at around 20-30 interviews[300]. Saturation in this study occurred at the slightly higher number of 37 and this is attributed to the purposive sampling technique and number of different hospitals that were included.

5.5.2.3 *Inclusion and exclusion criteria*

Any HCP holding a substantive post at any of the five NHS trusts and regularly involved in the pre-, peri- or post-operative management of patients with GI conditions requiring elective or emergency surgery were eligible for inclusion. General Practitioners in current clinical practice and referring patients with suspected gastrointestinal pathology were also eligible. Non-permanent staff, including Foundation Programme, Core and Higher surgical trainees were excluded because their practice will vary depending on the consultants for whom they are working. Exercise professionals who are not currently involved in the routine care of patients requiring major GI surgery were excluded.

5.5.3 **Interview schedule**

An interview schedule was developed with reference to the literature[303] and with input from the study steering group. Separate prompt sheets were developed for use with surgeons, allied health professionals, oncologists, anaesthetists and general practitioners. These prompt sheets enabled the interviews to be structured around certain key areas whilst also allowing freedom to explore different elements that came up in discussions by using open questions. The prompt sheet for GI surgeons is shown below for illustration (Table 18). The other prompt sheets are found in the study protocol (Appendix F).

5.5.4 **Reporting**

This study is reported with reference to the COREQ (Criteria for REporting Qualitative research) checklist[224].

Question: What treatment options would you normally consider for an older person with operable major GI pathology?
Surgical - Major resection - laparoscopic versus open Non resectional surgery or alternative procedure if unfit/frail e.g. stoma, stenting Oncological – neoadjuvant or adjuvant Palliative: chemotherapy, best supportive care
Question: What factors influence your choice of management for a particular patient?
Pathology: Location and size, operability/ stage, malignant versus non-malignant, specific guidelines Patient factors: Co-morbidities, cardiorespiratory fitness, functional status, cognitive impairment, frailty, patient choice, carer attitudes, age, stoma views Specific assessments: Clinical / judgement/ 'end of the bed', Geriatric assessment, formal risk assessment, pre-operative assessment Cardiopulmonary Exercise Testing, 6MWT, ISWT Anaesthetic considerations, access to critical care Specialist nurse opinion
Question: If in such patients there is the potential for choice of resectional surgery, non resectional surgery or palliative options what level of involvement does the patient play in the management decision? How do you help them to decide?
Shared decision-making versus paternalism, use of decision aids, role of specialist nurse, role of anaesthetic/geriatric assessment, role of relatives and friends, legal power of attorney and independent patient advocates in cognitive impairment, use of decision aids/booklets, psychological expertise, training courses Access to time sensitive palliative care service
Question: What factors have influenced your personal strategy for dealing with these patients?
Literature evidence, patient involvement, experience of cases over the years, unit policy, training and mentoring, specialist nurse input, MDT involvement
Question: What do you think older patients feel about having surgery?
Fear of death and 'not waking up', disfigurement, hospitalisation, burden on carers after surgery, loss of independence, complications
Question: What do you think older patients feel about chemotherapy?
Easier than having an operation, safer than having an operation, less certainty of cure, less hassle. Fear of chemotherapy side effects, hair loss, nausea, risk of death. Attending the hospital often rather than spending time with family.
Question: What do you think patients think about non-resectional surgery/ palliative procedures/ other options?
Fears of being in pain, shorter survival, less risky than major procedure, focused on improving quality of life/ preserving quality of life, returning to pre-procedure quality of life

Question: How does your management differ if the patient presents as an emergency?
Cancer –defunctioning stoma, palliative bypass or stent versus resection or palliative care Benign – trial of conservative management, optimisation of other pathologies acute/chronic, medication reversal/ cessation, anaemia correction, resuscitation, nutritional optimisation Baseline assessment – albumin, functional status (verbal/questionnaire), co-morbidities Approach – laparoscopic versus laparotomy Risk assessment – anaesthetic opinion, geriatric assessment, specific risk calculators (e.g. SORT, NELA) MDT – who is involved? Radiologist, anaesthetist, surgeon, other
Question: How do you personally assess the cardiorespiratory fitness and frailty of your patients?
On the basis of history and examination Specific questions – climb stairs, walking distance Validated questionnaire or cardiorespiratory fitness/frailty assessment CPET testing/ 6MWT/ Timed up and go
Question: Who do you formally cardiorespiratory fitness test?
Everyone having specific procedures Age specific, flowchart led Certain co-morbidities Those in whom you have doubts about their fitness
Question: What is your strategy for dealing with patients who you believe to have borderline cardiorespiratory fitness?
Refer for formal exercise testing (CPET) Seek anaesthetic opinion Advise them on how to get fit, give them an exercise regime Advise them to make an appointment with their GP Explore prehabilitation options, refer for physiotherapy, social services input, Surgical School Tell them to stop smoking, reduce alcohol
Question: What is your strategy for patients who you believe are unfit for an operation?
Advise them that surgery is not an option. Advise them that if they improve their cardiorespiratory fitness it may be an option. Advise them on other options – surgical, medical, palliative

Table 18. Prompt sheet for GI surgeons

5.5.5 Recruitment and data collection

5.5.5.1 *Recruitment*

The research departments at all five of the hospitals delivering major GI surgery within the South Yorkshire region were approached and local regulatory approvals for the study were obtained.

Principal investigators (PI) were identified at each of the trusts to facilitate identification of potential participants (Chapter 3; Table 12). PIs and lead CNSs were asked to discuss the study with relevant members of their team to determine willingness to participate. If willing, the researcher (SLD) contacted them via e-mail to make contact and provide them with the participant letter of invitation (Appendix P) and participant information sheet (PIS) (Appendix Q).

5.5.5.2 *Data collection*

All interviews were conducted 1-to-1 by the researcher (SLD). After initial contact with the participant to explain the rationale for the study and provide them with the PIS, a convenient time and place for the interview was arranged. The participant was then sent a reminder e-mail the day before the interview to confirm that they were still happy to proceed and given the opportunity to withdraw if they wished. Interviews were conducted in a private, non-clinical room at the place of work of the participant or via telephone in the latter stages of the project (due to the COVID-19 pandemic). The researcher explained the rationale for the study again and obtained written informed consent to conduct the interview and record the discussions. The interview prompt sheet (Table 18) was used to guide discussions initially and new themes were explored as they emerged. All interviews were digitally recorded and transcribed verbatim. All data collected was pseudo-anonymised. The first two interviews were used as an internal pilot. Field notes were made by the researcher immediately after interviews.

5.5.5.3 *Data analysis*

Data from the interviews were analysed using thematic analysis[304] housed within the framework approach[305] to organise the coding of the data. The framework was used to explore the theory that there is variation in current practice and reasons for this

using an inductive approach. Transcripts and field notes were read, annotated to identify themes and subthemes and then coded. Quotations from the interviews with line number references and summaries of the discussion on each theme were recorded in an Excel database (Microsoft Excel 365) to create a matrix of summarised data. Once entered into the database the coded quotations were sorted according to professional background of the participant. Mapping and interpretation of the dataset were undertaken taking each theme sequentially. Three transcripts (10% of the total number of transcripts) were coded by both the researcher (SLD) and an experienced qualitative researcher (MB; Maria Burton (Lecturer at Sheffield Hallam University)) to ensure validity of the themes and codes. Analysis focused on mapping the range of current practice and attitudes and whether this differed by professional background, subspeciality or treating unit and exploring the reasons behind different practices and attitudes.

5.5.5.4 *Transcription conventions*

Standard transcription conventions were adopted for the recording of direct quotations in the results section (Table 19).

Formatting	Meaning
Italics	Direct quotation from the participant
D4	Participant identification
…	Where text has been abridged to condense a quotation
[word]	Where text has been inserted by the author to clarify a quotation

Table 19. Transcription conventions

5.6 Results

5.6.1 Recruitment

Forty-two healthcare professionals were approached, of whom 37 (88%) consented to interview. These included 9 surgeons (7 colorectal, 1 OG and 1 HPB), 9 Specialist Nurses, 7 anaesthetists, 3 oncologists, 3 General Practitioners (GPs), 2 dieticians, 2 physiotherapists, one Geriatrician specialising in general surgical patients and one occupational therapist (OT)(Table 20). All interviews were conducted by the researcher (SLD). Interviews lasted between 13 and 63 minutes, median 29 minutes 16 seconds. Recruitment continued until saturation of themes occurred[300–302], which was at 37 interviews. See Appendix X for sample interview transcript and Appendix Y for sample of coding table for framework analysis.

HCP identifier	Profession	Specialty	Sex	Interview duration (minutes)
A1	Surgeon	OG	M	34:39
A2	Surgeon	HPB	M	30:55
A3	Nurse	HPB	F	25:46
A4	Anaesthetist		F	27:25
A5	Specialist Nurse	HDU	M	21:36
A6	Specialist Nurse	OG	F	32:45
A7	Geriatrician		F	29:27
A8	Anaesthetist		F	44:22
A9	Anaesthetist		M	31.45
A10	Oncologist	Colorectal	M	39:40
A11	Oncologist	OG/ HPB	F	32:22
A12	Oncologist	Colorectal	F	32:51
B1	Surgeon	Colorectal	F	31:01
B2	Physiotherapist		F	19:48
B3	OT		F	21:33
B4	Specialist Nurse	Colorectal	F	19:00
B5	Specialist Nurse	Colorectal	F	23:46
B6	Anaesthetist		F	28:07
B7	Anaesthetist		M	25:51
B8	Dietician		F	13:42
C1	Surgeon	Colorectal	M	22:13
C2	Surgeon	Colorectal	M	37:58
C3	Specialist Nurse	Colorectal	F	16:24
C4	Anaesthetist		M	36:28
D1	Surgeon	Colorectal	M	52:25
D2	Surgeon	Colorectal	M	26:42
D3	Dietician		F	23:54
D4	Physiotherapist		F	19:16
D5	Specialist Nurse	Colorectal	F	50:24
D6	Specialist Nurse	Colorectal	F	32:45
D7	Specialist Nurse	Colorectal	F	18:52
D8	Surgeon	Colorectal	M	34:23
E1	GP		M	33:00
E2	GP		F	26:57
E3	GP		M	31:10
F1	Anaesthetist		M	28:05
F2	Surgeon	Colorectal	M	63:47

Table 20 Interview participant characteristics

5.6.2 Findings

Three themes were set *a priori* based on review of the literature and interview questions. Several sub-themes were developed during interview analysis and are summarised in Table 21.

Theme 1: Attitudes towards surgical management of the older patient
Subtheme: Impact of age on treatment decisions Potential treatment trade-offs • The 'high-risk' patient • The 'unfit' patient Factors influencing decision-making • Symptom burden • Underlying pathology and presentation • Alternative treatment strategies • Physical inactivity • Nutritional deficiencies • Co-morbidities • Cognitive impairment • Outcomes of importance • Assessment tools and risk calculators • National audits and legislation Challenges in emergency GI surgery
Theme 2: Assessment of the older patient
Subthemes: Fitness for surgery • Cardiorespiratory fitness • Functional capacity • Nutritional • Psychological • Frailty and geriatric assessment • Co-existing medical conditions and risk calculators • Lifestyle • Peri-operative Barriers to assessment Facilitators to assessment Attitudes towards high-risk patients

Theme 3: Optimisation of the older patient
Subthemes: Usual practice • Cardiorespiratory fitness • Nutritional • Psychological • Co-existing medical conditions • Lifestyle • Geriatric • Peri-operative • Rehabilitation Barriers to optimisation • Patient factors • Lack of guidelines and evidence • Administrative burden • Time in the pathways • Allied HCP challenges Facilitators to optimisation • Population level polices and national guidelines/audits • Empowering patients • Flexible pathways • Marginal gains

Table 21 Themes and subthemes developed during interviews

5.6.3 Attitudes towards surgical management of the older patient

5.6.3.1 *Impact of age on treatment decisions*

All HCPs said that they do not take chronological age into account when deciding treatment options, however, many clinicians stated that older patients, particularly those in their late eighties would have to be 'incredibly' fit to tolerate many procedures and to gain long-term benefit from them. This suggests that age may be taken into account, with older individuals expected to be fitter than younger counterparts. HCPs emphasised the assessment of co-morbidities and functional abilities rather than age.

> C2 "We would not make our decision based on age. It is more of a physiological age rather than chronological age".

The oncologists interviewed stated that they were limited by the lack of research evidence to guide the use of chemotherapy in older patients. They voiced concerns regarding the higher incidence of chemotherapy side effects in older individuals, therefore they would consider dose reductions and be more cautious.

> A10 "Very few of the studies have patients over the age of 70, so the question of someone who's 75+ are they going to get the same level of benefit? The honest answer is we don't really know"

5.6.3.2 *Potential treatment trade-offs*

The 'high-risk' patient

Many HCPs spoke about the 'high-risk' or 'borderline' patient. This was usually defined as someone with severe co-morbidities, functional impairments or frailty. In the elective setting, surgeons spoke about the role of an anaesthetic assessment or objective physical tests to enable a more in-depth discussion and facilitate shared decision-making in high-risk individuals. It was often suggested that an older high-risk patient would be unlikely to tolerate complications and therefore might choose or be encouraged to pursue non-surgical management options.

B1 "The high-risk patients, the anaesthetists try to have a chat with them and the family at the time of CPET to set the background and suggest that this may not be a sensible option to have surgery"

Many clinicians commented that 'not operating' was the best way to preserve a 'high-risk' or frail patient's quality of life in the elective setting. Most HCPs had examples of patients who had chosen not to have an elective operation to preserve their quality of life.

A8 "To live longer you have to trade something and that something is often your quality of life".

Many surgeons discussed risk-adapted strategies that they might employ for high-risk patients. This included avoiding primary anastomoses in patients who were unlikely to tolerate anastomotic leaks, less extensive resections or 'quicker' procedures if they were felt to tolerate general anaesthetic poorly. Some surgeons also spoke about strategies that they had used to try to optimise such patients, such as advising weight loss, physical activity or nutritional optimisation. This will be covered in more detail below.

The 'unfit' patient

Some surgeons mentioned tailoring their initial investigations in patients who were immediately deemed to not be suitable for surgical management, such as performing a computed tomography (CT) rather than endoscopy in an 'unfit' patient. This was usually based on functional abilities, residential status, cognitive function, co-morbidities and frailty, although advanced age was also acknowledged to be a factor taken into consideration. Surgeons emphasised the importance of establishing a diagnosis to enable patients to access appropriate services and to help with advanced care planning, even if they would not be able to tolerate surgical intervention.

5.6.3.3 *Factors influencing decision-making*

Symptom burden

Symptom burden was emphasised as an important factor in deciding treatment options. Many surgeons felt that high-risk individuals with minimal symptoms are often better managed conservatively, particularly for non-malignant pathology. In contrast, there was a feeling that both patients and surgeons are more accepting of risk when the patient has significant symptoms. This was felt to be particularly relevant in the emergency situation.

Underlying pathology and presentation

It was felt that in elective surgical presentations there is the time to adequately assess an older patient's fitness for surgery and to have discussions about the relative advantages and disadvantages of surgery. It was generally felt that high-morbidity operations, such as oesophagectomy and pancreatectomy, should be reserved for patients without significant co-morbidities or frailty due to the extent of the surgery. Oncologists and anaesthetists were generally more reticent about aggressive treatment regimes in octogenarians. Again, in the emergency setting it was felt that symptom burden is usually significant, therefore surgeons voiced being more inclined to offer surgery.

Alternative treatment strategies

The availability of alternative, 'non-resectional' or palliative procedures were felt to be useful for patients who were deemed to be 'unfit' for or did not wish to undergo major surgery. Most HCPs felt that these alternative strategies should only be explored if the patient had troublesome symptoms. Palliative stenting of tumours, defunctioning stomas and palliative radiotherapy were all felt to be useful in selected patients. However, it was felt that symptom control from these procedures is generally inferior to resectional surgery and should be reserved for patients with limited life-expectancy but significant symptoms. Endoluminal stenting was the only alternative procedure discussed for OG patients. HPB HCPs discussed the role of radiofrequency ablation and biliary stenting in patients 'unfit' for resection. The

oncologists felt that it was rare that a patient judged to be 'unfit' for major surgery would be able to tolerate palliative chemotherapy.

One CNS commented that older patients are more accepting of not having resectional surgery whereas younger patients sometimes feel 'cheated.' The HPB CNS commented that in their experience, older patients who have already had major colorectal surgery often do not want to go through major surgery again and prefer to have a simpler procedure if this is available.

Physical inactivity

Physical inactivity was felt to be an increasing problem in the older surgical population, particularly by anaesthetists and CNSs. Many gave examples of patients with physical impairments, such as arthritis, that made patients 'high-risk' due to physical deconditioning. Many HCPs felt that this was an important aspect that needs addressing to improve outcomes.

Nutritional deficiencies

Surgeons, CNSs and dieticians spoke about the effects of malnutrition on surgical outcomes. This included weight loss and low BMI, as well as the increasing problem of obesity in older patients. They often felt that patients identified as malnourished would benefit from a period of optimisation if surgery could be delayed. Some spoke about arranging for a period of inpatient nutritional optimisation for those identified as severely malnourished.

Co-morbidities

Surgeons spoke about their caution in offering major surgery to patients with particular co-morbidities, such as severe heart, liver and renal failure, however there were no absolute contraindications. In contrast, the oncologists spoke about particular co-morbidities, in particular cerebrovascular and cardiovascular disease, being contraindications to certain chemotherapy regimens. The presence of a 'Do not attempt resuscitation' order was felt to be an important factor to be taken into consideration, particularly in the emergency setting, as it often signifies that the patient has another life-limiting condition that should be considered.

Cognitive impairment

Surgeons had differing opinions on major surgical procedures in patients with dementia. The majority felt that patients with mild dementia, who were still functionally independent could still benefit from elective surgery if they were well supported by family or friends and they retained the capacity to consent for the procedure themselves. Surgeons performing high-morbidity procedures and oncologists were less likely to say that they offer treatment to patients with dementia and this was attributed to difficulties in post-operative care, poorer overall prognosis, impact of major complications on delirium and fears over precipitating worsening cognitive decline.

In the emergency setting, it was felt that patients with dementia presenting with significant symptoms and a relatively simple to correct surgical pathology (e.g. obstructing hernia) should be considered for intervention in the absence of other major co-morbidities that would be a contraindication to a general anaesthetic. However, many mentioned reluctance from anaesthetists and intensive care doctors regarding post-operative care for patients with dementia.

Outcomes of importance

Many HCPs spoke about the importance of establishing the views and wishes of older patients, with some mentioning that in their experience older patients are more concerned with maintaining independence and quality of life rather than length of life.

> *D1 "I suppose it's about not keeping them alive with poor quality of life unnecessarily. Just because you can maybe extend their life by a few more months with operating, you're not necessarily going to improve their quality of life".*

Many surgeons and anaesthetists discussed the role of educating older patients about the potential complications and long-term sequelae of major surgery on deconditioning and muscle loss rather than thinking about mortality alone.

C1 "Especially that is important for patients who are enjoying independent living, some of them will decline surgery if you say that there is a very high risk of going into care after surgery".

The OT interviewed felt that patients over the age of 80 years are less likely to be able to go home without carers or a period of rehabilitation, therefore this should be something that is taken into consideration when planning surgery and discussions with patients.

Assessment tools and risk calculators

A number of surgeons and anaesthetists mentioned using risk calculators to help in their decision-making and discussions with patients, however some questioned the meaning of predicted mortality to patients as individuals. Performance Status (PS) was commonly used by MDT members for the assessment of oncology patients, particularly if they were referred from other hospitals. It was emphasised that it is the referring clinician's responsibility to make a case for a patient who might be of 'borderline' fitness or 'unfit' at diagnosis but with potential to improve their fitness. One CNS pointed out that a patient recorded as PS 2 or above at a District General Hospital would not be seen at the tertiary referral centre as their management would be 'best supportive care' only.

National audits and legislation

Many surgeons discussed the role of outcomes reporting on their own willingness to take on high-risk patients. National audits such the National Bowel Cancer Audit (NBOCA) and the National Emergency Laparotomy Audit (NELA), as well as the Getting it Right First Time (GIRFT) project, were all cited as reasons why their own practice had changed over recent years and were mentioned as driving service improvements. Many mentioned the NELA report in reference to wanting better geriatrician support for patients undergoing emergency laparotomy. Clinicians from the two units that have comprehensive CPET services said that funding was secured for these services on the back of results from NBOCA that suggested that they had above average mortality rates after elective colorectal resection. One surgeon mentioned the impact

that changes in the law surrounding the consent process had had on his own practice, leading to a more in-depth discussion with older patients about the potential long-term detrimental effects of surgery.

5.6.3.4 *Challenges in emergency GI surgery*

Surgeons described the challenges of decision-making in emergency GI surgery in older people, where decisions often need to be made quickly without the benefit of multi-disciplinary input or time to optimise. Often it was seen as being a dichotomous decision between potentially life-saving operations or palliation. In these situations, the importance of pre-operative discussions with the patient and their relatives, and careful documentation of these discussions was emphasised.

> *D1 "We see it a lot with emergency surgery, where you've got somebody who you feel is not going to do very well with an operation, but without an operation they're not going to survive."*

One surgeon discussed the difficulties with the consent process and shared decision-making in emergency surgery.

> *F2 "They're in extremis, they're in pain… and they just want that to go away. When you have that conversation and tell them that there's a 5 or 10% mortality risk, it's not a meaningful comparison for them when they're lying in a hospital bed with tubes everywhere and pumped up on morphine"*

5.6.3.5 *Summary*

HCPs emphasised the importance of physiological rather than chronological age, however there were differing opinions on high-risk procedures or treatments in patients over the age of eighty years. HCPs discussed a range of different factors that are taken into consideration when discussing treatment options with older patients.

5.6.4 Experience in assessment of suitability for major GI surgery in older adults

5.6.4.1 *Fitness for surgery*

The assessment of fitness for surgery was predominantly viewed as the responsibility of the surgeon, with an increasing role for anaesthetists in patients of uncertain fitness or prior to high-risk or emergency surgery. Many of the specialist nurses in particular spoke about how the assessment of fitness for treatment, whether surgical, medical or oncological, should be an ongoing process and something that should be easily replicable post-operatively. This would enable them to stratify follow-up or to promote re-assessment of non-operatively managed patients who manage to make lifestyle changes.

> *D5 "the whole pathway is influenced by the patient's fitness"*

General Practitioners agreed that they generally have detailed knowledge of their patients' medical backgrounds, social circumstances and health behaviours but that this was not always easy to convey within the confines of the standardised referral proformas.

> *E2 "I would try and put a sentence in about their current functional status so that you know that actually they may be physiologically 65, even though they're biologically, you know, I think that's really important isn't it?"*

Assessment of emergency patients was viewed as extremely difficult, particularly in the presence of acutely deranged physiology and the unpredictability of an older person's resilience to surgery. Lack of time for objective assessments meant that many felt that assessing fitness for major surgery in the emergency situation was much less robust than in the elective setting and largely 'guesswork' based on cumulative experience.

Cardiorespiratory fitness

Objective assessment of cardiorespiratory fitness varied between hospitals, with two performing universal CPET, two selectively testing and one having no provision. The

two hospitals with universal CPET perform it in all patients who are being considered for major GI surgery and this may be before they are seen in pre-operative assessment clinic or discussed at the MDT.

> *B1 "The vast majority of patients who we think there's a realistic possibility of surgery have cardiopulmonary exercise testing. That is then fed back into our weekly MDT meeting and they generally risk stratify them as normal or low risk, medium risk and then high risk".*

One hospital performs a 6MWT in pre-operative assessment on all patients booked for major GI surgery and only those who perform below a certain threshold are referred on for CPET delivered by another hospital. One hospital selectively refers patients for CPET on the basis of consultant referral (this varies according to subspecialty), performance on an Incremental Shuttle test (OG only) or pre-assessment recommendation. One hospital does not currently have access to either 6MWT or CPET testing. Objective fitness testing was seen as a useful adjunct in the decision-making process, both in helping patients to appreciate their level of fitness but also in enabling more detailed discussions on operative risk.

> *B6 "If a patient performs very badly on CPET I will usually personally discuss with the surgeon at the end of the clinic and make a plan"*

The two hospitals that routinely CPET test all patients both have participation in the cancer MDT by the CPET anaesthetists. One of these hospitals also invites physiotherapists to the MDT and the other has dietetics input. Oncologists were sceptical about the benefit of anaesthetists attending the cancer MDTs.

> *A11 "I don't think it would be worth their time, we discuss around 60 patients in the MDT and they might be needed for one of them".*

Surgeons without routine CPET testing felt that the MDT was more for staging and discussing optimal treatment, rather than assessing fitness. In contrast, surgeons at

units that CPET all patients spoke about giving provisional MDT outcomes pending CPET results if these were not available.

> *C1 "The role of the MDT is to stage the disease and to suggest the optimum treatment surgically if the patient is fit. The MDT cannot generally make a decision about patient fitness because you do not have all the information needed in the first place."*

There was a general feeling from HCPs that patients often overestimate their exercise tolerance. This was attributed to patients not knowing what levels of physical activity should be, comparing themselves to their peers and not wanting to be 'written off' by healthcare professionals or denied access to treatments. No HCPs reported routinely using patient questionnaires to assess physical activity.

> *D5 "In my experience, patients are not always truthful about how fit or unfit they are because they're guided by the worry that somebody's going to say they're not going to do something."*

Functional capacity

There was emphasis on the assessment of functional capacity, particularly by specialist nurses and surgeons, however this was not objectively assessed. Specialist nurses felt that their rapport with patients and their families often helps them to gain an insight into the actual functional capabilities of the patients.

> *D6 "For example if a patient's having a stoma, are they actually able to look after that and what interventions are available if they can't"*

Nutritional

Nutritional assessment was cited as an important factor for all GI surgical patients. However, many HCPs reported poor provision for nutritional screening and access to dietician-led assessments in the peri-operative period. Surgeons from OG and HPB were more likely to state that it formed part of their own assessments, including

screening for micronutrient deficiencies. The OG HCPs described arranging for their oesophageal cancer patients to have telephone consultations with a dietician prior to surgery due to constraints on dietetics support. The oncologists also highlighted that access to dietician support was very difficult for their patients.

Neither dietician interviewed routinely sees patients pre-operatively unless specifically asked to by the surgical teams. Both stated that they rely on the Malnutrition Universal Screening Tool (MUST) to identify patients admitted to the ward plus referrals from the nursing staff, however this was felt to be inadequate;

> *D3 "NICE guidance suggests that all outpatients are screened but that doesn't happen in this hospital just for capacity issues I suppose really."*

Psychological

Psychological assessment, particularly for depression or anxiety, was rated as important by HCPs. This was felt to help predict patients' tolerance of treatments, engagement with optimisation strategies and recovery. However, the surgeons interviewed rarely ask a focused history for psychological issues and predominantly rely on the specialist nurses to identify problems. None of the hospitals currently have formal screening for psychological problems in pre-operative assessment but this may be performed as part of the 'Holistic needs assessment' by CNSs for cancer patients. Psychological problems were felt to be under-recognised in patients with non-malignant disease who may have been living with chronic disease for many years.

Frailty and geriatric assessment

Many surgeons mentioned the importance of frailty in their clinical decision-making but only one said that they had incorporated a formal assessment of frailty into their own practice.

> *D8 "I'm very conscious of the fact that recently there's a lot of emphasis or a lot of data on just frailty as a general assessment. And it does seem to be really useful, so very recently I've certainly been talking about that more"*

Only two units currently include frailty assessment in their CPET assessment with one of these hospitals also including it in the pre-operative assessment of all older patients. Some surgeons performing high morbidity surgery commented that they do not commonly see patients who are frail in their elective practice because these patients would be classed as performance status 2 or above at the MDT discussion. A number of HCPs said that frailty assessment was not something that they currently do in their unit because they do not have geriatrician support to act on the assessment results.

> *B7 "The reason we haven't done it up until now is because there's no point doing a frailty assessment if you're not going to do anything about it… you need a setup don't you?"*

Only one hospital has a geriatrician-led team routinely involved in the post-operative care of older surgical patients and this is predominantly for emergency patients. The geriatrician spoke about the challenges of integrating with the different GI subspecialities and that some surgeons were resistant to geriatric input. Many HCPs expressed concern about the increasing prevalence of cognitive problems in the surgical population, however, screening for cognitive impairment and assessment of capacity were felt to be often overlooked, particularly in the emergency situation.

Co-existing medical conditions and risk calculators

There was variation in views regarding the role of pre-operative assessment. Some HCPs view it as a safety check to ensure that the patient is ready for their operation whereas others view it as encompassing fitness assessment, lifestyle modification and optimisation.

> *C2 "That's where we pick up if we need to do anything for prehabilitation in terms of their exercise tolerance or iron levels, or even medications-wise"*

In the emergency setting, many surgeons described using a risk calculator as part of their routine assessment, particularly for emergency patients, however, many felt that functional status should also be incorporated. Surgeons spoke about involving anaesthetists in the assessment and decision-making process as a surrogate for objective tests.

> *D2 "In that group of patients who are either very sick or who are severely co-morbid or poor functional status … I tend to involve the anaesthetist as part of the decision-making process with the patient and family".*

Lifestyle

Many HCPs said that they ask regarding lifestyle factors, such as smoking and sedentary behaviour. They less commonly ask about alcohol intake unless the patient has overt alcohol related disease. This was also felt to be included in the 'holistic needs assessments' for cancer patients and pre-operative assessment.

5.6.4.2 *Barriers to assessment*

The majority of HCPs stated that they had limited or no input from allied health professionals (dieticians, occupational therapist and physiotherapists) in the pre-operative period in the assessment of patients. This was attributed to lack of time in job plans which results in the majority of their assessments being performed in the post-operative period. All AHPs stated that they would like to be able to assess patients earlier in the pathway to be able to start interventions earlier. Access to geriatrician-led assessments was also limited in all hospitals due to lack of geriatricians and needing to make business cases for funding.

Many HCPs spoke about pre-operative assessment and objective fitness tests being too late in the pathway for assessments to inform decision-making, for targeted interventions to be put in place or for patients to make lifestyle changes. HCPs at hospitals without routine objective fitness assessment felt that there should be a fairer and more transparent assessment process for older patients.

5.6.4.3 *Facilitators to assessment*

HCPs from units that perform CPET in all patients were more likely to say it informs their decision-making and discussions with patients. HCPs at these hospitals described efforts to re-design their cancer pathways to enable the CPET results to be discussed at the MDT and also to maximise the amount of time for prehabilitation. One surgeon mentioned giving iron infusions to anaemic patients at the start of their pathway to enable the patients to perform as well as they could at CPET.

5.6.4.4 *Summary*

These interviews have demonstrated wide variation in practice across a single region in how older patients are assessed for suitability for major GI surgery. Differences in the use of objective fitness testing, frailty and nutritional assessment may result in variation in who is offered major GI surgery and also result in missed opportunities for optimisation. Standardised assessment protocols and treatment allocation on the basis of these assessments may reduce variation. Multi-professional assessment in the emergency setting is often lacking, suggesting that more needs to be done to co-ordinate care for these patients.

5.6.5 Experience in optimising older patients for major GI surgery

5.6.5.1 *Usual practice*

Physical activity

Many HCPs described how they currently encourage pre-operative improvements in physical activity in their own consultations. This was a spectrum from simple advice to go for a walk every day and keep physically active to more prescriptive advice involving timing and level of exertion. One hospital has an established 'Surgery School' and this is used as a platform for education, peer support and to make onward referrals to exercise programmes delivered at local exercise facilities. For most patients this is co-ordinated around their planned date for surgery, whereas a small number who are considered 'unfit' at their initial consultation are advised to attend an exercise programme and then undergo repeat CPET.

One hospital has a formal prehabilitation programme for colorectal cancer patients which is delivered by a local respiratory rehabilitation service and currently takes patients who are classified as 'unfit' for an operation (Anaerobic Threshold (AT) <10 on CPET). This is regarded as the first intervention for these patients in the cancer pathway and only if they engage with the programme and improve on repeat CPET testing will they be offered surgery. Another hospital also accesses a local cardiorespiratory rehabilitation programme to deliver prehabilitation but this is only on an *'ad hoc'* basis for patients with clear cardiac or respiratory co-morbidities that need optimising.

Nutrition

Surgeons emphasised the importance of nutritional advice in the pre-operative period with many giving this advice themselves due to lack of dietician support. Anaesthetists also give nutritional advice at the time of CPET and patients attending Surgery School usually attend a talk by a dietician. Some surgeons described prescribing nutritional supplements whilst others focused on advising a high protein diet.

In the post-operative period, clinicians emphasised the importance of early return to oral diet in the elective and emergency settings according to the ERAS pathway. The

dieticians interviewed described predominantly being involved in the care of post-operative patients who had had complications following surgery, usually after referral from the surgical and nursing teams.

Psychological

The central role of the CNSs in providing psychological support to cancer patients was acknowledged. The role of the cancer support centres for holistic therapies and the need to refer back to the GP for severe problems was also discussed. No HCPs reported involvement from psychologists. The role of peer support was emphasised and this was seen as a major advantage of both Surgery School and group-based prehabilitation programmes.

> *A2 "We send all patients to Surgery School to emphasise what has already been said to the patient but also for the peer support so that they know that they're not the only one on this journey"*

Co-existing medical conditions

In the elective setting, conditions for which there are clear guidelines were identified as being easier to optimise in pre-operative assessment.

> *A9 "Some things are very easy. So, if you take things like anaemia, hypertension, diabetes, they've all got very specific numbers to work to".*

Management of iron deficiency anaemia differed across hospitals. At some hospitals this was the responsibility of the surgeon, whereas at others it was arranged by pre-operative assessment or by the CPET anaesthetists. HCPs predominantly felt that iron infusions were more effective than oral iron in the pre-operative period. In the emergency setting, it was felt that there was insufficient time to optimise medical co-morbidities, however on call anaesthetists were often consulted if urgent pathology required addressing.

Lifestyle

GPs described optimisation of lifestyle factors that they may initiate at the same time as surgical referral, although time in the consultation was cited as a barrier to doing this for all patients.

> *E3 "If I think that it's likely that they're going to need a surgical opinion, then I would address risk factors for both their disease and their pre-op"*

HCPs from two hospitals stated that their pre-operative assessment policy is to refer all patients to smoking cessation services. HCPs from the other hospitals said that they advise patients to stop smoking and will offer referral. Two surgeons stated that they tell patients that they must stop smoking for them to be operated on

> *A1 "I tell them if you're smoking I'll not operate on you. So a lot of patients will have their last cigarette on the day they see me in the clinic".*

Geriatric

Only one hospital in the region currently has a geriatrician-led team for optimisation of surgical inpatients. Surgeons at hospitals without routine geriatrician input all expressed desire for geriatrician involvement, particularly for emergency patients. The expertise of a geriatrician was particularly valued in areas such as discharge planning, management of delirium and liaising with families.

Peri-operative

HCPs stressed the importance of the ERAS programme for encouraging early mobilisation after both elective and emergency surgery, stressing its role in reducing post-operative complications and length of stay. HCPs discussed different challenges that they had encountered with maintaining aspects of the ERAS pathway. The physiotherapists described having to be quite direct with patients to get them to engage, particularly emergency patients who rarely have had pre-operative counselling on the importance of early mobilisation.

Anaesthetists mentioned the role of the ERAS pathway in standardising peri-operative anaesthetic care; in particular routine use of regional analgesic techniques. Many surgeons said that they would attempt a laparoscopic procedure if feasible due to faster recovery times. The hospitals that routinely CPET all colorectal cancer patients stated that it helped to plan their post-operative HDU utilisation.

Rehabilitation

Physiotherapists described different post-discharge provision for additional support, however they felt that this is infrequently needed due to improvements in inpatient rehabilitation. No HCPs interviewed currently have access to routine post-discharge rehabilitation programmes for surgical patients.

5.6.5.2 *Barriers to optimisation*

Patient factors

In practice, many clinicians felt that patients struggle to make lifestyle changes on their own. This was felt to be a particular challenge for patients with non-malignant disease who often have higher levels of co-morbidity and lack motivation due to living with chronic disease. Many surgeons felt that cancer patients tend to be very motivated and frequently ask what they can do to prepare themselves for surgery, however, pre-diagnosis anxiety about cancer was seen as a common barrier to lifestyle modification in this period.

> *E3 "It's how much goes in, how much is retained and the motivation of somebody to do it… because if you say to somebody you've got a two week wait appointment [for suspected cancer diagnosis], they think they're going to die and that's it, nothing else happens until they're actually seen"*

Many clinicians mentioned that older patients often have caring responsibilities and that this often prevents them from engaging in lifestyle changes or attending additional hospital appointments. Lack of personal transport and not wanting to travel too far were frequently mentioned barriers for older people.

Clinicians working with patients with typically poor prognosis cancers mentioned that their patients often do not want to engage in peer support programmes post-operatively because they feel 'lucky' and just want to get on with their lives. They also mentioned that there is more stigma associated with cancers closely related to smoking and lifestyle choices, so as a result these patients do not engage as much with peer support.

Lack of guidelines and evidence

Some surgeons felt that the evidence base for exercise prehabilitation is not yet sufficient for them to be able to justify delaying cancer treatment to optimise fitness. Lack of evidence and cost effectiveness data was also seen as a barrier for making a case to hospital management for funding prehabilitation programmes for all patients rather than solely those considered 'unfit'. One CNS felt that lifestyle advice is not consistently given.

> *C3 "The consultants can be a bit hit and miss on what advice they give. Sometimes they might say "I want you to lose a certain amount of weight and walk so many hours, stop smoking and what have you". And then sometimes they don't say anything."*

Most clinicians are moving towards using iron infusions rather than oral iron supplements, however lack of guidelines and needing to secure funding were cited as barriers.

> *B7 "So we're doing them [pre-operative iron infusions] but the business case hasn't really gone through yet"*

Administrative burden

One GP described using a local lifestyle optimisation referral system for patients requiring elective surgery for non-malignant conditions, however filling in the form was seen as a significant administrative burden. Surgeons also mentioned the

administrative burden of CPET referral forms as a reason why they may not be requested for all patients.

Time in the pathways

Time in the cancer pathway was frequently mentioned as a barrier to improving patients' fitness pre-operatively, with frustration voiced at not being able to take the time to do interventions that could improve long-term outcomes. Often pre-operative assessment was seen as too late in the surgical pathway to be used for patient optimisation strategies.

> *A8 "And the emphasis seems to be a lot on actually just making these patients get from diagnosis to surgery to home as if on an escalator without being able to come off the escalator. But I think we're not doing the patients a service".*

Allied HCP challenges

The physiotherapists and OT all felt that they are involved too late in the patients' pathways and that this results in discharge delays. Many surgeons felt that current post-operative physiotherapy provision is inadequate and that many of their patients will not see a physiotherapist regularly when they are on a surgical ward. Physiotherapists described barriers including being reliant on nursing staff for handover of suitable patients, not being formally involved in the medical and nursing handovers, patients viewing physiotherapy as optional and staffing shortages.

5.6.5.3 *Facilitators to optimisation*

Population level policies and national guidelines/audits

GPs and anaesthetists in particular felt that we should be moving towards population level measures to promote physical activity rather than solely focusing on the pre-operative period and that NHS Trusts should take some responsibility for this.

> *A8 "I think the entire community needs to be more aware of the role physical activity plays in actually sustaining fitness in the knowledge that to sustain*

fitness sustains life and a better quality of life. I think the Trust itself has a role to play in sending that message out".

The recent inclusion of Malnutrition Universal Screening Tool (MUST) in the Care Quality Commission (CQC) requirements was cited as prompting a service improvement project at one hospital to try to improve compliance. The dieticians said that greater national focus on the importance of nutrition also means that many patients will now have simple interventions by the nursing staff without being reliant on dietician involvement. The surgeon from the hospital with a prehabilitation programme for unfit patients said that they had been able to make a business case for prehabilitation funding on the basis of NBOCA and GIRFT local data.

Empowering patients

A common theme that emerged was the idea of trying to empower patients to make lifestyle changes to improve their peri-operative course and the idea of entering into a partnership to treat their condition.

A6 "As soon as we meet them, if they're thought to be resectable then we actively say it is your responsibility to get fit for surgery because it's a massive insult to your body; the oncologists can give you chemotherapy, the surgeons can take the tumour out but we can't make you exercise and eat well; that's your responsibility"

Clinicians described using surgery as a motivating factor to encourage patients to use additional time to their advantage, such as during neoadjuvant therapy or whilst on the waiting list.

B1 "For patients who then want reversal surgery, I will often say to them "you need to get your physical fitness up before we think about reversing you. I wouldn't think about doing it for another six months. Use that as an opportunity to get yourself in as good a shape as you can"".

Anecdotally, many patients who had engaged in programmes pre-operatively were said to have continued self-directed exercise post-operatively.

> *A6 "He took the advice on board and he had his surgery about three years ago and he still does his exercise bike every day".*

Flexible pathways

Oncologists felt that there would be time for physical activity programmes during neoadjuvant chemotherapy or whilst being 'worked up' for surgery. However, programmes would have to be flexible enough to accommodate the range of different pathways and different experiences of chemotherapy side effects.

HCPs described ways that they were trying to change their pathways to allow more time for optimisation, such as 'straight to test' for suspected cancer referrals and CPET after endoscopy and prior to MDT discussion. The 're-branding' of pre-operative assessment clinics to 'preparation for treatment' clinics was also discussed.

The GPs interviewed described a range of different community services that could be utilised to help patients make lifestyle modifications prior to surgery. These included existing 'falls classes', pulmonary rehabilitation programmes, physiotherapists based within their own practices and lifestyle co-ordinators.

> *E1 "And so it is something that probably in terms of us organising wouldn't actually be that hard, because we could just ask our providers to provide it"*

Marginal gains

In general, it was felt that older people undergoing major GI surgery benefit from addressing multiple lifestyle, co-morbidity and disease-specific factors across the entire peri-operative pathway from diagnosis through to rehabilitation in the community. For emergency patients, the importance of timely presentation, diagnosis, intervention and rehabilitation were stressed.

5.6.5.4 *Summary*

There is wide variation in current practice across the region in optimising older patients undergoing major GI surgery. Efforts by individuals in three units have led to the introduction of a surgery school and prehabilitation programmes for a small number of patients. However, funding these programmes has been problematic. Lack of evidence-based guidelines to use to build business cases was a frequent problem. Cancer targets were common barriers to adequately optimising patients and providing individualised care. The majority of AHPs felt that they would like to do more to optimise older patients early in the pathway but that lack of staff and time in their job plans prevented this. Lack of geriatrician-led support was a frequently cited barrier to optimising patients identified as frail.

5.7 Discussion

5.7.1 "Fitness" for surgery

Available guidelines suggest that the decision for major GI surgery should be based on "fitness" rather than age[110–112,115] and the HCPs in this study agreed with this. However, interpretations of 'fitness for surgery' varied, as did how this was assessed in practice. Typically, it was used to refer to cardiorespiratory fitness rather than a holistic assessment of the older adult. Provision and utilisation of objective physical tests varied considerably, which is known to be an issue in the UK[34,306].

Malnutrition was a common reason why someone might be considered 'unfit' for an operation or might require optimisation prior to surgery. However, screening was not comprehensively performed in this study, despite the ESPEN guidelines[307]. Access to specialist dietician-led assessment and intervention was limited at all hospitals, with shortages of dieticians a commonly cited factor. This is a problem across the NHS, with dietetics being identified as a shortage profession.

Frailty was often cited as a reason why an individual might be considered 'unfit' for a major operation, however, this was rarely objectively assessed. This is despite mounting evidence in geriatric oncology[7,102,114,171] and emergency general surgery (EGS)[16,128,129,308] of its impact on outcomes and importance in decision-making. The International Society for Geriatric Oncology (SIOG) suggests that Comprehensive Geriatric Assessment should be performed in the assessment of all older patients before major GI cancer surgery, however, it was not performed pre-operatively in this study[102]. Lack of access to geriatrician-led multi-disciplinary teams was a common barrier, again, something which is known to be highly variable across the UK[140,162,309].

The majority of surgeons felt that if 'fit', an older adult should have access to the same treatment options as would be available to a younger patient. However, there was a feeling, particularly for high morbidity operations, that an older individual would need higher levels of fitness to counteract the effects of age-related physiological changes. This opinion may account for some of the age related differences in treatment practice

observed in rectal cancer[53], colorectal liver metastases[310], oesophagectomy[311] and pancreatectomy[312,313].

5.7.2 Decision-making in the older adult

The impact of major GI surgery on functional independence[84,161,295] and quality of life[298,314] in an older individual may be significant. There is some evidence that older individuals value quality over length of life[91]. This study suggests that HCPs may be more likely to explore alternative treatment options with older compared to younger patients with the aim of preserving quality of life and functional status. However, as already stated, the 'older adult' population is very heterogenous and clinicians making assumptions on patients' priorities for treatment based on age may contribute towards undertreatment of older patients and increased use of palliative procedures[27].

Opinion varied on the treatment of patients with cognitive impairment, which reflects the lack of published evidence on the surgical management of patients with dementia[315,316]. Many felt that major surgery was not appropriate in individuals with moderate or severe dementia. Further research into outcomes after major GI surgery in patients with dementia and the views of patients and their carers are urgently needed.

5.7.3 Interventions to improve outcomes

Lack of evidence of how treatment and optimisation strategies should be stratified to baseline health status results in variation. A small number of high-risk surgical patients account for the majority of surgical morbidity and cost[52], so efforts to optimise these patients and for greater multi-disciplinary management may improve outcomes.

Objective assessments are important in risk-assessment and decision-making but there needs to be appropriate evidence-based interventions if deficits are identified. There is widespread interest in developing prehabilitation programmes, but they need to be flexible to accommodate a wide range of different surgical pathways and patient choice. There remains an ethical debate regarding whether surgery should be rationed to those who engage with lifestyle modification.

Older patients undergoing emergency GI surgery have limited opportunity for pre-operative optimisation so efforts should focus on prompt assessment, diagnosis and management as well as peri-operative optimisation. Early, co-ordinated, multi-disciplinary post-operative care and rehabilitation will require significant resource allocation and new research.

5.7.4 Surgery as a teachable moment

Research suggests that patients are more likely to make lifestyle changes if advised by HCPs whilst facing an important life event, such as major surgery[146,317]. Lack of confidence and personal training in discussing lifestyle changes, alongside time pressures, are well known barriers to implementing this in practice[95,318,319]. HCPs in this study described differing experience in this regard, contributing towards practice variation.

5.7.5 Role of guidelines in clinical practice

National guidelines will help to standardise provision of services for older patients[314]. As already discussed in the results, many clinicians mentioned that they had difficulty in making a business case for optimisation strategies due to lack of national guidelines. This was particularly true for prehabilitation programmes and iron infusions. Surgeons must engage in national audits with robust data collection to drive service improvements. Studies with health economic analyses are needed to be able to demonstrate cost-effectiveness to NHS trusts. High-quality evidence will also help clinicians to justify interventions and potentially treatment delays to patients.

5.7.6 Strengths and weaknesses of this analysis

The use of semi-structured interviews for study has enabled the collection of a broad range of views and attitudes. The inclusion of members of the wider HCP team involved in the care of patients facing major GI surgery has enabled an exploration of the subject from multiple different viewpoints, including general practitioners and allied health professionals, who are often not considered in surgical research. The inclusion of only one geriatrician in a study of older people is a clear limitation of this study. However, this was due to a lack of geriatricians specialising in general surgical patients in the region. The single region recruitment was to enable an exploration of

variation within hospitals serving the same population of patients, however, it is acknowledged that practice within this region may not be a reflection of practice elsewhere in the UK.

Semi-structured interviews are prone to bias as it is likely that HCPs more interested in the research area agreed to participate. Despite this, very few HCPs approached declined to participate, suggesting that the study has wide clinical relevance. It is acknowledged that the researcher may introduce bias as interview participants may be inclined to try to answer questions in a way that they think the researcher wants them to. Equally, recall bias due to participants being asked to recall their experiences may lead to discussion of scenarios where there have been very good or very poor outcomes more than others.

5.8 Conclusion

This study demonstrates wide variation in attitudes towards major surgery in the older patient. Differences in practice in the assessment and optimisation in older adults across a region, suggests that not all patients are assessed in the same way or have the same access to interventions that might improve their outcomes.

6 Clinician questionnaires - Survey of practice

As mentioned at the start of chapter 5, data from chapters 5 and 6 have been published as a mixed methods paper:

Daniels SL, Burton M, Lee MJ, Moug S, Kerr K, Wilson TR, Brown SR, Wyld L. Healthcare professional preferences in the health and fitness assessment and optimisation of older patients facing colorectal cancer surgery. Colorectal Disease 2021;00:1-10. DOI: 10.1111/codi.15758

Permission from the publisher (Appendix U) and the co-authors (Appendix V) have been obtained for reproduction in this thesis.

My role in this study was in preparing the study protocol and grant application, applying for ethical approval, collecting and analysing the results and writing the manuscript for publication.

6.1 Abstract

Introduction

Rates of major gastrointestinal surgery decline with age, despite increasing incidence of gastrointestinal pathology. Higher prevalence of co-morbidities, frailty, functional and cognitive impairments in older age groups may account for some but not all of this difference. Older patients who undergo major surgery are more likely to experience complications and prolonged length of stay. Outcomes in older patients could be improved by comprehensive assessments and targeted optimisation when deficits are identified. Surgeon preference may account for some of the variation in practice in the older population.

Methods

An online questionnaire survey was designed and disseminated across the UK to gastrointestinal surgeons to quantitatively assess the importance of themes developed during semi-structured healthcare professional interviews. Descriptive statistics were used to analyse the data.

Results

The questionnaire was completed by 103 out of 256 surgeons (response rate 40.2%). There was difference in opinion regarding surgery in older patients, particularly when there is co-existing dementia. Assessment was not standardised, particularly with regard to the assessment of frailty, cognitive and psychological problems. Access to optimisation strategies was limited with poor access to allied health professionals (dieticians, geriatrician-led teams and occupational therapists) and poor provision of prehabilitation or rehabilitation programmes. Strategies to optimise patients undergoing emergency surgery were limited.

Conclusions

Lack of fitness stratified guidelines for the management of older patients with major gastrointestinal pathology contributes towards variation in practice. Differences in patient assessment, the value that surgeons place in these assessments and availability of optimisation strategies or allied healthcare professional input when deficits are identified contributes towards variation in outcomes in the older population.

6.2 Introduction

As discussed in Chapter 5, healthcare professional interviews identified variation across a region in views and practice regarding methods of assessment, optimisation and treatment options for older patients facing major GI surgery. The reasons for these variations are multi-factorial and include resource allocation, access to services and specialist input, lack of clear evidence-based guidelines and attitudes of individual clinicians and multi-disciplinary teams.

There is scarce published evidence on current UK surgical practice in this area[50,165]. Available evidence from the field of geriatrics and anaesthetics suggests that access to peri-operative geriatrician support[162] and pre-operative Cardio Pulmonary Exercise Testing (CPET)[306] is variable across the UK. Therefore, a clinician survey of practice was designed to capture the current practice and views of consultant GI surgeons from across the UK in both the emergency and elective settings.

The aim of the study presented in this chapter was to quantify the themes identified in the semi-structured interviews to enable generalisation of findings across a wide range of UK gastrointestinal surgeons. It aimed to survey current practice in both assessment and optimisation across elective and emergency presentations and opinion regarding factors that are considered important in treatment decisions. Specialists from all subspecialties of GI surgery, both malignant and non-malignant, were included to gain as broad a picture of practice as possible.

6.3 Methods

6.3.1 Questionnaire design

6.3.1.1 *Pre-piloting phase*

The preliminary questionnaire was designed by the researcher (SLD) with reference to the literature, the qualitative interviews and a previous study in the field of breast cancer by members of the study team[189]. The expert opinion of the study advisory group was used to ensure content validity

6.3.1.2 *Piloting phase*

Piloting was carried out with experienced surgeons outside the study team in Sheffield to ensure face and content validity as well as usability. Seven surgeons were approached which included six consultants and one Academic Clinical Lecturer in General Surgery. They were asked specifically for feedback on the length of the questionnaire, the user interface of the Google Forms platform, language and acceptability[320]. The predominant feedback was that the length of the questionnaire would be off-putting, but they all agreed that it was difficult to reduce the length without losing the structure and depth of the questionnaire. Many surgeons felt that the DCE only needed two options (offer major surgery or conservative options which could include palliative procedures) therefore the final questionnaire was changed to reflect this.

6.3.1.3 *Psychometrics of the questionnaire*

The psychometrics of the questionnaire were assessed during the piloting phase:

- Reliability was assessed by asking similar questions in Section 3 and the DCE. Test-retest reliability was not tested.
- Content validity was ensured by designing the questionnaire based on a systematic review of the literature, qualitative semi-structured HCP interviews and the expertise of the wider study team
- Face validity was ensured by consulting the wider study team as to whether it appeared suitable for the purposes of the study and whether they felt that anything additional should be included

- Criterion or concurrent validity was not assessed for this study as there are no validated questionnaires that could have been used.
- Construct validity was not assessed as it is not relevant to this study (no abstract concepts)
- Acceptability was assessed in the pilot phase in terms of length, comprehensibility and usability

6.3.1.4 *Final instrument design*

The final questionnaire design was submitted as an amendment to the original protocol. It was split into 5 sections:

1. Baseline demographics including year of qualification (Certification of Completion of Training, CCT), sex, deanery of practice and subspeciality of General Surgery (multiple choice questions).
2. Routine assessment for major GI surgery. Respondents were asked to indicate how they usually assess patients in the elective and emergency settings regarding physical fitness, nutritional status, psychological status, lifestyle factors and medical co-morbidities. Respondents were asked to indicate whether they do this for all patients, only patients in whom they have concerns about their 'fitness' to tolerate a major procedure or whether it doesn't form part of their usual assessment.
3. Optimisation for major GI surgery. Respondents were asked how they routinely optimise patients in the elective and emergency settings. Again, this was divided into physical fitness, nutritional status, psychological status, lifestyle factors, medical co-morbidities and peri-operative strategies. Respondents were asked to indicate whether they do this for all patients, only patients in whom they have concerns about their 'fitness' to tolerate a major procedure or whether it does not form part of their usual optimisation practice. Respondents were also asked for free-text responses of what they would like to be able to do to optimise their emergency and elective patients.
4. Influence of important factors on decision-making. Respondents were asked to rate using a Likert scale from 1-9 (1 denoting 'not important' and 9 denoting 'very important') ten different patient or pathology related factors that might

influence their decision-making. The factors were decided on based on the healthcare professional interviews and review of the literature.

5. Clinician preferences in hypothetical scenarios under controlled experimental conditions using the Discrete Choice Methodology (DCE). Five key variables were identified from the literature and subdivided into levels of clinical severity. The DCE aspect of the study is covered further in Chapter 7.

The final questionnaire included both closed and open questions using a range of question types (including nine-point Likert scales, yes/no, multiple choice, free text)[321,322]. For categorical choices, such as deanery of practice, an 'other' option was given with a free text box to ensure complete data. Some questions were also marked as 'required' so that the participant could not progress on to the next question without completing all parts of the question. The Likert scale in its standard 9-point scale was included to give participants the 'unsure/no preference' option as this was felt to reflect normal practice most closely.

The final questionnaire was converted into a structured web-based questionnaire (Google Forms, Palo Alto, California, USA) for dissemination and a screenshot is shown to demonstrate the format (Figure 11).

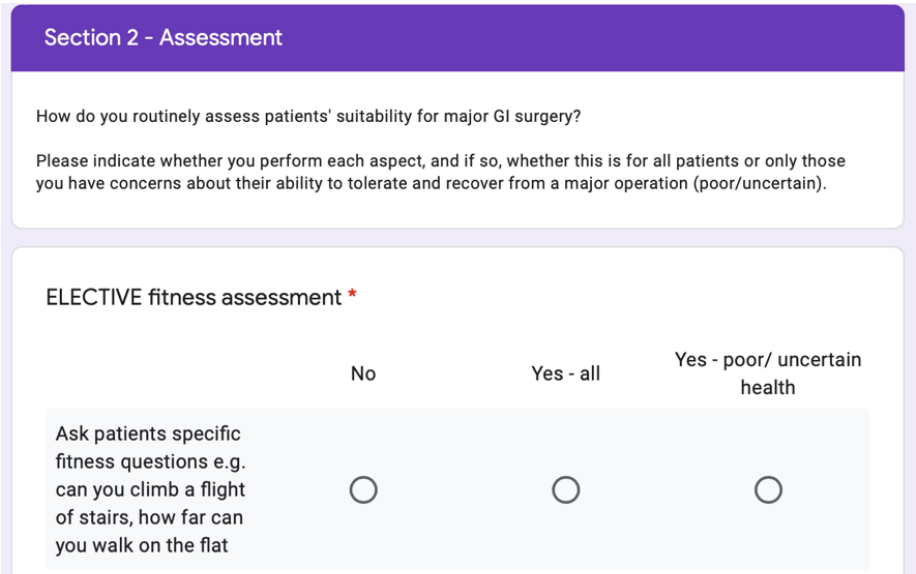


Figure 11 Screenshot of the first question of Section 2 of the online questionnaire

The full questionnaire in Word format (Word, Microsoft Corp. Redmond, WA, USA) is included below.

Sheffield Teaching Hospitals NHS Foundation Trust

The University Of Sheffield.

Clinician Preferences for Treatment of Older Patients facing Major Gastrointestinal Surgery

Healthcare Professional Questionnaire

All information that you provide will remain strictly confidential

If you have any queries about this questionnaire or would like more information about the study, please contact Sarah Daniels sarahdaniels1@nhs.net

Sheffield Teaching Hospitals NHS Foundation Trust

The University Of Sheffield.

Participant letter of invitation

Dear Colleague,

Clinician Preferences for the Treatment of Older Patients facing Major GI Surgery

We would like to invite you to participate in the above research study that has been funded by the Bowel Disease Research Foundation and the British Association of Surgical Oncologists.

There is wide variation in UK practice relating to the treatment of older patients (aged 65 years and older) with both malignant and non-malignant gastrointestinal diseases. Major surgery rates vary between regions and clinicians. Treatment variation is even more pronounced in older patients presenting as emergencies. In some situations non-resectional surgery or conservative management may be the most appropriate option but there is uncertainty about the age, fitness level and disease biology for which they are indicated.

We want to establish the practice of different UK surgeons in how they assess suitability for major surgery, how they optimise care and the importance of different factors in decision-making.

The questionnaire consists of five sections:

- Section 1 asks about your background
- Section 2 asks how you routinely assess patients in practice
- Section 3 asks how you routinely optimise patient pathways
- Section 4 asks about the importance you place on different risk factors for major surgery
- Section 5 presents 18 hypothetical patient scenarios and asks how you would manage them

We are writing to ask you to complete a web-based questionnaire on Google Forms. All information will be anonymous. If you would like to find out more about the study, please contact Miss Sarah Daniels: sarahdaniels1@nhs.net

Section One - Demographics

This section requires you to give brief information about yourself

1. What is your sex? (please tick appropriate box)							
Male		Female		Prefer not to say		Other	

2. What is your specialty? (please tick appropriate box)					
Colorectal Cancer Surgeon		Oesophagogastric Cancer Surgeon		HPB Cancer Surgeon	
Benign Colorectal Surgeon		Bariatric surgeon		Benign Upper GI Surgeon	

3. What year did you qualify (CCT) in your profession?	

4. Which area do you currently work in? (please tick appropriate box)			
East Midlands		Severn	
East of England		West Midlands	
Kent, Surrey and Sussex		Wessex	
London		Yorkshire and Humber	
North east and north Cumbria		Scotland	
North west		Northern Ireland	
Oxford		Wales	
Peninsula		Other (please specify)	

Section Two - Assessment

The following questions relate to your routine service in assessing older patients with operable GI pathology (malignant and non-malignant) in your own sub-specialty. Please indicate whether you perform each aspect, and if so, whether this is for all patients or only those you have concerns about their ability to tolerate and recover from a major operation (poor/uncertain).

	Elective			Emergency		
	No	Yes - all	Yes - Poor/ uncertain health	No	Yes - all	Yes – Poor/ uncertain health
Fitness						
Ask patients specific fitness questions e.g. can you climb a flight of stairs						
Ask patients specific functional questions e.g. do you need any help with washing, shopping, cooking						
Ask patients to complete a physical activity questionnaire						
Ask patients to complete a functional questionnaire e.g. ADL, WHO DAS						
Perform an objective test – e.g. 6 minute walk test, incremental shuttle test or CPET						
Use a specific risk calculator e.g. SORT, P-POSSUM						
Perform a frailty assessment						
Nutrition						
Ask regarding recent weight loss						
Ask patients to complete a nutritional risk assessment questionnaire e.g. NRS, MUST						
Perform biochemical tests of nutritional status e.g. vitamin deficiencies, anaemia						
Psychological						
Ask focused history for anxiety and depression						
Perform a validated screening questionnaire e.g. HADS						
Ask whether they have any memory problems						
Perform a validated cognitive test e.g. mini-COG, MMSE						

Section Three - Optimising

The following questions relate to your routine practice with optimising older patients. Please indicate whether you carry out each of the aspects, and if so, whether you do this for all patients, or only those who you have concerns about their ability to tolerate and recover from a major operation (poor/uncertain).

	Elective			Emergency		
Health status	No	Yes, all	Yes –poor/ uncertain health	No	Yes, all	Yes –poor/ uncertain health
Pre-operative - Fitness						
Give verbal or written exercise advice						
Signpost them to local sports centres/ programmes						
Refer them to a formal prehabilitation programme						
Refer them to a 'Surgery School'						
Advise them on deep breathing exercises						
Pre-operative - Nutrition						
Give verbal or written specific dietary advice						
Prescribe oral dietary supplements						
Arrange for them to speak to a specialist dietician						
Pre-operative - Psychological						
Give them verbal or written advice on reducing anxiety before surgery						
Signpost them to local services e.g. cancer support services						
Refer to a psychologist						
Pre-operative - Lifestyle						
Advise them to stop smoking						
Offer referral to local smoking cessation services						
Advise them to reduce alcohol consumption						
Pre-operative - Medical optimisation						
Follow ERAS principles						
Iron deficiency anaemia - arrange iron infusion or blood transfusion						
Arrange for a medication review e.g. by GP or pharmacist						
Arrange for a geriatrician review						
Refer to occupational therapy						
Refer to social services						
Intra-operative						
Attempt a laparoscopic procedure if feasible						
Follow ERAS principles						
Use regional analgesia e.g. wound catheters/epidurals						
Post-operative						
Physiotherapy input						

Follow ERAS principles						
Specialist nurse input						
Dietician review						
Geriatrician led input						
Occupational therapist review						
Social services/ discharge team input						
Refer them to a post-discharge rehabilitation programme						

Free text questions:

What would you like to be able to provide for your elective patients that you think would have the greatest impact on their outcomes? E.g. robotics, formal prehabilitation, access to a specialty dietician

_____
_____
_____
_____

What would you like to be able to provide for your emergency patients that you think would have the greatest impact on their outcomes? E.g. Specialist laparotomy (NELA) nurse, greater physiotherapy input post-operatively

_____
_____
_____
_____

Section Four – Important factors

The table below contains factors that may be considered when discussing treatment options with an older patient facing major GI surgery. Please rate the importance of each of these factors in your decision making regarding major elective or emergency surgery using the Likert scale (1 denotes not important and 9 denoting highly important).

	Elective									Emergency								
	1	2	3	4	5	6	7	8	9	1	2	3	4	5	6	7	8	9
Alternative treatment options are available to help manage symptoms (e.g. stenting, bypass, defunctioning stoma) in a frail or unfit patient																		
Age 85 years or over																		
The patient is judged to be at high risk of mortality or major morbidity after surgery																		
Severe obesity (BMI ≥ 40)																		
Severe recent weight loss or malnutrition																		
Immunosuppressant use for another condition																		
Moderate or severe heart/renal/liver impairment																		
Moderate or severe dementia																		
Moderate to severe dependency (relies on formal or informal carers for the majority of daily tasks)																		
Pre-existing ‘Do not resuscitate’ order																		

6.3.2 Recruitment

6.3.2.1 *Sampling*

Consultant surgeons (and post-CCT fellows) in current UK practice were invited to participate in the online survey. Recruitment was via a variety of means including personal email to contacts of the study team, advertisement on the RCS Centre for Peri-Operative Care (CPOC) website, dissemination to the memberships of the Association of Upper GI Surgeons (AUGIS) and British Association for Surgical Oncology (BASO~ACS) and via the social media platform Twitter. The CPOC website was chosen as it is a recently established collaboration between the Royal College of surgeons of England and the Royal College of Anaesthetists. Clinicians who receive their newsletter and visit the website were felt to be more likely to be interested in the study. AUGIS agreed to disseminate the questionnaire to all their members, including bariatric surgeons. Dissemination had to be through the organisations themselves to comply with data protection regulations. Participants who were emailed were sent a reminder email after 6 weeks. The post on social media was re-posted at regular intervals to try to boost recruitment.

The link to the survey was converted into a click-counting url link (bit.ly) to monitor visits to the questionnaire alongside completions to determine a proxy response rate.

6.3.2.2 *Inclusion and exclusion criteria*

Any surgeon (consultant or post-CCT fellow) in current practice in the UK could complete the survey. Responses from outside the UK were excluded. Surgeons in training were not invited to participate as their practice will vary by placement and supervisor.

6.3.2.3 *Power calculation*

Accepting a 10% margin of error and using the standard confidence level of 95% whilst assuming that the population size that we were sampling was roughly 1500, we calculated that 91 responders would be needed using an online sample size calculator (www.raosoft.com). Given that we were mainly aiming to demonstrate variation, a higher margin of error was accepted. The length of the questionnaire and the number of other e-mail requests for survey completions meant that a pragmatic sample size of 91 responses was chosen to be achievable and reasonable.

6.3.3 Data handling and statistics

6.3.3.1 *Data handling*

Data was collected by Google Forms and then downloaded into a spreadsheet (Excel, Microsoft Corp., Redmond, WA, USA). Descriptive statistics were performed in Microsoft Excel. Graphs were drawn in both Microsoft Excel and R.

6.3.3.2 *Statistics*

Descriptive statistics were used with range, median and percentages shown.

6.4 Results

6.4.1 Demographics

The survey was completed by 104 individuals; one response was excluded as they currently practice outside of the UK resulting in 103 responses after 256 visits to the questionnaire with a calculated response rate of 40.2%. All HCPs who started the questionnaire completed all sections and only 39 out of 10,094 data points were blank (0.39%). All major subspecialities of GI surgery were represented (bariatric 7/103 (7%), benign Oesophagogastric 10/103 (10%), HPB cancer 13/103 (13%), OG cancer 16/103 (15%), colorectal cancer 52/103 (50%) and benign colorectal 5/103 (5%)) (Figure 12). Three-quarters of respondents were male (77/103). The median duration of consultant practice was 8 years (range 0-39 years). Responses were gathered from across the UK, with the largest proportions working in the Yorkshire and Humber 32/103 (31%) and East Midlands 15/103 (15%) deaneries (Figure 12).

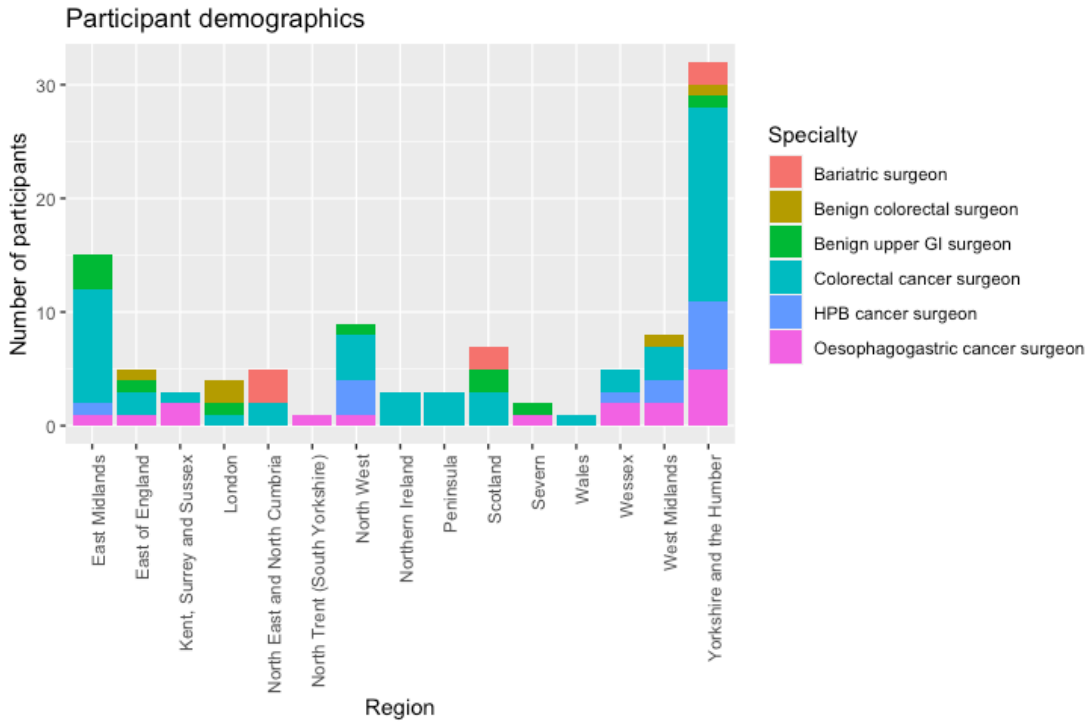


Figure 12. Stacked bar chart depicting deanery of current practice and declared subspecialty with number of participants shown.

6.4.2 Findings

6.4.2.1 *Attitudes towards treatment strategies in the older patient*

When asked about factors that affect their decision-making, surgeons rated pre-existing dementia, moderate to severe heart, liver or renal failure and functional impairments highly (Figure 13). The presence of dementia was rated highest in both setting; 99/103 (96.1%) surgeons rated pre-existing dementia as important (Likert score 6-9) for both elective and emergency patients. Moderate to severe heart, liver or renal failure and functional impairments were also rated highly in both settings.

The availability of alternative treatment strategies in a frail or otherwise 'unfit' older individual was also highly rated, with 86/103 (83.5%) surgeons rating it as important (Likert scale 7-9) in both the elective and emergency settings (

Figure 13). Surgeons also felt that a patient being assessed as at high operative risk using a risk-calculators was important (Likert 6-9) in both settings; emergency (94/103; 91.3%) and elective (91/102; 89.2%).

Interestingly, advanced age (85 years and above), severe obesity, immunosuppressant use and pre-existing 'do not resuscitate' orders were seen as less important than the other factors. However, advanced age was still viewed as important (Likert scale 6-9)

in their decision making; 54/103 (52.4%) and 67/103 (65.0%) in the elective and emergency settings respectively (

Figure 13). There was also a trend towards these factors being more important in decision-making in the emergency compared to the elective setting.

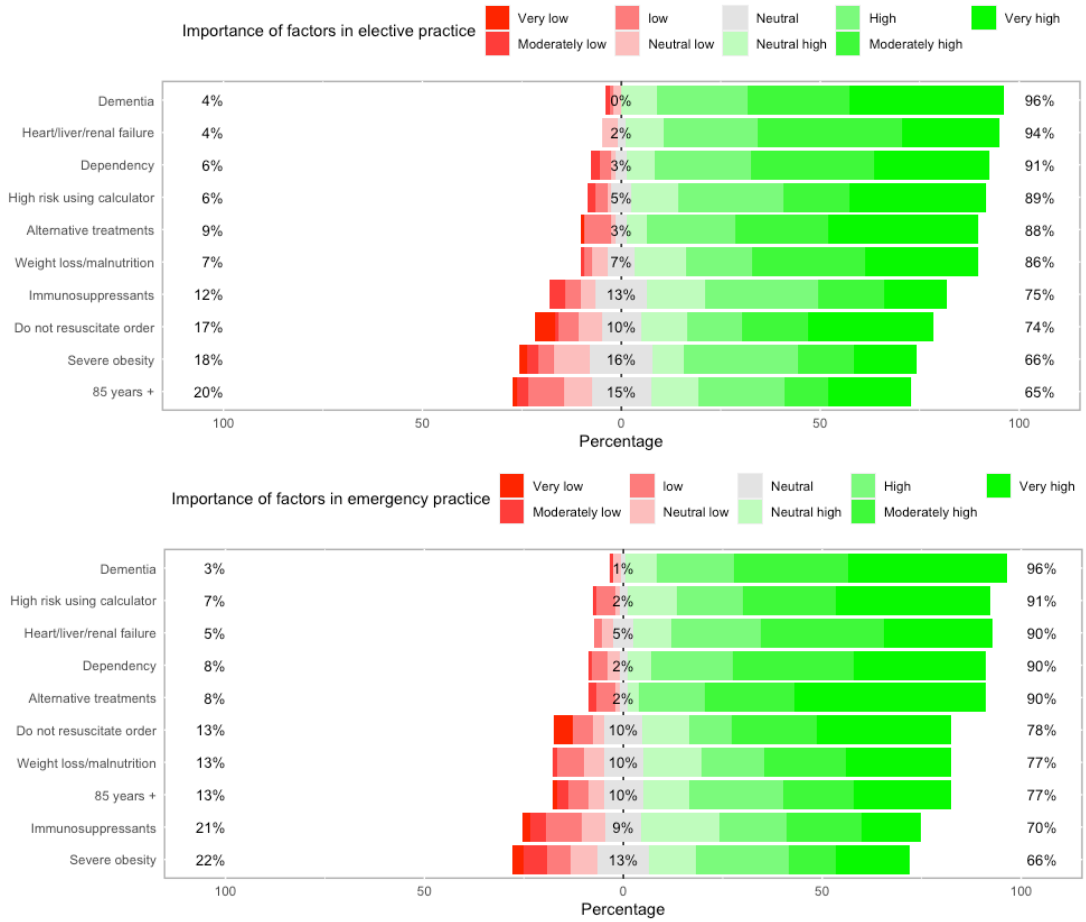


Figure 13. Likert diagrams

These illustrate the importance that clinicians place on different factors in the elective and emergency settings; Likert scale 1=very low (red), 2=moderately low, 3=low, 4=neutral low, 5=neutral, 6=neutral high, 7=high, 8=moderately high, 9=very high (green).

6.4.2.2 *Attitudes towards assessment of the older patient*

Cardiorespiratory fitness assessment

Practice varied regarding how older patients' cardiorespiratory fitness is assessed; 27/103 (26.2%) surgeons stated that they use objective physical tests (e.g. CPET) in all elective patients and 49/103 (47.6%) stated that they use them only in patients in whom they have concerns (Figure 14). There is infrequent use of patient questionnaires to assess physical activity; only 4/103 (3.9%) use them in their elective or emergency assessments of all patients respectively.

Functional assessment

In the elective and emergency settings respectively, 93/103 (90.3%) and 95/103 (92.2%) of surgeons stated that they ask all patients or those for whom they have concerns specific functional questions. However, validated questionnaires of functional status are rarely used with 11/103 (10.7%) and 6/103 (5.8%) using these in all patients in the elective or emergency settings respectively (Figure 14).

Nutritional assessment

Regarding nutritional assessment, 76/103 (73.8%) and 72/103 (69.9%) of surgeons said that they ask specifically about weight loss in all patients in the elective and emergency settings respectively. Many surgeons do not routinely screen for biochemical markers of nutritional deficiency; 61/103 (59.2%) and 79/103 (76.7%) never screen in the elective or emergency settings respectively.

Psychological assessment

The majority of surgeons do not routinely ask a focused history for psychological issues; 81/103 (78.6%) and 80/103 (77.7%) surgeons do not ask elective or emergency patients respectively. Neither do they perform validated psychological screening questionnaires; only 3/103 (3.0%) and 2/103 (1.9%) routinely use them in elective or emergency patients respectively.

Frailty and geriatric assessment

A frailty assessment is infrequently performed in clinical practice; only 51/103 (49.5%) and 58/103 (46.3%) of surgeons perform a frailty assessment in all or selected patients in the elective and emergency settings respectively. Despite dementia being rated highly as a factor taken into account in decision-making, 46/103 (44.7%) and 48/103 (46.6%) do not routinely ask regarding memory problems in elective or emergency patients respectively and 67/103 (65.0%) and 61/103 (59.2%) of surgeons do not perform cognitive testing in the elective and emergency settings respectively (Figure 14).

Co-existing medical conditions and risk calculators

Despite a patient being considered as high-risk according to a risk calculator being rated as important on the Likert scale in elective surgery, comprehensive use of a risk calculator was infrequent in the elective setting (20/103; 19.4%). It was more common in the emergency setting (67/103; 65%).

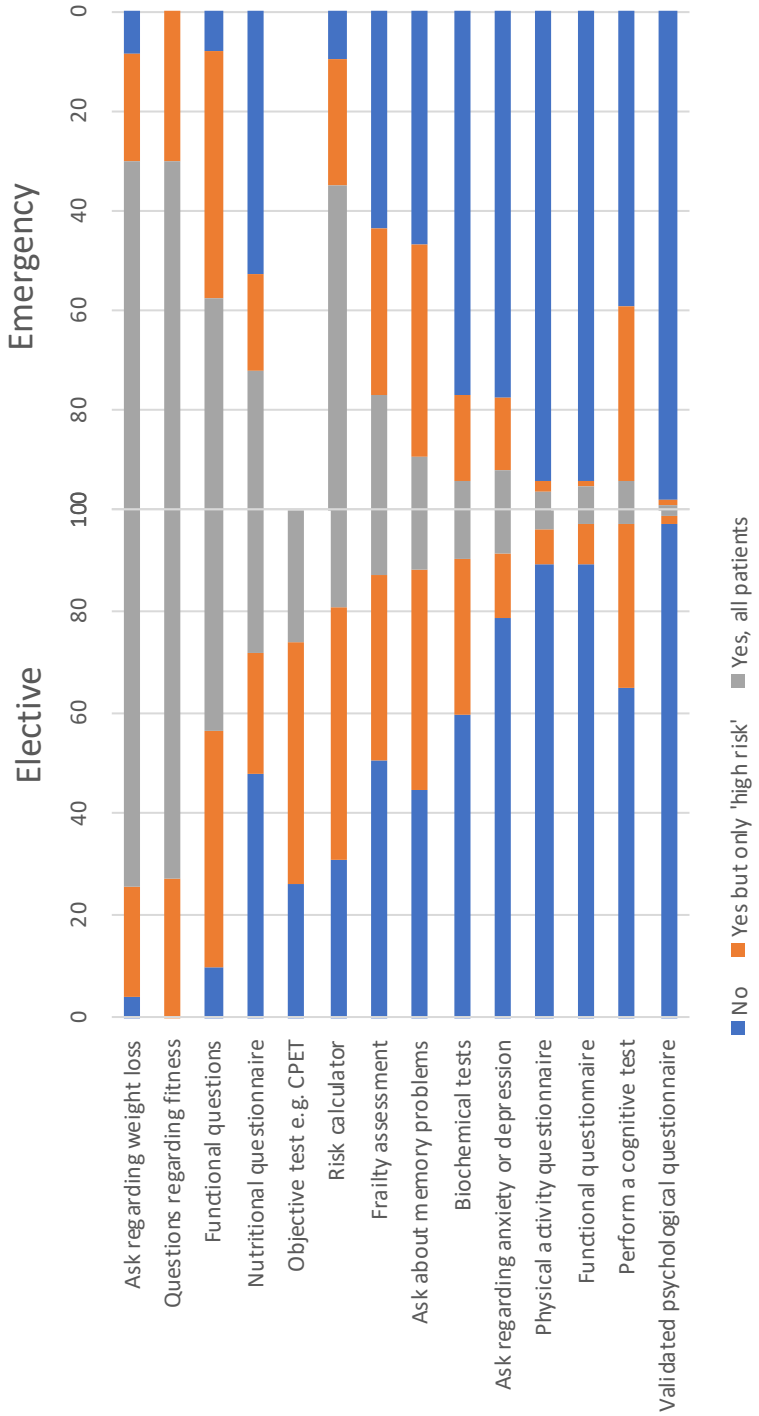


Figure 14. Bar chart illustrating assessment strategies in the elective and emergency settings

Surgeons were asked to indicate whether they did each aspect for all patients, only those whom they considered to be 'high risk' or whether it was not a part of their usual practice. Percentages are shown.

6.4.2.3 *Attitudes towards optimisation of the older patient*

Cardiorespiratory fitness

In the elective setting, 55/103 (53.4%) of surgeons advise all and 28/103 (27.2%) advise selected patients regarding physical activity. One third of surgeons (38/103) routinely advise both elective and emergency patients on deep breathing exercises. There was variable practice in signposting to exercise facilities, referring to prehabilitation programmes and Surgery School (see Figure 15). Only 17/102 (16.5%) surgeons state that they currently refer all of their older patients for prehabilitation. In the free text comments, many surgeons stated that they wanted better access to prehabilitation programmes (Table 22). Some surgeons felt that the evidence base for prehabilitation is not yet sufficient for them to be able to justify delaying cancer treatment to optimise fitness. Many surgeons stated that better access to physiotherapists for emergency patients would be beneficial (Table 23).

Nutritional

Regarding nutritional optimisation in the elective setting, 74/103 (71.8%) surgeons give advice, 77/103 (74.8%) prescribe oral supplements and 73/103 (71.6%) refer to dieticians in all or selected patients. In the emergency setting, surgeons are less likely to refer to dieticians pre-operatively; 38/100 (38.0%) routinely refer all or selected emergency patients pre-operatively.

Psychological

Surgeons themselves rarely advise on psychological preparation for elective or emergency patients, 81/103 (78.6%) and 91/103 (88.3%) surgeons do not give psychological advice respectively, but many will signpost elective patients for support 55/102 (53.9%).

Co-existing medical conditions and lifestyle

Optimisation of medical co-morbidities in the pre-operative period is variable. Optimisation of anaemia is frequently carried out; 86/103 (83.5%) surgeons state that they consider iron infusions or transfusion in all elective patients who are anaemic. In contrast, only 21/103 (20.4%) and 30/103 (29.1%) arrange for a medication review in

all elective and emergency patients respectively. Most surgeons do not routinely refer elective patients to a 'Surgery School'; 71/103 (68.9%). Surgeons more frequently advise elective patients on smoking cessation (95/103; 92.2% all) than alcohol reduction (61/103; 59.2% all). Only 51/103 (49.5%) surgeons give smoking cessation advice to all emergency patients.

Geriatric

Routine pre-operative input from geriatricians for all older patients is low but appears to be slightly higher for emergency patients 14/103 (13.6%) than elective patients 4/103 (3.9%). Pre-operative access for those in whom there are concerns is higher; 38/103 (36.9%) elective and 40/103 (38.8%) emergency patients. Geriatrician input in the post-operative period is higher with 76/103 (73.8%) reporting access for selected or all elective patients and 86/103 (83.5%) emergency patients. Many surgeons put in the free text comments that they would like better access to geriatrician-led support for their emergency patients (Table 23).

Peri-operative

Many surgeons employ enhanced recovery after surgery (ERAS) protocols (92/103; 89.3%), attempt laparoscopic procedures if feasible (97/103; 94.2%) and employ regional analgesic techniques (93/103; 90.3%) for all elective patients. In the emergency setting, many surgeons also attempt all of these strategies (Figure 15).

Many surgeons reported routine post-operative physiotherapy and specialist nurse input for all patients (83/103 80.6% and 85/103 82.5% respectively) with input from other allied health professionals and geriatricians reserved for patients in whom there are concerns (Figure 15). Occupational therapists are rarely involved routinely in all patients post-operatively; 2/103 (1.9%) and 9/103 (8.7%) in the elective and emergency setting respectively. Social workers are also infrequently involved.

Rehabilitation

Access to formal post-operative rehabilitation programmes is limited with only 10/103 (9.7%) and 7/103 (6.8%) surgeons stating that they refer all elective and emergency

patients respectively. Improved access to rehabilitation programmes, involvement of allied health professionals and geriatricians were commonly cited factors that were felt would improve the care of emergency patients (Table 23).

6.4.2.4 *Effect of demographics on responses*

Due to the relatively small sample size of this study it was decided not to perform more in-depth statistical analysis of subgroups within the respondents. It is likely that any differences observed between male and female respondents, respondents from different geographical regions, subspecialities or years of practice would not have been statistically significant given the small sample size.

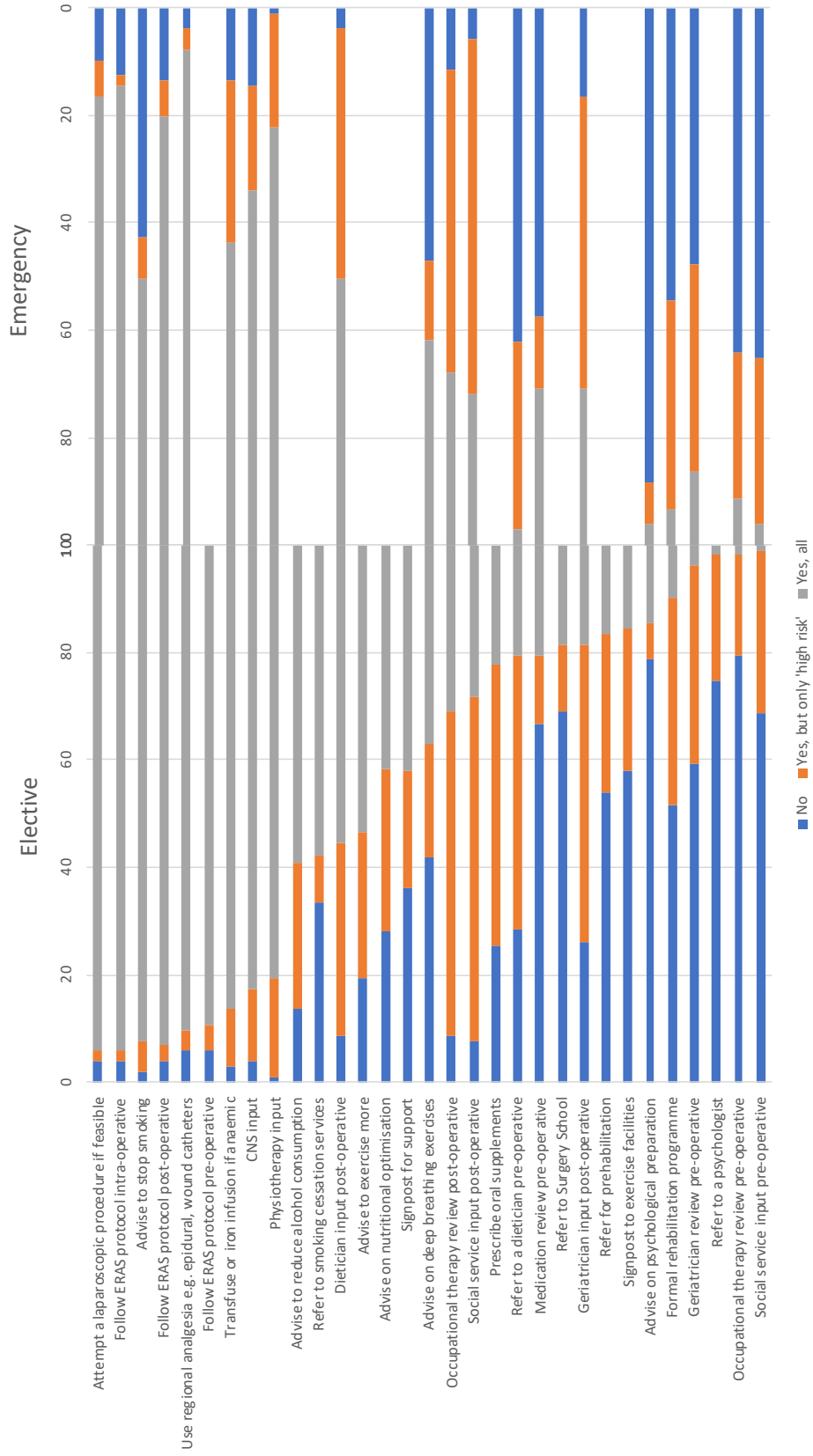


Figure 15. Bar chart demonstrating optimisation strategies in the elective and emergency settings

Surgeons were asked to indicate whether they did each aspect for all patients, only those they considered 'high risk' or whether it was not a part of their practice. Optimisation strategies not relevant in the emergency setting are shown as blank. Percentages are shown.

Question: What would you like to be able to provide for your elective patients that you think would have the greatest impact on their outcomes? Free text responses organized into themes
Theme: Cardiorespiratory fitness • Formal prehabilitation*** • "Exercise prescription" • Time for prehab for those that need it i.e. don't rush to surgery as those that are frail can gain a lot in s short space of time with prehab to improve their outcomes • More scope for prehab (currently just for those with cardiac/respiratory dysfunction but not formally for those just generally unfit). • Physiotherapy • Weight-loss program • Formal Prehab combined with Rehab programme • Remotely supervised exercise programme • Risk profiling and then surgical decision-making based on risk and expectations • Pre op referral to physiotherapy and OT - currently no funding to see pre-op. Preop referral to hospital social services. • Prehabilitation for all major resections not just cancer • CPET testing for high risk patients • Formal Cardiac/frailty tests available on request
Theme: Nutritional • Dietetic input and assessments • More dieticians
Theme: Psychological • Psychological assessment and interventions, coping mechanisms • Education on post-operative expectations
Theme: Optimising medical co-morbidities • Pre-operative pharmacological optimisation • Surgery School
Theme: Geriatric • Geriatrician led post op care • Pre-operative geriatrician input
Theme: Peri-operative

• Wound catheters • Good ERAS pathway, ERP practitioner • Help with mobilisation • Step down discharge unit • Dedicated GI anaesthetist • Full MDT for the service including dietetics physio OT, social services, pharmacy. • Continuity of care – those assessing the patients should be the ones operating on or anaesthetising the patients
Theme: Rehabilitation • Post-operative 'habilitation' • Formal multidimensional rehabilitation services. • Specialist nurse to co-ordinate allied health professions
Theme: Organisational • Centralisation • More theatre capacity to reduce waiting times
Theme: Technological • Robotic programme • Develop an App that promotes appropriate actions/ activities before, during and after surgery
Theme: Research • Evidence that interventions work

Table 22. Free text comments to question regarding optimisation of elective patients

****denotes the most frequent comment*

Question: What would you like to be able to provide for your emergency patients that you think would have the greatest impact on their outcomes? Free text responses organized into themes
Theme: Peri-operative • Specialist consultant decision making and input • Pre-operative MDT involvement and decision-making with objective risk stratification • Optimisation on HDU-type facility, better access to critical care • Earlier identification • Dedicated peri-operative team, consultant anaesthetist support 24/7 • Minimise interventions
Theme: Post-operative • ITU post-operative for all • Dedicated cohort care as per prehabilitation • Help with post-operative mobilization • Psychological support where needed
Theme: Allied health professionals • Specialist nurse who leads rehabilitation with OT, physiotherapy and geriatrics • Robust dietetics input (at present 3 day delay for dietician review) • Specialist nurse input including stoma nurse and wound management • Greater physiotherapy input*** (especially at weekends) • Geriatric input*** • Emergency specific ERAS programme and ERAS support from dedicated nurse
Theme: Rehabilitation • Increased social care support and more accessible intermediate care • Post-discharge rehabilitation programmes
Theme: Organisational • Rapid access to theatres • Increased levels of ward nursing • Dedicated Emergency General Surgery Specialty • Step-down discharge unit
Theme: Research • Evidence that something works

Table 23. Free text comments to question regarding emergency patient optimization

****denotes the most frequent comments*

6.5 Discussion

6.5.1 Variation in practice

Rates of surgery in the older population vary in the UK. Clinician opinion may account for some of these differences. This study has shown differences in attitudes towards major gastrointestinal surgery in older patients amongst surgeons involved in their care. It has demonstrated wide variation in practice in the methods of assessment and optimisation of older patients. This suggests that not all modifiable risk factors may be assessed for and therefore opportunities for optimisation missed. Access to resources for optimisation varies, as does availability of members of the wider HCP team.

Available guidelines for major gastrointestinal surgery state that age should not be used in surgical decision-making, however, there remains a paucity of evidence on what measures should be used instead. Guidelines often advise on what optimal management should be if a patient is 'fit' with the assessment of fitness left to the responsible surgeon[34,69,96,116]. This means that patients may be assessed differently if they present to different surgeons, subspecialties or hospitals within the UK. This study demonstrates this variation clearly.

6.5.2 Factors important in the decision-making process

This study suggests that HCPs are more cautious about major GI surgery in patients over the age of 85, which correlates with a previous survey conducted by SIOG[165]. The most recent NBOCA report also found that patients over the age of 65 are more likely to be objectively assessed using CPET than younger patients[27]. This study has found that surgeons rate functional and cognitive impairments highly in their decision-making but in the majority of patients this is not formally assessed. A previous study found that half of surgeons do not routinely offer major surgery to patients with dementia[165] and the latest NBOCA report highlighted the lower rates of major resection in this population[27]. Similarly, psychological problems are known to have a high prevalence in cancer populations, but this study has demonstrated that they are rarely assessed for objectively[323].

6.5.3 Availability of services and professionals

Differences in commissioning of services, availability of health professionals (particularly geriatric specialists), as well as attitudes towards and uptake of different optimisation strategies results in varying provision to older patients[324,325]. This will likely widen the difference in outcomes across the UK[50]. Interventions such as prehabilitation, rehabilitation and comprehensive geriatric assessment have been demonstrated to be safe in older GI surgical populations but proving their effectiveness on post-operative outcomes and cost-effectiveness have been harder to achieve[140,303,326]. These two outcomes are necessary for wider uptake by the surgical community, as well as investment by hospitals.

6.5.4 Provision for emergency patients undergoing major GI surgery

Older patients presenting with emergency GI conditions are an extremely challenging group and co-ordinated, multidisciplinary strategies to optimise their care peri- and post-operatively are needed[73,128]. The lack of objective assessments in the emergency setting in this study demonstrates that identifying correctable deficits pre-operatively is challenging. There is mounting evidence that the presence of frailty in older patients undergoing emergency GI surgery is an independent predictor of poor outcomes[128,308], however this study found that it is still not assessed in all patients. Access to geriatrician-led care, including professionals from occupational therapy and social services, in emergency GI surgery is known to be highly variable[73,107,325] and was confirmed in this study.

6.5.5 Strengths and weaknesses of this analysis

The relatively low response rate is a limitation of this study and limits the generalisability of results, however this is common in questionnaire studies[327]. The length of this questionnaire may have affected completions, however all surgeons who started the questionnaire completed all sections. Self-selection of respondents may have meant that surgeons more interested in this research area completed the questionnaire, however, wide variation was demonstrated despite this. It is also recognised that surgical decision-making is complex and dependent on multiple factors that are difficult to express within the limits of a questionnaire. It is acknowledged that some aspects of assessment may be performed by other members

of the team (e.g. holistic needs assessments by specialist nurses) and that this has not been captured in the survey.

6.6 Conclusion

Inconsistency in the methods of assessment and optimisation may contribute to variation in outcomes in the older population undergoing major GI surgery. This inconsistency is particularly notable in the emergency setting. Availability and utilisation of members of the wider multidisciplinary team, cost of assessments and interventions, clinician preference and lack of evidence-based guidelines all contribute towards this variation.

7 Clinician questionnaires – Discrete Choice Experiment

The data from this chapter is currently being prepared for publication.

My role in this study was in securing ethical approval, writing the scenarios and collecting and analysing the results.

7.1 Abstract

Introduction

Variation in major gastrointestinal surgery rates in the older population suggests that not all patients are offered the same treatments. Higher prevalence of co-morbidities, frailty and cognitive impairments in the older population may account for some of these differences. Clinician preference may also be important.

Methods

A survey was designed according to the discrete choice methodology. Questions were designed to test for associations between key variables (age, co-morbidity, urgency of presentation, pathology, functional and cognitive status) and treatment preference for major gastrointestinal surgery versus conservative management. The survey was disseminated electronically to UK gastrointestinal surgeons. Binomial logistic regression was used to identify associations.

Results

In total, 103 responses were received after 256 visits to the questionnaire (estimated response rate 40.2%). The 103 participants answered 1,847 out of the 1,854 scenarios (99.6%). There was a preference for major surgery in 1112/1847 (60.2%) of all scenarios, with an overall preference for major surgery in 11 out of the 18 scenarios (61.1%). There was variation in how often major surgery was selected by each surgeon, median 11 (range 1-18). On univariate analysis, all variables were independently associated with treatment preference for conservative management over major surgery ($p<0.05$). Binomial logistic regression demonstrated that all variables were important in decision-making, however, functional status was excluded from the final model as it is closely linked to other health variables.

Conclusion

Current guidelines state that age should not be used in surgical treatment decision-making. In this study, however, age appears to be an independent factor influencing decision-making, particularly in the presence of cognitive impairment. Variation in treatment preference was observed, suggesting that patients may be offered different management if they present to different surgeons.

7.2 Introduction

Many factors associated with ageing, such as co-morbidity, frailty, functional and cognitive impairments, increase peri-operative risk. HCPs take these factors into account to varying degrees when deciding treatment options for older patients. Available guidelines state that age should not be taken into consideration when deciding surgical management options and patients should be considered for standard treatments if they are 'fit'[110–112,115]. However, there is a paucity of evidence-based surgical guidelines on how patients should be assessed for 'fitness' or how surgical treatments should be stratified. Variation in resection rates between surgical units that cannot be explained by case-mix variation suggest that surgeon preference may be a source of some of this variation.

Major GI surgery is associated with significant risks of adverse post-operative events, even in the fittest of patients. This risk is amplified in the older population, particularly in the emergency setting[126,328]. Older patients are at risk of delirium, prolonged hospital stay and loss of functional independence[84]. In some situations, not performing surgery may help to preserve an individual's quality of life and independence. Studies suggest that preserving quality of life may be of greater importance than length of life to many older adults[91].

The aim of this study was to determine the impact of key factors on treatment allocation by GI surgeons using the discrete choice experiment (DCE) methodology and to explore variation in clinician opinion.

7.3 Methods

7.3.1 Establishing variables and levels

Five key variables were identified from the literature and qualitative semi-structured healthcare professional interviews (Chapter 5). Variables were subdivided into levels of severity based on a previous study by members of the study team[197] (detailed in Table 24).

Variable	Levels			
Patient age (years)	65-74	75-79	80-84	85+
Co-morbidity	No co-morbidity	Mild co-morbidity	Moderate co-morbidity	Severe co-morbidity
Pathology and presentation	Elective, non-malignant	Elective malignancy	Emergency non-malignant	Emergency malignant
Functional status	Fully independent	Mild dependence	Moderate dependence	Severe dependence
Cognition	Normal	Mild impairment	Moderate impairment	Severe impairment

Table 24. Discrete choice variables and levels

7.3.2 Determining choice sets

Twenty-five scenarios were randomly generated using IBM SPSS version 21 Orthoplan software. This was based on previous research by the study group in DCE design, which suggests that HCPs could review up to 25 scenarios without negatively affecting survey completion rates[197,199]. Each scenario was checked by the study team for plausibility (i.e. it would be unlikely that a person with severe cognitive impairment was fully independent, for example), which led to the exclusion of seven scenarios. For each scenario, respondents were asked whether they would recommend major GI surgery or conservative management. Conservative management could include palliative operations or procedures appropriate to their area of expertise, antibiotics or best supportive care.

7.3.3 Piloting

Piloting was carried out to ensure face and content validity, which resulted in a change in the management choices from three options (major surgery, non-resectional/palliative procedure or no surgery) to two options (major surgery or non-resectional/palliative/no surgery) as this was felt to reflect clinical practice more closely. This pair-wise choice design is also more well established in the DCE literature[329].

7.3.4 Dissemination

The eighteen scenarios were converted into a web-based questionnaire for dissemination (See chapter 6 for more details). A screenshot of a sample DCE scenario in Google Forms format is shown in Figure 16 with the full version of DCE questionnaire included below.

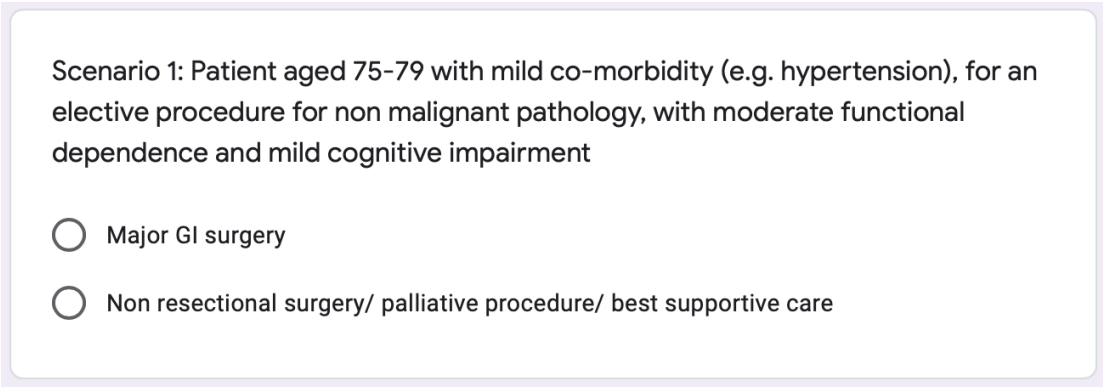


Figure 16. Screenshot of question 1 of the DCE in Google Forms.

7.3.5 Statistical analysis

Univariate analyses and binomial logistic regression were performed to test for associations between the dichotomous dependent variable (treatment preference 'major surgery' or 'conservative management') and the clinical characteristics (independent variables) given in the scenarios. 'Major GI surgery' was set as the reference category. Ordinal variables included age, co-morbidity, cognitive and functional status. The nominal variable was 'pathology and presentation'. Responses were clustered by participant due to lack of response independence (each participant answered all scenarios). Standard errors for the regression coefficient estimates were used to calculate confidence intervals and p-values. Analyses were performed using SPSS version 21 (IBM, Armonk, NY, USA). Details of the sample size calculation is detailed in Chapter 6.

Discrete Choice Experiment Questionnaire

This section comprises a series of 18 clinical scenarios on which you are asked to make a hypothetical decision. The scenarios are concerned with the importance that you place on various factors influencing your preferred option for resectional (major) GI surgery or non-resectional surgery/ palliative procedures/ best supportive care in older patients with operable major GI pathology.
Non-resectional surgery or palliative options may be something that you would consider to help manage symptoms for a patient who you do not consider would tolerate or benefit from major resection. For example, stenting as a definitive procedure, defunctioning stomas, palliative radiotherapy, intestinal bypass or percutaneous procedures for volvulus.

The 18 scenarios differ according to the following five aspects:

1. Patient age (years) Divided into the following age bands:

65 –74 75 –79 80 – 84 85 and over

2. Co-morbidity Divided into the following:

1. No co-morbidity
2. Mild co-morbidity, e.g. arthritis, visual impairment, hypertension (with or without regular treatment)
3. Moderate co-morbidity, e.g. diabetes, coronary heart disease, moderate COPD (symptomatically controlled with regular medication)
4. Severe co-morbidity, e.g. disabling stroke, congestive cardiac failure, severe COPD

3. Pathology and presentation. Divided into the following:

1. Elective non-malignant pathology e.g. diverticular stricture, incisional hernia
2. Elective malignancy amenable to resection
3. Emergency non-malignant pathology e.g. small bowel obstruction
4. Emergency malignancy e.g. obstructing cancer amenable to resection with no distant spread

4. Functional Status. Divided into the following:

1. Fully independent
2. Mild dependence e.g. requires help approximately once a week for domestic activities of daily living (shopping, cleaning, laundry).
3. Moderate dependence e.g. requires help at least once a day for personal activities of daily living (washing, dressing, continence management).
4. Severe dependence e.g requires 24-hour care (resides in a residential or nursing home)

5. Cognitive Function. Divided into the following:

1. Normal cognitive function
2. Mild cognitive impairment e.g. Slight memory loss but able to function normally in society
3. Moderate cognitive impairment e.g. Poor memory, unable to cope without help from either family or carers
4. Severe cognitive impairment e.g. Requires 24-hour care in own home or a skilled facility

Patient Scenarios

For each of the scenarios, based on the information provided, please indicate your preferred choice of treatment by placing a tick ✓ in the relevant box. Please assume that each hypothetical patient has asked for your advice on what treatment option they should choose and that they have a condition that you would commonly treat in your area of expertise.

Scenario 1

Patient age (years)	75-79
Co-morbidity	Mild
Pathology and presentation	Elective non-malignant
Functional Status	Moderate dependence
Cognitive Function	Mild cognitive impairment
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 2

Patient age (years)	85+
Co-morbidity	None
Pathology and presentation	Elective malignant
Functional Status	Moderate dependence
Cognitive Function	Moderate cognitive impairment
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 3

Patient age (years)	85+
Co-morbidity	Moderate
Pathology and presentation	Elective non-malignant
Functional Status	Severe dependence
Cognitive Function	Mild cognitive impairment
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 4

Patient age (years)	65-74
Co-morbidity	none
Pathology and presentation	emergency malignancy
Functional Status	mild dependence
Cognitive Function	mild cognitive impairment
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 5

Patient age (years)	65-74
Co-morbidity	none
Pathology and presentation	emergency malignancy
Functional Status	moderate dependence
Cognitive Function	severe
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 6

Patient age (years)	65-74
Co-morbidity	moderate
Pathology and presentation	elective non-malignant
Functional Status	mild dependence
Cognitive Function	normal
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 7

Patient age (years)	75-79
Co-morbidity	severe
Pathology and presentation	emergency malignancy
Functional Status	severe dependence
Cognitive Function	normal
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 8

Patient age (years)	65-74
Co-morbidity	moderate
Pathology and presentation	emergency non-malignant
Functional Status	moderate dependence
Cognitive Function	normal
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 9

Patient age (years)	80-84
Co-morbidity	Severe
Pathology and presentation	elective non-malignant
Functional Status	moderate dependence
Cognitive Function	normal
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 10

Patient age (years)	85+
Co-morbidity	none
Pathology and presentation	elective non-malignant
Functional Status	independent
Cognitive Function	normal
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 11

Patient age (years)	75-79
Co-morbidity	none
Pathology and presentation	emergency non malignant
Functional Status	independent
Cognitive Function	normal
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 12

Patient age (years)	80-84
Co-morbidity	none
Pathology and presentation	emergency non-malignant
Functional Status	independent
Cognitive Function	mild
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 13

Patient age (years)	65-74
Co-morbidity	none
Pathology and presentation	elective non-malignant
Functional Status	independent
Cognitive Function	normal
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 14

Patient age (years)	80-84
Co-morbidity	none
Pathology and presentation	elective non-malignant
Functional Status	severe dependence
Cognitive Function	severe
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 15

Patient age (years)	75-79
Co-morbidity	none
Pathology and presentation	elective non-malignant
Functional Status	mild dependence
Cognitive Function	moderate
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 16

Patient age (years)	65-74
Co-morbidity	mild
Pathology and presentation	emergency non-malignant
Functional Status	severe dependence
Cognitive Function	moderate
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 17

Patient age (years)	80-84
Co-morbidity	mild
Pathology and presentation	elective malignant
Functional Status	mild dependence
Cognitive Function	normal
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

Scenario 18

Patient age (years)	85+
Co-morbidity	mild
Pathology and presentation	emergency malignancy
Functional Status	independent
Cognitive Function	normal
Major GI surgery	[ ]
Non resectional surgery/ palliative procedure/ best supportive care	[ ]

7.4 Results

7.4.1 Response rate

The demographics of respondents and the response rate are detailed in Chapter 6.3.1.

7.4.2 Findings

The 103 participants answered 1,847 out of the 1,854 scenarios (103 x 18) indicating that 99.6% of questions were completed.

7.4.2.1 *Preference for major GI surgery*

There was a preference for major surgery in 60.2% (1112/1847) of all scenarios, with an overall preference for major surgery in 11 out of the 18 scenarios (61.1%). There was variation in how often major surgery was selected by each surgeon, median 11 (range 1-18) (Figure 17). There was no relationship between clinician sex, subspeciality or number of years in practice and number of times major GI surgery was chosen.

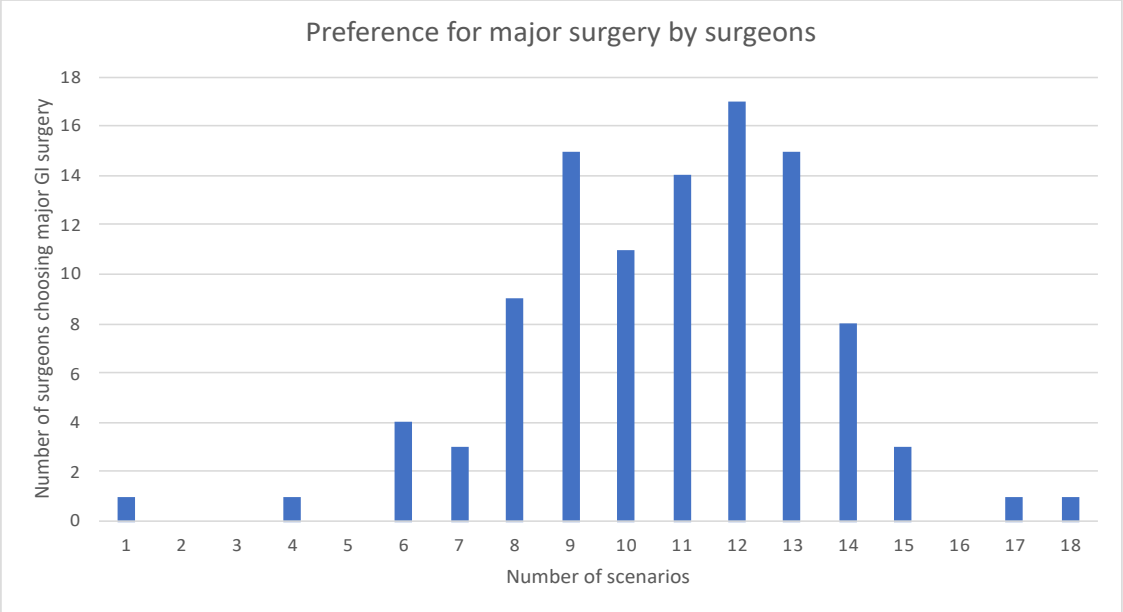


Figure 17. Number of surgeons selecting major surgery in all scenarios

There was clear management agreement (more than 85% respondents giving the same opinion) for 12 out of the 18 scenarios (Table 25). The six scenarios where there was treatment uncertainty were scenarios 1, 2, 5, 10, 15 and 16. These included 5/12 (41.7%) non-malignant scenarios compared to 1/6 (16.7%) malignant scenarios. It was observed that the scenarios where the patient had either moderate or severe cognitive impairment (scenarios 2, 5, 14, 15 and 16) were associated with lower preference for major surgery, regardless of other variables (Table 25).

Scenario	Patient age	Co-morbidity	Pathology and presentation	Functional impairment	Cognitive impairment	Preference for surgery, n (%)
1 *	75-79	Mild	Elective, non-malignant	Moderate	Mild	71 (68.9)
2 *	85+	None	Elective, malignant	Moderate	Moderate	46 (44.7)
3	85+	Moderate	Elective, non-malignant	Severe	Mild	6 (5.8)
4	65-74	None	Emergency, malignant	Mild	Mild	101 (98.1)
5 *	65-74	None	Emergency, malignant	Moderate	Severe	40 (38.8)
6	65-74	Moderate	Elective, non-malignant	Mild	None	92 (89.3)
7	75-79	Severe	Emergency, malignant	Severe	None	12 (11.7)
8	65-74	Moderate	Emergency, non-malignant	Moderate	None	92 (89.3)
9	80-84	Severe	Elective, non-malignant	Moderate	None	10 (9.7)
10 *	85+	None	Elective, non-malignant	Independent	None	80 (77.7)
11	75-79	None	Emergency, non-malignant	Independent	None	101 (98.1)
12	80-84	None	Emergency, non-malignant	Independent	Mild	96 (93.2)
13	65-74	None	Elective, non-malignant	Independent	None	101 (98.1)
14	80-84	None	Elective, non-malignant	Severe	Severe	8 (7.8)
15 *	75-79	None	Elective, non-malignant	Mild	Moderate	55 (53.4)
16 *	65-74	Mild	Emergency, non-malignant	Severe	Moderate	23 (22.3)
17	80-84	Mild	Elective, malignant	Mild	None	87 (84.5)
18	85+	Mild	Emergency, malignant	Independent	None	91 (88.3)

Table 25 Results by scenario for the DCE with number of respondents and percentage of total reported.

Scenarios marked with an "" were associated with treatment uncertainty with less than 85% of respondents in agreement.*

7.4.2.2 *Univariate analysis*

On univariate analysis increasing age, level of co-morbidity, functional and cognitive impairment were independently associated with a statistically significant treatment preference for conservative management over major surgery ($p<0.05$) (Table 26). Some individual variables (age 85 years or over, moderate co-morbidities and mild cognitive impairment) did not follow the general trend of odds ratios and this likely reflects the combination of variables presented in the scenarios.

For the nominal variable 'presentation and pathology' all of the variables were associated with a preference for major surgery over the reference category (elective surgery for non-malignant pathology). The greatest odds ratio was observed for elective surgery for malignant pathology over the reference category (OR = 4.146 95% CI 2.769 to 6.207) indicating that surgeons were much more likely to recommend elective surgery for malignant than non-malignant pathology. Surgeons were more than twice as likely to recommend surgery for patients with emergency presentations of non-malignant pathology compared to elective presentations (OR = 2.155 95% CI 1.832 to 2.536). Functional status was significant on univariate analysis, with increasing levels of impairment associated with decreasing odds ratio of selecting major GI surgery (Table 26).

Variable	Level	Odds ratio	95% Confidence interval	
			Lower	Upper
Age (p<0.05)	65-74	Ref		
	75-79	0.747	0.620	0.899
	80-84	0.572	0.484	0.676
	85+	1.489	1.124	1.973
Co-morbidities (p<0.05)	None	Ref		
	Mild	0.942	0.768	1.157
	Moderate	1.392	1.165	1.663
	Severe	0.056	0.035	0.089
Presentation and pathology (p<0.05)	Elective non-malignant	Ref		
	Elective malignant	4.146	2.769	6.207
	Emergency non-malignant	2.155	1.832	2.536
	Emergency malignant	1.848	1.529	2.234
Functional impairment (p<0.05)	None	Ref		
	Mild	0.293	0.205	0.419
	Moderate	0.079	0.053	0.119
	Severe	0.015	0.009	0.026
Cognitive impairment (p<0.05)	None	Ref		
	Mild	1.222	1.000	1.493
	Moderate	0.182	0.139	0.239
	Severe	0.057	0.040	0.082

Table 26. Univariate analysis of each of the different variables and their effect on treatment.

7.4.2.3 *Binomial logistic regression*

On binomial logistic regression the independent explanatory variables age, co-morbidities, presentation/pathology and cognitive impairment all significantly added to the model (all p<0.000) using the Wald Chi-squared test (Wald) to determine statistical significance (Table 27). 'B' refers to the coefficient for the constant in the null model. Functional status was excluded from the final model as it was felt to be too closely aligned (co-linear) with co-morbidity and cognitive impairment for it to be classed as an independent variable.

Influence of age on treatment preference

The effect of increasing age on treatment preference in the binomial model was significant (Wald 23.627, p<0.000). However, as can be seen in Table 27 age 80-84 on its own was not significant (B=0.282, 95% CI -0.405 to 0.970). This may be because there is uncertainty in the management of patients in this age group, whereas there

was more certainty for the group 85+. It could also have been influenced by the specific combination of scenarios that were in the DCE.

Influence of co-morbidities on treatment preference

The presence of increasing levels of co-morbidity had a significant effect on the binomial model (Wald 76.818, p<0.000) (Table 27). All levels were associated with a lower probability of choosing major GI surgery over the reference category of 'no co-morbidities'. The effect of severe co-morbidities was particularly pronounced (B=-6.949, 95% CI -7.850 to -6.047).

Influence of cognitive impairment on treatment preference

As expected, cognitive impairment was the most important contributor to the binomial model (Wald 89.175, p<0.000). Increasing levels of cognitive impairment were negatively associated with the selection of major GI surgery over the reference category of 'no cognitive impairment' (Table 27).

Influence of presentation and pathology on treatment preference

Pathology and presentation also contributed to the binomial model (Wald 17.616, p<0.000). All variables were associated with increasing likelihood to recommend major GI surgery, however, only emergency malignant compared to elective non-malignant was significant on its own (B=2.269, 95% CI 1.65 to 2.897) (Table 27).

Variable	Level	B	Std error	95% Confidence interval		Wald	Sig.
				Lower	Upper		
Age	65-74	Ref				23.627	0.000
	75-79	-0.563	0.258	-1.075	-0.050		
	80-84	0.282	0.347	-0.405	0.970		
	85+	-2.086	0.303	-2.686	-1.486		
Co-morbidities	None	Ref				76.818	0.000
	Mild	-2.097	0.247	-2.587	-1.607		
	Moderate	-1.881	0.314	-2.503	-1.259		
	Severe	-6.949	0.455	-7.850	-6.047		
Cognitive impairment	None	Ref				89.175	0.000
	Mild	-1.483	0.207	-1.894	-1.073		
	Moderate	-2.989	0.259	-3.502	-2.475		
	Severe	-6.453	0.489	-7.422	-5.484		
Presentation and pathology	Elective non-malignant	Ref				17.616	0.000
	Elective malignant	0.158	0.299	-0.436	0.752		
	Emergency non-malignant	0.229	0.192	-0.151	0.609		
	Emergency malignant	2.269	0.317	1.640	2.897		

Table 27. Binomial logistic regression analysis of the influence of DCE variables on treatment choice.

'B' is the coefficient for the constant in the null model. 'Std error' is the standard error around the coefficient for the constant. The 95% confidence interval is shown for the B coefficient. 'Wald' is the Wald chi-square test which tests the null hypothesis that the constant equals 0. 'Sig.' refers to the significance of the Wald test.

7.5 Discussion

7.5.1 Variation in treatment decision-making

This study has established the importance of different variables in GI surgeons' treatment decision-making under experimental conditions for clinical scenarios. It complements the interview and questionnaire findings as it examines what surgeons select in hypothetical scenarios alongside what they say they take into account. It has also enabled the interaction between different variables to be examined. As far as we are aware, this is the first application of the DCE in this clinical situation.

Lack of consensus on treatment preference was observed for six out of 18 scenarios. There was also wide variation in how many times individual surgeons recommended major surgery, suggesting variation in practice. This underscores the need for incorporation of fitness-based thresholds specific to older patients into clinical practice guidelines. Given the ageing population of patients presenting to GI surgeons, it also supports the need for training in geriatric assessment to be integrated into general surgical training.

7.5.2 Impact of age on decision-making

Available guidelines for GI surgery suggest that "fit" older adults should be offered the same treatments as younger individuals[74,110–112,115]. However, in this study, age does appear to be an independent factor taken into consideration in deciding treatment options, particularly for non-malignant disease. This reflects the lack of guidelines for the surgical management of older patients with non-malignant disease[74,129]. This contrasts with what HCPs said that they do in semi-structured interviews but is concordant with the questionnaire data finding that age 85 or over is a factor taken into consideration. It is likely that surgeons use age as a surrogate for fitness, frailty and life-expectancy, particularly in the absence of objective assessments[330].

7.5.3 Impact of co-morbidities

The prevalence of co-morbidities increases with age and is an important factor in the higher incidence of post-operative complications in the older surgical population. Available guidelines do not state which co-morbidities would be contraindications to major GI surgery or suggest how patients with these co-morbidities should be optimised prior to surgery. It is therefore the clinician's responsibility to decide which

co-morbidities and what severity of co-morbidities preclude major surgery. This study suggests that severity of co-morbidity is a significant factor in surgeon treatment decision-making in older patients.

7.5.4 Impact of functional impairments

Multiple studies have emphasised the negative impact of major GI surgery on functional independence[84,331,332], therefore it is not surprising that surgeons in this study were less likely to suggest major surgery when functional impairments were already present. Functional impairment also correlates with physical inactivity, another predictor of poor outcomes in older patients[32].

7.5.5 Impact of cognitive impairment

The increasing prevalence of cognitive impairment in the older population is a growing problem in the UK. Lack of research and guidelines regarding the treatment of individuals with cognitive impairment contributes to higher use of alternative treatments (such as stenting of colorectal tumours) and non-operative management strategies across the spectrum of GI surgical pathologies[27]. Whilst patients with severe dementia frequently have limited life expectancies, patients with mild dementia often have life expectancies that exceed their surgical pathology and the life expectancy of many other co-morbidities[333]. In addition, symptom burden may be significant in surgical GI pathologies and thus the benefits of operative intervention for someone who cannot retain why they are having troubling symptoms may outweigh the risks of intervention. This study has confirmed that moderate to severe cognitive impairment impacts surgical treatment decision-making significantly. The DCE is concordant with the interview findings that surgeons are willing to offer surgery to patients with mild cognitive impairment in the absence of significant functional impairments or other co-morbidities.

7.5.6 Impact of presentation and pathology

This study suggests that surgeons are more likely to offer major GI surgery in patients with malignant pathology and those who present as emergencies. This is concordant with the interview data where HCPs said that symptom burden is important in their decision-making and that there are often limited alternative options for patients who present as emergencies. Many HCPs said in the interviews that outcomes without

surgery in the emergency setting are generally poor, which meant that they were more likely accept higher levels of operative risk due to patient factors (co-morbidity, fitness, frailty and functional impairments). The DCE confirms this. Interestingly, surgeons were more likely to offer surgery for malignant compared to non-malignant pathology, which again suggests that surgery for non-malignant pathologies is much more dependent on symptom severity. In addition, some non-malignant pathologies may respond well to conservative management (for example antibiotics for recurrent flares of diverticulitis).

7.5.7 Limitations of this study

This study was adequately powered according to the power calculation and the literature for DCE[201]. However, due to an estimated response rate of only 40%, the generalisability of these results is limited. The dissemination of the survey to a wide range of GI surgeons may have also introduced heterogeneity into the results. Grade or stage of malignant pathology was not included in the scenarios but obviously would affect treatment decisions dependent on the subspeciality of GI surgery. Equally some non-malignant pathologies may be successfully treated with conservative measures whereas conservative measures in others results in poor symptom control.

The random selection of scenarios led to more scenarios for non-malignant than malignant pathology being included in the final model. In any future DCEs in this area, stratification in scenario selection should be considered. The exclusion of seven scenarios due to lack of plausibility may have also affected the orthogonal design of the study and potentially introduced bias.

A further potential limitation of the DCE study choice was that it forced surgeons to make decisions based on hypothetical scenarios with limited data, however, this is not dissimilar to the amount of information on GP referrals or considered at MDT meetings. Equally, with the shift to virtual consultations precipitated by the pandemic, opportunities for surgeons to assess patients ‘face-to-face’ are likely to continue to be limited in the future.

7.6 Conclusion

This study has confirmed that surgeons take a number of factors into consideration when deciding management options for older patients. It suggests that cognitive function and co-morbidities have most impact but that age is also taken into account. The range in number of scenarios selected by each surgeon suggests wide variation in practice and suggests that surgeon preference is a significant factor in treatment allocation. This may explain some of the variation in GI surgical outcomes seen across the UK.

8 Observational study

The protocol paper for this study has been published:

Daniels SL, Lee MJ, Moug S, Wilson TR, Burton M, George J, Brown SR, Wyld L. Protocol for a multi-centre observational and mixed methods pilot study to identify factors predictive of poor functional recovery after major gastrointestinal surgery and strategies to enhance uptake of peri-operative optimisation: OCTAGON. Colorectal Disease Feb 2021 doi: 10.1111/CODI.15603

My role in this study was in writing the study protocol, submitting applications for funding and ethical approval, collecting and analysing the results and as Chief Investigator of the study.

Permission from the publisher (Appendix U) and the co-authors (Appendix V) have been obtained for reproduction in this thesis.

The study has now commenced with baseline data collection complete at one hospital (STH) and in progress at two hospitals (Doncaster Royal Infirmary and Huddersfield Royal Infirmary). Commencement of recruitment at another 2 NHS sites has been delayed due to the COVID-19 pandemic.

The results presented in this chapter are from the patients recruited at Sheffield Teaching Hospitals alone.

8.1 Abstract

Introduction

National UK datasets report large variations in outcomes after major gastrointestinal surgery. This implies that not all patients receive the same level of care or access to resources. The aims of this study were to observe the provision of different peri-operative optimisation strategies and measure functional outcomes after surgery.

Methods

Patients aged 65 years and above with gastrointestinal conditions amenable to major surgery were identified prior to surgery at a single tertiary NHS hospital. Validated questionnaires were used to assess quality of life, physical activity levels, functional, nutritional and cognitive status at baseline. Data were collected on co-morbidities, surgical procedures and peri-operative optimisation strategies. Functional outcomes were assessed at 6 weeks post-surgery using the WHO Disability Assessment Schedule 2.0. Ethical approval was in place and the study was registered at clinicaltrials.org.

Results

Some 60 patients were included in the study; median age 74 years (range 65-93), 36/60 (60.0%) male. Forty-two patients underwent elective major gastrointestinal surgery, seven underwent emergency surgery and eleven underwent non-resectional management. At baseline, 23/59 (39.0%) were classified as ASA III or IV and 14/60 (23.3%) were identified as vulnerable or frail. Variable levels of post-operative allied health professional input was observed; 27/46 (58.7%), 21/46 (45.7%) and 10/46 (21.7%) patients reported input from physiotherapists, dieticians and occupational therapists respectively. The median LOS was 7 days for elective patients (range 1-33) and 30 days for emergency patients (range 24-49). There was no change in functional status of the whole cohort (50 patients at time of analysis) but there was deterioration in the non-resectional group from median 3 (range 0-20) to median 14 (range 0-22).

Conclusions

Older patients selected for major gastrointestinal surgery have variable levels of co-morbidity, frailty and functional impairments. Provision of peri-operative optimisation strategies is variable and generally poor. Standardised assessment of older patients and targeted optimisation strategies could improve outcomes but needs greater investment and research.

8.2 Introduction

As described in Chapter 1.1, the population is ageing and becoming increasingly heterogeneous in health status. The prevalence of co-morbidities, frailty, functional and cognitive impairments increase with age, however, many older people remain healthy and independent. The incidence of the majority of gastrointestinal cancers and surgically treated non-malignant conditions increase with age, in particular gastrointestinal conditions requiring emergency surgery. Lack of fitness stratified guidelines means that age is often used as a poor surrogate for "fitness", resulting in declining rates of major surgery with age.

There are a number of different interventions that may be used to optimise patients before, during and after major surgery but application of these in practice is unclear. Access to allied health professionals and geriatrician-led teams for the assessment and optimisation of older patients facing major GI surgery is variable within the NHS[309]. Lack of standardised assessment processes may mean that not all older people are offered the same treatments and opportunities for optimisation may be missed. This may account for some of the variation in resection rates observed in national surgical audits, such as the NBOCA[27].

This study aimed to objectively measure the functional recovery of older adults after a range of major GI operations and determine which optimisation strategies were used in practice to mitigate against identified patient risk factors. It also observed the functional trajectory of some patients who were deemed 'unfit' for major operative intervention. Functional outcomes at six weeks post-intervention (or post-treatment decision for those treated conservatively) are presented here.

8.3 Methods

The study was registered on the clinicaltrials.gov database (NCT04545125). Ethical approval was secured for the study and is detailed in Chapter 3. The paper for the protocol for this study was prepared according to the SPIRIT-PRO guidelines for the reporting of patient-reported outcomes in study protocol papers[334]. The study is reported here according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines[335].

8.3.1 Study Design

The study described here is a prospective observational single-centre cohort study performed as part of a larger multi-centre, mixed methods observational cohort study. Completion of the full study for the purposes of this thesis was not possible due to delays caused by the COVID-19 pandemic. Some of the reasons are detailed below:

- Delay in R&D approvals due to suspension of non-COVID-19 research studies
- Re-deployment of research staff at many of the hospitals to support the clinical response to the pandemic
- Prioritisation of COVID-19 studies over non-COVID-19 studies in terms of research support
- Reduction in elective operating capacity at all of the hospitals involved
- Move to virtual appointments and consultations resulting in fewer opportunities to approach elective patients to participate
- Reduction in emergency operating in the first wave of the pandemic due to a reduction in the number of patients presenting to hospital

Consequently, this thesis reports only on data from a single centre and no patient interview data are presented.

8.3.2 Study Schematic

An overview of the study design is presented in Figure 18.

Figure 18 Overview of OCTAGON study design. The boxes shaded in grey detail the patient questionnaires and timings. The timeline for data collection is illustrated.

Abbreviations: MDT, Multi Disciplinary Team; CFS, Clinical Frailty Scale; IADL, Instrumental Activities of Daily Living; MNA, Mini Nutritional Assessement; IPAQ-E, International Physical Activity Questionnaire-Elderly; ADL, Activities of Daily Living; WHODAS 2.0, World Health Organisation Disability Assessment Schedule 2.0; QoL, Quality of Life; ERAS, Enhanced Recovery After Surgery

8.3.3 Eligibility criteria

Inclusion: Patients aged 65 years or older with a diagnosis of GI pathology amenable to curative elective, urgent or emergency major GI surgery (surgical eligibility criteria are presented in Table 28). Participants could undergo major surgery, a risk-adapted procedure or conservative management due to patient wishes, co-morbidities or fitness. Participants were required to have mental capacity to consent and to be able to understand written and spoken English (due to insufficient resources to support translation services).

Exclusion: Individuals with unresectable malignant disease due to location, invasion or dissemination were excluded as any surgery would not be with curative intent. Individuals with permanent or transient lack of capacity (e.g. due to delirium) were not eligible to take part unless the delirium developed after enrolment in the study. Surgery for major trauma or primary gynaecological, vascular or urological disease were excluded.

	Elective presentations	**Emergency presentations**
Inclusion	**Malignant** Colon, rectal, gastric, oesophageal and pancreatic cancers, hepatocellular carcinoma, colorectal liver metastases, sarcoma, cholangiocarcinoma **Non-malignant** Complicated diverticular disease, complex abdominal wall hernias, Crohn's disease, ulcerative colitis, complicated gallstone disease (planned open or CBD exploration), reflux disease.	**Malignant** Obstructing/ symptomatic colon, rectal or gastric cancer, re-operations for complications of previous elective surgery **Non-malignant** Small bowel obstruction, obstructed hernias, bowel ischaemia, gastric/duodenal perforation, colonic perforation, peritonitis, large bowel obstruction, volvulus, complicated diverticulitis, Crohn's disease, ulcerative colitis
Exclusion	Planned laparoscopic treatment of uncomplicated gallstone disease, uncomplicated groin hernia, laparoscopic appendicectomy	Trauma, appendicitis, pancreatitis

Table 28 Inclusion and exclusion criteria for OCTAGON

8.3.4 Primary outcomes

The primary outcomes were feasibility and functional recovery at 6 weeks measured using the World Health Organisation Disability Assessment Schedule 2.0 [336] which has been validated as a measure of functional recovery in surgical populations[337,338].

8.3.5 Secondary outcomes

- Health related quality of life at 6 weeks (measured using the EQ-5D-5L[339])
- Length of hospital stay (days)
- Post-operative complications (including type and Clavien-Dindo grade of complication [340])
- Overall survival
- Rate of use and type of peri-operative assessment tools such as CPET, 6MWT.
- Rate of and type of peri-operative support such as formal prehabilitation programmes, physical activity interventions, nutritional support etc.

8.3.6 Participant recruitment

Patients were identified at multi-disciplinary team meetings, surgical outpatient clinics, elective and emergency operating lists and on call 'take' lists and screened for eligibility. Patients were approached by the local Principal Investigator (PI), delegated clinician, or nursing study team members with appropriate Good Clinical Practice (GCP) training. All potentially eligible patients were recorded on the local screening log and those who declined participation were also recorded. This was to reduce the risk of selection bias. Recruitment at Sheffield Teaching Hospitals commenced on 9th September 2020 and ceased 5th April 2021. Study visits were co-ordinated with usual clinical appointments or conducted by telephone to reduce the burden on patients. See Table 29 for summary of study data collection timeline.

	Baseline (first clinic to day 0/operation)	Discharge	6 weeks post-operative or after decision to not operate +/- 2 weeks	3 months post-operation or post-decision	6 months Post-operation or post-decision
Consent	x				
Demographics, co-morbidity, polypharmacy	x				
Questionnaires	ADL, IADL, EQ-5D -5L, CFS, MNA, IPAQ-E, mini-COG, WHO DAS 2.0	Bespoke questionnaire	EQ-5D-5L, ADL, WHO DAS 2.0	EQ-5D-5L, ADL, WHO DAS 2.0	EQ-5D-5L, ADL, WHO DAS 2.0
CPET/6MWT results (if available)	x				
Optimisation strategies		x			
Operation Details		x			
Post-operative details		x			
Complications		x			
Pathology			x		
Survival		x	x	x	x

Table 29 Timeline for OCTAGON

Abbreviations: CPET, CardioPulmonary Exercise Test; 6MWT, 6-minute Walk Test; ADL, Activities of Daily Living; IADL, Instrumental Activities of Daily Living; CFS, Clinical Frailty Scale; MNA, Mini Nutritional Assessment; IPAQ-E, International Physical Activity Questionnaire-Elderly; WHODAS 2.0, World Health Organisation Disability Assessment Schedule 2.0.

8.3.7 Data collection

At baseline, demographics, type of referral, pre-operative assessment date and admission details were collected for all patients using standardised Case Report Forms (CRFs) (Appendix Z). Co-morbidities were collected using the Charlson Co-morbidity index (CCI), a validated measure of the prognostic impact of multiple chronic illnesses[340] (Appendix AA). Polypharmacy was defined as 5 or more regular medications. Pre-operative blood test results relevant to the emergency and elective presentations were collected. Detailed baseline functional, nutritional and fitness assessments were performed using a number of validated questionnaires (Appendix AB); Barthel's Activities of Daily Living (ADL)[341], Lawton and Brody's Instrumental Activities of Daily living (IADL)[342], the Clinical Frailty Scale (CFS)[343], Mini Nutritional

Assessment (MNA)[344], International Physical Activity Questionnaire-Elderly (IPAQ-E)[345], Mini-Cog©[346] cognitive screening tool, the WHO Disability Assessment Schedule (WHODAS 2.0)[336] to assess functional status and the EQ-5D-5L[339] to assess health related quality of life. Questionnaires were chosen based on their relevance to the older population, review of the literature, expertise of the study team and ease of use and administration.

Questionnaires were completed by the patient themselves or with assistance from the research team if required. Patient records were reviewed for the results of objective tests, where performed. Approvals for use of validated questionnaires were obtained in advance, where required (Appendix AC).

At hospital discharge, all patients were asked to complete a bespoke questionnaire (see Appendix AD) regarding pre-, peri- and post-operative optimisation. Elective patients were asked whether they participated in any form of prehabilitation (exercise, nutrition, psychological, geriatric), attended 'surgery school' or attended for transfusion, iron infusion, physiotherapy appointment, smoking cessation services or dietician review and whether this was self-directed or arranged by the hospital. Elective and emergency patients were asked about peri-operative and post-operative optimisation and specialty reviews (e.g. geriatrician, cardiology). The hospital records were used to determine operative details, post-operative complications (using the Clavien-Dindo classification system), length of hospital stay and discharge arrangements.

8.3.8 Follow-up

At 6 weeks post-intervention, or decision not to operate, pathology results were reviewed, survival and re-admissions determined. Follow-up questionnaires (ADL, EQ-5D-5L and WHO DAS 2.0 (Appendix AE)) were completed to assess functional recovery at 6 weeks post-operation/ procedure or decision not to operate. Further follow-up data collection at 3 and 6 months is still in progress and is not presented in this thesis.

8.3.9 Integrated qualitative study

The integrated qualitative study was beyond the scope of this thesis due to COVID-19 pandemic delays and is not reported here. This will be completed in the post-doctoral phase as illustrated in Figure 4 in Chapter 2.

8.3.10 Scoring of questionnaires

This was performed according to the published guidelines for each of the validated questionnaires (Appendix AF):

- Quality of life assessed using the EQ-5D-5L – summary scores were produced using the UK population normalised values and 'cross-walking' the scores for each domain[347]
- The World Health Organisation Disability Assessment Schedule version 2.0 (WHODAS 2.0) short form questionnaire consists of 12 questions asking about how much difficulty the respondent has in doing each of the activities due to their health conditions. Each question is scored from 0 (no difficulty) to 4 (extreme difficulty or cannot do). A simple summary score is then generated by adding the score for each question. The minimum score is 0 (no difficulties), the maximum score is 48 (extreme difficulty). A complex scoring system is available but is only suitable for use with the WHODAS 2.0 long form[348].
- Activities of Daily Living (ADL) – each question was scored according to protocol[341] with a maximum score of 20 (independent) and a minimum score of 0.
- Instrumental activities of daily living (IADL) – each question was scored between 0 and 1 with the sum calculated; maximum score of 8 (independent) and a minimum score of 0[342].
- Cognitive screening using the Mini-COG which was scored with a maximum score of 5 (normal cognition) and a minimum of 0[346].
- Physical activity assessed using the International Physical Activity Questionnaire-Elderly (IPAQ-E) which calculates the Metabolic Equivalents (METs) per week depending on the number of hours per day and days per week spent doing light, moderate and vigorous exercise[345].
- Nutritional assessment was performed using the Mini Nutritional Assessment (MNA) and scored with each individual question scoring from 0 to 3. Question

scores were summed to give a subtotal; 12-14 indicating normal nutritional status, 8-11 at risk of malnutrition and 0-7 indicating that the patient was malnourished[344].

8.3.11 Statistical analysis

Descriptive analyses were performed to describe the population of patients aged 65 years and over undergoing major GI surgery via emergency and elective pathways, as well as those undergoing non-resectional management. Descriptive analyses were used to detail the optimisation pathways reported by patients and documented in their medical records. Medians with ranges or means with standard deviation are reported where appropriate. Fishers exact test was used to test for differences in baseline characteristics between elective major GI surgery patients and emergency major GI surgery patients. All graphs were created in Microsoft Excel (Excel, Microsoft Corp., Redmond, WA, USA). Statistical analysis was performed in SPSS (version 26, IBM, Armonk, NY, USA). As this was an observational study with a small sample size, no controlling for confounding was performed. Patients were subdivided into those who underwent major elective GI surgery, major emergency GI surgery and those who underwent non-resectional management (including procedures/ operations or best supportive care). Comparisons were made between those who underwent elective versus emergency major GI surgery and those who underwent major GI surgery versus conservative management. Missing data was chased up until the next point of data collection and if it was still not present at that point was marked as missing

8.3.12 Sample size calculation

An opportunistic sample size of 60 was estimated over the 6-month study recruitment period based on the number of patients undergoing major GI surgery at STH (pre-pandemic). This was to enable recruitment from the broad range of colorectal, oesophagogastric (OG) and hepatopancreaticobiliary (HPB) surgeries. A high uptake rate of this simple, questionnaire-based study was anticipated based on a study of frailty in emergency laparotomy patients[308] and a study of post-operative quality of life after emergency laparotomy[349].

This sample size correlated with the required number proposed by Teare *et al* to estimate effect size for dichotomous outcomes, or 60-100 for continuous outcomes in pilot studies[350]. It was also felt to be compatible with other methods of effect size estimation[351]. One aim of the study was capture variation in practice and a sample size of 60 was felt to be able to achieve this.

8.3.13 Patient and public involvement

A patient and public involvement group was involved in reviewing the study protocol and ensuring that the questions posed by the study were of relevance to a lay person. They also reviewed the patient-facing materials, which included checking that that the number and time taken to complete the questionnaires was not a burden for patients.

8.4 Results

8.4.1 Demographics

A total of 60 patients were recruited to this study between September 2020 and April 2021. A total of 296 elective patients were identified as eligible and 72 emergency patients, however only a small proportion were approached to participate due to a move to virtual consultations. Only five patients declined participation; two attributed to anxiety regarding their impending appointment and three due to lack of interest in the study. The median age was 74 (range 65-93) and 36/60 (60%) were male (Table 31). In total, 42 patients underwent an elective major GI surgical procedure, 73.8% (31/42) of whom had malignant pathology (14 colorectal cancer, five oesophageal cancer, two colorectal liver metastases, two duodenal cancer, two hepatocellular carcinoma, one pancreatic cancer, one neuroendocrine tumour, one GIST, one small bowel tumour, one ocular melanoma liver metastases and one sarcoma) (Table 30). Seven patients underwent an emergency GI procedure all of which were for non-malignant pathology (adhesion related small bowel obstruction). Eleven patients were recruited who did not undergo major GI surgery (termed 'non-resectional management'), nine were elective presentations and two emergency presentations. Eight patients in the non-resectional group had malignant disease and three had non-malignant disease. Three non-resectional patients underwent colonic stenting for malignancy (one as an emergency), one underwent palliative stenting of a resectable ampullary tumour, one underwent oesophageal stenting and one underwent percutaneous radiofrequency ablation of a liver lesion. Five patients in the non-resectional group did not undergo any procedure (Table 30).

Demographics and pathology	Major GI surgery		Non-resectional	All
	Elective, n=42	Emergency, n=7	Elective and emergency n=11 (9+2)	n=60
Age(years), median (range)	73 (65-89)	78 (67-90)	78 (73-93)	74 (65-93)
Male n, (%)	24/42 (57.1)	5/7 (71.4)	7/11 (63.6)	36/60 (60.0)
Malignant n, (%)	31/42 (73.8)	0	8/11 (72.7)	39/60 (65.0)
Oesophageal	5		1	6
Gastric (including GIST)	1		1	2
Colorectal	14		4	18
Colorectal liver metastases	2		0	2
Hepatocellular carcinoma	2		1	3
Pancreatic	1		1	2
Duodenal	2		0	2
Neuroendocrine	1		0	1
Small bowel	1		0	1
Melanoma liver metastases	1		0	1
Sarcoma	1		0	1
Non-malignant n, (%)	11/42 (26.2)	7/7 (100)	3/11 (27.3)	21/60 (35.0)
Colonic polyp	1		1	2
Diverticular disease	1		0	1
Pancreatic cyst	2		1	3
Hiatus hernia	2		0	2
Incisional/other hernia	3		0	3
Gallstone disease	1		0	1
Inflammatory bowel disease	1		1	2
Adhesional bowel obstruction	0	7	0	7

Table 30. Demographics and underlying pathology of patients included in study

Abbreviations: GIST: GastroIntestinal Stromal Tumour

8.4.2 Baseline health status

8.4.2.1 *Fitness*

According to the American Society of Anaesthesiologists (ASA) scoring system 36/59 (61.0%) patients were classified as ASA I or II (Table 31). A greater proportion of patients who underwent emergency GI surgery had an ASA grade III or IV compared to those who underwent elective surgery; 4/7 (57.1%) versus 13/41 (31.7%), Fisher's exact p=0.2256 (Figure 19).

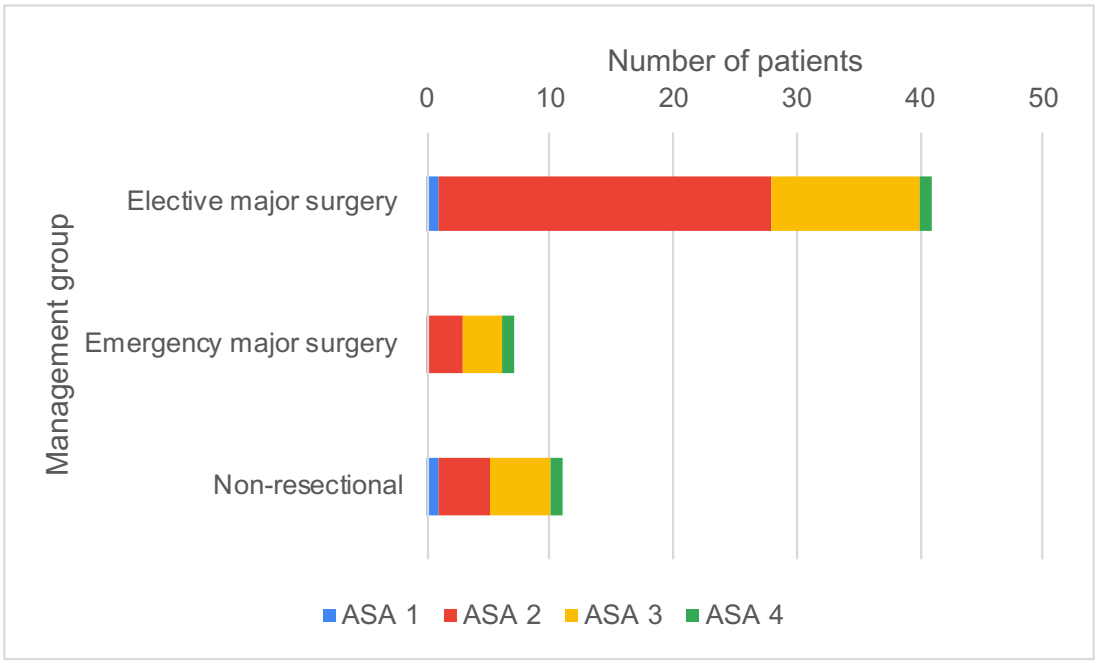


Figure 19. Stacked bar chart showing baseline fitness of each management group using the ASA grade. Abbreviations: ASA; American Society of Anaesthesiologists

One third of elective patients (14/42) underwent cardiopulmonary exercise testing (CPET) and two patients undertook the six-minute walk test. One further patient underwent CPET and was judged to be at high operative risk so decided not to undergo surgery. Levels of physical activity assessed using the elderly specific International Physical Activity Questionnaire (IPAQ-E) ranged from completely inactive (0 Metabolic Equivalents (METS) per week) to extremely active (19,278 METS per week) with a median of 2,772 METS per week for the whole cohort (Table 31). There was a trend towards older patients having lower levels of physical activity (

Figure 20). There was also a trend that those who underwent non-resectional management had lower levels of physical activity than those who underwent major GI

surgery (elective or emergency); median 472 METS/week (range 0-15,036) versus median 2,772 METS/week (range 0-19,278) (Figure 21).

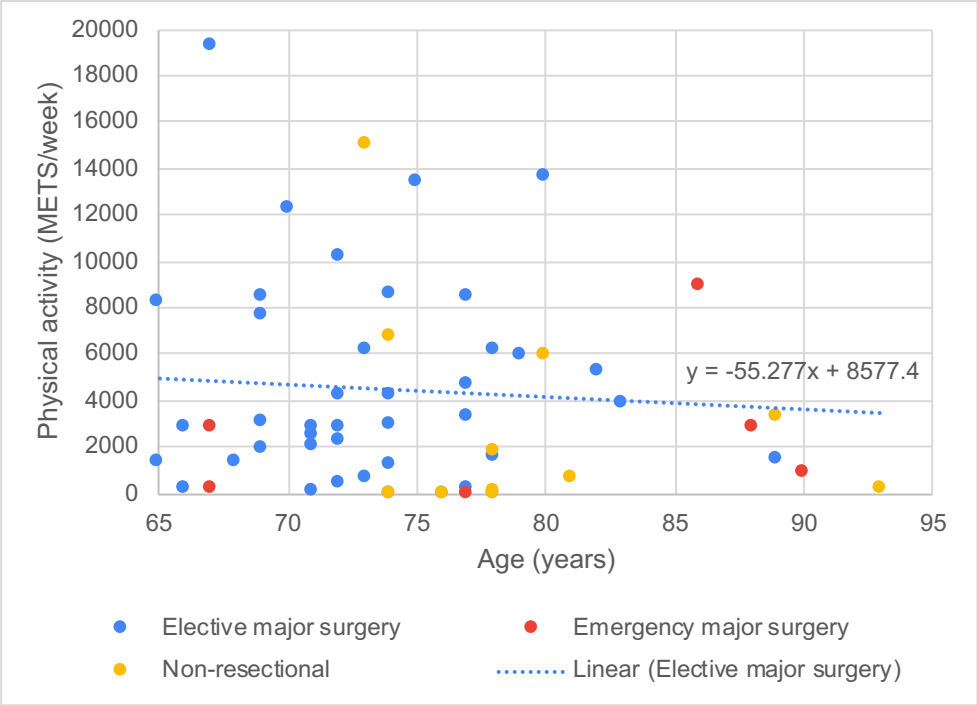


Figure 20. Scatter plot of level of physical activity (METS) per week by age

This was assessed using the IPAQ-E. Management group is indicated by colour; Blue = elective major surgery, Red = emergency major surgery, Yellow = non-resectional management (elective and emergency). Trend line shown for elective patients undergoing major surgery.

Abbreviation: METS, Metabolic Equivalent

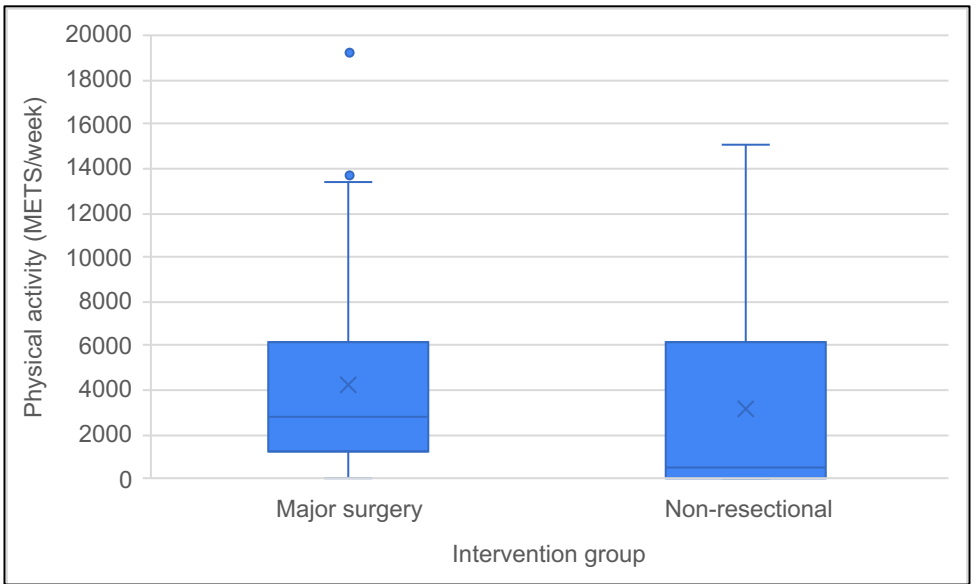


Figure 21. Box and whisker plots illustrating the physical activity levels of those who underwent major surgery compared to those who underwent non-resectional management.

8.4.2.2 *Nutritional status*

The mean weight of the cohort was 75.6kg (s.d. 18.9); there was a trend towards elective major surgery patients weighing more (mean 78.1kg s.d. 18.2) compared to emergency major surgery patients (mean 70.2kg s.d. 24.7) (Table 31). In addition, the median BMI was higher for elective major surgery patients compared to those who underwent emergency surgery; median 27 (range 19-45) versus median 21 (range 17-31). Three out of 41 elective major surgery patients were identified as having a low BMI (BMI equal or less than 20); none of these patients reported seeing a dietician pre-operatively, being prescribed oral nutritional supplements or being advised to improve their diets. Three out of seven emergency patients were identified as having a low BMI pre-operatively; two reported seeing a dietician in the post-operative period. The Mini Nutritional Assessment (MNA) identified 23/58 (40.0%) patients to be at risk of malnutrition (MNA score 8-11) and 7/58 (12.1%) to be malnourished (MNA score 7 or below). There was no difference between elective and emergency major GI surgery in the number at risk or malnourished according to the MNA score (Fisher's exact test p=0.1064). However, there was a difference when comparing the number with a low BMI with a greater proportion of emergency patients having a low BMI than elective patients (3/7 (42.9%) emergency versus 3/41 (7.2%) elective; Fisher's exact test p=0.0328). A trend was observed in MNA score with patients who underwent emergency major surgery having lower MNA scores than those who underwent elective surgery (indicating higher levels of malnutrition); median 9 (range 4-12) compared to median 12 (range 1-14) (Table 31). There was poor correlation between BMI and the MNA (Figure 22).

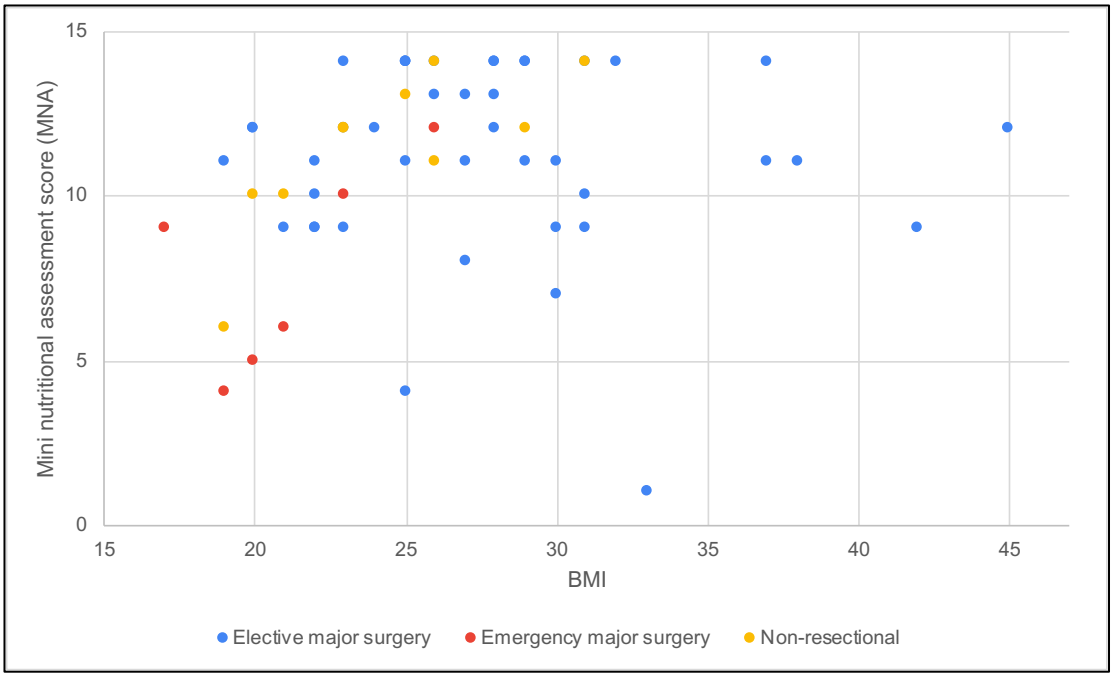


Figure 22. Scatterplot of Mini Nutritional Assessment (MNA) by Body Mass Index (BMI)

This illustrates poor correlation between the two measures. Management group is indicated by colour; Blue = elective major surgery, Red = emergency major surgery, Yellow = non-resectional management (elective and emergency).

8.4.2.3 *Co-morbidities*

The median Charlson Co-morbidity Index (CCI) was 5 for the whole cohort (range 2-14) with no differences observed between those who underwent major surgery or non-resectional management (Figure 23). Overall, 18/60 (30.0%) patients had had one or more hospital admissions in the preceding 12 months, with the highest proportion in the emergency surgery group 3/7 (42.9%). Almost one third (31.7%) of all patients were found to have polypharmacy (defined as 5 or more daily regular medications), the proportion being highest amongst elective patients 16/42 (38.1%). Few patients had had chemotherapy or radiotherapy in the preceding 12 months (Table 31). All patients who underwent emergency surgery had their calculated risk of mortality documented, with a median risk of death of 3.9% (range 1.8-29.2%) within 30 days of surgery. (Table 31).

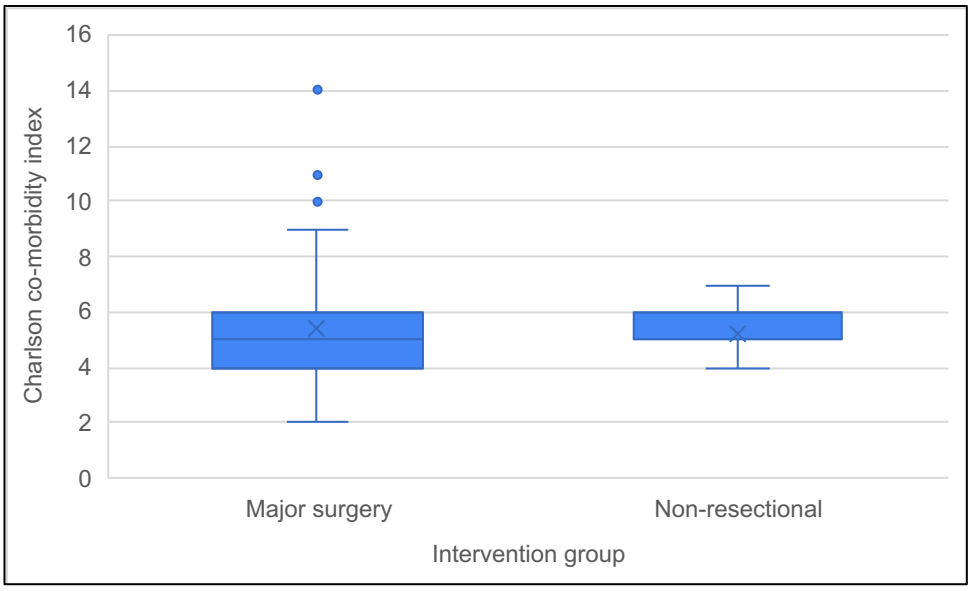


Figure 23. Box and whisker plots for co-morbidity.

No difference was observed in baseline co-morbidities between those who underwent major GI surgery or those who underwent non-resectional management.

Baseline health and fitness	Major GI surgery		Non-resectional	All
	Elective, n=42	Emergency, n=7	Elective and emergency n=11 (9+2)	n=60
Fitness				
ASA fitness grade, n (%)				
I-II	28/41 (68.3)	3/7 (42.9)	5/11 (45.5)	36/59 (61.0)
III-IV	13/41 (31.7)	4/7 (57.1)	6/11 (54.5)	23/59 (39.0)
Exercise testing				
CPET performed	14/42 (33.3)	n/a	1/11 (9.1)	15/53 (28.3)
6MWT performed	2/42 (4.8)	n/a	0/11 (0)	2/53 (3.8)
Physical activity (IPAQ-E) median (range)	2940 (0-19278)	1848 (0-8904)	472 (0-15036)	2772 (0-19278)
Nutritional				
Weight (kg), mean (SD)	78.1 (18.2)	70.2 (24.7)	68.5 (11.6)	75.6 (18.9)
BMI, median (range)	27 (19-45)	21 (17-31)	24 (19-31)	26 (17-45)
BMI 20 or less n (%)	3/41 (7.3)	3/7 (42.9)	2/10 (20)	8/58 (13.8)
Nutritional status (MNA score) median (range)	12 (1-14)	9 (4-12)	12 (6-14)	11 (1-14)
Normal status (12-14 points)	21/41 (51.2)	1/7 (14.3)	6/10 (60)	28/58 (48.3)
At risk (8-11 points)	17/41 (41.5)	3/7 (42.9)	3/10 (30)	23/58 (40.0)
Malnourished (0-7 points)	3/41 (7.3)	3/7 (42.9)	1/10 (10)	7/58 (12.1)
Co-morbidities				
Charlson CCI, median (range) (including age)	5 (2-14)	5 (4-6)	5 (4-7)	5 (2-14)
Polypharmacy (>5 meds), n (%)	16/42 (38.1)	1/7 (14.3)	2/11 (18.2)	19/60 (31.7)
Admissions in the previous year				
0	28/42 (66.7)	4/7 (57.1)	10/11 (90.9)	42/60 (70)
1+	14/42 (33.3)	3/7 (42.9)	1/11 (9.1)	18/60 (30)
Risk scoring (emergency), n (%)		7 (100)		
Mortality risk, median (range)		3.9 (1.8-29.2)		
Chemo/radiotherapy, n (%)	3/42 (7.1)	0	0	3/60 (5.0)

Table 31. Baseline health and fitness of study patients including fitness, nutrition and co-morbidities
Abbreviations: ASA: American College of Anaesthesiologists (ASA), CPET: CardioPulmonary Exercise Testing (CPET), 6MWT: 6-Minute Walk Test, BMI: Body Mass Index, MNA: Mini Nutritional Assessment, CCI: Charlson Co-morbidity Index.

8.4.2.4 *Lifestyle*

Only 6/60 (10.0%) of the cohort were current smokers and 24/60 (40.0%) said that they regularly drink alcohol; median 8.5 units/week (range 1-71) with 5 patients drinking over the recommended 14 units per week (Table 32).

8.4.2.5 *Frailty and cognitive impairment*

The majority of patients were not frail; the clinical frailty scale (CFS) median was 2 (range 1-7) (Figure 24). However, 3/7 (42.9%) of emergency patients and 3/11 (27.3%) of non-resectional patients were classified as vulnerable and 2/7 (28.6%) emergency and 2/11 (18.2%) non-resectional patients were classified as frail (Table 32). A greater proportion of patients who underwent emergency major surgery were classified as frail or vulnerable compared to those who underwent elective surgery (5/7 (71.4%) emergency versus 4/42 (9.5%) elective; Fisher's exact p=0.0012).

Despite dementia being an exclusion criterion for the study, 26/60 (43.3%) patients scored less than 5 on the mini-COG test indicating the need for further testing.

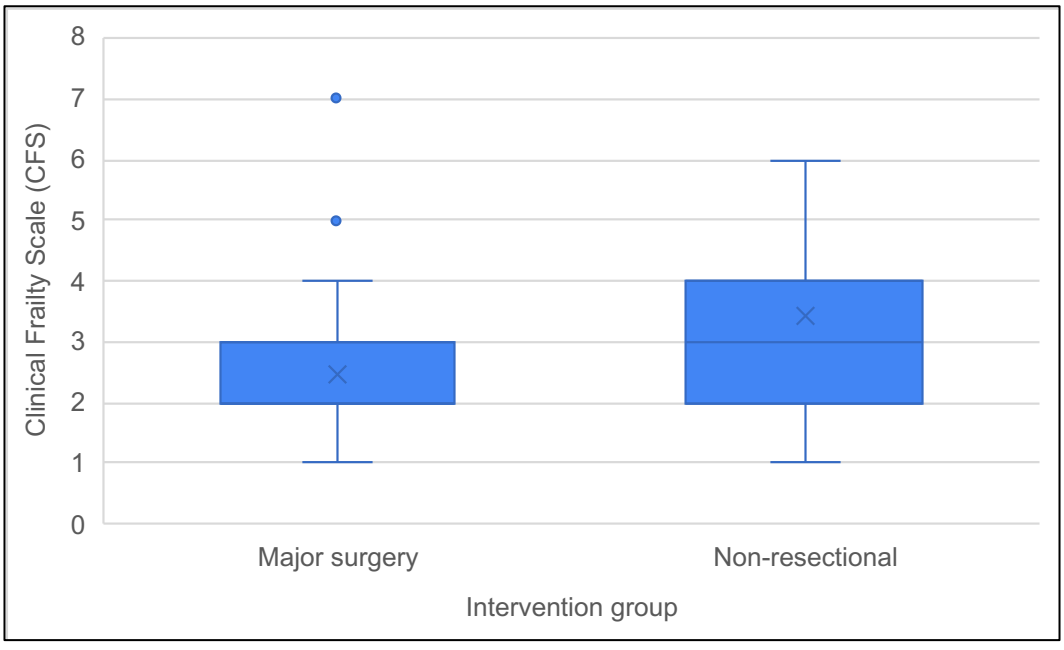


Figure 24. Box and whisker plots illustrating the frailty status of patients who underwent major GI surgery compared to non-resectional management.

8.4.2.6 *Quality of life*

Quality of life, assessed using the EQ-5D-5L, revealed a median population normalised summary score of 0.836 (range -0.017-1) for the whole cohort. The median summary score was observed to be lower for patients who underwent emergency compared to elective major surgery; 0.599 (-0.017-0.740) versus 0.837 (0.483-1.000) (Figure 25). Emergency patients reported deficits across multiple domains, with 4/7 (57.1%) patients reporting deficits in every domain. The median visual analogue scale score was also lower for emergency than elective major surgery patients; 40 (range 20-80) versus 80 (range 50-100). Half of all patients in the study reported some deficit in the pain domain of the EQ-5D-5L. Problems with mobility (25/60; 41.7%) and performing usual activities were also common (24/60; 40%). Over one third of patients reported some degree of deficit with their mood (anxiety or depression) (Table 32).

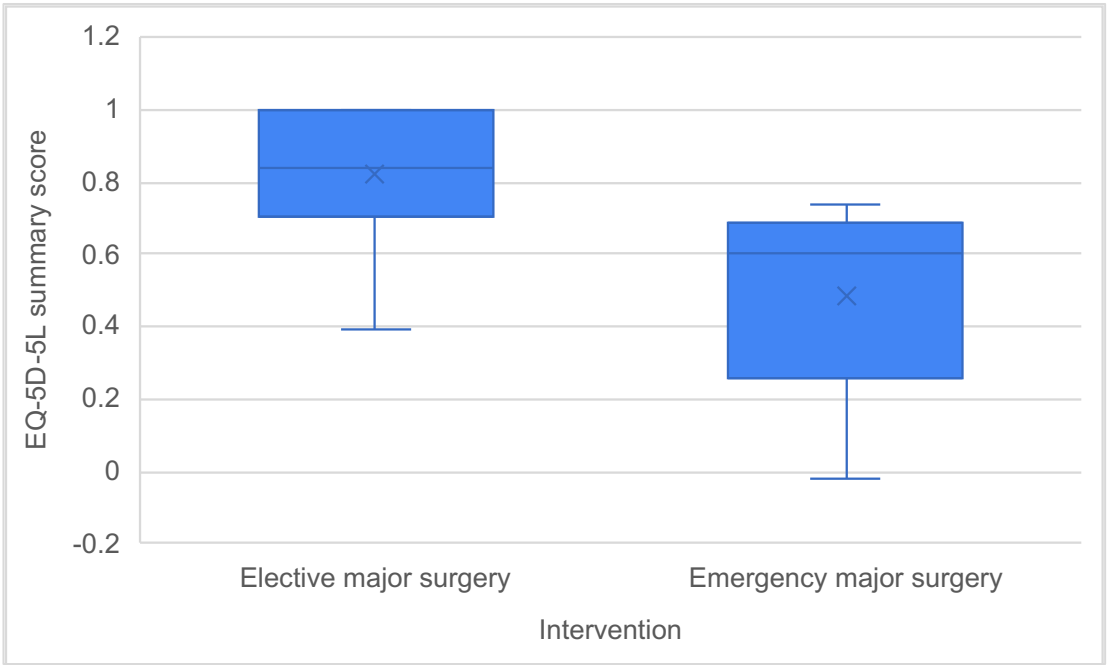


Figure 25. Box and whisker plots comparing EQ-5D-5L summary scores for elective versus emergency major surgery patients

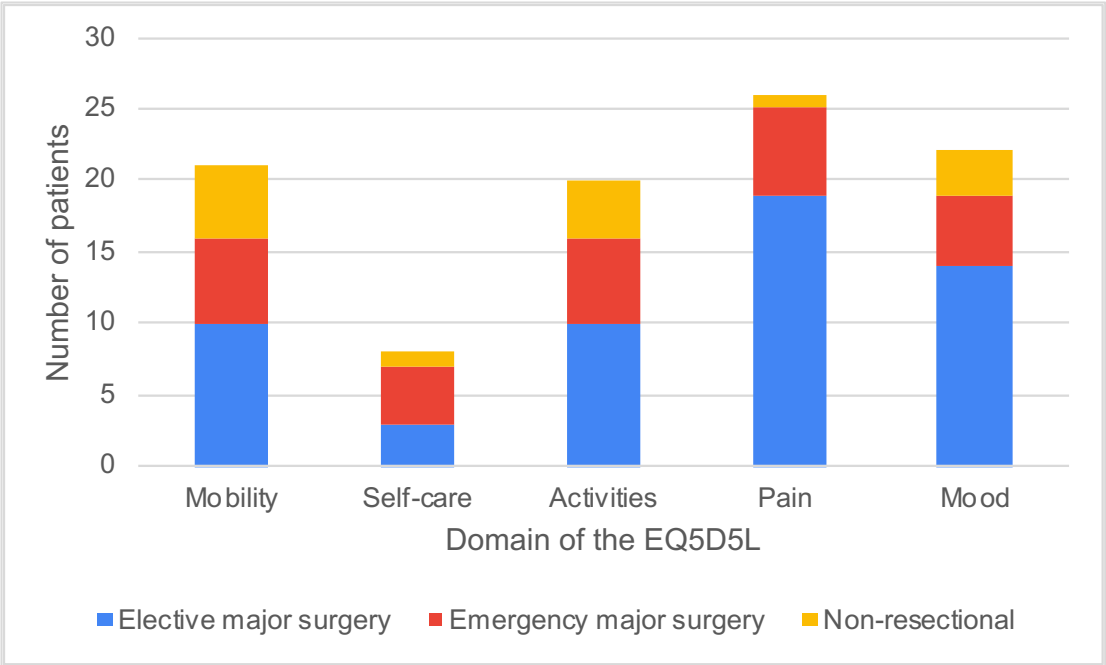


Figure 26. Stacked bar chart illustrating number of patients reporting any deficit in the five domains of the EQ5D5L.

Management group is indicated by colour; Blue = elective major surgery, Red = emergency major surgery, Yellow = non-resectional management (elective and emergency).

Baseline	Major GI surgery		Non-resectional	All
	Elective, n=42	Emergency, n=7	Elective and emergency n=11 (9+2)	n=60
Lifestyle				
Smoking status				
Current	3/42 (7.1)	1/7 (14.3)	2/11 (18.2)	6 (10)
Ex-smoker	20/42 (47.6)	4/7 (57.1)	4/11 (36.4)	26 (43.3)
Never smoked	19/42 (45.2)	2/7 (28.6)	5/11 (45.5)	28 (46.7)
Alcohol use, yes (%)	16/42 (38.1)	3/7 (42.9)	5/11 (45.5)	24 (40.0)
Frailty and cognitive impairment				
Frailty (CFS) median (range)	2 (1-4)	4 (3-7)	3 (1-6)	2 (1-7)
1-3, n (%)	38/42 (90.5)	2/7 (28.6)	6/11 (54.5)	46 (76.7)
4, n (%)	4/42 (9.5)	3/7 (42.9)	3/11 (27.3)	10 (16.7)
5+, n (%)	0	2/7 (28.6)	2/11 (18.2)	4 (6.7)
Cognitive function (Mini COG)				
5 (normal)	20/42 (47.6)	7/7	7/11 (63.6)	34/60 (56.7)
4	11/42 (26.2)	0	3/11 (27.3)	14/60 (16.7)
3	10/42 (23.8)	0	1/11 (9.1)	11/60 (18.3)
2	1/42 (2.4)	0	0	1/60 (1.7)
Quality of life				
EQ-5D-5L				
Summary score, median (range)	0.837 (0.483-1.000)	0.599 (-0.017-0.740)	0.836 (0.499-1.000)	0.836 (-0.017-1.000)
Visual analogue, median (range)	80 (50-100)	40 (20-80)	80 (10-100)	80 (10-100)
Reporting deficit in each domain				
Mobility	10/42 (23.8)	6/7 (85.7)	5/11 (45.5)	25/60 (41.7)
Self-care	3/42 (7.1)	4/7 (57.1)	1/11 (9.1)	12/60 (20.0)
Activities	10/42 (23.8)	6/7 (85.7)	4/11 (36.4)	24/60 (40.0)
Pain	19/42 (45.2)	6/7 (85.7)	1/11 (9.1)	30/60 (50.0)
Mood	14/42 (33.3)	5/7 (71.4)	3/11 (27.3)	22/60 (36.7)

Table 32. Baseline health and fitness status of study patients including lifestyle, frailty and cognitive impairment and quality of life.

Abbreviations: CFS: Clinical Frailty Score, Mini COG: Mini Cognitive test

8.4.2.7 *Functional status*

The majority of patients were living independently with only 11/58 (19.0%) stating that they receive informal help from friends or family (Table 33). The baseline questionnaires for activities of daily living (ADL) revealed that patients were generally independent with a median score 20 (range 12-20). Eight patients (13.3%) had a score of 18 or less (Table 33), with no difference between elective and emergency patients undergoing major surgery (4/42 (9.5%) elective versus 1/7 (14.3%) emergency, Fisher's exact p=0.5539). The instrumental activities of daily living (IADL) questionnaire results were similar, with a median score of 8 (range 2-8), however, 22/60 (36.7%) were identified as having a score of 7 or less suggesting some degree of dependency. A greater proportion of patients undergoing emergency compared to elective major surgery had an IADL score of 7 or less; 5/7 (71.4%) compared to 10/42 (23.8%), Fisher's exact p=0.0217) (Table 33).

The median WHODAS 2.0 summary score was 2.5 (range 0-23) for the whole cohort, with emergency major surgery patients having a median score of 7 (range 0-22) signifying greater levels of disability (Table 33). Looking at the individual domains of the WHODAS, half of patients reported that they had been affected emotionally to some degree by their health problems, with the greatest proportion being in the elective group (25/42; 59.5%) (Figure 27). Walking a long distance (such as a kilometre) (26/60; 43.3%) and standing for long periods (such as 30 minutes) (19/60; 31.7%) were other domains where deficits were common, frequently affecting emergency major surgery and non-resectional patients (Figure 27). One quarter of all patients (26.7%) said that they had been completely unable to carry out their usual activities on at least one day in the preceding month due to their health conditions (Table 33).

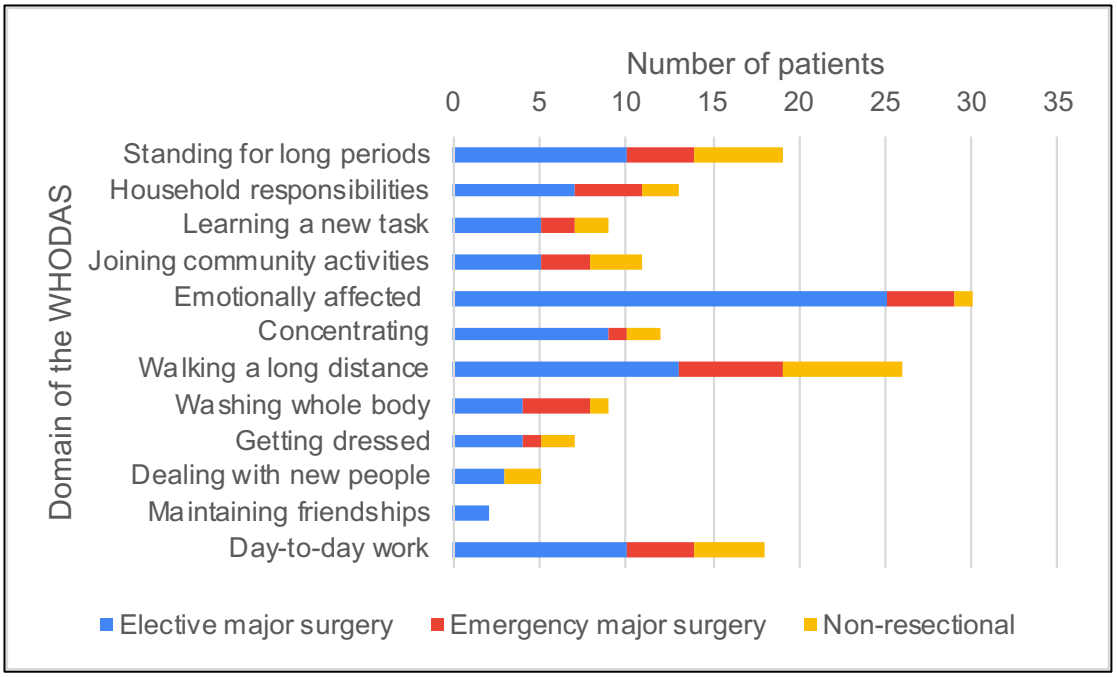


Figure 27. Stacked bar chart illustrating number of patients reporting any deficit in the twelve domains of the WHODAS 2.0.

Management group is indicated by colour; Blue = elective major surgery, Red = emergency major surgery, Yellow = non-resectional management (elective and emergency).

Abbreviations: WHODAS; World Health Organisation Disability Assessment Schedule

	Major GI surgery		Non-resectional	All
	Elective, n=42	Emerg, n=7	n=11	n=60
Assistance level baseline				
Own home (no carers), n (%)	36/40 (90)	3/7 (42.9)	8/11 (72.7)	47/58 (81.0)
Own home (informal carers)	4/40 (10)	4/7 (57.1)	3/11 (27.3)	11/58 (19)
Functional status (ADL score)				
Median (range)	20 (16-20)	20 (12-20)	20 (16-20)	20 (12-20)
Score = 19-20, n (%)	38/42 (90.5)	6/7 (85.7)	8/11 (72.7)	52/60 (86.7)
Score = 18 or less, n (%)	4/42 (9.5)	1/7 (14.3)	3/11 (27.3)	8/60 (13.3)
Functional status (IADL score)				
Median (range)	8 (3-8)	6 (2-8)	7 (4-8)	8 (2-8)
Score = 8, n (%)	32/42 (76.2)	2/7 (28.6)	4/11 (36.4)	38 (63.3)
Score = 7 or less, n (%)	10/42 (23.8)	5/7 (71.4)	7/11 (63.6)	22 (36.7)
Functional status (WHODAS 2.0)				
Median simple score (range)	2 (0-23)	7 (0-22)	3 (0-20)	2.5 (0-23)
Any difficulty, n (%)				
Standing long periods	10/42 (23.8)	4/7 (57.1)	5/11 (45.5)	19/60 (31.7)
Household responsibilities	7/42 (16.7)	4/7 (57.1)	2/11 (18.2)	13/60 (21.7)
Learning a new task	5/42 (11.9)	2/7 (28.6)	2/11 (18.2)	9/60 (15)
Joining community activities	5/42 (11.9)	3/7 (42.9)	3/11 (27.3)	11/60 (18.3)
Emotionally affected	25/42 (59.5)	4/7 (57.1)	1/11 (9.1)	30/60 (50)
Concentrating	9/42 (21.4)	1/7 (14.3)	2/11 (18.2)	12/60 (20)
Walking a long distance	13/42 (31.0)	6/7 (85.7)	7/11 (63.6)	26/60 (43.3)
Washing whole body	4/42 (9.5)	4/7 (57.1)	1/11 (9.1)	9/60 (15)
Getting dressed	4/42 (9.5)	1/7 (14.3)	2/11 (18.2)	7/60 (11.7)
Dealing with new people	3/42 (7.1)	0	2/11 (18.2)	5/60 (8.3)
Maintaining friendship	2/42 (4.8)	0	0	2/60 (3.3)
Day-to-day work	10/42 (23.8)	4/7 (57.1)	4/11 (36.4)	18/60 (30)
Days difficulties present				
1 day or more per month	17/42 (40.5)	5/7 (71.4)	6/11 (54.5)	28/60 (46.7)
Days totally unable usual activities				
1 day or more per month	14/42 (33.3)	1/7 (14.3)	1/11 (9.1)	16/60 (26.7)
Days cut back activities				
1 day or more per month	9/42 (21.4)	1/7 (14.3)	3/11 (27.3)	13/60 (21.7)

Table 33. Baseline functional status of patients

8.4.3 Peri-operative outcomes

At the time of analysis, follow-up data were available for 56 patients. Of the patients who underwent major surgery, over half of elective patients were admitted to HDU or enhanced recovery post-operatively (20/39 (51.3%)) compared to one third of emergency patients (2/6 (33.3%)). There were two in hospital post-operative deaths of emergency patients, one post-discharge elective patient death and two deaths in the non-resectional group. The median length of stay was seven days for elective patients (range 1-33 days), 30 days for emergency patients (range 24-49 days) and 3.5 days for non-resectional patients who underwent procedures (n=6, range 1-14 days) (Figure 28). All patients were discharged to their own homes without a formal package of care. There were few post-operative complications documented with only one elective patient requiring a radiological drain and one emergency patient developing a urinary tract infection. There were four readmissions within 30 days of discharge, all of whom were elective patients(Table 34).; one wound infection, one deep collection, one wound breakdown plus deep collection and one pulmonary embolus.

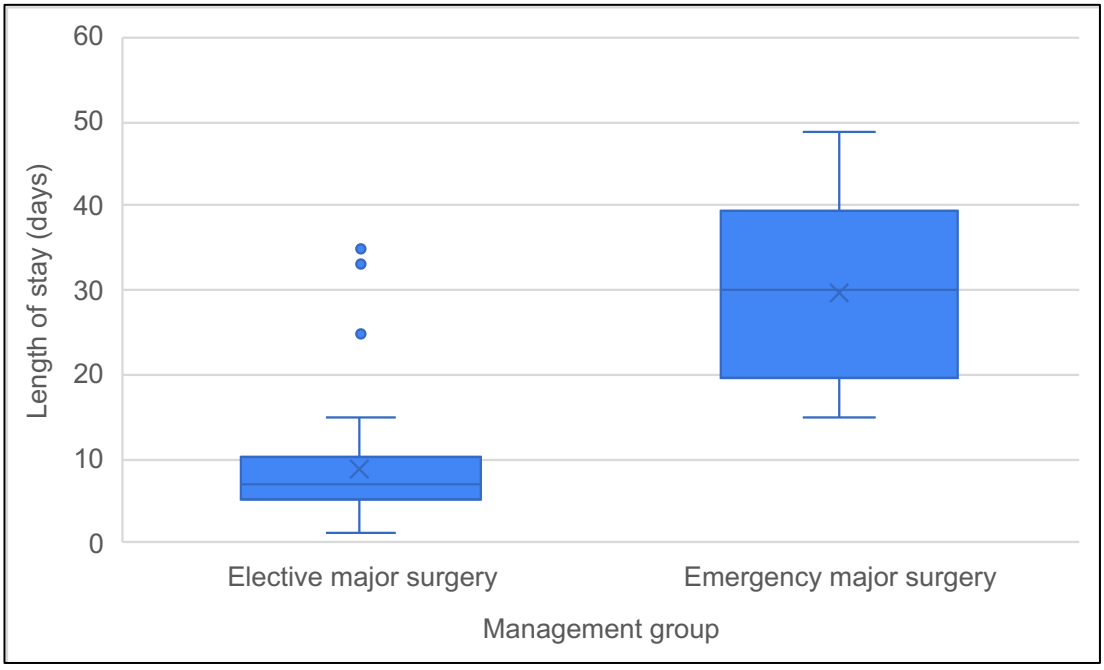


Figure 28. Box and whisker plots to illustrate length of hospital stay for elective and emergency major GI surgery patients.

Post-operative outcomes	Major GI surgery		Non-resectional	All
	Elective, n=42	Emerg, n=6	n=11 total n=6 procedure	n=54
Post-operative destination				
ITU	2/42 (4.8)	0/7	0/6	2/54 (3.7)
HDU/ERB	22/42 (52.4)	3/7 (42.9)	0/6	25/54 (46.3)
Ward	18/42 (42.9)	4/7 (57.1)	6/6 (100)	28/54 (51.9)
Deaths during index admission	0/42	2/6 (33.3)	0/6	2/54 (3.7)
Died after discharge	1/42 (2.4)	0/4	2/11 (18.2)	3/57 (5.3)
Length of hospital stay	n=42	n=5	n=6	n=53
median (range)	7 (1-35)	30 (15-49)	3.5 (1-14)	7 (1-49)
Length of HDU/ITU stay				
median (range)	1 (0-7)	1 (0-3)	n/a	0 (0-7)
Care needs on discharge, any	0/42	0/4	0/6	0/49
Complications				
Any	1/39 (2.6)	3/6 (50)	0/6	4/51 (7.8)
Urinary tract infection	0	1/6 (16.7)	0	1/51 (2.0)
Radiological drain	1/39 (2.6)	0	0	1/51 (2.0)
Unplanned HDU/ITU admission	0/39	0	0/6	0
In hospital deaths	0/42	2/6 (33.3)	0/6	2/54 (3.7)
Readmissions	4/40 (10.0)	0/4	0/6	4/50 (8.0)
Wound infection	1/40 (2.5)			1/50 (2.0)
Wound breakdown	1/40 (2.5)			1/50 (2.0)
Intra-abdominal collection	2/40 (5.0)			2/50 (4.0)
Pulmonary embolus	1/40 (2.5)			1/50 (2.0)

Table 34. Post-operative outcomes

Abbreviations: HDU, High Dependency Unit; ERB, Enhanced Recovery Bed; ITU, Intensive Therapy Unit

8.4.4 Peri-operative optimisation

According to the clinical records, only two elective and two emergency patients underwent any inpatient pre-operative optimisation before major GI surgery (Table 35). Approximately half of elective patients (20/42 (47.6%)) underwent peri-operative care according to the Enhanced Recovery After Surgery (ERAS) protocol as documented in the clinical notes. Of all patients undergoing major surgery, 22/49 (44.9%) underwent a laparoscopic procedure. Epidural analgesia was used more frequently in the elective than emergency setting; 12/42 (28.6%) versus 1/7 (14.3%) respectively. In contrast, wound catheters were used more frequently in the emergency setting 2/7 (28.6%) than elective setting 3/42 (7.1%) (Table 35).

Patients were asked what treatment options had been discussed with them at diagnosis in the bespoke questionnaire. Only a small number stated that alternatives to major GI surgery had been discussed; 7/58 (12.1%) and 5/58 (8.6%) stated that alternative treatment strategies and conservative management had been discussed respectively. A greater proportion of patients who underwent non-resectional management reported that alternatives to major surgery had been discussed (Table 36).

Patients were asked prior to discharge which optimisation strategies they had been advised about prior to surgery. Sixteen out of 38 elective patients (42.1%) reported having been advised to improve their fitness (physical activity) levels before surgery; there was no difference in median activity level of these patients compared to elective patients who were not advised (data not shown). Nine patients (23.7%) reported being told to improve their diet in the pre-operative period; these patients had a median BMI of 30 (range 27-42) and 7/9 (77.8%) were identified as ‘at risk’ or malnourished on the MNA. Only two elective patients attended a formal exercise programme before their surgery which was organised by the hospital, three were prescribed oral nutritional supplements and one received support for anxiety or stress. Over half of elective patients with cancer reported meeting a specialist nurse before their operation (20/31; 64.5%). Only three patients attended a Surgery School appointment

before their operation and only three were aware that they were on a 'fast-track' or ERAS pathway (Table 36).

Optimisation	Major GI surgery		Non-resectional	All
	Elective, n=42	Emerg, n=7	n=11	n=49
Pre-operative inpatient, Yes	2/42 (4.8)	2/7 (28.6)		4/49 (8.2)
Anaesthetic	1/42 (2.4)	1/7 (14.3)		2/49 (4.1)
Dietician	1/42 (2.4)	0		1/49 (2.0)
Cardiology	0/42	1/7 (14.3)		1/49 (2.0)
Physiotherapy	0/42	1/7 (14.3)		1/49 (2.0)
Transfusion/ iron infusion	0/42	0/7		0/49
ERAS	20/42 (47.6)	n/a		20/49 (40.8)
Peri-operative				
Laparoscopic procedure	20/42 (47.6)	2/7 (28.6)		22/49 (44.9)
Stoma formed	6/42 (14.3)	1/7 (14.3)		7/49 (14.3)
ERAS	25/42 (59.5)	0		25/49 (51.0)
Peri-operative analgesia				
Epidural	12/42 (28.6)	1/7 (14.3)		13/49 (26.5)
Spinal	4/42 (9.5)	0		4/49 (8.1)
PCA	1/42 (2.4)	0		1/49 (2.1)
Wound catheters	3/42 (7.1)	2/7 (28.6)		5/49 (10.2)
Post-operative ERAS	31/42 (73.8)	0/7		31/49 (63.3)

Table 35. Optimisation strategies documented in the clinical notes.

Further breakdown of peri-operative input by risk factors is not shown here as the numbers are very small.
Abbreviations: ERAS, Enhanced Recovery After Surgery; PCA, Patient Controlled Analgesia

Patients who underwent major GI surgery or a procedure were asked which allied health professionals they had had input from after their operation or procedure; 27/48 (56.3%) saw a physiotherapist, 21/48 (43.8%) saw a dietician and 10/48 (20.8%) saw an occupational therapist. Again, there were no differences observed in baseline characteristics of those who saw AHPs post-operatively compared to those who did not (data not shown). Three elective patients had input from the pain team, only one emergency patient had input from a geriatrician and one non-resectional patient had input from the palliative care team. No patients reported that they were planning on undertaking a rehabilitation programme after discharge from hospital (Table 36).

Optimisation questionnaire	Major GI surgery		Non-resectional	All
	Elective, n=42	Emerg, n=5	n=11	n=58
Treatment options discussed				
Major surgery	37/42 (88.1)	4/5 (80.0)	1/11 (9.1)	42/58 (72.4)
Risk adapted procedure	3/42 (7.1)	0/5	4/11 (36.4)	7/58 (12.1)
Conservative management	2/42 (4.8)	0/5	3/11 (27.3)	5/58 (8.6)
Lifestyle advice				
Improve fitness	16/38 (42.1)	n/a	1/6 (16.7)	17/44 (38.6)
Improve diet	9/38 (23.7)	n/a	1/6 (16.7)	10/44 (22.7)
Stop smoking	2/11 (18.2)	n/a	1/6 (16.7)	3/17 (17.6)
Reduce alcohol consumption	2/14 (14.3)	n/a	0/6	2/20 (10.0)
Formal support before surgery				
Exercise	2/38 (5.3)	n/a	0/6	2/44 (4.5)
Dietary supplements	3/38 (7.9)	n/a	2/6 (33.3)	5/44 (11.4)
Anxiety support	1/38 (2.6)	n/a	0/6	1/44 (2.3)
Pre-operative AHP review				
Physiotherapist	1/38 (2.6)	0/4	0/6	1/48 (2.0)
Dietician	0	0/4	0/6	0
Geriatrician	0	0/4	0/6	0
Specialist nurse	20/38 (52.6)	1/4	3/6 (50.0)	24/48 (50.0)
Pain team	1/38 (2.6)	0/4	0/6	1/48 (2.0)
Palliative care team	0	0/4	1/6 (16.7)	1/48 (2.0)
Attended Surgery School	3/38 (7.9)	n/a	n/a	3/38 (7.9)
Aware on ERAS pathway, yes	3/38 (7.9)	n/a	n/a	3/38 (7.9)
Post-operative AHP review				
Physiotherapist	23/38 (60.5)	2/4 (50.0)	2/6 (33.3)	27/48 (56.3)
Dietician	17/38 (44.7)	3/4 (75.0)	1/6 (16.7)	21/48 (43.8)
Occupational therapist	6/38 (15.8)	2/4 (50.0)	2/6 (33.3)	10/48 (20.8)
Geriatrician	0	1/4 (25.0)	0	1/48 (2.0)
Social worker	0	0/4	0	0
Pain team	3/38 (7.9)	0/4	0	3/48 (6.3)
Palliative care team	0	0/4	0	0

Table 36. Results of the bespoke questionnaire asking patients what optimisation strategies they underwent

Abbreviations: ERAS; Enhanced recovery after surgery, AHP; Allied Health Professional, GI; Gastrointestinal

8.4.5 Outcomes at 6 weeks

Six-week follow-up data were available for fifty patients at the time of analysis; this included 39 elective surgery patients, four emergency surgery patients and seven non-resectional management patients (Figure 29). Three patients died after discharge; one prior to the 6-week follow-up point and two after this.

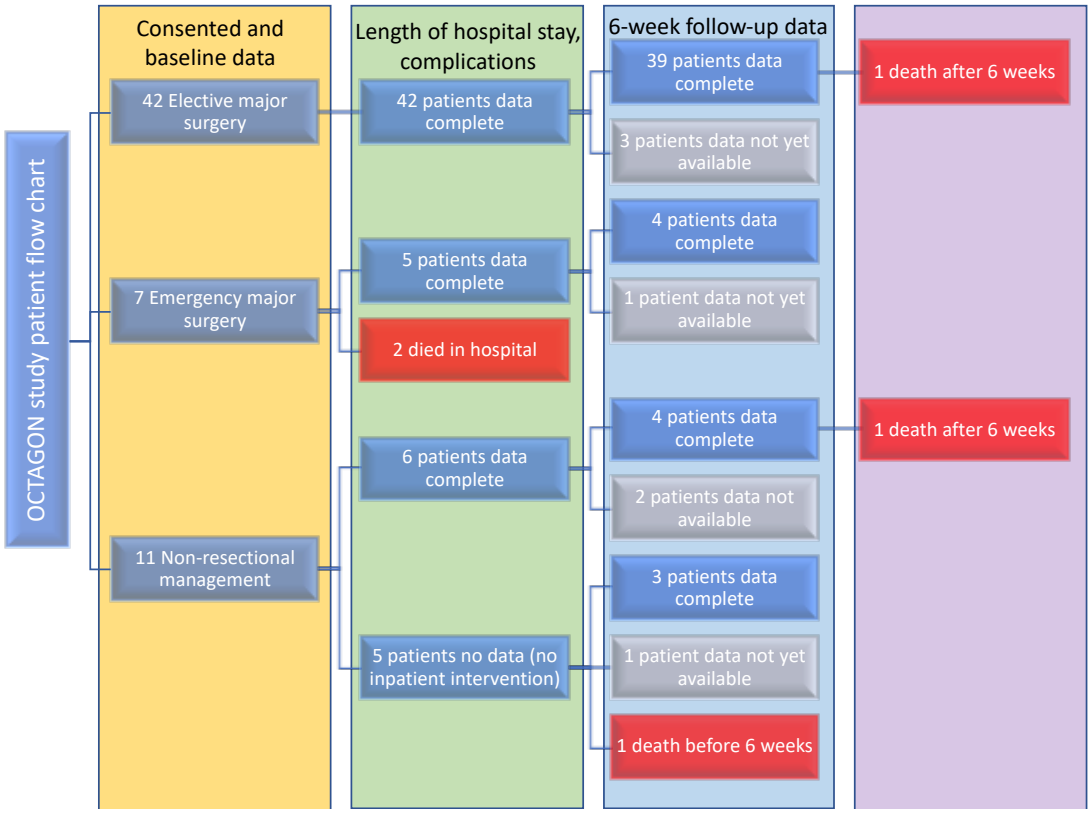


Figure 29. Patient flow chart through OCTAGON.

Numbers of patients who were recruited with baseline data collected (yellow box), patients who were admitted to hospital and details of their hospital stay have been collected (green box), patient data collection complete at 6-week follow-up point (blue box). Patients who died after recruitment to the study are indicated in red. The grey boxes indicate the number of patients in each group where 6 week follow-up data is not yet available.

8.4.5.1 *Functional outcomes*

There were no differences in functional ability of the whole cohort as assessed using the WHODAS 2.0 simple summary score; median score 2.5 at baseline (range 0-23) compared to median score 3.0 at 6 weeks (range 0-23). There appeared to an improvement in summary score for emergency surgery patients, however this is likely due to the two post-operative deaths in a small group. There also appeared to be a worsening in non-resectional patients; median pre-operative score 3 (range 0-20) compared to median at 6 weeks score 14 (range 0-22) (Figure 30). Looking at deficits

in particular tasks or domains of the WHODAS, more patients reported having difficulties in performing household tasks at 6 weeks compared to baseline; 24/50 (48.0%) versus 13/60 (21.7%) (Table 37). There was a reduction in patients stating that they were emotionally affected by their health from 30/60 (50%) to 15/50 (30.0%), which was predominantly observed in elective patients. There was also a reduction in patients reporting problems with concentration (12/60 (20.0%) versus 7/50 (14.0%)) and dealing with new people (5/60 (8.3%) versus 1/50 (2.0%)). A trend was observed in non-resectional patients with more reporting having days where they are completely unable to do usual activities due to health problems at 6 weeks compared to baseline; 6/7 (85.7%) versus 1/11 (9.1%) (Table 37).

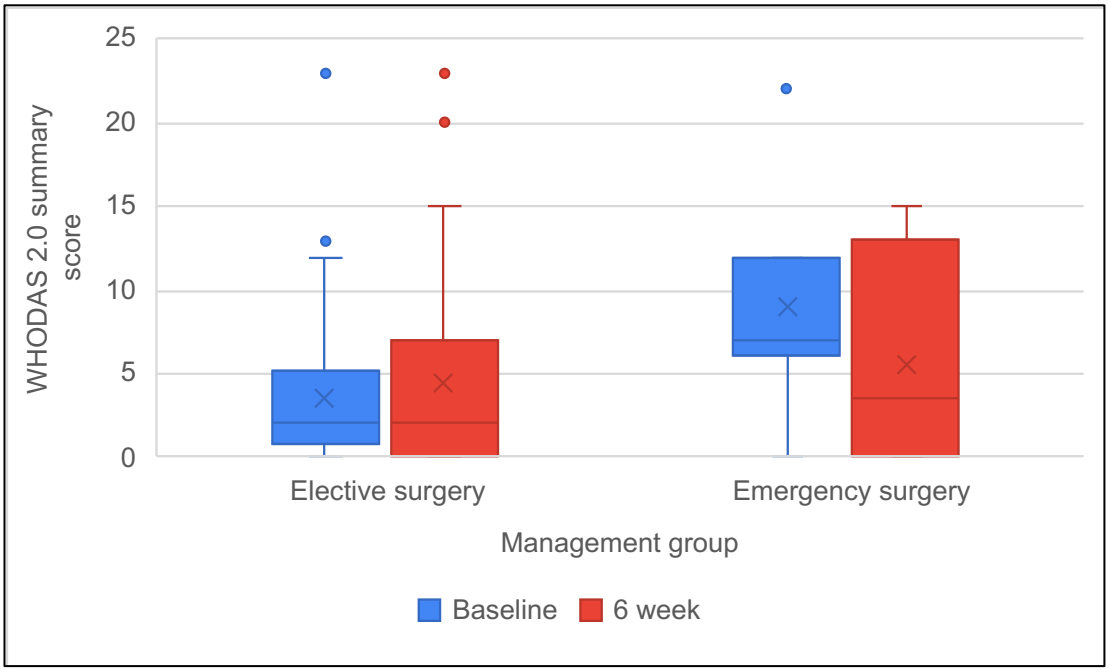


Figure 30. Box and whisker plots illustrating change in functional status as assessed by the WHODAS 2.0 from baseline to 6 weeks for elective and emergency major GI surgery patients

8.4.5.2 *Health related quality of life outcomes*

Regarding quality of life, as assessed using the EQ-5D-5L, again there was no difference in the summary score for the whole cohort at 6-weeks compared to baseline, however there appeared to be an improvement in health status for the emergency patients and a worsening of health status for the non-resectional patients (Table 37) (Figure 31). The visual analogue scale (VAS) also reflected this. Again, this is likely partly attributable to the two post-operative deaths in the emergency group. On

the individual domains of the EQ-5D-5L more patients reported deficits in performing their usual activities at 6 weeks, again, with this predominantly being the elective surgery patients; 10/42 (23.8%) versus 24/39 (61.5%). Interestingly, more non-resectional patients reported problems with pain or discomfort at 6 weeks than at baseline; 1/11 (9.1%) versus 5/7 (71.4%).

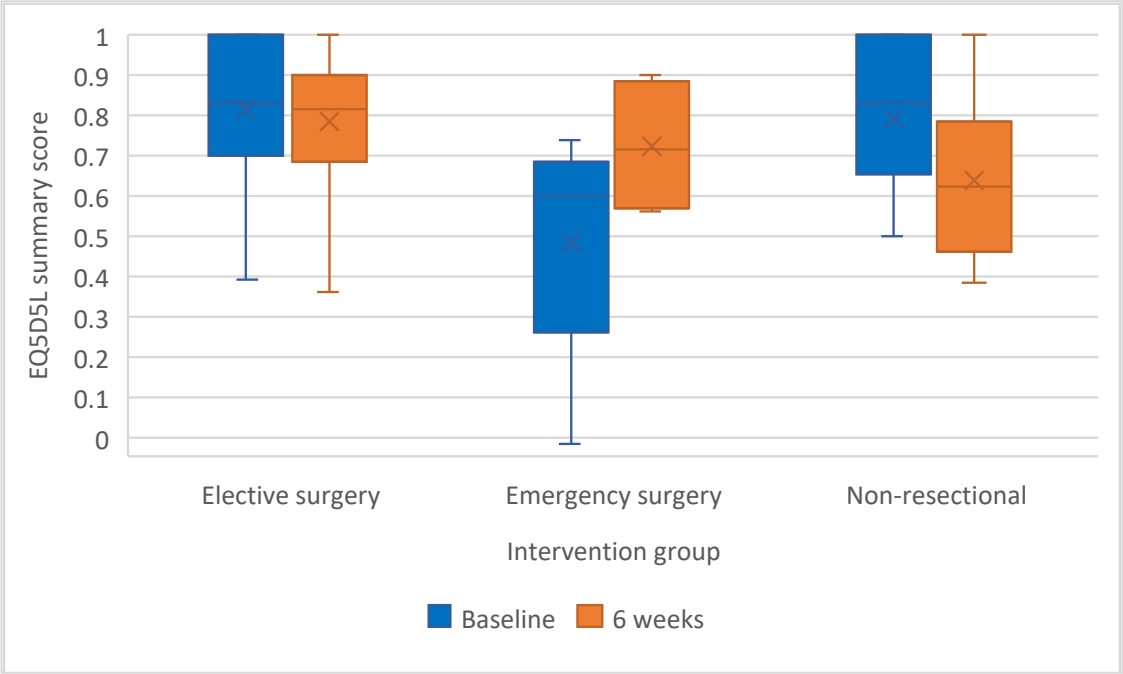


Figure 31. Change in health-related quality of life as assessed using the EQ5D5L summary score from baseline to 6 weeks for each of the intervention groups.

There were no differences in median ADL scores at 6 weeks compared to baseline, however, more elective patients scored 18 or less at 6 weeks suggesting an increase in dependency in some patients; 4/42 (9.5%) versus 7/39 (17.9%) (Table 37) (Fisher's exact p>0.05).

6-week compared to baseline	Major GI surgery				Non-resectional management		All	
	Elective Baseline n=42	Elective 6 week n=39	Emergency Baseline n=7	Emergency 6 week n=4	Baseline n=11	6 week n=7	Baseline n=60	6 week n=50
WHODAS 2.0								
Median simple score (range)	2 (0-23)	2 (0-23)	7 (0-22)	3.5 (0-15)	3 (0-20)	14 (0-22)	2.5 (0-23)	3 (0-23)
Any difficulty n (%)								
Standing long periods	10/42 (23.8)	14/39 (35.9)	4/7 (57.1)	1/4 (25)	5/11 (45.5)	6/7 (85.7)	19/60 (31.7)	21/50 (42.0)
Household responsibilities	7/42 (16.7)	16/39 (41.0)	4/7 (57.1)	2/4 (50)	2/11 (18.2)	6/7 (85.7)	13/60 (21.7)	24/50 (48.0)
Learning a new task	5/42 (11.9)	3/39 (7.7)	2/7 (28.6)	0	2/11 (18.2)	2/7 (28.6)	9/60 (15.0)	5/50 (10.0)
Joining community activities	5/42 (11.9)	4/39 (10.3)	3/7 (42.9)	1/4 (25)	3/11 (27.3)	3/7 (42.9)	11/60 (18.3)	8/50 (16.0)
Emotionally affected	25/42 (59.5)	12/39 (30.8)	4/7 (57.1)	1/4 (25)	1/11 (9.1)	2/7 (28.6)	30/60 (50.0)	15/50 (30.0)
Concentrating	9/42 (21.4)	4/39 (10.3)	1/7 (14.3)	1/4 (25)	2/11 (18.2)	2/7 (28.6)	12/60 (20.0)	7/50 (14.0)
Walking a long distance	13/42 (31.0)	16/39 (41.0)	6/7 (85.7)	2/4 (50)	7/11 (63.6)	6/7 (85.7)	26/60 (43.3)	24/50 (48.0)
Washing whole body	4/42 (9.5)	5/39 (12.8)	4/7 (57.1)	1/4 (25)	1/11 (9.1)	3/7 (42.9)	9/60 (15.0)	9/50 (18.0)
Getting dressed	4/42 (9.5)	3/39 (7.7)	1/7 (14.3)	0	2/11 (18.2)	3/7 (42.9)	7/60 (11.7)	6/50 (12.0)
Dealing with new people	3/42 (7.1)	1/36 (2.6)	0	0	2/11 (18.2)	0	5/60 (8.3)	1/50 (2.0)
Maintaining friendship	2/42 (4.8)	0	0	0	0	0	2/60 (3.3)	0
Day-to-day work	10/42 (23.8)	11/39 (28.2)	4/7 (57.1)	2/4 (50)	4/11 (36.4)	6/7 (85.7)	18/60 (30.0)	19/50 (28.0)
Days difficulties present								
0	25/42 (59.5)	21/39 (53.8)	2/7 (28.6)	2/4 (50)	5/11 (45.5)	1/7 (14.3)	32/60 (53.3)	24/50 (48.0)
1+ n	17/42 (40.5)	18/39 (46.2)	5/7 (71.4)	2/4 (50)	6/11 (54.5)	6/7 (85.7)	28/60 (46.7)	26/50 (52.0)

Days totally unable								
0	38/42 (90.5)	32/39 (82.1)	6/7 (85.7)	4/4 (100)	10/11 (90.9)	1/7 (14.3)	54/60 (90.0)	37/50 (74)
1+ n	14/42 (33.3)	7/39 (17.9)	1/7 (14.3)	0	1/11 (9.1)	6/7 (85.7)	6/60 (10.0)	13/50 (26.0)
Days cut back activities								
0	33/42 (78.6)	28/39 (71.8)	6/7 (85.7)	4/4 (100)	8/11 (72.7)	1/7 (14.3)	47/60 (78.3)	33/50 (66)
1+ n	9/42 (21.4)	11/39 (28.2)	1/7 (14.3)	0	3/11 (27.3)	6/7 (85.7)	13/60 (21.7)	17/50 (34.0)
EQ-5D-5L								
Summary score, median (range)	0.837 (0.483-1)	0.816 (0.364-1)	0.599 (-0.017-0.74)	0.721 (0.560-0.906)	0.836 (0.499-1)	0.553 (0.381-0.716)	0.836 (-0.017-1)	0.767 (0.381-1)
VAS, median (range)	80 (50-100)	70 (20-100)	40 (20-80)	72.5 (50-80)	80 (10-100)	40 (10-95)	80 (10-100)	65 (10-100)
Reporting deficit in each domain								
Mobility	10/42 (23.8)	13/39 (33.3)	6/7 (85.7)	2/4 (50)	5/11 (45.5)	5/7 (71.4)	25/60 (41.7)	20/50 (40.0)
Self-care	3/42 (7.1)	2/39 (5.1)	4/7 (57.1)	2/4 (50)	1/11 (9.1)	2/7 (28.6)	12/60 (20)	6/50 (12.0)
Activities	10/42 (23.8)	24/39 (61.5)	6/7 (85.7)	3/4 (75)	4/11 (36.4)	6/7 (85.7)	24/60 (40)	33/50 (66.0)
Pain	19/42 (45.2)	20/39 (51.3)	6/7 (85.7)	3/4 (75)	1/11 (9.1)	5/7 (71.4)	30/60 (50)	28/50 (56.0)
Mood	14/42 ((33.3)	15/39 (38.5)	5/7 (71.4)	1/4 (25)	3/11 (27.3)	1/7 (14.3)	22/60 (36.7)	17/50 (34.0)
Functional status (ADL score)								
Median (range)	20 (16-20)	20 (13-20)	20 (12-20)	20 (20)	20 (16-20)	20 (13-20)	20 (12-20)	20 (13-20)
Score = 19-20	38/42 (90.5)	32/39 (82.1)	6/7 (85.7)	4/4 (100)	8/11 (72.7)	4/7 (57.1)	52/60 (86.7)	40/50 (80.0)
Score = 18 or less	4/42 (9.5)	7/39 (17.9)	1/7 (14.3)	0	3/11 (27.3)	3/7 (42.9)	8/60 (13.3)	10/47 (20.0)

Table 37. Six-week outcome data alongside baseline status

8.5 Discussion

8.5.1 Health status

As discussed in Chapter 1, the health status of older adults varies considerably, from individuals who remain independent and in good health to those who have multiple long-term health conditions, frailty, cognitive and functional impairments. Individuals from lower socioeconomic backgrounds are disproportionately affected and are much more likely to have poor health in older age[352,353]. This variation in health status means that age cannot be used as a surrogate for 'fitness'.

This study has documented the diverse health status of older patients presenting to elective and emergency GI surgical services at a single UK hospital. It has shown that deficits are present across multiple domains, in particular ones that are not routinely assessed in clinical practice such as pain, mood and the emotional effects of health conditions. It also suggests that cognitive, functional and nutritional deficits may be missed unless they are formally assessed for; over half of elective patients in this study did not score fully on cognitive screening and half of all patients were assessed as at risk of malnutrition on the MNA compared to less than 10% by BMI alone. Only one third of elective patients underwent objective physical testing, which is in agreement with the interview and questionnaire data suggesting variable uptake of objective testing across GI surgery in the UK.

8.5.2 Fitness for surgery

As discussed in chapter 5, how surgeons decide on a patient's "fitness" for surgery in the older population is variable. National guidelines for the management of patients with GI cancers give little indication of how surgeons should make this assessment but give detailed guidance on how to manage those who are 'fit'[110,112,354]. There is also variation in opinion in whether this is the responsibility of the surgeon, the multi-disciplinary team or pre-operative assessment[355]. This means that patients may be assessed differently if they present to different surgeons, sub-specialists or hospitals with the same GI condition. They may also be assessed differently if they present through emergency or elective pathways. This is reflected in the variable provision and uptake of objective physical testing, anaesthetist-led assessment and geriatric assessment across the UK[107,162,306,356].

The presence of co-morbidities is an important factor in decision-making regarding suitability for surgery[355]. For this study, the Charlson Co-morbidity index (CCI) was used to record co-morbidities, with the majority of patients recorded as having very few co-morbidities. However, many patients were observed to have physical impairments (mobility problems, poor dexterity, visual and hearing impairments), which were not assessed in the CCI, but are common in the older population and may impair recovery. Further work is needed to determine whether these impairments identify patients at risk of poor outcomes separate to those with more standard co-morbidities or identified as frail.

In this study, eleven patients did not undergo major GI surgery with only one of these patients undergoing objective physical testing prior to this decision. The main aspects in which they differed from those who underwent elective surgery were in their frailty and physical activity levels, neither of which are routinely assessed by surgeons in practice. Interestingly, patients who chose not to undergo major GI surgery did not differ from those who did undergo surgery in their functional, nutritional or quality of life assessments at baseline. However, the patients who did not undergo major surgery were observed to deteriorate with regards to their functional abilities (assessed using the WHODAS 2.0) and quality of life (assessed using the EQ-5D-5L) at 6 weeks even without the physiological stress of major surgery. This suggests that they may have had poor outcomes if they had undergone surgery. Further work is needed to determine what distinguishes patients assessed as 'unfit' from those who are 'fit', with a potential role for biomarkers of frailty and senescence.

8.5.3 Older patients with malignant disease

The incidence of gastrointestinal cancers increases with age[357]. Despite this, older individuals are less likely to undergo surgery for the same stage of disease as younger patients and are less likely to be offered adjuvant treatments[27,53]. Palliative alternatives to surgery, such as endoluminal stenting, are more likely to be offered to older patients[27]. Variation in the health status of older patients may account for some of the differences in cancer specific and surgical outcomes. However, lower resection rates suggest that

older patients may be inappropriately denied treatments based on age that could improve their survival or quality of life. Other factors, such as socioeconomic status, are likely to disproportionately influence major surgery rates in older people.

The COVID-19 pandemic has disproportionately affected the care and treatment of older patients with GI cancers[358,359360,361]. Whilst cancer surgery has been prioritised throughout the pandemic, surgeons were encouraged to employ risk-reducing strategies, such as resection without anastomosis, to reduce the potential burden on critical care[362]. It is also likely that more patients were advised to 'watch and wait' rather than undergo surgery if they were considered to be at high risk of post-operative complications. In addition, many patients did not receive standard adjuvant therapies[358]. It is likely that the low levels of peri-operative optimisation observed in this study are in part a reflection of strained services functioning within a pandemic. For example, the Surgery School which was successfully delivering face-to-face sessions to patients undergoing major resection before the pandemic had to transition to the provision of virtual support. As older patients are less likely to be internet users, this may have had a negative impact on provision of this service to the study population. It is likely that Allied Health Professional input for surgical patients was impacted by re-deployment, remote working guidelines, shielding and staff isolation. Ideally, the study should be re-run once normal working practices are restored and it is the intention to continue the study as a multi-centre study. This may allow us the opportunity to re-run the study locally at Sheffield Teaching Hospitals.

8.5.4 Older patients with non-malignant disease

Many non-malignant GI conditions amenable to major surgery, such as diverticular disease, also increase in incidence with age[74]. Evidence suggests declining rates of elective surgery for non-malignant disease in the older population, however, data are scarce due to lack of national registries or audits for non-malignant GI conditions. This may mean that older patients are more likely to present as emergencies, contributing to poorer outcomes[126,331]. Patients presenting with GI conditions requiring emergency surgery are known to have greater levels of frailty, co-morbidity and dependency than patients presenting through elective pathways[128,129,363]. However, comprehensive assessment of older patients prior to major emergency surgery is still lacking. This is the first study that

we are aware of that has demonstrated the feasibility of using validated questionnaires completed by patients as a baseline assessment in the emergency GI surgery setting. It is clear that baseline quality of life is adversely affected by emergency presentation and that surgery may offer considerable improvement relative to this low baseline.

The patients who underwent emergency surgery in this study all had small bowel obstruction and this likely reflects the design of the study with consent and baseline questionnaires required before surgery. A number of potential patients were identified with peritonitis but either the timeframe before surgery was too short for them to be approached or they had delirium or were in significant pain, precluding approach for research purposes. Again, the COVID-19 pandemic has likely negatively affected the care of emergency patients recruited to this study through re-deployment of the geriatrician usually involved in post-operative emergency general surgery patients and constraints on critical care.

8.5.5 Optimisation strategies

There are a wide range of optimisation strategies of relevance to the older patient that may be implemented before, during or after surgery. These range from physical activity programmes and nutritional optimisation through to ERAS programmes and post-operative delirium interventions. However, the evidence base for the majority of these interventions is poor, particularly in the older population[303]. There also remain questions as to how best to measure the effectiveness of interventions as many may not affect standard surgical outcomes, such as length of stay, but do have the potential to improve patient experience and quality of care[260,262,265,293]. There are concerns that variable provision of services, particularly prehabilitation programmes, may accentuate healthcare inequalities due to difficulties in engaging those patients with most potential to improve[169] and variation in provision between hospitals.

Optimising the treatment pathways of older adults undergoing major GI surgery is of increasing importance with growing waiting lists and constraints on NHS resources accentuated by the pandemic. Patients are likely to be waiting longer for their surgical treatment to commence, therefore efforts need to be made to maximise the use of this

time to ensure that patients are as prepared as possible before any surgery. There is a national drive to transform surgical waiting lists into 'preparation lists' so that elective patients can use the time that they are waiting for their operation to be optimally prepared rather than it be seen as a negative time period[364]. It is hoped that this will result in a greater focus on optimisation and preparation for surgery, both for clinicians and patients. Encouragingly, many patients in this study reported that they had been advised to improve their fitness levels and diets before their operations, however, very few reported receiving any support in doing this.

Little is known about older patient's awareness of optimisation strategies surrounding major GI surgery. The literature suggests that whilst there is enthusiasm from the surgical and peri-operative community, implementation and sustaining ERAS pathways in practice is difficult due to financial constraints, staff shortages and patient engagement[365]. This study found that many elective patients were managed according to ERAS principles but very few patients had any awareness of this. The majority of patients did not recall that alternatives to major surgery had been discussed with them or whether they had met AHPs during their stay. This may be in part attributed to recall bias. It is hoped that semi-structured patient interviews that will conducted in the post-doctoral phase of this project will help to explore some of these issues.

8.5.6 Outcomes

Multiple reports over the last two decades have highlighted the poor outcomes for older individuals undergoing major GI surgery[52,73,126]. National audits and reports such as the NELA and GIRFT have also focused attention on improving outcomes in high-risk groups. This has led to a greater focus on peri-operative medicine, geriatric assessment, objective physical testing and increased use of risk calculators and scoring systems to try to identify those at risk of complications. It is widely recognised that prolonged hospital admissions are detrimental to older individuals' functional abilities, due to prolonged periods of time spent in bed, poor nutritional intake and loss of routines. A number of studies have suggested that functional recovery is prolonged in older patients undergoing major surgery and that many do not get back to their previous levels of functioning[84,136]. It has been suggested that maintaining functional independence is of greater importance than

survival for many older patients, however data is scarce due to lack of qualitative studies in GI surgery and very few studies report functional outcomes[337].

This study found no significant change in overall functional status as assessed using the WHODAS 2.0 from baseline to 6 weeks post-surgery for elective patients. However, a trend was observed with patients reporting more problems with performing household tasks after surgery than before. An improvement in overall functional status was observed in emergency surgery patients, however, conclusions are limited by small numbers and may have been affected by two post-operative deaths in a small group. Overall functional status appeared to deteriorate in those who did not undergo major surgery over the six-week follow-up period. This is concerning and warrants further study.

This study collected complications according to the Clavien Dindo classification, a commonly used system in surgical studies. Interestingly, very few patients with a prolonged length of stay were recorded as having complications. This suggests that either these patients suffered complications that were not captured by the Clavien Dindo classification (such as post-operative ileus requiring TPN) or that their recovery was prolonged due to other factors (e.g. poor mobility, pain control). Again, this requires further study to determine the most appropriate outcome measures for this population.

8.5.7 Limitations of this study

This study is limited in its conclusions by the small sample size and single centre recruitment, particularly when looking at the patients undergoing emergency surgery and non-resectional management. Results are currently not generalisable to wider populations due to this. It is hoped that ongoing patient recruitment at other hospitals in the region will enable more in-depth analyses to be performed on a larger, more diverse sample. Despite the small sample size, this study has been able to demonstrate high levels of heterogeneity of baseline health and fitness status within the patient population, low uptake of peri-operative optimisation strategies and variable functional outcomes. It has also demonstrated the feasibility of collecting questionnaire-based patient reported baseline assessments and outcomes in this population. However, it is also acknowledged that recall bias may have affected the bespoke questionnaire results, with patient recall

of details from clinical consultations known to be highly variable and likely affected by treatment strategy[366]. The relatively short follow-up period of this study currently is another limitation of this study but ongoing follow-up at 3 months and 6 months will add greater depth to the final analyses.

Various baseline demographics were collected in this study, chosen according to the published literature. However, socioeconomic class and ethnicity were not collected. This was an oversight in the study design and may have introduced bias in the interpretation of results. Postcode was collected which may be used in further analyses as a proxy for socioeconomic class. Future studies should collect standard data on protected characteristics.

The observational nature of this study means that no cause and effect relationships between optimisation strategies and outcomes in older adults can be made. This requires appropriately designed and funded multi-centre trials. However, it is hoped that data from this study may help to inform their design. In addition, this study was not suitable for health economic analyses to be conducted due to the range of different interventions and observational nature of the study.

As already discussed, the context of this study being performed during the COVID-19 pandemic has likely affected the findings and generalisability of results to non-pandemic practice. It is likely that changes to pathways, surgical practice and strain on the entire healthcare system has exacerbated any variation in practice previously observed in this field. It is possible that increased focus on frailty and risk of poor outcomes after peri-operative COVID-19 infection may have led to this taking more prominence in clinical decision-making[367].

The semi-structured patient interviews and mixed methods triangulation of findings, detailed in the study protocol[368], have not yet been performed. These will be carried out in the post-doctoral phase and will help to explore the issues raised by the study from the perspective of patients and look at barriers and facilitators to improving care.

8.6 Conclusion

This study has observed the functional trajectories of older surgical patients across a diverse range of GI subspecialities and presentations at a single tertiary referral centre. It has documented wide variation in baseline health status of patients and low uptake of optimisation strategies. Further studies are needed to address variation in practice in the older surgical population and methods of optimisation to improve outcomes.

9 Mixed methods synthesis of findings

This mixed methods study has derived data from a range of sources: the literature, interviews, a questionnaire, a discrete choice experiment and an observational cohort study to explore attitudes towards surgical management of older patients and identify the role and value of peri-operative assessment and optimisation and the barriers and facilitators to their implementation. The literature suggests that there are many different strategies to optimise patients pre-operatively but the evidence specific to older patients and effect on surgical outcomes is currently limited. The interviews and questionnaires suggest that key drivers for variation are clinician opinion, resource limitation, lack of standard guidelines and lack of expertise and resources to assess and optimise older patients adequately. The observational data suggests variation in the application of these measures, even when clinically indicated. The findings from these diverse sources have been triangulated according to the triangulation protocol[177] using a convergence coding matrix. They are summarised below.

9.1 Attitudes towards major surgery in the older patient

The key findings of the studies from this thesis in relation to this meta theme are summarised in Table 38.

9.1.1 Impact of age and health status on treatment choice

This study has revealed variation in attitudes and practice regarding major GI surgery in the older patient, with consistent findings across most data sources. Whilst surgeons state that they do not take age into account, there is evidence from the questionnaire and DCE that it is taken into account in decision-making, most likely as a proxy for fitness, due to lack of use of objective tests. The interview, questionnaire and DCE findings suggest that patients at the upper end of the age range are more likely to be treated conservatively, which is also supported by the literature.

9.1.2 Potential treatment trade-offs

Healthcare professionals discussed the potential detrimental effects of major surgery on an older person in the semi-structured interviews, with the need to protect the vulnerable from over-investigation or treatment. They described the complex decision-making process between the risks of surgical procedures, underlying pathology, risk profile of individual patients and symptom burden. This likely results in reluctance to offer elective surgery to patients with benign disease if patient or procedure related risks are high. Similarly, there was a feeling that the highest morbidity operations, such as pancreatectomy and oesophagectomy, should only be offered to the fittest of patients.

The bespoke questionnaire performed as part of the observational study revealed that many patients were not aware of alternative treatment options available to them apart from major surgery which suggests that surgeons may not always offer a choice of options to all patients. However, this may also be explained by recall bias. This will be explored further in the semi-structured patient interviews which will be performed in the post-doctoral phase of this research.

9.1.3 Symptom burden as an important factor

A common theme that emerged was the impact of symptom burden on treatment decision-making in older patients. In the semi-structured interviews, it was commonly stated that if an older patient had minimal symptoms, whether from malignant or non-

malignant pathology, they may be better managed conservatively to preserve their quality of life and functional status. This was particularly emphasised in 'unfit' or frail individuals. This was also reflected in the Discrete Choice Experiment, where surgeons were more likely to recommend surgery in the emergency setting for non-malignant disease (where symptom burden is usually high) than the elective setting.

9.1.4 Management of patients with cognitive impairment

The semi-structured interviews revealed reluctance of surgeons and the wider HCP team to offer major surgery to patients with moderate to severe cognitive impairment, but opinions differed on the management of patients with mild impairment. This was confirmed in the survey and DCE. Despite cognitive impairment being an exclusion criterion for the observational study, a number of patients who underwent surgery were identified on cognitive screening to require further assessment, suggesting that it is under-recognised in practice. This is concordant with the survey data where many surgeons stated that it was important in their decision-making but that they did not perform objective assessments in their own practice. This is cause for concern as patients with cognitive impairment are more likely to suffer post-operative delirium and confusion, again with missed opportunities to employ preventative strategies.

Meta theme 1: Attitudes towards surgical management of the older adult
1. Age does have a role in surgical treatment decisions Interviews: Age is not taken into account in decision making *(Divergent)* Physiological rather than chronologic age *(Convergent)* Only fittest of patients considered for certain elective procedures (*Convergent*) Lack of evidence to guide decisions in the older patient (*Convergent*) Questionnaire: Advanced age was rated as important (Likert scale 6-9) by 54/103 (52.4%) and 67/103 (65.0%) surgeons in the elective and emergency settings respectively (*Convergent*) DCE: On univariate analysis age was associated with treatment preference for conservative management over major surgery (p<0.05) univariate (*Convergent*) In the binomial model age was significant on treatment preference (Wald 23.627, p<0.000) (*Convergent*)
2. Potential treatment trade-offs should be considered in older adults Interviews: High risk or 'borderline' patient might be encouraged or choose non-operative management options or risk adapted strategies (*Convergent*) Risk of doing harm from major surgery in unfit patients (*Convergent*) More likely to discuss alternatives to major surgery in older age (85+) (*Convergent*) Questionnaire: The availability of alternative treatment strategies was rated as important (Likert scale 7-9); 86/103 (83.5%) surgeons for both elective and emergency patients (*Convergent*) Observational: Very few patients recalled alternatives to major surgery being discussed with them at diagnosis; elective 5/42 (11.9%) emergency 0/5 (0%) (*Divergent*)
3. Symptom burden an important factor in older adults Interviews: In emergency presentations (high symptom burden), both patients and clinicians are accepting of higher levels of peri-operative risk (*Convergent*) Reluctance to operate on 'unfit' elective patients with non-malignant disease (*Convergent*) DCE: Surgeons were more likely to recommend surgery for emergency presentations of non-malignant pathology than elective (OR = 2.155 95% CI 1.832 to 2.536) on univariate analysis (*Convergent*)
4. A diagnosis of cognitive impairment is an important factor in decision-making Interviews: Patients with mild dementia could still benefit from elective surgery if symptom burden is high (*divergent*) Reluctance to operate on patients with dementia (C*onvergent*) Questionnaire: The presence of dementia was rated as important (Likert score 6-9) by the majority of surgeons; 99/103 (96.1%) surgeons for both elective and emergency patients (*Convergent*) DCE: On univariate analysis, moderate/ severe cognitive impairment associated with lower odds of selecting major GI surgery (*Convergent*) Cognitive impairment was the most important contributor to the binomial model (Wald 89.175, p<0.000) (*Convergent*)

Table 38. Meta theme 1: Attitudes towards surgical management of the older patient.

9.2 Assessment of fitness for surgery in the older adult is variable

The key findings of the studies from this thesis in relation to this meta theme are summarised in Table 39.

9.2.1 There is variation in the general assessment of older patients

Comprehensive baseline assessment using validated questionnaires in the observational study revealed a high prevalence of malnutrition, physical inactivity, cognitive and functional impairments that would not necessarily be detected during routine surgical assessment processes. In the questionnaire, there was variation in how surgeons assess patients with regards to frailty, cognition, cardiopulmonary fitness, nutritional and functional status. Many surgeons stated that these factors were important in their decision-making but did not have access to objective testing or assessments. Time to adequately assess patients within the current pathways and also within current consultations was also a frequent barrier.

9.2.2 There is variation in the use of objective physical tests

In the semi-structured interviews, healthcare professionals reported varying access to objective physical testing and also differing opinions regarding its role in treatment decision-making and optimisation. This was reflected in the questionnaire, where less than a quarter of surgeons routinely assess all elective patients using objective physical tests whereas almost half will request them only in patients for whom they have concerns. The results from the observational study were similar, with only one third of elective patients undergoing CPET testing.

9.2.3 Frailty and geriatric assessment are important in treatment decision-making

Surgeons spoke about frailty becoming increasingly relevant in surgical decision-making. However, many stated that they did not routinely assess frailty in their own practice, and this was also reflected in the questionnaire study, where less than half of surgeons perform a frailty assessment as part of their own practice. In the questionnaire, despite cognitive impairment being highly rated in decision-making, almost half of surgeons do not routinely ask older patients whether they have memory problems. Many surgeons in the interviews and free-text comments of the questionnaire stated that they would like better access to geriatrician-led input, particularly for emergency patients. This difficulty accessing geriatrician-led support was clear in the observational study where no patients

had geriatric input pre-operatively and only one post-operatively, despite over half of emergency and non-resectional patients being identified as frail or vulnerable. Whilst this is attributed to re-deployment of the general surgical geriatrician during the pandemic, it does illustrate how vulnerable such services are.

9.2.4 There is a lack of allied health professional input in the pre-operative period

Allied Health Professionals spoke in the interviews about challenges they face in accessing patients before surgery, with their assessments often being carried out in the post-operative period as a result. They felt that earlier assessments would enable earlier interventions by AHPs. This was reflected in the questionnaire study where surgeons reported variable levels of AHP involvement, with even lower levels actually observed in the observational study.

9.2.5 Nutritional assessment is important in gastrointestinal surgery patients

Healthcare professionals emphasised the importance of nutritional assessment due to the high prevalence of malnutrition in GI surgical patients and its detrimental effects on outcomes. Despite this the majority of healthcare professionals interviewed stated that access to dietician-led assessments was limited in their hospitals. Many surgeons stated that nutritional assessment formed part of their own assessment due to lack of dieticians. This was reflected in the questionnaire, where two thirds of surgeons ask specifically regarding weight loss. However, screening for micronutrient deficiencies did not form part of their routine assessment and surgeons rarely use validated nutritional screening questionnaires. The observational study confirmed the high prevalence of malnutrition and risk in the study population, whilst also demonstrating low pre-operative dietician input.

9.2.6 Psychological assessment is important

Surgeons and healthcare professionals emphasised in interviews the importance of psychological assessment due to the impact of psychological problems on engaging with treatment and post-operative recovery. The observational study confirmed a high prevalence of psychological problems in the study population as reported by patients using validated questionnaires. Despite this, very few surgeons stated that it forms part of their own assessment in the questionnaire.

Meta theme 2: Assessment of fitness for surgery in the older adult is variable and contributes towards variation in practice

1. Variation exists in the general assessment of older patients prior to major surgery

Interviews: Healthcare professionals have different opinions regarding responsibility for the assessment of fitness for surgery *(convergent)*
Healthcare professionals value face-to-face assessment *(convergent)*

Questionnaire: Variable practice regarding specific functional, physical activity, psychological and cognitive questions and use of objective questionnaires *(convergent)*

2. Variable use of objective physical tests in the assessment of older patients prior to major surgery

Interviews: Variation in use of and access to objective physical tests (*convergent*)
Role of objective tests to guide optimisation *(convergent)*
Objective tests to help guide decision-making in those of 'borderline' fitness *(convergent)*
Limited by evidence-base for effectiveness on surgical outcomes (*divergent*)

Questionnaire: Variable use of objective tests in practice: 27/103 (26.2%) surgeons use objective physical tests in all elective patients and 49/103 (47.6%) only use them in patients for whom they have concerns *(convergent)*

Observational: Variable use of objective tests in practice: 14/42 (33.3%) elective patients underwent CPET testing, 2/42 (4.8%) performed a 6MWT and only 1/11 (9.1%) patients who underwent non-resectional management had CPET testing *(convergent)*

3. Frailty and geriatric assessment is important in treatment decision-making

Interviews: Frailty increasingly important in clinical decision-making but rarely formally incorporated into their own practice *(convergent)*
Patients identified as frail are not offered high morbidity operations *(convergent)*
No access to geriatric assessment in the pre-operative period for elective patients and rarely the time for emergency patients *(divergent)*
Geriatrician-led care important for emergency patients *(convergent)*

Questionnaire: Only 51/103 (49.5%) and 58/103 (46.3%) of surgeons perform a frailty assessment in all or selected patients in the elective and emergency settings respectively *(divergent)*
Despite dementia being rated highly in decision-making, 46/103 (44.7%) and 48/103 (46.6%) do not routinely ask regarding memory problems in elective or emergency patients respectively *(divergent)*

Observational: No patients saw a geriatrician pre-operatively and only 1/48 (2.0%) saw a geriatrician in the post-operative period *(divergent)*
High prevalence of frailty and vulnerability; in the emergency setting 3/7 (42.9%) vulnerable and 2/7 (28.6%) frail and non-resectional setting 3/11 (27.3%) vulnerable and 2/11 (18.2%) frail *(convergent)*

4. Lack of allied health professional input in the pre-operative period means that opportunities for optimisation are missed

Interviews: Lack of time in AHP job plans mean that it is rare for them to assess elective or emergency patients pre-operatively *(convergent)*

Earlier assessments would enable earlier interventions *(convergent)*

Questionnaire: Low levels of AHP involvement pre-operatively; 21/102 (20.6%) and 37/103 (35.9%) surgeons report input from OT in the elective and emergency settings respectively and 32/102 (31.4%) and 36/103 (35.0%) report input from social workers in the elective and emergency settings respectively, predominantly for patients for whom they have concerns *(convergent)*

Observational: Low levels of AHP involvement pre-operatively; 1/48 (2.0%) recalled seeing a physiotherapist, 0/42 recalled seeing a dietician or geriatrician, 1/48 (2.0%) recalled seeing the pain team, 1/48 (2.0%) recalled seeing the palliative care team *(convergent)*

5. Nutritional assessment is important in GI surgery patients

Interviews: Important for all patients, however access to dietician-led assessments difficult, particularly in the pre-operative period *(convergent)*

Nutritional screening forms part of some surgeon's assessment due to lack of dieticians *(convergent)*

Questionnaire: 76/103 (73.8%) and 72/103 (69.9%) of surgeons ask for weight loss in elective and emergency settings respectively *(convergent)*

61/103 (59.2%) and 79/103 (76.7%) surgeons never screen for micronutrient deficiencies in the elective or emergency settings respectively *(divergent)*

Observational: High prevalence of nutritional risk according to MNA; 23/58 (40.0%) were at risk, 7/58 (12.1%) were malnourished *(convergent)*

Only one elective patient 1/42 (2.4%) was assessed by a dietician pre-operatively *(divergent)*

6. Psychological assessment is important in GI surgery patients

Interviews: Psychological assessment rated as important but not formally assessed for by surgeons *(convergent)*

High burden for patients with non-malignant disease but limited access to specialist nurses or other sources of support (e.g. cancer support centres) *(convergent)*

Questionnaire: The majority of surgeons do not routinely ask a focused history for psychological issues; 81/103 (78.6%) and 80/103 (77.7%) surgeons do not ask elective or emergency patients respectively *(divergent)*

Validated screening questionnaires are rarely used routinely *(divergent)*

Observational: The EQ-5D-5L revealed overall quality of life to be lower for patients who underwent emergency compared to elective major surgery; 0.599 (-0.017-0.740) versus 0.837 (0.483-1.000) *(convergent)*

22/60 patients reported some degree of deficit with their mood (anxiety or depression) at baseline *(convergent)*

25/42 (59.5%) elective, 4/7 (57.1%) emergency and 1/11 (9.1%) non-resectional patients reported pre- operatively that they had been emotionally affected by their health (WHODAS 2.0) *(convergent)*

Table 39. Meta theme 2: Assessment of fitness for surgery in the older adult is variable and contributes towards variation in practice

9.3 Variation in the provision for and uptake of optimisation strategies

The key findings of the studies from this thesis in relation to this meta theme are summarised in Table 40.

There are multiple potential strategies to optimise older patients in the pre-, peri- and post-operative periods. These range from pre-operative exercise programmes, geriatrician-led optimisation, peri-operative strategies including ERAS through to early post-operative physiotherapy, delirium prevention strategies and post-discharge rehabilitation programmes. As demonstrated in the systematic review, the evidence base for pre-operative interventions in the older population is scarce, with comparison of available studies limited by diverse interventions and outcome measures. Multi-modal, exercise alone, nutritional and geriatrician-led prehabilitation programmes may help to reduce post-operative complications and length of stay but interventions designed specifically for the needs of the older population and robust studies to test their effectiveness are needed. The interviews, questionnaire and observational study have demonstrated variable provision for and uptake of pre- and peri-operative optimisation strategies, with poor provision of post-discharge rehabilitation programmes. Differences in HCP opinion regarding optimisation strategies may account for some of the variation observed alongside limited resources and poor integration between primary and secondary care. Prehabilitation and rehabilitation programmes have the potential to improve access to surgical treatments, as well as improve the long-term health and wellbeing of individuals, but varying access and provision may exacerbate existing variation in practice.

Optimisation strategies tailored to individual patients are urgently needed, alongside the resources to support their availability. The HCP interviews and questionnaires revealed variation in the involvement of allied health professionals in the care of older patients undergoing major surgery. In particular, access to geriatrician-led care and dieticians was limited at most hospitals, with many HCPs emphasising that they believe that greater involvement of these professionals would improve outcomes. Allied health professionals are ideally placed to advise on improving physical activity levels, nutritional optimisation and psychological coping strategies, depending on their background and level of

experience. However, underinvestment by hospitals means that the majority of their involvement is reactive rather than proactive. Variation in funding of services will likely widen differences in post-operative outcomes.

Meta theme 3: Variation in optimisation strategies for the older adult
1. Pre-operative promotion of physical activity and exercise-based prehabilitation improves outcomes Systematic review: Some evidence that exercise prehabilitation reduces complications In individual studies but was not confirmed on meta-analysis (mean difference -0.07 (95% CI -0.21 to 0.07); p=0.31, I^2 = 59%) *(Convergent)* Non-significant trend towards lower length of stay with exercise intervention seen on meta-analysis (mean difference -0.18 (-2.29 -0.14); p=0.08; I^2 = 31%) *(Convergent)* Interviews: Getting patients fitter improves post-operative recovery *(Convergent)* Role of prehabilitation in elective patients 'unfit' at presentation *(Convergent)* Promotion of physical activity important but many patients require support to make meaningful improvements *(Convergent)* Difficult to access/fund prehabilitation programmes *(Convergent)* Questionnaire: 55/103 (53.4%) of surgeons advise all and 28/103 (27.2%) advise selected patients regarding physical activity *(Convergent)* Only 17/102 (16.5%) currently refer all older patients for prehabilitation *(Divergent)* Lack of evidence currently to justify delaying treatment *(Divergent)* Observational: Variable patient recall of advice to improve fitness prior to surgery; 16/38 (42.1%) elective patients *(Divergent)* Only 2/38 patients (5.3%) attended formal exercise programmes before surgery *(Divergent)* Unable to comment on effect on outcomes due to low uptake
2. Optimisation of nutritional status improves outcomes Systematic review: Some evidence that nutritional prehabilitation reduces post-operative complications; meta-analysis (Risk difference -0.18 (95% CI - 0.26 to -0.10); p<0.001, I^2 = 0%) *(Convergent)* Only one study demonstrated a reduction on length of stay, with no difference seen on meta-analysis *(Divergent)* Interviews: Nutritional optimisation important but difficult due to lack of dieticians, difficult to get input pre-operatively *(Convergent)* Surgeons and nursing team often prescribe supplements themselves or give basic advice *(Convergent)* Questionnaire: Nutritional optimisation in the elective setting: 74/103 (71.8%) surgeons give advice, 77/103 (74.8%) prescribe oral supplements and 73/103 (71.6%) refer to dieticians in all or selected patients *(Convergent)* Less frequent referral to dieticians in the emergency setting: 38/100 (38.0%) refer all or selected emergency patients *(Divergent)* Observational: Only 3/38 (7.9%) elective patients and 2/6 (33.3%) non-resectional patients were prescribed dietary supplements *(Divergent)* No patients recalled seeing a dietician pre-operatively but 17/38 (44.7%) elective, 3/4 (75%) emergency and 1/6 (33.3%) non-resectional patients recalled post-operative input *(Divergent)*

3. Optimisation of psychological status is important

Systematic review: One study reported a reduction in length of stay with intervention
One study reported no difference in complication rate *(Divergent)*

Interviews: Many patients with cancer diagnoses would benefit from psychological support but little or no access to psychologists *(Convergent)*
CNS provide majority of psychological support *(Convergent)*
Peer support beneficial through Surgery School and group prehabilitation *(Convergent)*

Questionnaire: Surgeons themselves rarely advise on psychological preparation for elective or emergency patients, 81/103 (78.6%) and 91/103 (88.3%) give no psychological advice respectively *(Divergent)*

Observational High burden of psychological morbidity in the elective group (predominantly patients with cancer) *(Convergent)*
Only 1/38 (2.6%) elective patients reported receiving formal support to reduce anxiety pre-operatively *(Divergent)*
Specialist nurses were involved pre-operatively in 20/38 (52.6%) elective patients, 1/4 (25%) emergency and 3/6 (50%) non-resectional patients *(Convergent)*

4. Multimodal prehabilitation improves patient outcomes

Systematic review: Multimodal prehabilitation may reduce post-operative length of stay; three studies reported a significant reduction but this was not confirmed on meta-analysis (risk difference -0.7 (95% CI -1.76 to 0.37); p=0.2,I^2 = 68%) *(Convergent)*
Multimodal prehabilitation may reduce overall post-operative complications; meta-analysis (risk difference -0.1 (95%CI -0.18 to –0.02); p=0.01, I^2 = 18%) *(Convergent)*

Interviews: Role of addressing multiple deficits simultaneously *(Convergent)*
Challenges of engaging patients in addressing multiple adverse lifestyle factors simultaneously *(Divergent)*

Questionnaire: Prehabilitation programmes more likely to be unimodal exercise *(Divergent)*

5. Geriatrician-led optimisation improves patient outcomes but provision variable

Systematic review: A reduction in length of stay was observed with intervention in two studies *(Convergent)*
One study reported a reduction in complications *(Convergent)*

Interviews: Valuable particularly for emergency patients *(Convergent)*
Difficulty in securing funding for geriatrician-led input *(Convergent)*
Mixed opinions regarding their value in the elective setting *(Divergent)*

Questionnaire: Routine pre-operative input from geriatricians is rare *(Divergent)*
Pre-operative geriatric review for those in whom there are concerns is higher; 38/103 (36.9%) elective and 40/103 (38.8%) emergency *(Convergent)*
Post-operative geriatric input is more common; 76/103 (73.8%) reporting access for selected or all elective patients and 86/103 (83.5%) emergency patients *(Convergent)*

Observational: Only one emergency patient out of the whole cohort reported seeing a geriatrician in the post-operative period *(divergent)*

6. Post-operative AHP input after major GI surgery improves recovery but provision is variable	
Interviews:	Poor provision at most hospitals means patients do not get timely input *(Convergent)*
	Lack of integration of AHPs into surgical teams *(Convergent)*
Questionnaire:	Variable routine involvement of AHPs; Physiotherapists 83/103 (80.6%) all patients, specialist nurses 85/103 (82.5%) all patients, OTs 2/103 (1.9%) and 9/103 (8.7%) elective and emergency respectively *(Convergent)*
Observational:	Variable levels of AHP involvement in the post-operative period; 27/48 (56.3%) recalled seeing a physiotherapist, 21/48 (43.8%) recalled seeing a dietician and 10/48 (20.8%) recalled seeing an OT *(Convergent)*
	Unable to comment at present on whether this affected length of hospital stay or functional recovery
7. Post-operative rehabilitation programmes after major GI surgery are rare	
Interviews:	May have a role alongside prehabilitation but no current provision *(Convergent)*
Questionnaire:	Limited access with only 10/103 (9.7%) and 7/103 (6.8%) surgeons stating that they refer all elective and emergency patients respectively *(Convergent)*
	Many surgeons stated that improved access would benefit emergency patients *(Convergent)*
Observational:	No patients reported that they were planning on undertaking a rehabilitation programme (either arranged by the hospital or themselves) after discharge *(Convergent)*

Table 40. Meta theme 3: Variation in the provision of and uptake of optimisation strategies in the older adult

10 Discussion

Older patients can benefit from major GI surgery, with outcomes similar to younger cohorts, however, they need to be appropriately selected and optimised where possible. Older patients who are considered “fit” may not have geriatric conditions at the start of their treatment, however, the physiological stress of major surgery, post-operative complications and chemotherapy toxicities have the potential to render them vulnerable.

Variation in the assessment process for older patients likely contributes towards regional differences in major surgery rates. This is particularly relevant for patients with malignant disease who are classified as performance status 2 but may have the potential to improve with access to appropriate optimisation strategies. Also, for patients with non-malignant GI conditions where guidelines are scarce.

This thesis has explored some of the challenges related to the assessment and optimisation of older patients undergoing major GI surgery both from the perspectives of healthcare professionals and by studying the experiences of patients undergoing major GI surgery using patient reported outcomes and questionnaires. Optimisation strategies tailored to individual patients are urgently needed, alongside the resources to support their availability. Low levels of AHP involvement in the pre-operative period and variable involvement in the post-operative period may have contributed towards the prolonged lengths of stay observed in the observational study. Resource funding is often front-loaded with targets for speed of access and prompt treatment focusing resources at the start of the pathway. There are no targets relating to the quality of discharge care (other than to drive reduced length of stay which may have the reverse impact) and hence resources are not prioritised for this area.

In general, there was predominantly convergence of findings across the different data sources with agreement that older patients can undergo major GI surgery safely but that they should be appropriately assessed and optimised. Some divergence of findings between objective and subjective data is largely related to HCP perceptions such as the

importance of age and dementia being downplayed in interviews but clearly shown to be considered in practice suggesting a degree of denial about bias and/or unconscious bias.

There is an increasing role for primary care in the management of surgical patients at all stages of their treatment pathways[371]. As explored in the clinician interviews, there is potential for prehabilitation, patient optimisation and rehabilitation to be delivered in the community, co-ordinated by primary care rather than relying on overstretched secondary care. There is also a move for cancer to be managed as a long-term condition, with increasing emphasis on survivorship and late effects of cancer treatments[372]. This will require increased collaboration between primary and secondary care but has the potential to broaden opportunities for patient optimisation.

The limitations of the different methods used within this thesis have been discussed in each chapter. Applying a mixed-methods approach with application of the triangulation protocol[177] has hopefully reduced the impact of these limitations on the overall findings.

10.1 Effects of the pandemic on surgical practice and this thesis

The wide-ranging effects of the pandemic on surgical practice and the health and activity levels of the older population will have repercussions for years to come. The pandemic may have also influenced the findings of the studies included in this thesis in a number of ways.

10.1.1 Effects of COVID-19 on surgical practice during the pandemic

During the first wave of the pandemic there was evidence of 'risk-reducing' surgical practice related to guidelines from the surgical Royal Colleges[362]. There was a dramatic reduction in laparoscopic surgery due to concerns about aerosol generating potential. There was also an increase in stoma formation rather than primary anastomosis because hospital resources were stretched and anecdotal evidence to suggest that intensivist colleagues asked surgeons to employ strategies to reduce the risk of major complications requiring intensive care input. The very real risk of severe pulmonary complications from developing COVID-19 in the post-operative period may have led clinicians to advise patients against major surgery, particularly if they were considered to be at high risk of complications. There may have also been a change in practice regarding the assessment of frailty in surgical patients[367,370], again due to guidance from the Royal Colleges[362].

Changes to NHS working practices as a result of the COVID-19 pandemic now means that some patients may not meet their surgeon in person until late in the surgical pathway. This means that the face-to-face surgical assessment or 'end of the bed test' still valued by surgeons in the interviews and questionnaire study may need to be adapted in the face of this change. It is possible that virtual consultations may lead to over-investigation of older patients as clinicians seek to compensate for lack of face-to-face assessment. Conversely, it may mean that assessments prompted by subtle clinical findings do not happen, leading to a higher incidence of adverse events.

10.1.2 Effects of COVID-19 on physical activity and independence

Government advice throughout the pandemic has been for patients over the age of 70 and those with long-term health conditions to shield. This means the validity of a number of the questions in the physical activity and functional questionnaires in the observational study is debatable. In addition, many patients recruited to the observational study

reported not having left their homes for the previous 8 months due to the government guidance. Therefore, questions regarding engagement with community activities, doing their own shopping independently and using public transport may have been affected. It remains to be seen whether the oldest patients and those with frailty and co-morbidities will return to previous levels of physical activity and independence after the pandemic.

10.1.3 Effect of COVID-19 on patient decision-making

It is likely that more older patients decided not to undergo surgery during the pandemic for both malignant and non-malignant pathologies for a number of reasons. These include concerns regarding catching COVID-19 in hospital and general anxiety regarding their health. Cancer services have been severely impacted by the pandemic with delayed access to primary care and diagnostic tests resulting in delayed diagnoses. There has also been a reduction in patients presenting with cancer symptoms and a rise in late-stage cancer diagnoses, suggesting that the pandemic has affected health advice seeking behaviour. Changes in radiotherapy use during the pandemic for certain GI cancers suggests that radiotherapy may have been used to compensate for reduced surgical activity[373].

10.1.4 Effect of COVID-19 on this research project

As mentioned above, the pandemic has potentially affected the findings of this research project in a number of ways. More general effects on the research project included a significant delay in receiving health research authority approval and local R&D approvals for the observational study which has resulted in only the single centre data being included in this thesis. Delays at multiple stages in this project have meant that the planned patient interviews will now be performed in the post-doctoral period. Much of the research support that was anticipated at smaller hospitals in the region to deliver the observational study was affected by redeployment, shielding of research staff and prioritisation of COVID studies. These factors are likely to continue to affect surgical research projects in the future.

10.2 Future research

10.2.1 Research in the older adult population

As stated in the introduction, older patients are under-represented in the majority of surgical and oncology trials due to concerns over the interaction of co-morbidities with interventions or strict inclusion and exclusion criteria. This study has demonstrated the feasibility of recruiting older patients to an observational study and willingness to participate despite the context of the pandemic. Only two patients who were approached declined participation in the observational study. Research efforts should focus on interventions to improve the fitness of 'high-risk' older individuals, interventions that can be delivered to all surgical patients, outcome measures that are of importance and relevance to older patients and the cost-effectiveness of interventions.

There is a lack of research evidence on the surgical management of patients with cognitive impairment. Research including cognitively impaired patients is challenging with a higher level of ethical oversight required, so the majority of data available is from observational sources. National audits, such as NBOCA, suggest that patients with dementia do not have equitable access to the same surgical treatments as patients without cognitive impairment[27].

The observational study has demonstrated that it is feasible to ask older patients to complete self-assessment questionnaires and that the results of these could potentially be used to inform decision-making and optimisation strategies. If no deficits are identified on self-assessment, patients could proceed to surgery with generic advice, however if deficits are identified it could trigger more detailed assessment, support and shared decision-making.

10.2.2 Research in the emergency GI surgery population

Numerous studies have demonstrated that older patients undergoing emergency surgery are at elevated risk for poor outcomes[128,294374]. They have high levels of baseline co-morbidity, frailty, malnutrition, physical inactivity and functional impairments, the majority of which were confirmed in the observational study. As explored in the interview chapter, there is little time for pre-operative assessments or optimisation, therefore efforts must focus on streamlining their pathway to surgery and early multidisciplinary

input in the post-operative period. Research is needed to determine the impact of early multi-disciplinary input and post-operative interventions on length of stay and cost effectiveness to enable appropriate investment by hospitals.

Enrolment of emergency GI surgery patients to research studies is challenging due to their frequent presentation outside of normal working hours and the short time period from presentation to surgery. Whilst the number of patients undergoing emergency GI surgery in the observational study were low, the observation of improvements in functional status across multiple domains from baseline to 6 weeks warrants further study. Engagement and training of surgical trainees in research skills via the surgical research networks is vital to facilitate recruitment from this challenging population.

10.2.3 Research in older patients who are deemed 'unfit' for surgery

There is an increasing population of patients developing GI surgical conditions amenable to major surgery but who are deemed "unfit" or who decline surgery. They represent a diverse group of patients from those who are managed in the community due to severe functional or cognitive impairments, those who are managed under medical specialists for other health problems, those who are managed in district general hospitals but do not see subspecialists due to poor performance status and those judged to be 'unfit' by surgeons or on objective testing. Determining best practice in this group is challenging due to a lack of research or evidence-based guidelines. It may be that some patients in this heterogenous group could benefit from major surgery if they undertake a period of personalised optimisation. There may be other patients who could potentially undergo non-resectional procedures that could improve their quality of life, symptom control or disease outcomes. Others could potentially benefit from multi-disciplinary assessment and optimisation alone.

The observational study has shown that it is feasible to recruit from this population and there is a suggestion from the results that patients in this group experience functional decline by as early as 6 weeks. It is hoped that ongoing recruitment to the observational study at other sites in the region may be able to strengthen these findings. As discussed in Chapter 8, patients who underwent 'non-resectional' management did not differ

significantly in the majority of domains at baseline from those who underwent major surgery. It is possible that frailty and senescence biomarkers may have a role in helping to objectively define those 'unfit' for major surgery. Many HCPs in the semi-structured interviews spoke about not operating to try to preserve an 'unfit' patient's quality of life, however, this is mainly based upon anecdotal evidence. Research into addressing the palliative care needs of older patients who undergo both major surgical and non-resectional management for surgical pathology is also urgently needed[374].

The Emergency Laparotomy Frailty study (ELF-2) currently underway in the UK is looking at outcomes for patients who do not undergo an emergency laparotomy[375]. It is hoped that this study will help to define the group in whom major emergency surgery is considered to be futile. It is also hoped that it will generate more interest in this overlooked field of surgical research.

10.2.4 Research in assessment and optimisation of older adults

There is an urgent need for National guidelines and standards for the assessment and optimisation of older people undergoing major GI surgery. As already demonstrated by NELA[376], these will drive improvements and investment in services. Investment is needed in the provision of allied health professional (including geriatric specialists) input pre- and post-operatively to enable multi-professional input and optimisation for patients most at risk of poor outcomes as early as possible.

This thesis has demonstrated that the evidence base for prehabilitation interventions in the older patient is low and there is a lack of consensus of what outcomes should be measured. The clinician interviews and questionnaires reveal a lack of equipoise regarding how older patients should be assessed and optimised.

10.2.5 Economic utility of peri-operative optimisation strategies in the older patient

As demonstrated in the healthcare professional interviews and questionnaire study there is wide variation in optimisation strategies currently used in UK surgical practice. These range from inexpensive (advice leaflets, virtual surgery school) through to highly expensive (individualised intensive prehabilitation programmes with CPET assessments).

There is a paucity of published literature addressing the economic utility of the majority of these interventions, particularly in relation to quality of life outcomes, and this is urgently needed. These data will help to drive investment in services, particularly those at risk of being 'overlooked' as simple or routine. It is also possible that low cost interventions may actually be more acceptable to older adults and associated with improved patient reported outcomes. This requires appropriately designed studies with health utility integrated in the study design.

10.2.6 Recommendations for future research

This thesis has revealed a number of different research questions that could be addressed in future research studies. Some of the most pressing questions are discussed below:

1. *What is the prevalence of occult cognitive impairment in the elective GI surgical population? Does it predispose to the development of post-operative delirium and what interventions are available/effective?*
   This could be addressed by a simple observational study or service improvement project with the involvement of geriatric specialists.

2. *How should patients with dementia with major GI pathology be investigated and managed?*
   This could be addressed by a mixed methods study with multi-professional involvement. It would be a complex study and require high levels of ethical oversight. There are a number of different aspects that could be explored such as attitudes of patients with dementia, their carers and healthcare professionals (particularly primary care doctors) towards major surgery and intensive investigations in patients with dementia.
   Long term longitudinal studies of patients with dementia diagnoses would also be useful to look at the incidence of major GI pathology in this population, investigations, interventions and outcomes.

3. *What can be done to improve the outcomes of older patients 'unfit' for major surgical procedures?*
   This would be an excellent collaborative project with palliative care and geriatric colleagues. This could be addressed using qualitative methodologies to explore the needs and wishes of older patients, their carers and families.

4. *What is the impact of standardised comprehensive patient self-assessment at point of referral on surgical decision-making and treatment?*
   This could be addressed using a number of different methodologies, both research and service improvement models. One potential would be to present clinicians with patient self-assessment reports (including physical activity levels, cognitive, nutritional and frailty measures) after they have made their surgical plan and then explore whether this information would have changed their surgical strategy or led them to perform more objective tests.

5. *Which patients deemed 'unfit' at GI cancer MDTs would benefit from a personalised prehabilitation programme? How many of these would go on to have surgical resection? What is the effect of prehabilitation on overall and disease specific outcomes in this population?*
   This could be addressed using a conventional RCT design whereby patients deemed 'unfit' but with operable disease at the MDT could be randomised to prehabilitation or best supportive care.

10.3 Digital technologies

The pandemic has driven digital innovations within the NHS, in particular the introduction of virtual consultations. This has the advantage of enabling patients to attend appointments from the comfort of their own homes and offers the potential for remote delivery of optimisation strategies such as prehabilitation, specialist interventions and Surgery School[370377–379]. However, efforts will be needed to ensure that older patients, particularly those from low socioeconomic backgrounds (in whom Information Technology literacy levels may be low), are not disadvantaged by these innovations.

The role of digital technologies has not been addressed in this thesis, but they are likely to have an important role in patient care in the future. Already, they are being shown to be useful in promoting behaviour change and monitoring the effects of optimisation strategies[380381]. It is likely that they will be used to monitor for the development of post-operative complications, even once patients leave hospital, which will likely result in shorter lengths of stay but quicker investigation and intervention when problems are identified[382]. The role of telemedicine in delivering prehabilitation has also expanded during the pandemic, with a number of studies reporting early favourable experience[377–379].

10.4 Implications for policy makers

This thesis has identified variation in attitudes towards older patients facing major GI surgery and in views and practice regarding how they are assessed and optimised. This variation could contribute towards lower surgery rates in older adults and poorer outcomes observed in both the elective and emergency settings for patients who do undergo surgery. It is vital that policy makers consider strategies to reduce variation across GI surgery, particularly in relation to older patients and those with cognitive impairment.

10.5 Conclusion

This study has explored the opinions of healthcare professionals regarding major GI surgery in the older population, methods of assessment and optimisation. It has looked at the evidence base for pre-operative interventions and their effects on surgical outcomes. It has studied variation in the views of healthcare professionals, access to resources and multi-disciplinary input for older patients facing major GI surgery across the UK. Finally, it has studied the implementation of assessment and optimisation strategies in clinical practice with functional outcomes measured. It is hoped that recognition of the variation in practice in older adults detailed in this thesis will stimulate further research, highlight the importance of standardising practice and direct additional resources to deliver service improvements to try to address this. The increasing age of the UK population means that these issues are becoming more important and optimising care pathways for these more vulnerable patients needs to be prioritised.

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12 Appendices

Appendix A: BDRF grant application

Bowel Disease Research Foundation

1. Name of the investigator	Sarah Daniels
2. Job title	Clinical research fellow
3. Email address	sarahdanielsx@gmail.com
4. Tel. No.	07941605424
5. Institution	University of Sheffield
6. Name of supervisor	Prof Steve Brown
7. Name of Co-investigators	Prof L Wyld, Dr G Holmes, Dr C Mitchell, Mr M Lee
8. Name of investigator who is an ordinary member of ACPGBI	Steve Brown
9. Title of Project	Optimising the care and treatment pathways for older patients requiring emergency major abdominal surgery
10. Lay Title	Improving outcomes for older people undergoing emergency abdominal surgery
11. Length of project	20 months
11a. Proposed start date	1/02/19
12. Have you received any grants from BDRF before?	no

Funding requested

11.a Total amount	£8647
11.b Breakdown of costs	REDCap database £500 Consumables (photocopying, postage, envelopes) £200 Health economics support (G Holmes directly incurred): 69 hours = £2,213 Statistical support via Sheffield Statistical support Unit (directly incurred): 165 hours = £4,433 Travel expenses between recruiting sites in region to set up study and monitor data quality £500 Interview transcription costs £800
11.c How many instalments	n/a
11.d In which months instalments are to be paid	n/a
11.e Justification of support requested (Explain why each item of expenditure is needed)	Funding for the REDCap database will enable secure storage of patient data. Health economic analysis will be performed with support from an experienced health economist from ScHARR and statistical support that will be provided by the University of Sheffield Statistics Support Unit.

	Funding for consumables and travel expenses will facilitate running of the study across multiple sites. Funding is also required for transcription costs for the qualitative arm.
12. Has the institution administering funding agreed exemption from overheads?	Yes ☐ ☐

Project Details

13. Background to project

In England and Wales it is estimated that ~30,000 patients require emergency major abdominal surgery annually. Of these 15% will not survive to discharge and those that do survive experience high rates of postoperative disability. Despite a higher proportion of elderly patients presenting with emergency surgical conditions, the proportion that undergo an operation is far lower than for younger populations[1]. Over 50% of emergency cases are over the age of 65 years and they suffer a disproportionately high mortality rate compared with younger cohorts[2]. The National Emergency Laparotomy Audit shows wide variation in mortality rates across the UK, and suggests that outcomes could be improved[3]. UK outcomes are worse than those in other comparable European countries and the US, demonstrating room for improvement[2]. Whilst some excess mortality is inevitable due to the increasing rates of senescent organ dysfunction, multi-morbidity, and frailty in older patients, outcomes may be improved by detailed examination of the care pathways for these patients and ensuring that evidence-based age and fitness optimised care is provided at each step. There is a lack of evidence-based guidance in this area, as the elderly are underrepresented in clinical trials and there is often no stratification for baseline health status[4].

Many older patients are inadequately assessed by surgical teams in the emergency situation, with many not having their previous levels of fitness, frailty, care needs, or estimated risk of morbidity and mortality clearly documented prior to commencing major surgery[1]. This is in contrast to the detailed assessments made by specialist geriatric teams, which can identify areas where health problems may be improved or abrogated before and during surgery and facilitate discharge care planning to take into account frailty and dependency. There is a wide range of proven techniques to enhance outcomes in the perioperative period. These are infrequently applied in the emergency setting, often due to time constraints. Such care is often delivered 'out of hours' and may not be consultant led, multi-professional or multi-disciplinary. Assessments may include nutritional assessment and support, prehabilitation and rehabilitation, medical optimisation, comprehensive geriatric assessment, adequate pain control and social services engagement to provide discharge support for example.

There is a paucity of knowledge about the treatment experiences and wishes of elderly patients within emergency surgery. The limited available literature suggests that older patients value independence and quality of life highly and are fearful of burdening friends and family. Inadequately planned care, poor preparation and poor decision making may increase risks of such adverse outcomes, as well as emergency readmission and prolonged length of stay, all of which place huge burdens on the NHS and social care.

Aims: To determine the range of different pathways an elderly person undergoing major abdominal surgery may take and which interventions in these pathways are associated with better outcomes. This will include:
- Retrospective and prospective cohort data to evaluate utilisation of interventions and estimate efficacy in the NHS
- Health economics assessment of a range of identified interventions
- Qualitative assessment of intervention impact, efficacy and utility from a patient, carer and health professional standpoint

14. Methodology

i) Cohort study We are undertaking a prospective, multicentre observational cohort study with pathway mapping to look at older patients' emergency general surgical pathways from initial presentation through to discharge into the community and at 6 months follow up. 130 patients aged 75 and older presenting as an emergency with a bowel condition requiring emergency or urgent (unscheduled) surgery at three hospitals (University hospital, large District General hospital, small-mid size District General Hospital) within the region. Written informed consent will be obtained from the patient or next of kin at the time of consenting for theatre for access to their clinical records, permission to send them questionnaires and to contact them for interviews. Data collection will be supported through surgical trainees via the regional trainee research collaborative, and research nurses. Ethics and R&D approval is currently being sought.
In depth baseline data including age, multi-morbidity (CCI), frailty level (CFS), cognitive impairment (MMSE), malnutrition score (MUST), social deprivation index will be obtained from clinical notes and summary care records for all patients. In addition, route of entry to hospital and access to pre-hospital services will be obtained from Yorkshire Ambulance Service. Hospital stay details will be obtained from clinical notes and include timing of imaging, peri-operative optimisation and reviews, operative details, post-operative destination, ITU/HDU length of stay and timing and frequency of physiotherapy, occupational therapy, and social services input. The primary outcome is 30 day mortality. Secondary outcomes will include length of stay, discharge destination, care needs on discharge, readmission rate at 30 days, comprehensive complication index, Hospital Anxiety and Depression score (HADS) and patient reported outcomes (SF36, GIQLI) at 6 weeks and 6 months. A modified, bespoke CSRI (Client Service Receipt Inventory) focused on healthcare resource-use will be collected to facilitate health economic analysis (i.e. healthcare resource-use and associated costs over the six month study-period and six-month pre-baseline) as well as the EQ-5D-5L to assess generic health status, both to be collected at baseline and six months post-baseline, with the EQ-5D-5L also collected at 6 weeks post-baseline. Statistical analyses will include Cox proportional hazards and the accelerated failure time models to assess simultaneously the effect of several risk factors on survival time. All statistical analyses will be performed in SPSS.
ii) Qualitative interviews A series of semi-structured interviews will be performed with patients, their carers and members of the wider healthcare professional team. These will explore two key areas: the preferences for care, the barriers and facilitators to best practice. It is anticipated that up to 25 participants will be required for each group of interviewees, although recruitment may terminate early if saturation is reached. Analysis will use a framework approach to derive themes, with triangulation across researchers and sources using NVIVO software.

Patient integration: Improving outcomes following emergency surgery in the elderly has been identified as a priority by the James Lind Alliance. Sheffield Teaching Hospitals has an emergency surgery PPI panel, and this study will be developed further with input from this group. This will include integration of a lay member onto the steering group, and to provide additional review of interview transcripts or findings. They will also be involved in the dissemination of findings.

Anticipated outputs: This application is for funding to supplement a specific part of an extensive mixed-methods project that will address ways to optimise the care and treatment pathways for elderly patients undergoing major abdominal surgery. Findings of this project will directly benefit patients by identifying feasible interventions. Data from this project will be used to support a grant application for a trial of interventions to improve outcomes of frail patients in the emergency general surgery setting.

The project team have extensive experience in this area; L. Wyld conducted the large AGEGAP prospective cohort study that showed significant rates of undertreatment in older patients, C. Mitchell has experience from a primary care perspective of conducting RCTs in community based pre-habilitation, S. Brown has experience of complex interventions in colorectal disease trials and G Holmes has experience in the economic evaluation of studies focussed on an older population (aged 65+ years). M Lee has experience of delivering multi-centre cohort studies in emergency surgery.

15. References (if any): Maximum of 4

16. Sample size and source of statistical advice (if appropriate)

Prospective cohort study with expected prevalence of primary outcome (death at 30 days) of 15%. 95% CI +/- 0.06 gives a sample size of 137 patients

17. Have you applied for or acquired funding from any other sources(s) to support this work? No

18. **Lay summary**

a) Problem addressed, background and strategic significance

Improving emergency surgery outcomes particularly in the elderly is a key priority for the NHS. More and more people are living into old age and developing multiple medical conditions, long-term disabilities and frailty. Those admitted with surgical emergencies are increasingly difficult to treat and may not be fit enough for standard surgery. If they do undergo surgery, they do not tend to do as well as younger patients.

b) Method(s) used

The study will collect detailed information on a group of elderly patients from when they arrive in hospital, about the preparation for emergency surgery, what happens to them afterwards and following them up for 6 months after discharge. Information includes events leading up to hospital admission, choice of operation and what risk or fitness assessments were carried out, questionnaires about quality of life, return to previous activities, healthcare usage and cost to the NHS. Some patients, their relatives and healthcare professionals will be interviewed to explore how they feel that care could be improved.

c) Hoped for results of this research

This study will be the first to look in detail at the entire pathway for older emergency surgical patients. In collaboration with colleagues from other disciplines involved in the care of these patients we will identify which aspects of care could be improved

and how. Ultimately we hope to be able develop an enhanced pathway of care for these patients, to be tested in a larger trial.

d) What this research is expected to add to the knowledge of bowel disease and what is the impact you hope to achieve for patients?

Elderly patients presenting with emergency bowel problems have not been studied extensively. And yet, because the outcomes are generally poorer than younger patients or those undergoing planned surgery, this is an area desperate for improvement. It is hoped that this project, through mapping different pathways in detail, will identify areas where improvements can be made and tested to improve these outcomes.

Appendix B: BDRF award letter

BDRF Grant application

Glen Saffery <gsaffery@bdrf.org.uk> 13 February 2019 at 13:39
To: "sarahdanielsx@gmail.com" <sarahdanielsx@gmail.com>

Dear Sarah

Further to the BDRF Board of Trustees meeting held on 12th February 2019 I am delighted to inform you that your application for a BDRF Research Grant has been successful.

BDRF has agreed to fund £8,647 towards the project titled: 'Optimising the care and treatment pathways for older patients requiring emergency major abdominal surgery'

This is upon signed agreement by you to the Terms and Conditions stated in the attached document.

BDRF will need a letter on your organisation's letterhead to enable us to release payment of your grant in due course.

The letter should include:

A) Signed agreement by you (the Project Lead) to the BDRF Grant Terms And Conditions

B)The amount of the grant, to whom BDRF's cheque should be paid and details of where and who to send it;

C) The proposed start date for the project and planned end date (we recognise these may change);

D) Confirmation that the full amount of the grant will be applied towards this research and that no deduction from it will be made by your organisation before such application.

Payment of Funds

Payment of funds will be made in arrears upon receiving an itemised invoice for the work agreed in your application.

Please outline your preferred payment dates and amounts for your project.

In finalising the payment date(s) BDRF's main priority will be to ensure the smooth operation of your project but we will also wish to maximise our cash flow to facilitate the funding of future research projects.

Payment details will be agreed with you after receiving your letter of grant confirmation outlined above.

Any amount of the grant which is not spent on the designated project by the date which is 6 months after the proposed end date provided for in (B) above shall be returned to BDRF unless otherwise agreed by BDRF in writing.

Please can you e-mail back confirming your acceptance of the attached Terms & Conditions along with a copy of your acceptance letter?

Such acceptance is a pre-condition to any advance of funds.

NIHR Portfolio

BDRF is a National Institute for Health Research (NIHR) non-commercial Partner. This means the studies that we fund may be eligible to access NIHR Clinical Research Network (CRN) support.

If your study will be of benefit to patients and the NHS, (this includes relevant research in public health and social care) we expect you to apply, where appropriate, for NIHR CRN support and subsequent inclusion in the NIHR CRN Portfolio of studies to fully benefit from the support that the CRN offers through their Study Support Service. To find out more, please visit www.supportmystudy.nihr.ac.uk

If your study involves NHS sites in England you will need to apply for Health Research Authority Approval. For guidance on submitting an application please visit: www.hra.nhs.uk

Finally……

Congratulations on the success of your application. We look forward to working with you and hope your project proves to be a great success. If you need a hard copy of this email, please let me know and tell me your postal address.

Best wishes

Glen

Glen Saffery
Coordinator

Bowel Disease Research Foundation

gsaffery@bdrf.org.uk

T: 0207 869 6946

c/o Royal College of Surgeons of England| 35-43 Lincoln's Inn Fields|London|WC2A 3PE

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Appendix C: Re-submitted BDRF grant application

Bowel Disease Research Foundation

1. Name of the investigator	Sarah Daniels
2. Job title	Clinical research fellow
3. Email address	sarahdanielsx@gmail.com
4. Tel. No.	07941605424
5. Institution	University of Sheffield
6. Name of supervisor	Prof Steve Brown
7. Name of Co-investigators	Prof L Wyld, Dr C Mitchell, Dr Maria Burton, Mr M Lee
8. Name of investigator who is an ordinary member of ACPGBI	Steve Brown
9. Title of Project	Optimising the care and treatment pathways for older patients facing major gastrointestinal surgery (OCTAGON)
10. Lay Title	Improving outcomes for older people facing major gastrointestinal surgery
11. Length of project	12 months
11a. Proposed start date	1/07/20
12. Have you received any grants from BDRF before?	no

Funding requested

11.a Total amount	£8,647
11.b Breakdown of costs	STH costs: 5% Directorate Co-ordinators time 0.09 WTE for 3 months for study set up and archiving £800 Clinical trials assistant time at £100 per patient for 30 patients £3000 Consumables (photocopying, postage) £200 Statistical support via Sheffield Statistical support Unit (directly incurred): 82 hours = £2,200 Interview transcription 30x30minutes @ £72/hour = £1,080 ACPGBI meeting attendance £467 Open access publication £900
11.c How many instalments	n/a
11.d In which months instalments are to be paid	n/a
11.e Justification of support requested (Explain why each item of expenditure is needed)	Funding towards the setup and co-ordination of the study from Sheffield Teaching Hospitals will facilitate the running of the study and obtaining necessary regulatory approvals. Funding to support Clinical Trials Assistant (CTA) time at STH

	has been requested as this will likely be the highest recruiting centre and will enable the PI to spend more time engaging with other centres and performing patient interviews. The CTA will be able to facilitate recruitment and follow-up of patients. Funding is required for transcription costs for the qualitative arm (this is increased from the original application as the cost per minute is higher than originally estimated). Funding has been requested for statistical support that will be provided by the University of Sheffield Statistics Support Unit. Funding towards conference attendance and open access publication fees will facilitate dissemination of the research findings. Funding for access to the REDCap database is no longer required as we have managed to secure this for free through the University of Sheffield. Health economic analysis will no longer be performed due to the complexities of the patient population and interventions that we are aiming to study. This formed a substantial part of the original funding application, which is why we are asking to redistribute the funds that were originally allocated to this on study set-up/running, digital transcription and publication/dissemination costs.
12. Has the institution administering funding agreed exemption from overheads?	Yes [X] ☐

Project Details

13. Background to project

The UK population is aging. Under-investigation and under-treatment of older people is common, with rates of surgery declining with age, despite the incidence of surgically treated gastrointestinal (GI) pathology increasing with age (1). There are large variations in outcomes in older people, between different surgical units in the UK, which suggests that not all patients are receiving the same level of care or access to resources(2). In GI surgery, the concern is that patients in centres with low elective surgery rates will be inappropriately denied the benefits of operative intervention (disease control, symptom improvement), with consequently higher rates of emergency admission and intervention(2). Conversely, in centres with high rates of elective surgery, patients may be inappropriately subjected to the morbidity or even mortality of surgery with limited or no benefit.

Major surgery remains one of the most debilitating events that an older person may experience and may profoundly influence functional decline and disability. Adverse factors associated with ageing include co-morbidity, polypharmacy, cognitive impairment, dependency and frailty. There is also a natural decline in cardiorespiratory fitness with age, however this may be modifiable with physical activity or exercise. Malnutrition and psychological problems are also very common in patients requiring GI

surgery. When these at-risk individuals are exposed to the stress of major abdominal surgery, post-operative mortality and morbidity also increase(3). Common lifestyle choices, including smoking, excess alcohol consumption and sedentary behaviours, add to this risk.

Whilst some excess mortality is inevitable due to the increasing rates of senescent organ dysfunction, multi-morbidity, and frailty in older patients, outcomes may be improved by multi-professional input and tailored care pathways for these patients and ensuring that evidence-based age and fitness optimised care is provided at each step(4). There is a lack of evidence-based guidance in this area, as older people are underrepresented in clinical trials and there is often no stratification for baseline health status.
There are a wide range of proven techniques to enhance outcomes in the perioperative period, but there is variation between hospitals and clinicians in whether and how these are implemented(4). These are infrequently applied in the emergency setting, often due to time and resource constraints. Techniques may include nutritional support, prehabilitation and rehabilitation, medical optimisation, comprehensive geriatric assessment, pain management and social services engagement to provide discharge support, for example.
There is a paucity of knowledge about the treatment experiences and wishes of older patients within gastrointestinal surgery. The limited available literature suggests that older patients value independence and quality of life highly and are fearful of burdening friends and family. Inadequately planned care, poor preparation and poor decision-making may increase risks of such adverse outcomes, as well as emergency readmission and prolonged length of stay, all of which place huge burdens on the NHS and social care.
Aims: This study aims to determine:

- The range of different pathways an elderly person undergoing major gastrointestinal surgery may take
- Which baseline characteristics of older patients with GI pathology amenable to major surgery are predictive of poor post-operative functional recovery
- Whether certain baseline characteristics mean that an individual is more likely to undergo a risk-adapted procedure or conservative management.
- What the views of older patients who have undergone elective and emergency surgical management are regarding enhanced perioperative support measures and fitness/risk assessment.

14. Methodology

i) Retrospective pathway mapping exercise A regional, retrospective pathway mapping exercise will be carried out over a set period to determine the range of different pathways that older patients may take at different surgical units in the region. This will be registered as a service evaluation by a local trainee at each of the participating units.
ii) Observational study We are undertaking a prospective, multicentre observational cohort study to look at older patients' GI surgical pathways from initial presentation through to discharge into the community and at 6 months follow up. 130 patients aged 65 and older presenting with bowel and GI conditions requiring emergency, urgent or elective surgery at up to five hospitals (University hospital, large District General hospital, small-mid size District General Hospitals) within the region will be recruited. Written informed consent will be obtained from the patient for access to their clinical

records, for completion of validated and bespoke questionnaires and to contact them for one-to-one interviews. Data collection will be supported through surgical trainees via the regional trainee research collaborative, research nurses through NIHR portfolio adoption and a clinical trials assistant. HRA and REC approval have been granted.
In depth baseline data including age, co-morbidity, frailty level, cognitive impairment and malnutrition score, will be obtained from clinical notes and through questionnaires for all patients. Hospital stay details, operative details, post-operative destination and complications will be obtained from clinical notes and a bespoke questionnaire will gather information from patients on peri-operative optimisation and reviews. The primary outcome is functional recovery at 6 weeks post-operation/procedure or decision not to operate. Secondary outcomes will include health related quality of life at 6 weeks, length of stay, treatment related adverse events and overall survival. Statistical analyses will include multiple regression to assess the impact of baseline health and fitness on functional and surgical outcomes. All statistical analyses will be performed in SPSS.
iii) Qualitative interviews A series of semi-structured interviews will be performed with patients, either face-to-face or via telephone. These will explore their views on peri-operative support measures, what they feel are the barriers and facilitators to implementing these, what more they feel could be done and how they would like this to be delivered. We will also explore perceptions of fitness and risk assessment and what this means to individuals. It is anticipated that up to 25 participants will be required, although recruitment may terminate early if saturation is reached. Analysis will use a framework approach to derive themes using NVIVO software.
Patient integration: Improving outcomes following GI surgery in older people has been identified as a priority by the James Lind Alliance. The PPI panel at Doncaster and Bassetlaw NHS Foundation Trust has been involved in reviewing the study protocol and developing it. Two lay members have been integrated onto the steering group, and they will provide additional review of research outputs. They will also be involved in the dissemination of findings.
Anticipated outputs: This application is for funding to supplement a specific part of an extensive mixed-methods project that will address ways to optimise the care and treatment pathways for older patients undergoing major GI surgery. Findings of this project will directly benefit patients by identifying feasible interventions for further study. Data from this project will be used to support a grant application for a trial of interventions to improve outcomes of frail patients in the GI surgery setting.
The project team have extensive experience in this area; L. Wyld conducted the large AGEGAP prospective cohort study that showed significant rates of undertreatment in older patients, C. Mitchell has experience from a primary care perspective of conducting RCTs in community based pre-habilitation, S. Brown has experience of complex interventions in colorectal disease trials and M Burton has extensive qualitative research experience. M Lee has experience of delivering multi-centre cohort studies in emergency surgery.
15. References
16. Sample size and source of statistical advice if appropriate

Prospective observational study: pragmatic sample size estimation of 120 patients

17. Have you applied for or acquired funding from any other source(s) to support this work? No

18. **Lay summary**

e) Problem addressed, background and strategic significance

Improving gastrointestinal (GI) surgery outcomes, particularly in the older population, is a key priority for the NHS. More and more people are living into old age and developing multiple medical conditions, long-term disabilities and frailty. Those presenting with GI pathology are increasingly difficult to treat and may not be fit enough for standard surgery. If they do undergo surgery, they do not tend to do as well as younger patients.

f) Method(s) used

The study will collect detailed background health information on a group of older patients from when they are first referred to GI surgeons, what strategies are used to try to ensure that they make a good recovery after surgery, what type of operation they undergo and whether they have any problems whilst in hospital and follow them up for 6 months after discharge. Information includes how healthy and independent they are before any intervention, choice of operation and what risk or fitness assessments were carried out, questionnaires about quality of life and return to independent living. Some patients will be interviewed to explore how they feel that care could be improved.

g) Hoped for results of this research

This study will be the first to look in detail at the entire pathway for older GI surgical patients, both planned and emergency. In collaboration with colleagues from other disciplines involved in the care of these patients we will identify which aspects of care could be improved and how. Ultimately we hope to be able develop interventions for these patients, to be tested in a larger study.

h) What this research is expected to add to the knowledge of bowel disease and what is the impact you hope to achieve for patients?

Older patients presenting with GI problems requiring surgery have not been studied extensively, and yet, because the outcomes are generally poorer than younger patients, this is an area desperate for improvement. It is hoped that this project, through mapping different pathways in detail and assessing patients thoroughly at different time points, will identify areas where improvements can be made and tested to improve these outcomes.

Appendix D: BASO grant application

BASO~The Association for Cancer Surgery

at The Royal College of Surgeons of England
35-43 Lincoln's Inn Fields, London WC2A 3PE
Telephone 020 7869 6854 Email admin@baso.org.uk
www.baso.org.uk

BASO~ACS Project Grant

2018 APPLICATION FORM

1. Personal Details

Surname : Daniels	
Forenames *(in full)*: Sarah Louise	
Dr/Mr/Mrs/Miss/: Miss	**Male/Female: Female**
Date of Birth: 28/09/1984	**Nationality: British**
Current Home Address: **Steep Meadows** **Sheffield Road** **Hathersage S32 1DA**	
Tel. No: 07941605424	**Day-time Tel. No.:**
E-mail address: sarahdanielsx@gmail.com	
BASO Membership Number: 104309	

2. Details of Appointment

Title of Current Position: Specialist trainee year 4 (StR4)
Surgical Specialty: General Surgery
When did you take up the appointment? 2012 (as an ACF in Surgical Oncology)
Name of Institution: University of Sheffield Medical School
Address: **The Medical School** **Beech Hill Road** **Sheffield** **S10 2RX**

Telephone Number: 0114 222 5522	**Mobile Number: 07941605424**
E-mail: sarahdanielsx@gmail.com	
Head of Department: Allan Pacey	

3. The Research

Title of Research (not more than 20 words):
Optimising the Care and Treatment Pathways for Older Patients with colorectal cancer

Summary of your Research Programme, including study design and methodology, objectives and appropriateness of study for specialty *(form to include a lay abstract of up to 300 words, an introduction setting out the background of the project and why it is necessary (up to 1000 words) and including a defined set of aims and objectives, a methods sections (500 words), a section detailing outputs planned, details of collaborators (including letters of support in appendices)***:**

Lay abstract (300 words)

The UK population continues to age due to increasing life expectancy, however there are also more people living longer with chronic diseases and disability. This population with high levels of frailty and multiple medical problems is presenting new challenges to health and social care. Due to advances in anaesthetic techniques and post-operative management we are now able to safely operate on patients with multiple medical problems (e.g. diabetes, chronic kidney disease) and frailty, however their bodies have a reduced capacity to cope with the trauma of surgery, particularly if complications occur. This may result in prolonged hospital stays, increased care and rehabilitation needs on discharge and some patients may never return to their previous levels of independence, fitness or function.

There is much interest in how we assess elderly colorectal cancer patients so that we can offer them the most appropriate treatment(s) for their cancer. Assessment includes fitness, frailty, cognitive and functional testing to determine how fit a patient is, whether they have the physiological reserve to undergo standard management for their condition or whether they need a less intensive option or palliation only if they are very unfit. This has led to a number of different interventions, such as formal exercise programmes, either before or after their operations with the aim of improving outcomes and reducing costs. However, the evidence base for these interventions in the elderly is poor partly attributable to both the complexity of the patient group being studied but also of the interventions. This study aims to review the current evidence for interventions in this group, develop guidelines based on this review and with the help of a panel of experts, carry out a study looking at a wide range of different patient pathways to determine current practice and conduct interviews with healthcare professionals, patients and their carers.

Introduction, background, aims and objectives (1000 words)

The UK population is aging rapidly, as is the burden of chronic disease, senescent organ dysfunction, sarcopenia and frailty in this older population[1]. Cancer care of elderly patients in both the emergency and elective surgical setting is very heterogeneous and outcomes are generally poorer than for younger patients. The causes of these inferior outcomes is multifactorial but includes inadequate assessment of baseline health and fitness, poor provision of pre and rehabilitation, poor integration of secondary, primary and social care, failure to optimise chronic health conditions by liaison with medicine for the elderly or primary care and poor decision making when there are age and fitness stratified treatment options[1-3]. There is a lack of evidence-based guidance in this area, as the elderly are underrepresented in clinical trials and there is often no stratification for baseline health status[4]. There is also a paucity of knowledge about the treatment experiences and wishes of elderly patients with colorectal cancer. The limited available literature suggests that older patients value independence and quality of life highly and are fearful of burdening friends and family. Failure to provide adequate support to permit them to retain their independence and dignity is a source of

distress. Inadequately planned care, poor preparation and poor decision making may also increase risks of adverse outcomes, emergency readmission and prolonged length of stay, all of which place huge burdens on the NHS and social care.

Frailty is a distinct health state related to the aging process of reduced reserve and resistance to stressors and increased vulnerability to adverse outcomes[5]. Approximately 10% of people over the age of 65 are thought to be frail and this increases to 25-50% in the population over the age of 85 years[6]. There is no agreed definition of frailty and there are numerous validated tools and scoring systems for the assessment of frailty in different populations[7]. It has been consistently shown across surgical oncology that regardless of how it is assessed, frailty is a strong predictor of adverse surgical outcomes[7-9]. This has led to interest in the assessment of frailty both as a tool for predicting outcomes and response to treatment but also as something that is potentially targetable pre- and post-operatively to improve outcomes[7,10]. Despite this there is limited evidence from randomised controlled trials on interventions to improve outcomes in frail people undergoing surgical and medical treatment of colorectal cancer, with the available evidence being relatively small studies, at high risk of bias and across a wide range of interventions[8,11]. Current evidence suggests that exercise interventions have the potential to improve functional and quality of life outcomes in frail patients, however further high quality studies are required[8,12].

Hypothesis

Variations in the care pathway of older patients presenting with potentially operable colorectal cancer results in poorer outcomes. Outcomes could be improved by developing and implementing elderly specific integrated care pathways based on evidence-based practice.

Aims

1. To establish variation in practice in the older colorectal cancer patient and how this is affected by age, multi-morbidity, cognition, polypharmacy and frailty. This will be achieved by:
    a) Systematic literature review performed according to PRISMA guidelines to look at areas of practice that have the potential to optimise or worsen outcomes across the care pathway and generate an evidence summary
    b) Establishing an expert reference group (ERG) drawn from surgeons, geriatricians, oncologists, general practice, social care, physiotherapy, occupational therapy, anaesthesia, dietetics, carer groups and commissioners to review the evidence summary and distil a series of evidence based guidelines
    c) Undertake a regional cohort study to collect risk stratified data (age, multi-morbidity, frailty, dementia, social deprivation index) and treatment practice (decision to operate, surgery type, chemotherapy protocol (standard or reduced), radiotherapy, nutritional support, adjuvant therapies) and outcomes (length of stay, Clavien Dindo classified adverse events, discharge date and destination, emergency readmission rates, patient reported outcome measures including quality of life, 30 day survival rates, overall and cancer specific survival and health utility (EQ5D)). Data analysis will use propensity score matching to bias adjust outcomes for heterogeneous baseline characteristics.

2. To establish the management preferences, and factors affecting them, for older patients with colorectal cancer using qualitative and quantitative methodologies:
    a) Qualitative interviews will be undertaken with members of the core and extended healthcare team including surgeons, occupational therapists, physiotherapists, nutritionalists/ pharmacists, oncologists, general practitioners, anaesthetists, geriatricians and palliative care. This will focus on the barriers and facilitators to best practice, views about rehabilitation, prehabilitation and engagement with primary care, baseline health assessments and discharge planning
    b) Qualitative interviews with older patients and their carers, to explore their good and bad experiences of care received and their future care concerns and preferences.

3. To apply the Delphi consensus method to generate an evidence summary that will be based on the findings from the systematic review, cohort study and interviews. It is anticipated that this could then be developed into an integrated care pathway for subsequent pilot testing in clinical practice.

References

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10. Wildiers H, Heeren P, Puts M, et al. International Society of Geriatric Oncology consensus on geriatric assessment in older patients with cancer. J Clin Oncol 2014; 32(24): 2595-603.
11. Pallis AG, Papamichael D, Audisio R, et al. EORTC Elderly Task Force experts' opinion for the treatment of colon cancer in older patients. Cancer Treat Rev 2010; 36(1): 83-90.
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Methods (500 words)

1. Systematic literature review and drafting of evidence synthesis

Systematic review methods will adhere to PRISMA guidelines. A review protocol will be developed in collaboration with the steering/ advisory group and published on PROSPERO before the review begins. Evidence synthesis will use a range of methods depending on study design; including narrative synthesis, meta-analysis for quantitative studies if appropriate, and thematic synthesis for qualitative studies. Two reviewers will conduct quality assessment of all studies using the appropriate standards e.g. CONSORT for RCTs, ROBINS for non-randomized studies and CASP checklists for qualitative studies.

2. Expert reference group

An expert reference group (ERG) will be drawn from surgeons, oncologists, geriatricians, general practice, patients and carers, social care, physiotherapy, occupational therapy, specialist nursing, anaesthesia and commissioners to review the developed evidence summary and distil a series of evidence based guidelines.

3. Pathway mapping study.

Ethics and R and D approval will be sought. Recruit a regional prospective observational cohort of older patients with colorectal cancer. This will include a range of units including large teaching centres and district hospitals serving both urban and rural communities. Patients will be asked to give written informed consent.

Eligibility criteria: Age over 70, emergency or elective presentation of potentially operable colorectal cancer

Data on baseline age, frailty, multimorbidity, nutritional status, cognition and treatment type and intention will be collected.
Outcomes will include: age, Charlson Comorbidity Index (CCI), Activities of Daily Living (ADL), Instrumental activities of daily living (IADL), mini mental state examination (MMSE), Nutrition Score, Hospital Anxiety and Depression score (HADS), adverse events (classified using the Calvien Dindo system), length of stay, discharge destination, readmissions rate at 30 days, overall survival and cancer free survival, Quality of Life at 1 and 6 months. The CSRI (Client Service Receipt Inventory) will be collected to facilitate health economic costs analysis as well as the EQ5D health utility score. Propensity score matching will be used to adjust for baseline variables to enable determination of optimal tailored treatment for this older age group and to identify the treatment pathway, treatment delays and a bespoke PROMs relating to levels of care and support for both the patient and their carer.

4. Qualitative methods

Qualitative interviews with clinical care teams will assess current practice, perceived gaps in knowledge/ support to patients, and suggestions for improvements. Up to 40 interviews with health care professionals directly involved in the surgical patient pathway (including geriatricians, surgeons, specialist nurses, oncologists, GPs, physicians, occupational therapists, physiotherapists and social workers) will be performed. Recruitment will continue until saturation of themes occurs. Interviews will be digitally recorded, transcribed verbatim and analysed thematically using NVivo software.
Qualitative interviews with older patients themselves and their carers (~20-30) will be conducted to explore their experiences of care, what they felt they needed during their care, worries and preferences. Recruitment will continue until saturation of themes occurs. Patients and carers will be interviewed at their first post surgery follow up visit. Interviews will be recorded and analysed as above.

Outputs planned

It is anticipated that this project will result in an evidence summary that will be used to perform a Delphi consensus exercise in collaboration with the expert reference group. This will be published in a peer-reviewed journal. The pathway mapping study and qualitative arm of the study will also be submitted for publication separately. It is anticipated that the results from this study will be used as pilot data to apply for RfPB funding to conduct a cluster randomized trial in the future.

Details of collaborators including letters of support

1. Lynda Wyld, Professor of Surgical Oncology, Department of Oncology and Metabolism, Room EU36, University of Sheffield Medical School, Beech Hill Road, Sheffield. l.wyld@sheffield.ac.uk.
2. Steve Brown, Professor of Surgery, Sheffield Teaching Hospitals NHS Foundation Trust, Northern General Hospital, Herries Road, Sheffield. Steven.brown@sheffield.ac.uk
3. Caroline Mitchell, Senior lecturer in General Practice, University of Sheffield, Academic Unit of Primary Medical Care, Samuel Fox House, Northern General Hospital, Herries Road, Sheffield. C.mitchell@sheffield.ac.uk
4. Maria Burton, Senior Research Fellow, Centre for Health and Social Care Research, Collegiate Crescent, Sheffield Hallam University. M.burton@SHU.ac.uk

Detailed costing

The applicant's salary and university fees are covered by a Clinical Research fellow position at Northern General Hospital, Sheffield.
Systematic literature review: Minimal costs.

Qualitative interviews:
Interview recording: 1x digital Dictaphone ~£100
Interview transcription for 20 interviews with HCPs of 30 minutes each and 20 patient or carer interviews of 60 minutes each at 3 hours of typist time per hour of dictation (30 hours) = £900.

Costs for cohort mapping study

Travel costs to sites for study set up and monitoring (Doncaster, Sheffield, Barnsley, Chesterfield, Rotherham), £1000.

Travel and subsistence costs for a Delphi consensus exercise.
14 members to attend (estimated will require 4PPI members, 1 geriatrician, 1 GP, 1 social worker, 2 surgeons, 2 nurses, 1 NHS manager, 1 physiotherapist, 1 OT) at cost of £1000.
Total costs: £3000

The sum of £1000 for the project has already been secured from discretionary funds. The costs for the pathway mapping cohort study will be minimal if this study is successful in being funded by BASO as the NIHR portfolio adoption will enable access to the clinical research networks (CRN) at each trust to assist in recruitment and data collection.

4. Lay Details

Simple description of the proposed research using clear lay terminology, which should be readily understandable to members of the general public.

This should include the following and should not exceed 100 words:

- A simple, heading 'headline' – type title (maximum 6 words)
- Details of the disease/condition and any associated conditions, ie who suffers, the symptoms and numbers affected
- How this research might help those sufferers in the short/long term

The ability of The BASO~ACS to award research grants is dependent *on the success in raising funds.*

Improving elderly patient outcomes in colorectal cancer

The UK population is aging and there are increasing numbers of people living with long-term health conditions, frailty and disability. Colorectal cancer rates rise as people get older, however they may not be offered standard treatment for their cancer due to their age, they may not be fit enough for standard treatment (surgery and/or chemotherapy) and are more likely to suffer complications. This study will look at the role of different interventions (such as supervised exercise programmes) before and after surgery, chemotherapy or radiotherapy to improve outcomes in elderly patients.

5. Financial Details

Financial details of the grant requested from BASO~ACS:	
Item:	**Amount:**
Dictaphone	**£100**
Interview transcription costs	**£900**
Travel and set up costs for cohort mapping study set up	**£1000**
	Total : £2000

I have read the details for the BASO~ACS Project Grants and, if my application is successful, I agree to submit a report to BASO~ACS on the use I have made of the award within six months after completion of the work.

Signature of Applicant: ....Sarah Daniels..... **Date:** .....15/9/18.....

Please return the application and supporting documents by **Friday, 28th September 2018** to:
BASO~ACS
The Royal College of Surgeons
35-43 Lincoln's Inn Fields
London WC2A 3PE

The application should comprise:

(i) This form, completed in typescript.
(ii) A supporting letter from your Head of Department. This letter should make clear the degree of departmental support which will be made available to you.
(iii) A Curriculum Vitae of two pages or less.
(iv) A list of your publications.

Any queries should be directed to the above address or by email to the Association Manager at rattandeepjhita@baso.org.uk.

Appendix E: BASO award letter

BASO~The Association for Cancer Surgery
at The Royal College of Surgeons of England
35-43 Lincoln's Inn Fields, London WC2A 3PE
Telephone 020 7869 6854 Email admin@baso.org.uk
www.baso.org.uk

28th February 2019

Miss Sarah L Daniels
Steep Meadows
Sheffield Road
Hathersage
S32 1DA

Dear Miss Daniels,

BASO~ACS (NIHR) Research Project Grant, 2018

Thank you for applying for the 'BASO (NIHR) Research Project Grant.' The standard of applications this year was extremely high; therefore, we have had a lengthy assessment process to ensure that the grant is awarded to the deserving project. I am delighted to inform you that the BASO~ACS Committee has agreed to award a grant of £2,000 in support of your project "*Optimising the Care and Treatment Pathways for Older Patients with colorectal cancer.*"

The grant fund will be transferred to the University or the Hospital's R&D Account. Kindly, confirm the details with the BASO~ACS Manager, Mrs Rattandeep Jhita at rattandeepjhita@baso.org.uk as soon as possible.

The recipients of this award are requested to submit a written report six months following the completion of the work to ensure key targets have been met and the applicant will be invited to present their findings at the BASO~ACS Annual Scientific Conference. Our Admin team will be in touch with you once the dates for 2020 Annual Scientific Conference is confirmed.

Also, we will request you to add the BASO~ACS logo to your project report. Logo will be emailed to you by the BASO admin team.

BASO~ACS is a National Institute for Health Research (NIHR) non-commercial Partner. This means the studies that we fund may be eligible to access NIHR Clinical Research Network (CRN) support.

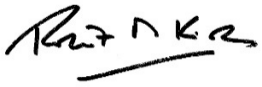
If your study will be of benefit to patients and the NHS, (this includes relevant research in public health and social care) we expect you to apply, where appropriate, for NIHR CRN support and subsequent inclusion in the NIHR CRN Portfolio of studies to fully benefit from

the support that the CRN offers through their Study Support Service. To find out more, please visit www.supportmystudy.nihr.ac.uk.

If your study involves NHS sites in England you will need to apply for Health Research Authority Approval. For guidance on submitting an application please visit: www.hra.nhs.uk

On behalf of BASO~ACS, many congratulations on being awarded the Grant and we trust that you will gain excellent experience from it.

Yours sincerely,



Professor Robert Kirby
President, BASO~ACS

Mr Zaed Hamady
Hon. Secretary, BASO~ACS

Clinician Preferences for Treatment of Older Patients facing Major GI Surgery

Protocol Version 1.0

4th June 2019

Study Protocol version:	1.0
Date:	4th June 2019
Study Start Date:	July 2019
Funders:	British Association for Surgical Oncology
	Bowel Disease Research Foundation
Funding Type:	Educational grants
Sponsoring Body:	Doncaster Teaching Hospitals NHS Foundation Trust

Study Team.

Chief Investigator:
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Jenna Morgan, Specialty Registrar in General Surgery, Department of General Surgery, Doncaster Royal Infirmary, Doncaster Teaching Hospitals NHS Foundation Trust, Armthorpe Road, Doncaster, DN2 5LT Email: j.morgan@sheffield.ac.uk

Susan Moug, Honorary Professor of Surgery and Consultant Colorectal Surgeon, Department of Surgery, Alexandra Hospital, Paisley, NHS Greater Glasgow and the Clyde, Corsebar Road, PA2 9PN. Email: susanmoug@nhs.net

Hassan Malik, Honorary Professor of Surgery and Consultant HPB Surgeon, Department of General Surgery, Aintree University Hospitals NHS Foundation Trust, Lower Lane, Fazakerly, Liverpool. L9 7AL. Email: hassan.malik@aintree.nhs.uk

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Executive Summary

The UK population is aging. Underinvestigation and undertreatment of older people is common, with rates of surgery declining with age, despite the fact that surgically treated pathology rates increase with age (1–6). There are large variations in outcomes in older people, between different surgical units in the UK, which suggests that not all patients are receiving the same level of care or access to resources(7–11). Major surgery remains one of the most debilitating events that an older person may experience and may profoundly influence functional decline and disability(12). Optimisation of outcomes in older patients with comorbidities and frailty requires multiprofessional input which is often lacking (13).

There are few age and fitness specific evidence-based guidelines for major gastrointestinal (GI) surgery. The majority of trials exclude older, less fit patients (14–18). Whether an older patient is offered resectional (major) surgery as opposed to non-resectional surgery or palliative procedures is variable. Decision making is multifactoral and influenced by the patient and their clinician. Adequate assessment of fitness and frailty and subsequent targeted intervention to enhance resilience is often lacking (4,5). There are a range of proven techniques to enhance outcomes in the perioperative period, however there is variation between individual clinicians and multidisciplinary teams in how and whether these are applied. Interventions may include nutrition support, exercise programmes, psychological support, rehabilitation programmes, medical optimisation, comprehensive geriatric assessment and social services engagement to facilitate discharge planning, for example(19).

This mixed methodology study spanning emergency and elective major gastrointestinal surgery aims to determine how clinicians make decisions in older patients regarding fitness for surgery and what strategies they employ to optimise patients who are considered high risk. This will be achieved by

1. a systematic review of the current published literature on preoperative strategies to optimise patients fitness for surgery

2. semi-structured, purposively selected interviews with specialist health care professionals regarding how they make assessments of fitness for major GI surgery

and what options they consider if a patient is deemed high-risk or 'unfit' for resectional surgery

3. a questionnaire to quantify the results of the semi-structured interviews with hypothetical patient scenarios using discrete choice methodology

Lay Summary

The UK population is ageing with around 18% of the population now over the age of 65 years. Whilst many people remain active and in good health as they get older, ageing is associated with the development of many common medical problems, as well as memory and mobility problems. There is a natural decline in heart and lung fitness with age, which may be lessened with exercise and physical activity. The majority of bowel, oesophagus and stomach conditions that require surgery to treat (such as bowel cancer) are more common in older people. These operations can have a significant negative effect on an older persons' ability to look after themselves and their quality of life. In some cases there may be a trade-off whereby a smaller operation (such as bringing the bowel out onto the abdominal wall; creating a 'stoma') or procedure (e.g. inserting a tube inside the bowel or oesophagus to open up a blockage; insertion of a 'stent') with a lower chance of cure may be possible but is associated with a faster recovery and fewer problems immediately after the procedure. Some patients may be advised or may choose not to undergo any form of treatment.

Deciding whether a person is fit enough to undergo a major operation is complex and depends on patient factors (e.g. heart and lung fitness, other medical conditions, patient wishes), procedural/ technical factors (location of disease, availability of other options for treatment) and the treating clinicians (preference for different procedures, expertise). This study aims to explore:

1. how different healthcare professionals assess suitability for a major operation
2. what methods they use to try to improve health and fitness before an operation
3. in what circumstances they decide to offer alternative procedures or treatments
4. how they involve patients in these decisions.

This will involve a review of published work in the area, interviews with a range of healthcare professionals (e.g. doctors, specialist nurses, physiotherapists, General Practitioners; estimated 20-30 individuals) and a questionnaire based on the findings of the interviews to gauge wider opinion of healthcare professionals. It is anticipated that the project will take 12-24 months to complete.

This research will contribute towards a larger project looking at how we can improve outcomes for older patients facing major surgery and potentially may lead to the development of a decision-making tool for use in clinical practice.

The results of this project will be published in a scientific journal as well as presented at conferences and meetings attended by a range of healthcare professionals and at individual hospitals.

Background.

An Ageing Population.

The population of the UK is aging and average life expectancy has increased by 30 years during the last century, with most people now expected to live into their 80s(20). The over 85 year group are the most rapidly increasing population group(20) and the overall health status of this group is also improving(21). Improved disease prevention, with better control of chronic diseases, means that older people are living longer even in the presence of chronic health problems(20,22). Despite this, there is wide variation in the health status of this age group, with some who are fit and healthy, living an active lifestyle, whilst others are frail, with multiple co-morbidities, necessitating assisted living. There is a natural decline in cardiorespiratory fitness (CRF) with age, however this may be modifiable with physical activity or exercise. Determining best practice in this group is therefore complicated and treatment requires tailoring to individual patients, not to their chronological age.

Surgical Management of Older People.

Two thirds of cancers diagnosed in the UK each year occur in people over the age of 65 years(23). However, recent reports demonstrate a widening survival gap for older versus younger patients with cancer(24). The UK Department of Health has set out a strategy to address age related cancer treatment variation in the UK(25) and the James Lind Alliance has also identified the management of patients with multiple conditions in later life as a research priority(26). Older patients tend to present with more advanced gastrointestinal cancers and more often as an emergency (27–30); this is reflected in the fact that older people with cancer are more likely to have incompletely staged disease(9). However, later stage of presentation alone does not account for the sharp decline in resection rates in older people(5).

There are also a number of non-malignant gastrointestinal conditions that are more common in older people that span both the emergency and elective settings; such as complicated diverticular disease, bowel ischaemia, intestinal volvulus, adhesional obstruction and complicated hernias. In the emergency setting, some of these conditions may be immediately life-threatening, with surgery being the only potential option for survival. This means that decisions are often made ‘out of hours’ without the benefit of consultant presence or multi-disciplinary team input. Decisions are often made on a

patients' suitability for an operation without adequate knowledge of background CRF, frailty or co-morbidities. However for some non-malignant conditions, there may be a time window of hours to days where adequate assessment and optimisation may be performed to enhance post-operative outcomes: this is especially true for diseases where a trial of conservative management is routine such as adhesional small bowel obstruction and diverticulitis.

Non-malignant gastrointestinal pathologies that are not life-threatening may still have a significant impact on a person's quality of life; for example a patient with a diverticular colovaginal fistula with persistent faecal leakage or a patient with recurrent episodes of intestinal obstruction due to a complex hernia. The balance of operative risk versus quality of life may be difficult, particularly when considering multiple co-morbidities and frailty(31).

Treatment of Gastrointestinal Cancer in the Older Patient: Resectional surgery, non-resectional surgery/ palliative procedure or chemo-radiotherapy versus conservative management

Gastrointestinal cancers form a diverse group of cancers, the commonest being colorectal, oesophageal, gastric and pancreatic, all of which increase in incidence with age. Major surgical resection remains the mainstay of curative treatment for these cancers, although there is an increasing role for the use of neo-adjuvant chemotherapy and radiotherapy to improve resectability as well as local and distant disease control. In certain situations local endoscopic resection may be an alternative option with curative intent. When a patient is considered to be at high risk of adverse outcome following major curative resection (due to prolonged anaesthesia, extensive resection, blood loss) due to poor CRF or frailty they may be offered non-resectional surgery or a palliative procedure to help control the disease, alleviate symptoms or prevent complications (e.g. defunctioning stoma, colonic stenting, oesophageal stenting, bypass procedure, radiofrequency ablation). Palliative chemotherapy or radiotherapy may be an option, but again requires adequate patient fitness to be considered. There may be a trade off between a potentially highly morbid curative resection and an operation or procedure that is better tolerated but with a lower chance of long term cure. Assessing the impact that different procedures have on a patient's quality of life is therefore of great importance. Some patients who are relatively asymptomatic but with co-morbidities,

poor CRF or frailty may be managed conservatively with involvement of palliative care teams.

Treatment of non-malignant gastrointestinal conditions in the Older Patient: Resectional surgery versus non resectional surgery/ palliative procedures versus conservative treatment

There are a number of non-malignant but potentially fatal conditions where surgery is often a major modality of treatment. In patients who are have lower CRF, surgery may be avoided or minimised in some cases, although usually with a lower expectation of long-term cure. Several examples are given below.

Diverticular disease is one of the most common non-malignant bowel conditions and is increasing in incidence due to population ageing and poor diets. Complications resulting from it include recurrent episodes of diverticulitis, abscess formation, perforation leading to peritonitis, bleeding, strictures and fistulae. The majority of people with diverticular disease are managed conservatively with diet and lifestyle advice. Radiological drainage is frequently utilised when there are localised abscesses, however, in complicated diverticular disease associated with peritonitis, fistulae or strictures, surgery is the main treatment option. This may involve a Hartmann's procedure (sigmoid colectomy and colostomy) or a resection with anastomosis (+/- temporary stoma). Less invasive options for some patients may be laparoscopic lavage or a defunctioning stoma. Other benign conditions seen in emergency general surgery include colonic volvulus, adhesion related small bowel obstruction, obstructed hernias, colonic ischaemia and perforations resulting in peritonitis. Sigmoid volvulus is initially treated conservatively with a flatus tube, which results in resolution of symptoms in the majority of cases. Recurrent sigmoid volvulus may be treated surgically by sigmoid colectomy with colostomy formation or by Percutaneous Endoscopic Colostomy (PEC), a minimally invasive procedure, if a patient is deemed unfit or 'high risk' for resectional surgery. The majority of cases of adhesional small bowel obstruction are managed conservatively for the first few days with nasogastric drainage unless there is a suspicion of ischaemia or 'closed loop' obstruction. If the obstruction fails to resolve then laparoscopic or open adhesiolysis will be required. 'Sealed off' or contained perforations caused by pathologies such as peptic ulcer disease may also be treated with conservative management and radiological drainage if the patient is systemically well. In the presence of generalised peritonitis, suspected ischaemia or failure to respond to conservative measures, surgery is the only curative option, however it is associated with high morbidity and mortality rates(32). A patient assessed as being

too unfit or high risk for operative intervention would be managed conservatively, with involvement of palliative care. Despite high mortality rates with non-operative management, there may be short-term quality of life gains compared to high morbidity emergency surgery.

Assessment of baseline health, fitness and frailty

The ability to tailor management decisions to baseline health, CRF and frailty status relies on accurate and timely assessments. In the UK, the majority of patients undergoing elective general surgical procedures will be first assessed by a surgeon and subsequently by either a nurse or anaesthetist in a pre-operative assessment clinic depending on local arrangements. Patients felt to be at increased operative risk either due to the extent of the procedure or due to patient characteristics may undergo formal exercise testing in the form of CardioPulmonary Exercise Testing (CPET), although this is not universally available(33). Only a handful of units include a geriatrician in pre-operative assessment for older patients, in contrast to orthopaedics where they have been successfully integrated as part of the standard of care. It addition it is not yet routine practice country wide to assess frailty, cognitive status or functional abilities in elective older patients. All patients have their BMI documented in surgical and pre-operative assessment clinics but despite the ESPEN guidelines, the majority of patients are not assessed by a dietician pre-operatively. Specialist nurses have an important role in gathering more in-depth health and CRF information about patients with malignant diagnoses and will help to guide MDT discussions regarding suitability for interventions. General practitioners also have much greater knowledge of the chronic health issues and social circumstances of their patients and may be able to give insight into how tolerant a patient may be to surgical intervention. However, they are rarely involved in management decisions after referral, despite having to deal with the repercussions of surgical morbidity in the community.

In the emergency setting, there is often insufficient time for detailed baseline assessments, there may not be access to previous medical records and patients may have delirium or altered conscious level that precludes detailed information gathering. They may also present without their relatives or usual care givers. Time constraints may mean that decisions regarding investigation and management are frequently made ‘out of hours’ by junior members of the team without consultant or multi professional input.

Optimising patient health prior to surgery

The term 'prehabilitation' is defined as "the process of enhancing one's functional and mental capacity to buffer against the potential deleterious effects of a significant stressor"(34). Prehabilitation programmes commonly involve one or more of the following: exercise regimes, nutritional optimisation or psychological interventions. Prehabilitation in the context of optimising the older adult for elective surgery may also include pre-operative geriatric assessment and optimisation. It is also advocated that more general health advice and behavioural support should also be given including smoking and alcohol cessation, as well as optimisation of underlying health conditions, in particular anaemia and cardiovascular disease. There is increasing acceptance that prehabilitation should encompass all of the above, referred to as 'multimodal' prehabilitation(35). There is evidence to support many of the aspects of prehabilitation programmes, however significant heterogeneity of studies including interventions tested, goals of treatment and outcomes measured limit the comparability of studies(36,37). Many studies focus on only one aspect of prehabilitation, most frequently exercise interventions, whereas there is an argument, particularly in the elderly, for the role of simultaneously addressing multiple adverse factors with the aim of aggregating marginal gains(38). There is a need to determine what combination of prehabilitation interventions is required in older people, how to facilitate engagement in those who are most likely to benefit and also the cost effectiveness of such interventions.

Enhanced Recovery After Surgery

Enhanced Recovery After Surgery (ERAS) protocols or 'fast-track' programmes were originally developed in colorectal surgery following the recognition that a small number of elective procedures contributed disproportionately to surgical morbidity, length of stay and unplanned readmissions(39,40). ERAS protocols have now been successfully implemented into the majority of cancer surgery disciplines. They have also been shown to be safe and effective in older populations, where the risk of post-operative deconditioning and complications resulting from pre-existing medical conditions are far greater(41,42). Despite this, it is well recognised that adherence to all elements of the protocol may be difficult to achieve, in particular to the post-operative mobilisation guidelines(43), which is lower in older compared to younger adults(44).

Post-operative rehabilitation programmes

Older patients are particularly at risk of functional decline following major surgery, which contributes towards prolonged length of hospital stay and increased care needs on discharge(12). Disuse atrophy of muscles occurs very rapidly, especially when compounded by a post-operative catabolic state and reduced food intake. Early mobilisation after surgery, such as sitting out of bed, standing and walking, decreases the risk of complications and length of hospital stay(45,46), however, the majority of patients in hospital for acute medical or surgical conditions spend >94% of their time inactive(47). Physiotherapists, occupational therapists and nursing staff provide much of the post-operative rehabilitation to older adults following major surgery in the NHS, however, staff shortages in the majority of hospitals limit how much time can be spent with each patient. Other countries with different models of healthcare often use 'post-acute care facilities'(48) or specialist rehabilitation beds to care for patients once the immediate post-operative period has ended. The involvement of specialist geriatric teams into post-operative care of older patients, such as the Proactive care of Older Persons undergoing Surgery (POPS) initiative in the UK, has resulted in improvements in length of stay and cost savings(49). However, a National survey of geriatrician provision in surgical services in the UK(50) and the National Emergency Laparotomy Audit(51) indicate that the majority of older patients undergoing major abdominal surgery still do not receive input from a geriatrician-led team.

Patient-centred outcomes

Patient-centred outcomes are increasingly recognised to be of importance in surgical research, particularly in older populations where there may be different goals of treatment(52–54) . Major surgery in all patients leads to a decrease in CRF and functional capacity(55), however in older adults this contributes towards disability and loss of independence(56,57). Many older patients never regain their previous level of functioning after major surgery(12). Increasing age alone is a risk factor for discharge to a rehabilitation facility rather than home post-operatively, even in people who were functionally independent prior to their procedure and who have an uneventful postoperative course(48). Other outcomes of importance to patients' functional recovery include fatigue, sleep disturbances, reduced cognitive function and low mood(55,58). Multi-disciplinary shared decision-making is advocated in older adults with cancer to

ensure that clinicians, patients and their carers are aware of the risks and benefits of complex oncological management(52). There is evidence that undergoing a geriatric assessment, as part of multidisciplinary management, changes the treatment plan in 39% of older adults with cancer, predominantly to a less aggressive treatment regimen(54).

Variation in Practice.

In the UK there is wide variation in practice relating to the treatment of older people with both malignant and non-malignant gastrointestinal pathologies. The concern in cancer surgery is that patients in centres with low elective surgery rates will be inappropriately denied operative curative intervention, with the long-term consequences of disease progression, necessitating a change in management including salvage and emergency surgery(6,59). In patients with non-malignant conditions, failure to refer for surgical management and lower rates of elective surgery in older patients is known to contribute to higher rates of emergency surgery and readmission, particularly in the over eighty age group(4,5). Conversely, in regions with high rates of surgery, patients may be inappropriately subjected to the morbidity or even mortality of surgery with limited or no benefit.

Regionally, variance may be explained in part by deprivation levels. Deprivation levels are linked to higher burdens of chronic disease, rates of smoking and lower screening uptake rates. These factors may contribute to patients presenting at a later stage in their disease and being less able to undergo safe surgery(5). However, deprivation is unlikely to account for the almost 5-fold difference in major rectal resection rate in the over 80s in the English NHS(9). Regional differences in clinical commissioning and referral practice of individual primary care doctors may account for some of the differences in both elective and emergency surgery rates.

Clinician preference may also form a substantial aspect of practice variance. Anecdotal evidence in cancer surgery indicates that some surgeons have a very strong preference for surgery and others feel that palliative procedures (e.g. stenting), chemotherapy, radiotherapy or best supportive care is more appropriate for older patients, particularly those with co-morbidities. There is a commonly held perception that chemotherapy and radiotherapy are poorly tolerated in older patients with higher rates of adverse

events(60). In emergency surgery for non-malignant pathologies, some surgeons may place more value on chance of survival, whilst others consider likelihood of survival to discharge, quality of life and functional outcomes to be more important(7,61). The causes of this varying opinion are not known but may include personal experience, interpretation of the literature or unit protocols. It may also be affected by anaesthetic staff attitudes to anaesthesia in older patients and critical care bed availability and admission criteria(32,62). Regarding optimising patient pathways prior to, during and after surgery, again, there is variation in opinions regarding the value of prehabilitation, smoking cessation and geriatric assessment, which affects the advice given to patients as well as the commissioning of services.

This study will examine the variance in practice by two means. Initially, a series of interviews with health care professionals will be undertaken in different units offering emergency and elective, malignant and non-malignant GI surgery within a region. This will establish the factors taken into account when assessing older patients for treatment and the personal weights that clinicians place on these. They will also explore clinician views on prehabilitation and how patient pathways can be optimised. Following this a bespoke questionnaire will be used to quantify these factors. This will incorporate a number of scenarios relating to hypothetical older patients with varying levels of health, CRF, cognition etc. using a discrete choice methodology(63). This will enable exploration of the contribution of physician opinion to treatment decisions and how this varies by hospital. A separate study which is not included in this protocol (and is part of a separate ethics application) will study regional elective and emergency gastrointestinal surgery, looking at what pre-, peri- and post-operative interventions are used to try to optimise outcomes in older patients and what characteristics of patients and their pathways are associated with surgery with good outcomes, surgery with poor outcomes and outcomes of non-surgical treatment modalities and conservative treatment.

Summary

Consistently, research has reported that older patients (≥65 years) have huge variation in their gastrointestinal disease treatment pathways compared to younger patients in both the emergency and elective settings.

Given than most GI surgical pathologies occur in older age it is important that this group receive appropriate treatment options based on their personal health status and treatment preferences rather than their chronological age. There is a need for more standardised assessment of patient CRF, taking into account individual co-morbid status and frailty.

This study will give an insight into the factors that are taken into account when clinicians are deciding on treatment plans for older patients. It is part of a larger programme of research that will also determine the factors the older patients themselves take into account when they decide on how they wish to be treated, their views on peri-operative optimisation and the outcomes of different treatments in this age group. It is hoped that the research will enable the development of guidelines and a decision aid for optimised, individualised care of older patients with malignant and non-malignant GI conditions.

Aims and Objectives

Aims

1. To explore the views of specialist healthcare professionals towards the management of older patients (≥65yrs) with operable gastrointestinal pathology, particularly in terms of resectional (major) surgery, non-resectional/ palliative procedures or conservative management.

2. To determine the factors underlying treatment decision-making and patient optimisation by health care professionals relating to older patients with operable gastrointestinal pathology

3. By means of a bespoke questionnaire, to quantitatively assess the above factors on a larger group of healthcare professionals and correlate these findings with social and demographic factors.

Objectives.

1. To undertake a systematic review of the current published literature according to PRISMA guidelines on preoperative strategies to optimise patients fitness for resectional abdominal and gastrointestinal cancer surgery

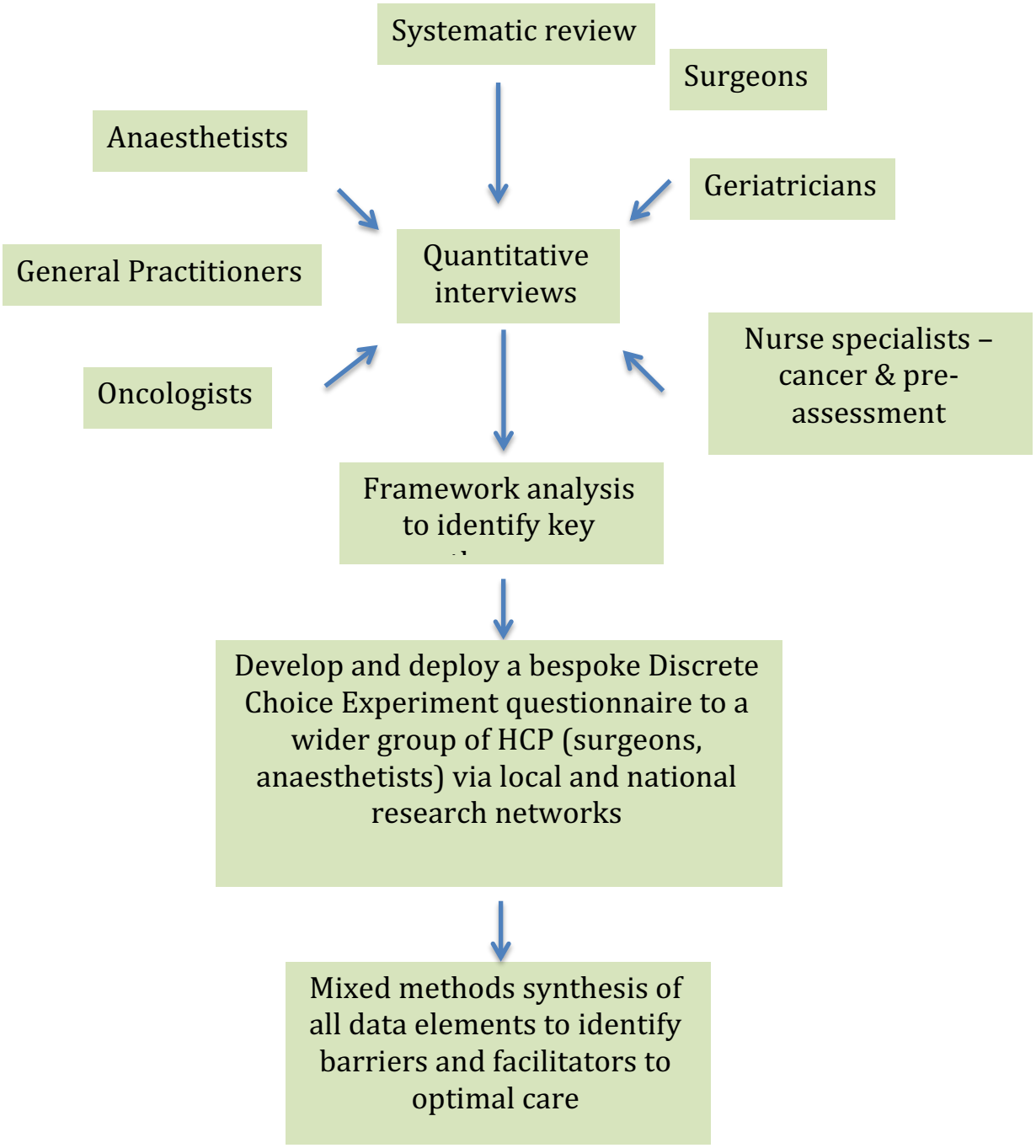
2. To undertake 20-30 semi-structured interviews with gastrointestinal surgeons, anaesthetists, geriatricians, oncologists, cancer specialist nurses, pre-assessment

specialist nurses and general practitioners within the South Yorkshire region using a pre-prepared interview prompt sheet. Key topics will include assessment of cardiorespiratory fitness, optimisation, palliative/ conservative treatment options and decision-making. Interviews will take place until there has been saturation of themes.

3. To undertake a discrete choice experiment using the factors identified in the semi-structured interviews to quantitatively assess fitness assessment and treatment decision making in a range of healthcare professionals (surgeons and anaesthetists).

4. Mixed methods synthesis of qualitative and quantitative aspects to identify barriers and facilitators to optimal care

Research Methods.
Study Design:



Study Outcomes

Primary Outcome:

To determine the factors underlying treatment decision-making in health care professionals relating to older patients facing resectional (major) gastrointestinal surgery

Secondary Outcome:

To determine the strength of these factors in causing variance in decision-making practice amongst health care professionals.

Detailed Methodology

Stage 1: Literature Review.
Search Strategy.
A systematic search of studies, both published and unpublished, focusing on the effects of prehabilitation on surgical outcomes after elective gastrointestinal or abdominal cancer surgery will be performed. Additionally, cohort studies looking at the treatment of this group of patients will be sought to further clarify current practice.

The following electronic databases will be searched as primary resources; the Cochrane Library, Medline, EMBASE, Psychinfo, CINAHL. Searching of key websites, for example the website of the Royal College of Surgeons, will also be undertaken. Grey literature will be searched. Reference lists of relevant papers and reviews will also be hand-searched. Quality assessment of all included sources will be undertaken using the Mixed Method appraisal tool (MMAT)(64). An evidence synthesis will be drafted. The review protocol and search criteria will be published on the PROSPERO database and two experienced reviewers will assess all publications. Meta analysis will be performed if applicable using REVMAN software.

Stage 2: Qualitative interviews with health care professionals

This study will establish the views and preferences of a range of health care professionals with expertise in gastrointestinal surgery, and the factors influencing these, regarding the following:

a) GI cancer treatment options;

- Neoadjuvant chemotherapy or radiotherapy
- Resectional (major) surgery
- Adjuvant chemotherapy or radiotherapy
- Endoscopic or local resection
- Other local resection/ non resectional/ palliative surgery
- Palliative chemotherapy or radiotherapy
- Best supportive care

b) Non-malignant elective treatment options

- Resectional (major) surgery
- Other non resectional surgery or palliative surgery/procedure (e.g. stenting, defunctioning stoma, intestinal bypass)
- Best supportive care

c) Emergency malignant and non-malignant treatment options

- Resectional (major) surgery
- Other non resectional surgery or palliative surgery/procedure (e.g. stenting, defunctioning stoma, intestinal bypass, laparoscopic lavage, PEC)
- Best supportive care

A particular focus will be the thresholds used to decide between treatment options and any pre/peri or post-operative support that may be provided in higher-risk individuals.

Data will be collected via semi-structured qualitative interviews. The interviews will be on a 1:1 basis either face to face or over the phone and will be conducted by a member of the study team (under the supervision of experienced qualitative researchers). Maximal variation sampling will be used to include different types of HCP (surgeons, anaesthetists, geriatricians, oncologists, specialist nurses and general practitioners) and HCP from different units within the region. Interview data analysis using the Framework Approach(65) will occur alongside recruitment, and recruitment will cease on

achievement of data saturation. From previous work in the field it is anticipated approximately 20-30 interviews will be required. A range of professionals will be interviewed including surgeons, anaesthetists, oncologists, geriatricians, specialist nurses and general practitioners (relevant to initial decision making and post-operative care in the community).

Regulatory Approvals.

Research and Development approval will be obtained for the project. All study researchers will have undergone full GCP training and hold valid NHS research passports.

Sites.

The study will recruit health care professionals from across the South Yorkshire region. A local Principle Investigator will be identified at each unit who will be asked to identify surgeons, oncologists, anaesthetists, geriatricians and specialist nurses for contact. General practitioners to approach will be identified by Dr Caroline Mitchell, a member of the project team.

Units identified include:

Units Identified	PI
Sheffield	Steve Brown
Doncaster	Tim Wilson
Barnsley	Alison Payne
Chesterfield	Harjeet Narula

Recruitment.

A local Principle Investigator (PI) will be identified at each site by direct contact from a member of the study team. The PI will be asked to provide a list of names of suitable health care professionals working within the unit who agree to be contacted by the study team. Individuals will then be sent a study pack by post or e-mail that will contain the following: a letter of invitation, a participant information sheet (PIS), a study reply slip and a freepost envelope. A sample letter of invitation is contained in Appendix I. This will invite the HCP to complete a reply slip to agree to be contacted about taking part. A sample participant information sheet is in Appendix II. On receipt of a reply slip or confirmatory e-mail (Appendix III) agreeing to participate, the research team will contact the interview

candidate and arrange a time and place to meet. This will be agreed verbally and confirmed in writing before the scheduled date. A consent form will be signed before the interviews commence on the day of the interview (Appendix IV). Individuals who request a telephone interview will be sent the consent form to complete prior to this commencing. A copy of the consent form will be given to the HCP and the original retained in the Investigator Site File. Each member of staff will be given a unique study ID number that will be recorded on the enrolment log along with their name, date of birth and consent date. This will be retained in the Investigator Site File at the main site (DRI).

Conduct of the Interviews.

Participants will be contacted again the day before their interviews to ensure they still wish to proceed. They will be given an opportunity to decline if they so wish. All interviewees will be reassured that they may terminate or pause the interview at any point without stating a reason for doing so and that their participation is entirely voluntary. If this happens the information recorded up to that point will be transcribed. If wished, telephone interviews may be offered. All interviews will be digitally recorded and transcribed verbatim. All data collected will be pseudo-anonymous.

Interview Schedule and Content.

An interview schedule has been developed by the study team. This will enable the interviews to explore key issues but also give opportunity for free expression of views with open questions. The areas for discussion are based on previous interviews by members of the study team with health care professionals in the field of breast cancer screening and treatment choices(66,67) where similar issues were explored.

The interviews will explore the following areas:

Prompts for GI surgeons

Question	Prompts
What treatment options would you normally consider for an older person with operable major GI pathology?	Surgical Major resection - laparoscopic versus open Non resectional surgery or alternative procedure if unfit/frail e.g. stoma, stenting Oncological Neoadjuvant chemotherapy or radiotherapy Adjuvant chemotherapy Short course vs. long course

	Palliative: chemotherapy, best supportive care
What factors influence your choice of management for a particular patient?	Pathology: Location and size, operability/ stage, malignant versus non-malignant Patient factors: Co-morbidities, cardiorespiratory fitness, functional status, cognitive impairment, frailty, patient choice, carer attitudes, age, views on a stoma Specific assessments: Clinical assessment/ judgement/ 'end of the bed' Geriatric assessment Formal risk assessment Pre-operative assessments Cardiopulmonary Exercise Testing, 6MWT, ISWT Anaesthetic considerations Access to critical care Specialist nurse opinion Specific guidelines
If in such patients there is the potential for choice of resectional surgery, non resectional surgery or palliative options what level of involvement does the patient play in the management decision? How do you help them to decide?	Shared decision making versus paternalism, use of decision aids, role of specialist nurse, role of anaesthetic/geriatric assessment, role of relatives and friends, legal power of attorney and independent patient advocates in cognitive impairment, use of decision aids/booklets, psychological expertise, training courses Access to time sensitive palliative care service Acute pain service
What factors have influenced your personal strategy for dealing with these patients?	Literature evidence, patient involvement, experience of cases over the years, unit policy, training and mentoring, specialist nurse input, MDT involvement
What affects the amount of information you relay to a patient with major GI pathology?	Patient demand, cognitive status, relatives and carers information needs, recent changes in the law (Montgomery v Lanarkshire)
What do you think older patients feel about having surgery?	Fear of death and 'not waking up', disfigurement, hospitalisation, burden on carers after surgery, loss of independence, complications, post-traumatic stress
What do you think older patients feel about chemotherapy?	Easier than having an operation, safer than having an operation, less certainty of cure, less hassle. Fear of chemotherapy side effects, hair loss, nausea, risk of death. Attending the hospital often rather than spending time with family. Accept the quantity of time gained at the loss of quality
What do you think patients think about non-resectional	Fears of being in pain, shorter survival, less risky than major procedure, focused on improving quality of life/ preserving quality of life, getting back to

surgery/ palliative procedures/ other options?	their normal, returning to pre-procedure quality of life
Emergency	
How does your management differ if the patient presents as an emergency?	Cancer –defunctioning stoma, palliative bypass or stent versus resection or palliative care Benign – trial of conservative management, optimisation of other pathologies acute/chronic, medication reversal/ cessation, anaemia correction, resuscitation, nutritional optimisation Baseline assessment – albumin, functional status (verbal/questionnaire), co-morbidities Approach – laparoscopic versus laparotomy Risk assessment – anaesthetic opinion, geriatric assessment, specific risk calculators (e.g. SORT, NELA) MDT – who is involved? Radiologist, anaesthetist, surgeon, other Time of day
Fitness	
How do you personally assess the cardiorespiratory fitness and frailty of your patients?	On the basis of history and examination Specific questions – climb stairs, how far they can walk Validated questionnaire or cardiorespiratory fitness/frailty assessment CPET testing/ 6MWT/ Timed up and go Allow others to assess this for you
Who do you formally cardiorespiratory fitness test?	Everyone having specific procedures Age specific Certain co-morbidities Those in whom you have doubts about their fitness Flowchart lead
What is your strategy for dealing with patients who you believe to have borderline cardiorespiratory fitness?	Refer for formal exercise testing (CPET) Seek anaesthetic opinion Advise them on how to get fit Give them an exercise regime Advise them to make an appointment with their GP Explore prehabilitation options, refer for physiotherapy, social services input, Surgical School Tell them to stop smoking, reduce alcohol Shared decision-making Are you aware of what is available for those with borderline fitness; are these in house or out house services
What is your strategy for patients who you believe are unfit for an operation?	Advise them that surgery is not an option. Advise them that if they improve their cardiorespiratory fitness it may be an option.

	Advise them on other options – surgical, medical, palliative

Prompts for anaesthetists

Question	Prompts
What treatment options would you normally consider for an older person with operable major GI pathology?	Major resection - laparoscopic versus open Non resectional surgery or alternative procedure if unfit/frail e.g. stoma, stenting
What factors influence your choice of management for a particular patient?	Patient factors: Co-morbidities, functional status, cognitive impairment, cardiorespiratory fitness, frailty, patient choice, carer attitudes, age, need for critical care Specific assessments: Clinical assessment/ judgement/ 'end of the bed' Geriatric assessment Formal risk assessment Pre-operative assessments Cardiopulmonary Exercise Testing, 6MWT, ISWT Access to critical care Specialist nurse opinion Specific guidelines
What impact does this have on your decision to anaesthetise/ choice of anaesthetic?	Advise shorter procedure if possible/ non surgical option Suitability for epidural, wound infiltration catheters
If in such patients there is the potential for choice of resectional surgery, non resectional surgery or palliative options what level of involvement does the patient play in the management decision? How do you help them to decide?	Shared decision making versus paternalism, use of decision aids, role of specialist nurse, role of geriatric assessment, role of relatives and friends, legal power of attorney and independent patient advocates in cognitive impairment, use of decision aids/booklets, psychological expertise, training courses. Access to time sensitive palliative care services. Acute pain services
What factors have influenced your personal strategy for dealing with these patients?	Literature evidence, patient involvement, experience of cases over the years, unit policy, training and mentoring, specialist nurse input, MDT involvement
What affects the amount of information you relay to a patient facing major surgery?	Patient demand, cognitive status, relatives and carers information needs, recent changes in the law (Montgomery v Lanarkshire), expected outcome
What do you think older patients feel about having surgery and anaesthesia?	Fear of death and 'not waking up', disfigurement, hospitalisation, burden on carers after surgery, loss of independence, complications, post traumatic stress, attending the hospital often rather than

	spending time with family, acceptance of quantity of time gained at the loss of quality
What do you think patients think about non-resectional surgery/ palliative procedures/ other options?	Fears of being in pain, shorter survival, less risky than major procedure, focused on improving or maintaining quality of life, getting back to their normal, returning to pre-procedural quality of life
Emergency	
How does your management differ if the patient presents as an emergency?	Baseline assessment – albumin, functional status (verbal or formal questionnaire), co-morbidities, cardiorespiratory fitness Optimisation – chronic/acute pathologies, nutritional, anaemia, medication reversal/ cessation Modalities – Goal directed fluid therapy, invasive monitoring, spinal/epidural/ wound infiltration catheters Risk assessment – P-POSSUM/SORT/NELA, geriatric assessment Critical care/ extended recovery MDT – who is involved? Radiologist, anaesthetist, surgeon, other Time of day
Fitness	
How do you personally assess the cardiorespiratory fitness and frailty of your patients?	On the basis of history and examination Specific questions – climb stairs, how far they can walk Validated questionnaire or CRF/frailty assessment CPET testing/ 6MWT/ Timed up and go Allow others to do it for you
Who do you formally cardiorespiratory fitness test?	Everyone having specific procedures Age specific Certain co-morbidities Those in whom you have doubts about their fitness Flowchart lead
What is your strategy for dealing with patients who you believe to have borderline fitness?	Formal exercise testing (CPET) Advise surgeon that patient at elevated risk Advise them on how to get fit Give them an exercise regime Advise them to make an appointment with their GP Explore prehabilitation options, refer for physiotherapy, social services input, Surgery School Tell them to stop smoking, reduce alcohol Shared decision-making Are you aware of what is available for those with borderline fitness; are these in house or out house services

What is your strategy for patients who you believe are unfit for an operation?	Advise them that surgery is not an option. Advise them that if they improve their cardiorespiratory fitness it may be an option. Advise them on other options – surgical, medical, palliative care

Prompts for oncologists

Question	Prompts
What treatment options would you normally consider for an older person with operable major GI pathology?	Surgical Major resection - laparoscopic versus open Non resectional surgery or alternative procedure if unfit/frail e.g. stoma, stenting Oncological Neoadjuvant chemotherapy or radiotherapy, novel agents Adjuvant chemotherapy Short course vs. long course Palliative Chemotherapy, radiotherapy, best supportive care
What factors influence your choice of management for a particular patient?	Pathology: Location and size, operability/ stage Patient factors: Co-morbidities, cardiorespiratory fitness, functional status, cognitive impairment, frailty, patient choice, carer attitudes, age, views on a stoma, tolerability of side effects of oncological therapies Specific assessments: Clinical assessment/ judgement/ 'end of the bed' Geriatric assessment Formal risk assessment Pre-operative assessments Exercise testing Specialist nurse opinion Specific guidelines
If in such patients there is the potential for choice of resectional surgery, non resectional surgery or palliative options what level of involvement does the patient play in the management decision? How do you help them to decide?	Shared decision making versus paternalism, use of decision aids, role of specialist nurse, role of anaesthetic/geriatric assessment, role of relatives and friends, legal power of attorney and independent patient advocates in cognitive impairment, use of decision aids/booklets, psychological expertise, training courses
What factors have influenced your personal strategy for dealing with these patients?	Literature evidence, patient involvement, experience of cases over the years, unit policy, training and mentoring, specialist nurse input, MDT involvement

What affects the amount of information you relay to a patient with GI cancer?	Patient demand, cognitive status, relatives and carers information needs, recent changes in law (Montgomery v Lanarkshire)
What do you think older patients feel about having surgery?	Fear of death and 'not waking up', disfigurement, hospitalisation, burden on carers after surgery, loss of independence, complications, post-traumatic stress
What do you think older patients feel about chemotherapy?	Easier than having an operation, safer than having an operation, less certainty of cure, less hassle. Fear of chemotherapy side effects, hair loss, nausea, risk of death. Attending the hospital rather than spending time with family, accept quantity of time gained at the loss of quality
What do you think patients think about non-resectional surgery/ palliative procedures/ other options?	Fears of being in pain, shorter survival, less risky than major procedure, focused on improving/preserving quality of life, getting back to their normal, returning to pre-procedure quality of life
Fitness	
How do you personally assess the CRF and frailty of your patients?	On the basis of history and examination Specific questions – climb stairs, how far they can walk Validated questionnaire or fitness/frailty assessment CPET testing/ 6MWT/ Timed up and go
Who do you formally cardiorespiratory fitness test?	Everyone having specific procedures Age specific Certain co-morbidities Those in whom you have doubts about their CRF
What is your strategy for dealing with patients who you believe to have borderline fitness?	Refer for formal exercise testing (CPET) Advise anaesthetic opinion Advise them on how to get fit Give them an exercise regime Advise them to make an appointment with their GP Explore prehabilitation options, refer for physiotherapy, social services input, Surgery School. Tell them to stop smoking, reduce alcohol Shared decision-making
What is your strategy for patients who you believe are unfit for an operation?	Advise them on other options – chemotherapy, radiotherapy, palliative procedures e.g. RFA, stenting, palliative care

<u>Prompts for Geriatricians</u>

Question	Prompts
What options would you normally consider for an older	<u>Surgical</u> Major resection - laparoscopic versus open

person with surgical gastrointestinal pathology?	Non resectional surgery or alternative procedure if unfit/frail e.g. stoma, stenting Oncological Neoadjuvant chemotherapy or radiotherapy Adjuvant chemotherapy Short course vs. long course Palliative: chemotherapy, best supportive care
What is your involvement in elective general surgical patients?	Pre-operative assessment Post-operative assessment and advice or shared care
What factors influence your advice on management for a particular patient?	Patient factors: Co-morbidities, cardiorespiratory fitness, functional status, cognitive impairment, frailty, patient choice, carer attitudes, age, views on a stoma Symptom burden Specific assessments: Comprehensive Geriatric Assessment, frailty screens
If in such patients there is the potential for choice of resectional surgery, non resectional surgery or palliative options what level of involvement does the patient play in the management decision? How do you help them to decide?	Shared decision making versus paternalism, use of decision aids, role of specialist nurse, role of anaesthetic assessment, role of relatives and friends, legal power of attorney and independent patient advocates in cognitive impairment, use of decision aids/booklets, psychological expertise, training courses, access to time sensitive palliative care services and acute pain services
What factors have influenced your personal strategy for dealing with these patients?	Literature evidence, patient involvement, experience of cases over the years, unit policy, training and mentoring, specialist nurse input, MDT involvement
What affects the amount of information you relay to a patient with major GI pathology?	Patient demand, cognitive status, relatives and carers information needs, recent changes in the law (Montgomery v Lanarkshire)
What do you think older patients feel about having surgery?	Fear of death and 'not waking up', disfigurement, hospitalisation, burden on carers after surgery, loss of independence, complications, post traumatic stress
What do you think older patients feel about chemotherapy?	Easier than having an operation, safer than having an operation, less certainty of cure, less hassle. Fear of chemotherapy side effects, hair loss, nausea, risk of death, attending the hospital often rather than spending time with family, trade-off of quantity of time gained at the expense of quality
What do you think older patients think about non-	Fears of being in pain, shorter survival, less risky than major procedure, focused on improving/

resectional surgery/ palliative procedures/ other options?	maintaining quality of life, getting back to their normal
Emergency	
What is your involvement in emergency general surgical patients?	Pre-operative input when time available Post-operative – routinely review all laparotomy patients or just on request
How does your management differ if the patient presents as an emergency?	Baseline assessment – albumin, functional status, co-morbidities, cardiorespiratory fitness assessment Optimisation of geriatric syndromes pre-/post-op Risk assessment – anaesthetic opinion, specific risk calculators MDT – who is involved? Radiologist, anaesthetist, surgeon, critical care, other Time of day
Fitness	
How do you personally assess the CRF and frailty of your patients?	On the basis of history and examination Comprehensive Geriatric Assessment Specific questions – climb stairs, how far they can walk Validated CRF/frailty questionnaire CPET testing/ 6MWT/ Timed up and go
Who do you think should be formally cardiorespiratory fitness tested?	Everyone having specific procedures Age specific, certain co-morbidities Those in whom you have doubts about their fitness
What is your strategy for dealing with older surgical patients who you believe to have borderline fitness?	Medical and geriatric optimisation Refer for formal exercise testing (CPET) Seek anaesthetic opinion Advise them on how to get fit Give them an exercise regime Advise them to make an appointment with their GP Explore prehabilitation options, refer for physiotherapy, social services input, Surgery School. Tell them to stop smoking, reduce alcohol Shared decision-making Are you aware of what is available for those with borderline fitness; are these in house or out house services
What is your strategy for patients who you believe are unfit for an operation?	Advise them on other options – surgical, medical, palliative

<u>Prompts for Specialist Nurses</u>

Question	Prompts

What treatment options would you normally consider for an older person with operable major GI pathology?	Surgical Major resection - laparoscopic versus open Non resectional surgery or alternative procedure if unfit/frail e.g. stoma, stenting Oncological Neoadjuvant chemotherapy or radiotherapy Adjuvant chemotherapy Short course vs. long course Palliative: chemotherapy, best supportive care
What factors influence your recommendations on management for an older person?	Pathology: Location and size, operability/ stage, malignant versus non-malignant Patient factors: Co-morbidities, cardiorespiratory fitness, functional status, cognitive impairment, frailty, patient choice, carer attitudes, age, views on a stoma Specific assessments: Clinical assessment/ judgement/ 'end of the bed' Geriatric assessment Formal risk assessment Pre-operative assessments Cardiopulmonary Exercise Testing, 6MWT, ISWT Anaesthetic considerations, access to critical care Specific guidelines
If in such patients there is the potential for choice of resectional surgery, non resectional surgery or palliative options what level of involvement does the patient play in the management decision? How do you help them to decide?	Shared decision making versus paternalism, use of decision aids, role of anaesthetic/geriatric assessment, role of relatives and friends, legal power of attorney and independent patient advocates in cognitive impairment, use of decision aids/booklets, psychological expertise, training courses, access to time sensitive palliative care and acute pain services
What factors have influenced your personal strategy for dealing with these patients?	Literature evidence, patient involvement, experience of cases over the years, unit policy, training and mentoring, specialist nurse input, MDT involvement
What affects the amount of information you relay to a patient with major GI pathology?	Patient demand, cognitive status, relatives and carers information needs, recent changes in law (Montgomery v Lanarkshire)
What do you think older patients feel about having surgery?	Fear of death and 'not waking up', disfigurement, hospitalisation, burden on carers after surgery, loss of independence, complications, post traumatic stress
What do you think older patients feel about chemotherapy?	Easier than having an operation, safer than having an operation, less certainty of cure, less hassle. Fear of chemotherapy side effects, hair loss, nausea, risk

	of death, attending the hospital often rather than spending time with family, trade-off of quantity of time gained at the expense of quality
What do you think patients think about non-resectional surgery/ palliative procedures/ other options?	Fears of being in pain, shorter survival, less risky than major procedure, focused on improving/preserving quality of life, getting back to their normal
Emergency	
How are you involved in the management of patients presenting as an emergency?	<u>Pre-operative</u> Cancer patients may be known to specialist nurses, may be first point of contact in emergency situations e.g. bleeding or obstructive symptoms Stoma siting/ counselling <u>Post-operative</u> Stoma education, counselling, follow-up
Fitness	
How do you personally assess the CRF and frailty of your patients?	On the basis of history and examination Specific questions – climb stairs, how far they can walk Validated questionnaire or CRF/frailty assessment CPET testing/ 6MWT/ Timed up and go Allow others to do it for you
Who do you formally cardiorespiratory fitness test?	Everyone having specific procedures Age specific Certain co-morbidities Those in whom you have doubts about their fitness
What is your strategy for dealing with patients who you believe to have borderline CRF?	Advise formal exercise testing (CPET) Advise anaesthetic opinion Advise them on how to get fit Give them an exercise regime Advise them to make an appointment with their GP Explore prehabilitation options, refer for physiotherapy, social services input, Surgery School Tell them to stop smoking, reduce alcohol Advise them of other options Shared decision-making Are you aware of what is available for those with borderline fitness; are these in house or out house services
What is your strategy for patients who you believe are unfit for an operation?	Advise them on other options – surgical, medical, palliative

<u>Prompts for General Practitioners</u>

Question	Prompts

What options do you consider when an older patient presents with symptoms suggestive of resectable GI pathology?	Elective– suspected cancer pathway, routine referral, watch and wait in community Emergency – refer to general surgery, refer to medicine – geriatrics/ gastroenterology, manage in the community
What factors influence your choice of management for a particular patient?	Suspected pathology Patient factors: Co-morbidities, cardiorespiratory fitness, functional status, cognitive impairment, frailty, patient choice, carer attitudes, age Specific guidelines
If in such patients there is the potential for choice of resectional surgery, non resectional surgery or palliative options do you ever have any input into the treatment decision making? Do patient ask you for advice? How do you help them to decide?	Shared decision making versus paternalism, use of decision aids, role of relatives and friends, legal power of attorney and independent patient advocates in cognitive impairment, use of decision aids/booklets, psychological expertise, training courses
What factors have influenced your personal strategy for dealing with these patients?	Literature evidence, patient involvement, experience of cases over the years, training and mentoring
What affects the amount of information you relay to a patient with major GI pathology?	Patient demand, cognitive status, relatives and carers information needs, recent changes in law
What do you think older patients feel about having surgery?	Fear of death and 'not waking up', disfigurement, hospitalisation, burden on carers after surgery, loss of independence, complications, Post traumatic stress
What do you think older patients feel about chemotherapy?	Easier than having an operation, safer than an operation, less certainty of cure. Fear of chemotherapy side effects, hair loss, nausea, risk of death, attending the hospital often rather than spending time with family, trade-off of quantity of time gained at the expense of quality
What do you think patients think about non-resectional surgery/ palliative procedures/ other options?	Fears of being in pain, shorter survival, less risky than major procedure, focused on improving/ maintaining quality of life, getting back home/ returning to normal
Emergency	
How does your management differ if the patient presents as an emergency?	More likely to refer for surgical review Discussion of LPA, resuscitation status, future wishes
Fitness	

How do you personally assess the CRF and frailty of your patients?	On the basis of history and examination Specific questions – climb stairs, how far they can walk Validated questionnaire or CRF/frailty assessment
What is your strategy for dealing with patients who you believe to have borderline fitness?	Advise that you are referring them to surgeons but that surgery may not be an option Advise them on how to get fit Explore prehabilitation options, refer for physiotherapy, social services input. Tell them to stop smoking, reduce alcohol Shared decision-making
What is your strategy for patients who you believe are unfit for an operation?	Refer them for surgical assessment Advise them on other options – surgical, medical, palliative
What are the issues that you face in the community regarding older people undergoing major surgery	Inappropriate discharge, readmission, management of complex wounds, inadequate care packages Access to formal community rehabilitation programmes

Data Analysis qualitative interviews

Qualitative interview transcript analysis will follow the National Centre for Social Research "Framework" approach, to identify recurrent themes(65). The Framework approach permits the systematic analysis of large volumes of textual data and permits within and across case and theme comparison. Analysis will be undertaken by Sarah Daniels with prior training and supervision from two experienced qualitative researchers (MB and LW). A thematic index will be drawn up and applied to the data. Data will be distilled, summarised and entered into thematic charts to allow examination and interpretation of the data and to identify any relationships between themes. Analysis will use NVivo software.

Stage 3: Questionnaire study

Recruitment to questionnaire study

Gastrointestinal surgeons, including oesophagogastric, colorectal, hepatobiliary, pancreatic, and general surgeons who perform elective or emergency gastrointestinal surgery will be approached to participate in the questionnaire study. This will be via an online survey platform (SurveyMonkey) to members of relevant specialty associations (Association of Coloproctologists, Association of Upper GI Surgeons, Association of Surgeons of Great Britain and Ireland and British Association of Surgical Oncologists) and via a paper based form to surgeons within the North Trent and the Yorkshire and Humber

region and via contacts of the study team. Anaesthetists involved in elective and emergency gastrointestinal surgical patients and peri-operative care will be approached in the same way; via specialty associations (Association of Anaesthetists of Great Britain and Ireland, Age Anaesthesia UK, Peri-operative Society) and via regional networks and contacts of the study team. Respondents will be asked some details about their surgical/anaesthetic practice and to tick a box to state whether their area is rural or urban, affluent, intermediate or deprived. They will also be asked to estimate their own use of formal CRF and frailty testing, as well as pre-operative methods of optimisation, ERAS protocols and post-operative rehabilitation programmes. They will be asked questions related to how they risk assess patients and their management strategies for patients who are unfit or have borderline CRF. All responses will be anonymous. A letter of invitation (Appendix VI) will be sent to potential participants alongside the questionnaire (Appendix VII: Sample questionnaire). The letter of invitation and questionnaire will be made up into packs together with a prepaid envelope and sent to individuals as specified above. The letter will be converted into an email with an embedded link to the online questionnaire for dissemination via the specialty associations. The specialty associations will send the email to their own mailing lists in line with the GDPR. One email reminder will be sent but no reminders will be sent to recipients of the paper based form.

A record of the number of packs sent out will be kept and correlated with the number returned to give the response rate. The associations will be asked for the number of emails sent and a record of the number of online responses will be kept. Based on previous similar study a response rate of 40% is expected(67).

Questionnaire design

The discrete choice questionnaire will involve different scenarios and treatment preferences for resectional (major) surgery, non resectional surgery or palliative procedures or best supportive care. Discrete choice scenarios provide information on the relative weights individual professionals attach to the various dimensions (variables) involved in the decision-making process and how willing they are to trade these off against each other in reaching a decision. Respondents will be provided with treatment choices for hypothetical scenarios and asked to choose their preferred management for

each scenario. These choices can then be used to infer the trade-offs people are willing to make with respect to changes in the levels of the attributes.

Scenarios will be developed in conjunction with Dr Arturo Vilches-Moraga (Geriatrician) to determine whether all are realistic representations of real life older people and also to estimate whether individual scenarios would be associated with a predicted life expectancy of less than 1 years, 1-5 years or greater than 5 years. This is based on the time periods selected in a similar study in breast cancer, however there are key differences in gastrointestinal surgery as it may be performed for immediate life-threatening pathology, relief of acute or chronic symptoms or to prevent future complications, for example.

For pragmatic reasons (survey length and acceptability), a limited number of variables can be incorporated into the study design. Key variables that may be included in this survey include patient age, comorbidity status, pathology (malignant or non-malignant), presentation (emergency or elective presentation), functional status and cognitive function. Scenario descriptions will then be generated by 'Orthoplan' software from SPSS, converting an orthogonal array of dimensions and their levels into an additive model, generating all possible combinations of levels of the key variables. The hypothetical combinations will be presented in the form of a survey, as scenarios composed of the different levels of the variables.

Respondents will be asked to make a choice between the different models proposed for each scenario. At this stage of the design it is not possible to specify the factors and levels to be included in the hypothetical scenarios for the discrete choice scenarios. However, previous work with health care professionals in the field of breast cancer has suggested that respondents can look at up to 25 scenarios with 5 factors (with up to five levels for some of the factors) (66,68).

A draft questionnaire is presented in Appendix VII with discrete choice elements. The final version will be submitted for chairman's approval/ amendment approval once the interview data has been incorporated and the questionnaires have been piloted using a focus group of between 5 and 8 surgeons of various GI disciplines to confirm usability, face and content validity.

Power calculation and sample size for questionnaire study

The power calculation to determine the required sample size will be based on the discrete choice element as the primary endpoint. This cannot be performed until the questionnaire has been finalised and will be performed in conjunction with the study statistician (Dr J Lewis).

Statistical analysis plan for the questionnaire study

The first part of the questionnaire is essentially descriptive and will be analysed by calculation of median response and range to the Likert style questions. Correlation of response medians with surgeon characteristics such as age subgroup and professional subtype will be performed using Chi squared test.

Training of the Research Student in Qualitative Research Methodology.

The student will be formally mentored by Professor Wyld and Dr Burton throughout her research attachment and will access a qualitative research lecture module run by ScHARR at the University of Sheffield. She will also attend a 1 day training course on interviewing techniques run by Dr Michelle Winslow of the University of Sheffield (a specialist in oral history and qualitative interviewing techniques). The student will also be accompanied by Dr Burton or Professor Wyld during her first few interviews and quality control applied subsequently by means of review of audio recordings.

Project Gantt Chart and Time Lines.

Action (Months)	**3**	**6**	**9**	**12**	**15**	**18**	**21**	**24**
Literature Review								
Write-up literature review for publication								
Recruitment and interviewing								
Transcribe and analyse interviews								
Develop and send out questionnaire								
Data analysis								
Report, write up and publication								

Data Management and Confidentiality

All data will be handled, computerised and stored in accordance with the Data Protection Act 1998. The database will be stored on an encrypted, password protected computer. All packs will be sent to the researcher, Sarah Daniels, either in paper form or electronically via secure nhs.net e-mail. All participant identifiers will be removed from interview recordings, transcripts of interviews and questionnaires and replaced with a unique research identification code. The key to this code will be held separately in a secure location in the University in a locked research office. Consent forms, which are a legal document, will retain identifiers but will be held securely in a locked research office in a secure area of the University. Feedback from the research will be offered to all study participants on study completion in the form of a final study report. The results may also be disseminated at appropriate forums/ conferences. At no point will staff names be used. Data will be held by the study team for 10 years after the completion of the study and then confidentially destroyed.

If any participant wishes to withdraw consent at any time and for any reason, this will be respected. If they wish for their records to be destroyed (both paper based, digital audio files and on line), this will be done using secure means. The study team will simply keep a numeric record of the number of withdraws for transparency purposes.

Patient and Public Involvement

The Doncaster NHS Foundation Trust Patient and Public Involvement group have been involved in the development of this protocol. Alan Spencer and Mandy Ashton will form part of the study steering group and will be invited to assist with transcript analysis and interpretation, drafting of participant information sheets and any publications or presentations arising from this work.

Regulatory Approvals

University of Sheffield Ethics approval will be obtained before the study commences. NHS ethics committee review will not be required. Health Research Authority approval will be obtained for this study. Confirmation of Capacity and Capability at each hospital site will be obtained. All study researchers will have undergone full GCP training and hold valid

NHS research passports. The study will be conducted in accordance with the principles of GCP according to the EU Directive 2005/28/EC(69).

Archiving

A Site File of study documentation will be archived by all sites for a minimum of 5 years after study completion. All interview digital recordings, transcriptions and consent forms will be archived at the University for 10 years. After the archiving period and following authorisation from the sponsors, arrangements for confidential destruction will then be made.

Study Sponsorship and Indemnity

This study will be sponsored by Doncaster Teaching Hospitals NHS Foundation Trust who therefore will be liable for negligent harm caused by the design of the study. There are no patients involved in this study and therefore no risks to patients.

Responsibilities and Operational Structure.

Lynda Wyld (Professor of Surgical Oncology at the University of Sheffield Medical School and Consultant Surgeon at DRI) will be the research student's primary supervisor and project lead. Qualitative and mixed methodological expertise will be provided by Dr Maria Burton. Statistical advice will be provided for analysis of the questionnaire data by Dr Jen Lewis.

Study Management Group

The study management group will meet regularly to review progress with meetings annually face to face and by e mail/telephone every 6 months. This will include all of the study collaborators listed above.

Funding

The day-to-day conduct of the study will be undertaken by the research fellow (during a 24 month research placement). Miss Daniels will be employed by Sheffield Teaching Hospitals NHS Trust for the duration of the project as a Clinical Research Fellow. Salary funding is provided by the STH Trust from a clinical research fellow post. The necessary digital transcription machines are already available in the Department. Stationary, postage and printing costs for the study will be supported by two project grants from the Bowel Disease Research Foundation (BDRF) and the British Association for Surgical Oncology (BASO).

Appendix G: University of Sheffield Medical School Ethics review outcome

Downloaded: 13/11/2019
Approved: 27/06/2019

Sarah Daniels
Registration number: 180255328
Oncology
Programme: MD in research

Dear Sarah

PROJECT TITLE: Clinician Preferences for Treatment of Older Patients facing Major GI Surgery
APPLICATION: Reference Number 028079

On behalf of the University ethics reviewers who reviewed your project, I am pleased to inform you that on 27/06/2019 the above-named project was **approved** on ethics grounds, on the basis that you will adhere to the following documentation that you submitted for ethics review:

- University research ethics application form 028079 (form submission date: 06/06/2019); (expected project end date: 04/06/2021).
- Participant information sheet 1063395 version 1 (06/06/2019).
- Participant information sheet 1063393 version 1 (06/06/2019).
- Participant consent form 1063394 version 1 (06/06/2019).

The following optional amendments were suggested:

Please consider Niocola Brown's comments. Thank you.

If during the course of the project you need to deviate significantly from the above-approved documentation please inform me since written approval will be required.

Your responsibilities in delivering this research project are set out at the end of this letter.

Yours sincerely

Melanie Viphakone
Ethics Administrator
Medical School

Please note the following responsibilities of the researcher in delivering the research project:

- The project must abide by the University's Research Ethics Policy: https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/approval-procedure
- The project must abide by the University's Good Research & Innovation Practices Policy: https://www.sheffield.ac.uk/polopoly_fs/1.671066!/file/GRIPPolicy.pdf
- The researcher must inform their supervisor (in the case of a student) or Ethics Administrator (in the case of a member of staff) of any significant changes to the project or the approved documentation.
- The researcher must comply with the requirements of the law and relevant guidelines relating to security and confidentiality of personal data.
- The researcher is responsible for effectively managing the data collected both during and after the end of the project in line with best practice, and any relevant legislative, regulatory or contractual requirements.

Appendix H: Completed IRAS form for clinician preferences study

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Clinician Preferences for Older Patients undergoing GI Surgery

1. Is your project research?

(•) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
(•) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (•) No
b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (•) No
c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (•) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

[x] England
[ ] Scotland

☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◉ England
○ Scotland
○ Wales
○ Northern Ireland
○ This study does not involve the NHS

4. Which applications do you require?

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ Her Majesty's Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

◉ Yes ○ No

4b. Please confirm the reason(s) why the project does not require review by a REC within the UK Health Departments Research Ethics Service:

☐ Projects limited to the use of samples/data samples provided by a Research Tissue Bank (RTB) with generic ethical approval from a REC, in accordance with the conditions of approval.
☐ Projects limited to the use of data provided by a Research Database with generic ethical approval from a REC, in accordance with the conditions of approval.
☐ Research limited to use of previously collected, non-identifiable information
☐ Research limited to use of previously collected, non-identifiable tissue samples within terms of donor consent
☐ Research limited to use of acellular material
☐ Research limited to use of the premises or facilities of care organisations (no involvement of patients/service users as participants)
☑ Research limited to involvement of staff as participants (no involvement of patients/service users as participants)

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative in all study sites?

Please see information button for further details.

○ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

(●) Yes ( ) No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

( ) Yes (●) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

( ) Yes (●) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

( ) Yes (●) No

9. Is the study or any part of it being undertaken as an educational project?

( ) Yes (●) No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

( ) Yes (●) No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

( ) Yes (●) No

Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Clinician Preferences for Older Patients undergoing GI Surgery

Please complete these details after you have booked the REC application for review.

REC Name:

REC Reference Number: **Submission date:**

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Clinician Preferences for the Treatment of Older Patients Facing Major Gastrointestinal Surgery

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Sarah	Daniels
Post	Clinical Research Fellow		
Qualifications	MBChB BSc MRCS MSc		
ORCID ID	0000 0001 9452 3344		
Employer	Sheffield Teaching Hospitals NHS FT		
Work Address	General Surgery		
	Northern General Hospital		
	Herries Road		
Post Code	S5 7AU		
Work E-mail	sarahdaniels1@nhs.net		
* Personal E-mail	sarahdanielsx@gmail.com		
Work Telephone	01142266210		
* Personal Telephone/Mobile	07941605424		

Fax

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Dr	Debby	Hawkins
Address	General Surgery		
	Northern General Hospital		
	Heries Road		
Post Code	S5 7AU		
E-mail	debby.hawkins@nhs.net		
Telephone	01142266210		
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	STH20693
Sponsor's/protocol number:	
Protocol Version:	1.0
Protocol Date:	08/10/2019
Funder's reference number (enter the reference number or state not applicable):	N/A
Project website:	

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language*

easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.

The UK population is aging. Under investigation and undertreatment of older people is common, with rates of surgery declining with age, despite the fact that surgically treated pathology rates increase with age. There are large variations in outcomes in older people, between different surgical units in the UK, which suggests that not all patients are receiving the same level of care or access to resources. Major surgery remains one of the most debilitating events that an older person may experience and may profoundly influence functional decline and disability. Optimisation of outcomes in older patients with comorbidities and frailty requires multiprofessional input which is often lacking.

There are few age and fitness specific evidence-based guidelines for major gastrointestinal (GI) surgery. The majority of trials exclude older, less fit patients. Whether an older patient is offered resectional (major) surgery as opposed to non-resectional surgery or palliative procedures is variable. Decision making is multifactoral and influenced by the patient and their clinician. Adequate assessment of fitness and frailty and subsequent targeted intervention to enhance resilience is often lacking. There are a range of proven techniques to enhance outcomes in the perioperative period, however there is variation between individual clinicians and multidisciplinary teams in how and whether these are applied.

This mixed methodology study spanning emergency and elective major surgery aims to determine how clinicians make decisions in older patients regarding fitness for surgery and what strategies they employ to optimise patients who are considered high risk. This will be achieved by:

1. semi-structured interviews with specialist health care professionals regarding how they make assessments of fitness for major GI surgery and what options they consider if a patient is deemed high-risk
2. questionnaire to quantify the results of the semi-structured interviews with hypothetical patient scenarios

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

The ethical, legal and management issues arising from this study are minimal. The study will involve Health Care Professional interviews from multiple NHS sites and General Practitioners. No patients will be involved.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☑ Qualitative research
- ☑ Questionnaire, interview or observation study
- ☐ Randomised controlled trial

☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

What are the factors underlying treatment decision-making in health care professionals relating to older patients facing resectional (major) gastrointestinal surgery?

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

To determine the strength of these factors in causing variance in decision-making practice amongst health care professionals.

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

It has been reported that older patients (≥65 years) have huge variation in their gastrointestinal disease treatment pathways compared to younger patients in both the emergency and elective settings. Given than most GI surgical pathologies occur in older age it is important that this group receive appropriate treatment options based on their personal health status and treatment preferences rather than their chronological age. There is a need for more standardised assessment of patients, taking into account individual co-morbid status and frailty.

This study will give an insight into the factors that are taken into account when clinicians are deciding on treatment plans for older patients. It is part of a larger programme of research that will also determine the factors the older patients themselves take into account when they decide on how they wish to be treated, their views on peri-operative optimisation and the outcomes of different treatments in this age group. It is hoped that the research will enable the development of guidelines and a decision aid for optimised, individualised care of older patients with malignant and non-malignant GI conditions.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

This is an interview study for health care professionals (n=20-30). The interviews will take place at NHS sites in England or by telephone. The HCP will be given a letter of invitation and participant information sheet and asked to sign a consent form.

The study is set out in the following stages:

1. To undertake 20-30 semi-structured interviews with gastrointestinal surgeons, anaesthetists, geriatricians, oncologists, cancer specialist nurses, pre-assessment specialist nurses and general practitioners within the South Yorkshire region using a pre-prepared interview prompt sheet. Key topics will include assessment of cardiorespiratory fitness, optimisation, palliative/ conservative treatment options and decision-making. Interviews will take place until there has been saturation of themes.

2. To undertake a discrete choice experiment using the factors identified in the semi-structured interviews to quantitatively assess via a questionnaire involving hypothetical patient scenarioshow individuals perform fitness assessment and treatment decision making in a range of healthcare professionals (surgeons and anaesthetists).

3. Mixed methods synthesis of qualitative and quantitative aspects to identify barriers and facilitators to optimal care

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

☑ Design of the research
☐ Management of the research
☐ Undertaking the research
☐ Analysis of results
☑ Dissemination of findings

☐ None of the above

Give details of involvement, or if none please justify the absence of involvement.
Doncaster PPI group have reviewed the protocol and will be involved in the dissemination of the findings.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- ☐ Blood
- ☑ Cancer
- ☐ Cardiovascular
- ☐ Congenital Disorders
- ☐ Dementias and Neurodegenerative Diseases
- ☐ Diabetes
- ☐ Ear
- ☐ Eye
- ☐ Generic Health Relevance
- ☐ Infection
- ☐ Inflammatory and Immune System
- ☐ Injuries and Accidents
- ☐ Mental Health
- ☐ Metabolic and Endocrine
- ☐ Musculoskeletal
- ☐ Neurological
- ☑ Oral and Gastrointestinal
- ☐ Paediatrics
- ☐ Renal and Urogenital
- ☐ Reproductive Health and Childbirth
- ☐ Respiratory
- ☐ Skin
- ☐ Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit:	No upper age limit

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Health Care Professionals working in Gastrointestinal or General Surgery units at NHS sites and General Practitioners who see patients with suspected gastrointestinal pathology will be approached for the healthcare professional interviews. The questionnaire will be disseminated to anaesthetists and surgeons routinely managing

patients undergoing either elective or emergency major GI surgery.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Staff who are not involved in the care pathway of patients with major GI pathology

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Consent	1	0	30	PI or delegated member of team with GCP training
Semi structured interview of HCP	1	0	30	PI or delegated member of team with GCP training
Online questionnaire using Discrete Choice Methodology (SurveyMonkey)	1	0	30	Online by participant

A21. How long do you expect each participant to be in the study in total?

30 minutes per semi-structured interview, 30 minutes for completion of the online questionnaire.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

None

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

○ Yes ◉ No

A24. What is the potential for benefit to research participants?

May benefit older GI patients in the future by standardising treatment options.

A26. What are the potential risks for the researchers themselves? *(if any)*

None

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

For the interviews, a local Principle Investigator (PI) will be identified at each site by direct contact from a member of the study team. The PI will be asked to provide a list of names of suitable health care professionals working within the unit who agree to be contacted by the study team. In the case of GPs, these HCPs will be identified by Caroline Mitchell who is a Senior Lecturer and GP on the study team.

Individuals will then be sent a study pack by post or e-mail that will contain the following: a letter of invitation, a participant information sheet (PIS), a study reply slip and a freepost envelope. This will invite the HCP to complete a reply slip to agree to be contacted about taking part. On receipt of a reply slip or confirmatory e-mail agreeing to participate, the research team will contact the interview candidate to schedule the interview. This will be agreed verbally and confirmed in writing before the scheduled date. A consent form will be signed before the interviews commence on the day of the interview. Individuals who request a telephone interview will be sent the consent form to complete prior to this commencing. A copy of the consent form will be given to the HCP, the original retained in the local Investigator Site File and a copy retained at the Sponsor site by the CI for monitoring purposes.

HCPs will be interviewed by the CI at the NHS site or by phone. In the case of GPs, this will be by phone only.

For the questionnaires, an email with an explanation of the project, invitation to participate and embedded link to the online survey will be sent to relevant specialty associations (with membership including Anaesthetists or Gastrointestinal surgeons) by the CI. In line with GDPR, the specialty associations will be asked to forward the email to their own membership and to give the researcher an estimate of the number of members contacted.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

Participants for the clinician interviews will be approached either directly by the CI or delegated study team member at STH or via the PI at each site.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

The HCP will be given a participant information sheet and asked to sign a consent form before the interview commences. Participants of the online questionnaire will be assumed to have consented to their data being used in the research study by completing the online survey.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

(●) Yes ( ) No

A31. How long will you allow potential participants to decide whether or not to take part?

24 hours or more.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

N/A

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

( ) The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

( ) The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

( ) The participant would continue to be included in the study.

( ) Not applicable – informed consent will not be sought from any participants in this research.

(●) Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- [ ] Access to medical records by those outside the direct healthcare team
- [ ] Access to social care records by those outside the direct social care team
- [ ] Electronic transfer by magnetic or optical media, email or computer networks
- [ ] Sharing of personal data with other organisations
- [ ] Export of personal data outside the EEA
- [ ] Use of personal addresses, postcodes, faxes, emails or telephone numbers
- [x] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals

- [x] Use of audio/visual recording devices
- [x] Storage of personal data on any of the following:
  - [x] Manual files (includes paper or film)
  - [x] NHS computers
  - [ ] Social Care Service computers
  - [ ] Home or other personal computers
  - [x] University computers
  - [ ] Private company computers
  - [ ] Laptop computers

Further details:
The recruitment log and consent forms will be filed in the Investigator Site File and will remain at the local NHS site.

Consent forms will also be retained by the Sponsor site for monitoring purposes. HCP contact details will also be retained at the Sponsor site.

The pseudonymised data will be analysed by the study team at the Sponsor site and University of Sheffield. The UoS and STH will be joint data controllers.

A37. Please describe the physical security arrangements for storage of personal data during the study?

The Investigator Site File will be in a secure locked room or filing cabinet, only accessible to NHS staff.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

The staff will be given a unique ID number. No staff or patient names will be used during the interview or during translation of the interview. No identifiable information will be collected during the online questionnaire.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The PI at each site will have access to the staff details at their own site but not the recordings or transcripts from the interviews.

The CI at the Sponsor site will hold the consent forms of all participants in the study.

The online questionnaire will use a web based Survey Monkey organised through STH. Information from the online questionnaire will be stored securely on the online platform. Data reports generated from this will be stored on NHS and University of Sheffield computers.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

The interviews will be transcribed and analysed by the CI and study team at the Sponsor site (STH) and University of Sheffield. Data from the questionnaires will be analysed by the CI, study team, study statistician and supervisors at both the University of Sheffield and STH.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Dr	Sarah	Daniels
Post	Clinical Research Fellow		
Qualifications	MBChB BSc MRCS MSc		
Work Address	General Surgery		
	Herries Road		
	Sheffield		
Post Code	S5 7AU		
Work Email	sarahdaniels1@nhs.net		
Work Telephone	01142266210		
Fax			

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ◉ 6 – 12 months
- ○ 12 months – 3 years
- ○ Over 3 years

A44. For how long will you store research data generated by the study?

Years: 5
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

The study will be archived locally as advised by the local R&D Departments.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

○ Yes ◉ No

Please give details, or justify if not registering the research.
Not a clinical trial.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☑ Internal report
- ☑ Conference presentation
- ☐ Publication on website
- ☐ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- ☐ No plans to report or disseminate the results
- ☐ Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Staff will not be identifiable.

A53. Will you inform participants of the results?

◉ Yes ○ No

Please give details of how you will inform participants or justify if not doing so.
The results will be presented at regional meetings and conferences that participants may attend.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [x] Independent external review
- [ ] Review within a company
- [ ] Review within a multi−centre research group
- [ ] Review within the Chief Investigator's institution or host organisation
- [ ] Review within the research team
- [ ] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
Reviewed by the funders -British Association for Surgical Oncology and Bowel Disease Research Foundation

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- [ ] Review by independent statistician commissioned by funder or sponsor
- [ ] Other review by independent statistician
- [ ] Review by company statistician
- [x] Review by a statistician within the Chief Investigator's institution
- [x] Review by a statistician within the research team or multi−centre group
- [ ] Review by educational supervisor
- [ ] Other review by individual with relevant statistical expertise
- [ ] No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Dr	Jen	Lewis
Department	Medical Statistics		
Institution	School of Health and Related Research		
Work Address	University of Sheffield		
	Regent Court		
	Sheffield		
Post Code	S1 4DA		
Telephone	01142220839		
Fax			
Mobile			
E-mail	jen.lewis@sheffield.ac.uk		

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

To determine the factors underlying treatment decision-making in health care professionals relating to older patients

facing resectional (major) gastrointestinal surgery

A58. What are the secondary outcome measures?*(if any)*

To determine the strength of these factors in causing variance in decision-making practice amongst healthcare professionals.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	30
Total international sample size (including UK):	30
Total in European Economic Area:	30

Further details:
For the interviews, the proposed sample size is 30 participants. For the questionnaire study the proposed sample size is 100 participants. This will be a total of approximately 130 participants.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

Participants for the interviews will be recruited until there has been saturation of themes. The sample size for the questionnaire study will be finalised once the questionnaire has been amended in light of the findings from the clinician interviews

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Thematic analysis of clinician interviews. Questionnaires will be designed and analysed using the Discrete Choice methodology.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Professor	Lynda	Wyld
Post	Professor of Surgical Oncology		
Qualifications	MBChB PhD FRCS		
Employer	University of Sheffield		
Work Address	Academic Unit of Surgical Oncology		
	Room EU36		
	University of Sheffield Medical School		
Post Code	S10 2JF		
Telephone	01142159066		
Fax			

Mobile	
Work Email	l.wyld@sheffield.ac.uk

Title	Forename/Initials	Surname
Prof	Steven	Brown

Post	Honorary Professor of Colorectal Surgery
Qualifications	MBChB MD FRCS
Employer	Sheffield Teaching Hospitals NHS FT
Work Address	General Surgery, Northern General Hospital Herries Road Sheffield
Post Code	S5 7AU
Telephone	01142715279
Fax	
Mobile	
Work Email	steven.brown@sth.nhs.uk

Title	Forename/Initials	Surname
Dr	Tim	Wilson

Post	Consultant Colorectal and General Surgeon
Qualifications	MBChB PhD FRCS
Employer	Doncaster Teaching Hospitals NHS FT
Work Address	Doncaster Royal Infirmary Armthorpe Road Doncaster
Post Code	DN2 5LT
Telephone	01302644389
Fax	
Mobile	
Work Email	tim.wilson1@nhs.net

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- (●) NHS or HSC care organisation
- ( ) Academic
- ( ) Pharmaceutical industry
- ( ) Medical device industry
- ( ) Local Authority
- ( ) Other social care provider (including voluntary sector or private organisation)
- ( ) Other

Commercial status: Commercial

If Other, please specify:

Contact person

Name of organisation	Sheffield Teaching Hospitals NHS FT
Given name	Dipak
Family name	Patel
Address	CRIO, D Floor, Royal Hallamshire Hospital
Town/city	Sheffield
Post code	S10 2JF
Country	UNITED KINGDOM
Telephone	01142265934
Fax	
E-mail	dipak.patel12@nhs.net

A65. Has external funding for the research been secured?

Please tick at least one check box.

- [x] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [ ] No application for external funding will be made

What type of research project is this?

- (•) Standalone project
- ( ) Project that is part of a programme grant
- ( ) Project that is part of a Centre grant
- ( ) Project that is part of a fellowship/ personal award/ research training award
- ( ) Other

Other – please state:

Please give details of funding applications.

Organisation	British Association for Surgical Oncology
Address	35-43 Lincoln's Inn Fields London
Post Code	WC2A 3PE
Telephone	
Fax	
Mobile	
Email	admin@baso.org.uk

Funding Application Status: (•) Secured ( ) In progress

Amount: £2000

Duration
Years: 2
Months:

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

Organisation	Bowel Disease Research Foundation
Address	Royal College of Surgeons of England
	35-43 Lincoln's Inn Fields
	London
Post Code	WC2A 3PE
Telephone	02078696946
Fax	
Mobile	
Email	gsaffery@bdrf.org.uk

Funding Application Status: (•) Secured ( ) In progress

Amount: 8647

Duration
Years: 2
Months:

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

( ) Yes (•) No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

( ) Yes (•) No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

Title	Forename/Initials	Surname
Dr	Modhumita	Harris

Organisation	STH NHS FT
Address	Clinical Research and Innovation Office
	D Floor

	Royal Hallmshire Hospital
Post Code	S10 2JF
Work Email	modhumita.harris@nhs.net
Telephone	01142713570
Fax	
Mobile	

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A68-2. Select Local Clinical Research Network for NHS Organisation identified in A68-1:

Yorkshire and Humber

For more information, please refer to the question specific guidance.

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/11/2019
Planned end date: 31/10/2021
Total duration:
Years: 1 Months: 11 Days: 31

A71-1. Is this study?

- ○ Single centre
- ◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☑ England
- ☐ Scotland
- ☐ Wales
- ☐ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study 4

Does this trial involve countries outside the EU?

○ Yes ◉ No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☑ NHS organisations in England	4
☐ NHS organisations in Wales	
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☐ GP practices in England	

☐ GP practices in Wales
☐ GP practices in Scotland
☐ GP practices in Northern Ireland
☐ Joint health and social care agencies (eg community mental health teams)
☐ Local authorities
☐ Phase 1 trial units
☐ Prison establishments
☐ Probation areas
☐ Independent (private or voluntary sector) organisations
☐ Educational establishments
☐ Independent research units
☐ Other (give details)

Total UK sites in study: 4

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

◉ Yes ○ No

A73-2. If yes, will any of these organisations be NHS organisations?

○ Yes ◉ No

If yes, details should be given in Part C.

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

Monitoring is the responsibility of the Sponsor site as per their SOP.
STH will collect consent forms for monitoring purposes.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:* in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland**

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☑ NHS indemnity scheme will apply (NHS sponsors only)
☐ Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- [x] NHS indemnity scheme will apply (protocol authors with NHS contracts only)
- [ ] Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- [x] NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- [ ] Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

- ( ) Yes
- (•) No
- ( ) Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site	Investigator Name
IN1	◉ NHS/HSC Site ○ Non-NHS/HSC Site	Forename: Tim Middle name: Family name: Wilson Email: tim.wilson@nhs.net Qualification (MD...): MBChB PhD FRCS Country: UNITED KINGDOM
	Organisation name: DONCASTER AND BASSETLAW TEACHING HOSPITALS NHS FOUNDATION TRUST Address: DONCASTER ROYAL INFIRMARY ARMTHORPE ROAD DONCASTER SOUTH YORKSHIRE Post Code: DN2 5LT Country: ENGLAND	
IN2	◉ NHS/HSC Site ○ Non-NHS/HSC Site	Forename: Alison Middle name: Family name: Payne Email: Qualification (MD...): MBChB FRCS Country: UNITED KINGDOM
	Organisation name: BARNSLEY HOSPITAL NHS FOUNDATION TRUST Address: GAWBER ROAD BARNSLEY SOUTH YORKSHIRE Post Code: S75 2EP Country: ENGLAND	
IN3	◉ NHS/HSC Site ○ Non-NHS/HSC Site	Forename: Harjeet Middle name: Family name: Narula Email: harjeet.narula@nhs.net Qualification (MD...): MBChB Country: UNITED KINGDOM
	Organisation name: CHESTERFIELD ROYAL HOSPITAL NHS FOUNDATION TRUST Address: CALOW CHESTERFIELD DERBYSHIRE Post Code: S44 5BL	

Country	ENGLAND

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.
3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
4. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
5. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
7. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
9. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 2018.
10. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.
11. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 2018.
12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

HRA would like to include a contact point with the published summary of the study for those wishing to seek further

information. We would be grateful if you would indicate one of the contact points below.

- (●) Chief Investigator
- ( ) Sponsor
- ( ) Study co-ordinator
- ( ) Student
- ( ) Other – please give details
- ( ) None

Access to application for training purposes *(Not applicable for R&D Forms)*
Optional – please tick as appropriate:

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Ms Sarah Daniels on 11/10/2019 11:50.

Job Title/Post:	Clinical Research Fellow
Organisation:	Sheffield Teaching Hospitals NHS Foundation Trust
Email:	sarahdanielsx@gmail.com

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*
7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.
8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Dr Erica Wallis on 11/10/2019 11:14.

Job Title/Post:	Research Coordinator
Organisation:	Sheffield Teaching Hospitals NHS Foundation Trust
Email:	erica.wallis1@nhs.net

Appendix I: Health Research Authority approval letter Clinician preferences study

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Sarah Daniels
Clinical Research Fellow
Sheffield Teaching Hospitals NHS FT
General Surgery
Northern General Hospital
Herries Road
S5 7AU

Email: hra.approval@nhs.net
HCRW.approvals@wales.nhs.uk

07 November 2019

Dear Dr Daniels

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Clinician Preferences for the Treatment of Older Patients Facing Major Gastrointestinal Surgery**
IRAS project ID:	**272619**
REC reference:	**19/HRA/5964**
Sponsor	**Sheffield Teaching Hospitals NHS FT**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NH
HRA and HCRW Approval does not apply to nor
your non-NHS organisations to obtain local agre

https://www.myresearchproject.org.uk
hlpsitespecific.aspx#non-NHS-SSI

What are my notification responsibilities during the study?

The *"After HRA Approval – guidance for sponsors and investigators"* document on the HRA website gives detailed guidance on reporting expectations for studies with HRA and HCRW Approval, including:

- Registration of Research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **272619**. Please quote this on all correspondence.

Yours sincerely,
Alex Thorpe

Approvals Manager

Email: hra.approval@nhs.net

Copy to: *Dr Debby Hawkins, Sponsor's Representative*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Interview schedules or topic guides for participants [Interview Schedule Appendix V]	1.0	08 October 2019
IRAS Application Form [IRAS_Form_16102019]		16 October 2019
IRAS Application Form XML file [IRAS_Form_16102019]		16 October 2019
IRAS Checklist XML [Checklist_16102019]		16 October 2019
Letter from funder		
Letters of invitation to participant [Reply Slip Appendix III]	1.0	08 October 2019
Letters of invitation to participant [Letter of Invitation Questionnaire Appendix VI]	1.0	08 October 2019
Letters of invitation to participant [Letter of Invitation Interview Appendix I]	1.0	08 October 2019
Non-validated questionnaire [HCP Questionnaire Appendix VII]	1.0	08 October 2019
Organisation Information Document		
Participant consent form [Interview Consent Form Appendix IV]	1.0	08 October 2019
Participant information sheet (PIS) [PIS Appendix II]	1.0	08 October 2019
Summary CV for Chief Investigator (CI) [CI CV]		16 April 2019

Appendix J: Non-substantial amendments for clinician preferences study

Non substantial amendment number 1

Partner Organisations:
Health Research Authority, England
NHS Research Scotland
HSC Research & Development, Public Health Agency, Northern Ireland
NIHR Clinical Research Network, England
NISCHR Permissions Co-ordinating Unit, Wales

Notification of Non-Substantial/Minor Amendments(s) for NHS Studies

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.
If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

Instructions for using this template

- For guidance on amendments refer to http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/ . If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

1. Study Information

Full title of study:	Clinician Preferences for Treatment of Older Patients facing Major Gastrointestinal Surgery
IRAS Project ID:	272619
Sponsor Amendment Notification number	1
Sponsor Amendment Notification date:	04.12.19
Details of Chief Investigator:	
Name [first name and surname]	Sarah Daniels
Address:	Old Nurses Home, Northern General Hospital, Sheffield Teaching Hospitals NHS FT, Herries Road, Sheffield
Postcode:	S5 7AU
Contact telephone number:	0114 2266210
Email address:	Sarahdaniels1@nhs.net
Details of Lead Sponsor:	
Name:	Sheffield Teaching Hospitals NHS FT
Contact email address:	Modhumita.harris@nhs.net
Details of Lead Nation:	
Name of lead nation *delete as appropriate*	England
If England led is the study going through CSP? *delete as appropriate*	Yes
Name of lead R&D office:	CRIO, STH

Partner Organisations:
Health Research Authority, England
NHS Research Scotland
HSC Research & Development, Public Health Agency, Northern Ireland
NIHR Clinical Research Network, England
NISCHR Permissions Co-ordinating Unit, Wales

2. Summary of amendment(s)

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.
If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

No.	Brief description of amendment *(please enter each separate amendment in a new row)*	Amendment applies to *(delete/ list as appropriate)*		List relevant supporting document(s), including version numbers *(please ensure all referenced supporting documents are submitted with this form)*		R&D category of amendment *(category A, B, C) For office use only*
		Nation	Sites	Document	Version	
1	Addition of a new site PI: Mr Richard Slater Consultant General Surgeon The Rotherham NHS Foundation Trust Moorgate Rd Rotherham S60 2UD	England	All sites or list affected sites	N/A	N/A	
2						
3						
4						
5						

[Add further rows as required]

3. Declaration(s)

Declaration by Chief Investigator

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment(s) to be implemented.

Signature of Chief Investigator: .....

Print name: SARAH DANIELS

Date: 4/12/19

Optional Declaration by the Sponsor's Representative (as per Sponsor Guidelines)

The sponsor of an approved study is responsible for all amendments made during its conduct.

The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules on delegated authority should be adhered to.

- I confirm the sponsor's support for the amendment(s) in this notification.

Signature of sponsor's representative: .....

Print name:.....

Post: .....

Organisation:.....

Date:.....

Non substantial amendment number 2

Notification of Non-Substantial/Minor Amendments(s) for NHS Studies

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.
If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

Instructions for using this template

- For guidance on amendments refer to http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/ . If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

1. Study Information

Full title of study:	Clinician Preferences for Treatment of Older Patients facing Major Gastrointestinal Surgery
IRAS Project ID:	272619
Sponsor Amendment Notification number	2
Sponsor Amendment Notification date:	05.05.20
Details of Chief Investigator:	
Name [first name and surname]	Sarah Daniels
Address:	Old Nurses Home, Northern General Hospital, Sheffield Teaching Hospitals NHS FT, Herries Road, Sheffield
Postcode:	S5 7AU
Contact telephone number:	0114 2266210
Email address:	Sarahdaniels1@nhs.net
Details of Lead Sponsor:	
Name:	Sheffield Teaching Hospitals NHS FT
Contact email address:	Modhumita.harris@nhs.net
Details of Lead Nation:	
Name of lead nation *delete as appropriate*	England
If England led is the study going through CSP? *delete as appropriate*	Yes
Name of lead R&D office:	CRIO, STH

2. Summary of amendment(s)

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.
If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

No.	Brief description of amendment *(please enter each separate amendment in a new row)*	Amendment applies to *(delete/ list as appropriate)*		List relevant supporting document(s), including version numbers *(please ensure all referenced supporting documents are submitted with this form)*		R&D category of amendment *(category A, B, C) For office use only*
		Nation	**Sites**	**Document**	**Version**	
1	Finalised HCP Invite letter for the questionnaire follow on study	England	All sites	Letter of Invitation – questionnaire (Appendix VI)	Version 2.0 dated 05.05.20	
2	The HCP questionnaire has been finalised following interviews from HCPs.	England – All sites		Finalised HCP Questionnaire	Version 2.0 dated 05.05.20	
3						
4						
5						

[Add further rows as required]

3. Declaration(s)

Declaration by Chief Investigator

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment(s) to be implemented.

Signature of Chief Investigator:  ……Sarah Daniels……

Print name: Sarah Daniels

Date: 21/5/20 ……

Optional Declaration by the Sponsor's Representative (as per Sponsor Guidelines)

The sponsor of an approved study is responsible for all amendments made during its conduct.

The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules on delegated authority should be adhered to.

- I confirm the sponsor's support for the amendment(s) in this notification.

Signature of sponsor's representative: ……

Print name:……Mod Harris……

Post: ……

Organisation: ….STH NHS FT……

Date:……05.05.20……

Non substantial amendment number 3

Amendment Tool

v1.1 22 May 2020

For office use

QC: Yes

Section 1: Project information

Short project title*:	Clinician Preferences for Treatment of Older Patients Facing Surgery
IRAS project ID* (or REC reference if no IRAS project ID is available):	272619
Sponsor amendment reference number*:	Non-Substantial Amendment # 3
Sponsor amendment date* (enter as DD/MM/YY):	18 June 2020
Summary of amendment including justification*:	This amendment is applicable to stage 3 of the study, which involves the Sponsor site sending out a web based survey to clinicians to complete. The amendment involves the change in web-based survey tool from 'Survey Monkey' to 'Google Forms' due to availability. The study documents have been updated accordingly to reflect this change.

Project type:	◉ Specific study ○ Research tissue bank ○ Research database	
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	○ Yes	◉ No
Is review by a UKECA-recognised Research Ethics Committee (REC) being sought for the first time because of this amendment?:	○ Yes	◉ No
Did the study involve NHS/HSC organisations prior to this amendment?:	◉ Yes	○ No
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	○ Yes	◉ No

	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	◉	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☑	☐	☐	☐
Which nations will have participating NHS/HSC organisations after this amendment?	☑	☐	☐	☐

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Changes" tab. To add another change, tick the "Add another change" box.

Change 1	
Area of change (select)*:	Study Design
Specific change (select - only available when area of change is selected first)*:	Data collection, transfer or processing of identifiable participant information - Changes in arrangements or organisations involved (other than the addition of new participating organisations)
Further information (free text):	The web based survey tool to be sent out by the Sponsor site to HCPs for completion will be 'google forms' and not 'survey monkey' as originally planned.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some?:	○ All		◉ Some	

Add another change: ☑

Change 2	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Other minor document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information (free text):	The protocol, survey and survey invite letter have been amended from 'survey monkey' to 'google forms'.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some?:	○ All		◉ Some	

Add another change: ☐

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]:*	Modhumita Harris
Email address:*	Modhumita.harris@nhs.net

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a PDF copy of the completed amendment tool that can be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

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Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:			
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:						Y				Y									B
Change 2:						(Y)				(Y)									C
Overall reviews for the amendment:																			
Full review:						Y				Y									
Notification only:						N				N									
Overall amendment type:	Non-substantial																		
Overall Category:	B/C																		

Non substantial amendment number 4

Amendment Tool

v1.1 22 May 2020

For office use

QC: No

Section 1: Project information

Short project title*:	Clinician Preferences for Treatment of Older Patients Facing Surgery
IRAS project ID* (or REC reference if no IRAS project ID is available):	272619
Sponsor amendment reference number*:	Non-Substantial Amendment # 4
Sponsor amendment date* (enter as DD/MM/YY):	29 June 2020
Summary of amendment including justification*:	This amendment is applicable to stage 3 of the study, which involves the Sponsor site sending out a web based survey to clinicians to complete. The amendment involves a minor change in the protocol, invite letter and survey.

Project type:	◉ Specific study ○ Research tissue bank ○ Research database	
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	○ Yes	◉ No
Is review by a UKECA-recognised Research Ethics Committee (REC) being sought for the first time because of this amendment?:	○ Yes	◉ No
Did the study involve NHS/HSC organisations prior to this amendment?:	◉ Yes	○ No
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	○ Yes	◉ No

	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	◉	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☑	☐	☐	☐
Which nations will have participating NHS/HSC organisations after this amendment?	☑	☐	☐	☐

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Changes" tab. To add another change, tick the "Add another change" box.

Change 1	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Correction of typographical errors
Further information (free text):	The protocol version and date was not updated throughout the protocol v1.1 as part of NSAm#3 submitted on the 18th June 2020. This is now consistent.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some?:	○ All		◉ Some	

Add another change: ☑

Change 2	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Other minor document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information (free text):	The invite letter for the questionnaire/survey study has been amended to inform clinicians that this survey is looking at usual practice and not how it has been affected by COVID-19.The wording in the survey has also been amended. The changes have been tracked.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some?:	○ All		◉ Some	

Add another change: ☐

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]:*	Modhumita Harris
Email address:*	Modhumita.harris@nhs.net

Lock for submission

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Lock for submission

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:			
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	**UKSW Governance**	REC (MCA)	CAG	HMPPS	**HRA and HCRW Approval**	REC (AWA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:						N				N									N/A
Change 2:						(Y)				(Y)									C
Overall reviews for the amendment:																			
Full review:						N				N									
Notification only:						Y				Y									
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	C																		

Appendix K: OCTAGON study protocol

Optimising the Care and Treatment Pathways for Older Patients facing Major GastroIntestinal Surgery

(OCTAGON)

Study Protocol version:	3.0
Date:	02nd March 2021
Study Start Date:	18th August 2020
Sponsor:	Sheffield Teaching Hospitals NHS Foundation Trust
Sponsor reference:	STH20694
Funder:	Bowel Research UK (formerly Bowel Disease Research Foundation)
Funding Type:	Educational grant
REC Reference:	20/SC/0076
CT.gov Reference:	NCT04545125
IRAS ID:	277161
Chief Investigator:	Miss Sarah Daniels

Abbreviations

AE	Adverse Event
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
NHS	National Health Service
PI	Principal Investigator
PPI	Patients and Public Involvement
R&D	Research and Development
REC	Research Ethics Committee
SOP	Standard Operating Procedure
STH	Sheffield Teaching Hospitals NHS Foundation Trust

Study Team.

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Secondary supervisor:
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Lay Summary

The UK population is ageing. Whilst many people remain active and in good health as they get older, getting older is associated with the onset of many common medical conditions, as well as memory and mobility problems. There is a natural decline in heart and lung fitness with age, although this may be slowed by regular exercise and physical activity. The majority of digestive system problems that require operations (such as bowel cancer) are more common in older people. These operations can reduce an older person's ability to look after themselves and their quality of life. In some cases there is a trade-off between major surgery and a smaller operation or procedure with a lower chance of cure, but a faster rate of recovery and fewer problems immediately after the procedure. (Examples of smaller operations include bringing the bowel out onto the abdominal wall; creating a 'stoma'. Examples of procedures include inserting a tube inside the bowel or oesophagus to open up a blockage; insertion of a 'stent'). Some patients may be advised or may choose not to undergo any form of treatment.

Deciding whether a person is fit enough to undergo a major operation is difficult and depends on patient factors (e.g. heart and lung fitness, other medical conditions, patient choice) and technical factors (location and spread of disease, availability of other options for treatment).

In the outpatient setting there are a number of tests that can be used to try to work out what the risks of a major operation will be for a particular person. These can then guide different approaches to try to lessen these risks. Examples include exercise programmes, dietary supplements and anxiety management programmes in the period before the operation. In the emergency setting there is often not sufficient time before their operation but there are still a number of ways of improving the chances of a good recovery, such as meeting with a physiotherapist and early planning for discharge needs.

This study aims to explore:

- Whether patients who have poor outcomes after surgery can be identified at the start of their surgical journey
- Whether there are specific patient characteristics that are associated with whether individual patients undergo major surgery or not.
- What patients feel about different support measures that may be put in place to try to improve outcomes

This will be studied by following patients from when they are first diagnosed (asking them to complete questionnaires regarding health conditions that they already have and how this impacts on their day to day activities) and following them through their treatment to assess their recovery up to 6 months after their procedure. Dr Sarah Daniels or delegated member of the study team at Sheffield Teaching Hospitals will also carry out detailed interviews with some patients to explore their views on how they could be helped to prepare for major surgery and to recover afterwards.
This research will contribute towards a larger project looking at how we can improve outcomes for older patients facing major surgery and potentially help streamline patient journeys.

The results of this project will be published in a scientific journal as well as presented at conferences and meetings attended by a range of healthcare professionals and at individual hospitals.

Research Question

Can we identify older patients prior to major elective and emergency GI surgery from their baseline characteristics who are at risk of poor functional outcomes?

Background

The UK population is aging. Under-investigation and under-treatment of older people is common, with rates of surgery declining with age, despite the incidence of surgically treated gastrointestinal pathology increasing with age (1–6). There are large variations in outcomes in older people, between different surgical units in the UK, which suggests that not all patients are receiving the same level of care or access to resources(7–11). In GI surgery, the concern is that patients in centres with low elective surgery rates will be inappropriately denied the benefits of operative intervention (disease control, symptom improvement), with consequently higher rates of emergency admission and intervention(4,5). Conversely, in centres with high rates of elective surgery, patients may be inappropriately subjected to the morbidity or even mortality of surgery with limited or no benefit.

Major surgery remains one of the most debilitating events that an older person may experience and may profoundly influence functional decline and disability(12). Optimisation of outcomes in older patients with comorbidities and frailty requires multi-professional input which is often lacking (13). Adverse factors associated with ageing include co-morbidity, polypharmacy, cognitive impairment, dependency and frailty, all of which are associated with increased all cause mortality in the general population(14). There is also a natural decline in cardiorespiratory fitness with age, however this may be modifiable with physical activity or exercise. Malnutrition and psychological problems are also very common in patients requiring gastrointestinal surgery. When these at-risk individuals are exposed to the stress of major abdominal surgery, post-operative mortality and morbidity also increase(15,16). Common lifestyle choices, including smoking, excess alcohol consumption and sedentary behaviours, add to this risk.

Baseline assessment

The ability to tailor management decisions to baseline health, cardiorespiratory fitness and frailty status relies on accurate and timely assessments, which is often lacking(4,5,17). In the UK, the majority of patients undergoing elective gastrointestinal surgery will be assessed by a member of the pre-operative assessment team. Patients felt to be at increased operative risk either due to the extent of the procedure or due to patient characteristics may be reviewed by an anaesthetist or undergo formal exercise testing in the form of CardioPulmonary Exercise Testing (CPET), although this is not universally available(18).

In the emergency setting, there is often insufficient time for detailed baseline assessments, there may not be access to previous medical records, patients may present without their relatives or usual care givers and they may have delirium or altered conscious level that precludes detailed information gathering. Time constraints may mean that decisions regarding investigation or treatment are often made ‘out of hours’ without the benefit of consultant presence or multi-disciplinary team input. The balance

of operative risk versus quality of life may be difficult, particularly when considering multiple co-morbidities and frailty(19).

Prehabilitation

It may be possible to modify some adverse factors and improve patients' resilience to both major surgery and adverse events by implementing tailored 'prehabilitation' programmes(20). 'Prehabilitation' is defined as the process of enhancing an individual's functional capacity prior to elective surgery with the aim of improving tolerance to the anticipated physiological stress of major surgery(20). Prehabilitation programmes vary in their components but may include exercise programmes, pulmonary training, nutritional optimisation, psychological interventions and lifestyle modifications(21). Where they encompass more than one type of intervention, they are referred to as 'multimodal'(22).

There is evidence to support many of the aspects of prehabilitation programmes, however significant heterogeneity of studies including interventions tested, goals of treatment and outcomes measured limit the comparability of studies(23–26). There is a need to determine which combination of prehabilitation interventions are required in older people, how to facilitate engagement in those who are most likely to benefit and also the cost effectiveness of such interventions. Time constraints in emergency GI surgery preclude many of the pre-operative strategies, however, in conditions where there is commonly a trial of conservative management, interventions such as physiotherapy or stoma education may be performed.

Enhanced Recovery After Surgery

Enhanced Recovery After Surgery (ERAS) protocols are multi-disciplinary peri-operative packages of care to promote recovery after surgery(27). They were originally developed following the recognition that a small number of elective colorectal procedures contributed disproportionately to surgical morbidity, length of stay and unplanned readmissions(28,29). ERAS protocols encompass pre-, peri- and post-operative components to improve patient education, reduce the stress response to major surgery and promote faster recovery. Pre-operative aspects of ERAS protocols include patient information, reduction in fasting time, carbohydrate loading and avoidance of mechanical bowel preparation. Peri-operative aspects include anaesthetic techniques such as avoidance of certain anaesthetic agents, use of regional anaesthesia and use of agents to prevent post-operative nausea and vomiting. Peri-operative surgical aspects include laparoscopic surgery and avoidance of routine abdominal drains. Post-operative aspects include early mobilisation, resumption of oral diet and early removal of catheters and drains.

ERAS protocols have now been successfully implemented in the majority of cancer surgery disciplines and have been shown to reduce length of hospital stay and costs(30). They have also been shown to be safe and effective in older populations(31–33). Some aspects of ERAS protocols may be applied in the emergency setting, although implementation may be challenging(34,35).

Post-operative rehabilitation

Post-operative rehabilitation programmes aim to reduce hospital length of stay, promote return to function, prevent complications and long-term sequelae of major surgery. They are typically delivered by physiotherapists and ward staff and may be encompassed within ERAS protocols whilst patients remain in hospital following their surgery(36). However, there is interest in whether progressive strength training and higher intensity rehabilitation programmes in the community following discharge may improve long-term outcomes(37).

Geriatric assessment and intervention

The integration of specialist geriatric teams into the post-operative care of older patients undergoing major surgery, such as the Proactive care of Older Persons undergoing Surgery (POPS) initiative in the UK, has shown improvements in length of stay and cost savings(38). However, a national survey of geriatrician provision in surgical services in the UK(39) and the latest report from the National Emergency Laparotomy Audit(40) indicate that the majority of older patients undergoing major abdominal surgery still do not have input from a geriatrician-led team. Interventions may include medication review, optimisation of co-morbidities, early engagement with social services to facilitate discharge planning and delirium prevention strategies, for example.

Enhanced Peri-operative Support (EPS)

Enhanced peri-operative support (EPS) encompasses all of the pre-, peri- and post-operative interventions that may be used in an individual to help prepare them for surgery, minimise the surgical stress response and help them to recover and regain their independence afterwards. Not all patients will require all aspects of EPS, which highlights the importance of thorough baseline assessments and targeted interventions to provide personalised care.

The table 1 below summarises some of the interventions that may be implemented.

	Pre-operative	**Peri-operative**	**Post-operative**
Cardiorespiratory fitness	Exercise programmes Physical activity promotion Respiratory physiotherapy (Inspiratory muscle training)	ERAS protocols (early mobilisation)	Physiotherapy Rehabilitation programmes
Nutrition	Screening and optimisation Nutritional supplementation	ERAS protocols (reduced fasting time, carbohydrate loading)	Early re-introduction of diet Dietician assessment
Psychological	Tailored information Anxiety reduction Skills training (stoma, wound care) Cognitive behavioural therapy	Anxiety reduction Skills training (stoma, wound care)	Skills training (stoma, wound care) Referral to appropriate support

Geriatric	Comprehensive Geriatric Assessment and optimisation	Medication review Avoidance of certain anaesthetic agents	Delirium prevention Multi-disciplinary input Discharge planning
Haematinic	Blood transfusion Iron infusion	Blood transfusion	Blood transfusion Iron infusion
Behavioural	Smoking cessation and alcohol reduction advice Motivational interviewing	Nicotine replacement, alcohol detoxification regimes	Referral to appropriate support

Table 1

Patient-centred outcomes

Major surgery in all patients leads to a decrease in cardiorespiratory fitness and functional capacity(41), however in older adults this contributes towards long-term disability and loss of independence(42,43). Many older patients never regain their previous level of functioning after major surgery(12). Increasing age alone is a risk factor for discharge to a rehabilitation facility rather than home post-operatively, even in people who were functionally independent prior to their procedure and who have an uneventful postoperative course(44). Other outcomes of importance to patients' functional recovery include quality of life, fatigue, sleep disturbances, reduced cognitive function and low mood(41,45).

GI surgery

There are few age and fitness specific evidence-based guidelines for major gastrointestinal (GI) surgery. The majority of trials exclude older, less fit patients(46–50). Whether an older patient is offered resectional (major) surgery as opposed to risk-adapted surgery or procedures is variable. Determining best practice in this group is therefore complicated and treatment requires tailoring to individual patients, not to their chronological age.

Malignant pathology

Major surgical resection remains the mainstay of curative treatment for gastrointestinal cancers, although there is an increasing role for the use of neo-adjuvant chemotherapy and radiotherapy to improve resectability as well as local and distant disease control. When a patient is considered to be at high risk of adverse outcome following major curative resection due to poor cardiorespiratory fitness, co-morbidities or frailty they may be offered risk-adapted surgery or a palliative procedure to help control the disease, alleviate symptoms or prevent complications (e.g. defunctioning stoma, colonic stenting, oesophageal stenting, radiofrequency ablation (Table 2 for examples)). Palliative chemotherapy or radiotherapy may be an option, but again requires adequate patient fitness to be considered in most cases. There may be a trade off between a potentially highly morbid curative resection and an operation or procedure that is better tolerated but with a lower chance of long-term cure. Assessing the impact that different procedures have on a patient's quality of life is therefore of great importance. Some patients who are

relatively asymptomatic but with co-morbidities, poor cardiorespiratory fitness or frailty may be managed conservatively with involvement of palliative care teams.

Non-malignant pathology

There are also a number of non-malignant conditions where surgery is a major modality of treatment. In some cases, patients who are less fit may be advised against major surgery or there may be risk adjusted strategies, although usually with a lower expectation of long-term cure (examples are summarised in Table 2). For some emergency conditions that are associated with high mortality rates without intervention, there may be short-term quality of life gains for non-operative management compared to high morbidity emergency surgery.

	Standard care	Risk adapted
Malignant diagnoses		
Oesophageal cancer	Oesophagectomy	Stenting
Gastric cancer	Gastrectomy	Stenting (if obstructing)
Pancreatic cancer	Pancreatic resection	Intestinal bypass
Liver cancer (primary or secondary)	Liver resection (hepatectomy)	Radiofrequency ablation
Colorectal cancer	Resection +/- anastomosis	Defunctioning stoma, stenting
Non-malignant diagnoses		
Complicated diverticular disease	Hartmann's procedure or resection with anastomosis	Laparoscopic peritoneal lavage or defunctioning colostomy
Sigmoid volvulus (recurrent)	Sigmoid colectomy	Percutaneous Endoscopic Colostomy (PEC)
Adhesional small bowel obstruction	Laparoscopic or open adhesiolysis	Trial of conservative management
Perforated peptic ulcer disease	Laparoscopic or open washout and repair	Radiological drainage of abscess
Incisional hernias	Laparoscopic or open repair	

Table 2. Examples of malignant and non-malignant GI diagnoses and their potential management strategies.

Importance of the problem

The majority of older people are not frail, have minimal co-morbidities, remain fit and active and therefore should be offered standard surgical treatment options for their condition. However, when patients are at the extremes of age, are considered unfit or frail, particularly if they have a diagnosis of dementia, they often receive non-standard care(5). This may be due to fears of higher mortality and morbidity from major operations. It may also be felt that the trade-off of reduced morbidity for poorer long-term control is justified for someone with a limited life expectancy. Non-guideline based management practices are more prevalent with increasing patient age and levels of co-morbidity, however there is a paucity of evidence on which to base fitness based thresholds(16,51–53).

Patients with complex chronic illnesses and frailty often require input from multiple different health and social care professionals, requiring co-ordination of this care to achieve good outcomes and efficiency(13). There are a number of different methods of peri-operative optimisation that have been shown to be effective in different settings. There is limited evidence of how these interventions are applied in current clinical practice, particularly in older populations. Key gaps in the current evidence:

- What are the baseline characteristics of older patients who have poor post-operative functional outcomes who could be targeted for enhanced perioperative support
- Are there any differences in the baseline characteristics of patients who are offered major surgery compared to risk adapted procedures and does this vary by treating surgical unit.
- What are the views of patients regarding peri-operative optimisation strategies and how do they feel these would be best implemented.

Summary

Consistently, research has shown that older patients (≥65 years) have huge variation in their gastrointestinal disease treatment pathways compared to younger patients in both the emergency and elective settings. Given that most GI surgical pathologies occur in older age it is important that this group receive appropriate treatment options based on their personal health status and treatment preferences rather than their chronological age. There is a need for more standardised assessment of patient cardiorespiratory fitness, taking into account individual co-morbid status and frailty.

This study will look at which characteristics and assessments identify patients who have poor functional outcomes and therefore could be targeted for an enhanced package of perioperative support. It will also give an insight into whether there are differences in the baseline characteristics of patients who undergo major GI surgery or risk-adapted management strategies at different surgical units across a region. This study will capture some patients who do undergo elements of enhanced support and the effect of this on outcomes will be studied if there are sufficient numbers. It will also explore the views of older patients themselves regarding different methods of peri-operative optimisation and fitness/risk assessment. It is part of a larger programme of research that will also determine the views of a wide range of healthcare professionals on peri-operative optimisation of older surgical patients and what the different patient pathways of enhanced perioperative support currently involves at each of the surgical units in the region. The findings of this study will directly benefit patients by identifying which older patients have poor functional outcomes, which interventions are currently used in practice and what the barriers and facilitators are to implementing enhanced peri-operative support.

Aims & Objectives

Aims:

The aims of this study are to determine:

- Which baseline characteristics of older patients with GI pathology amenable to major surgery are predictive of poor post-operative functional recovery
- Whether certain baseline characteristics mean that an individual is more likely to undergo a risk-adapted procedure or conservative management.
- What the views of older patients who have undergone elective and emergency surgical management are regarding enhanced perioperative support measures and fitness/risk assessment.

Objectives:

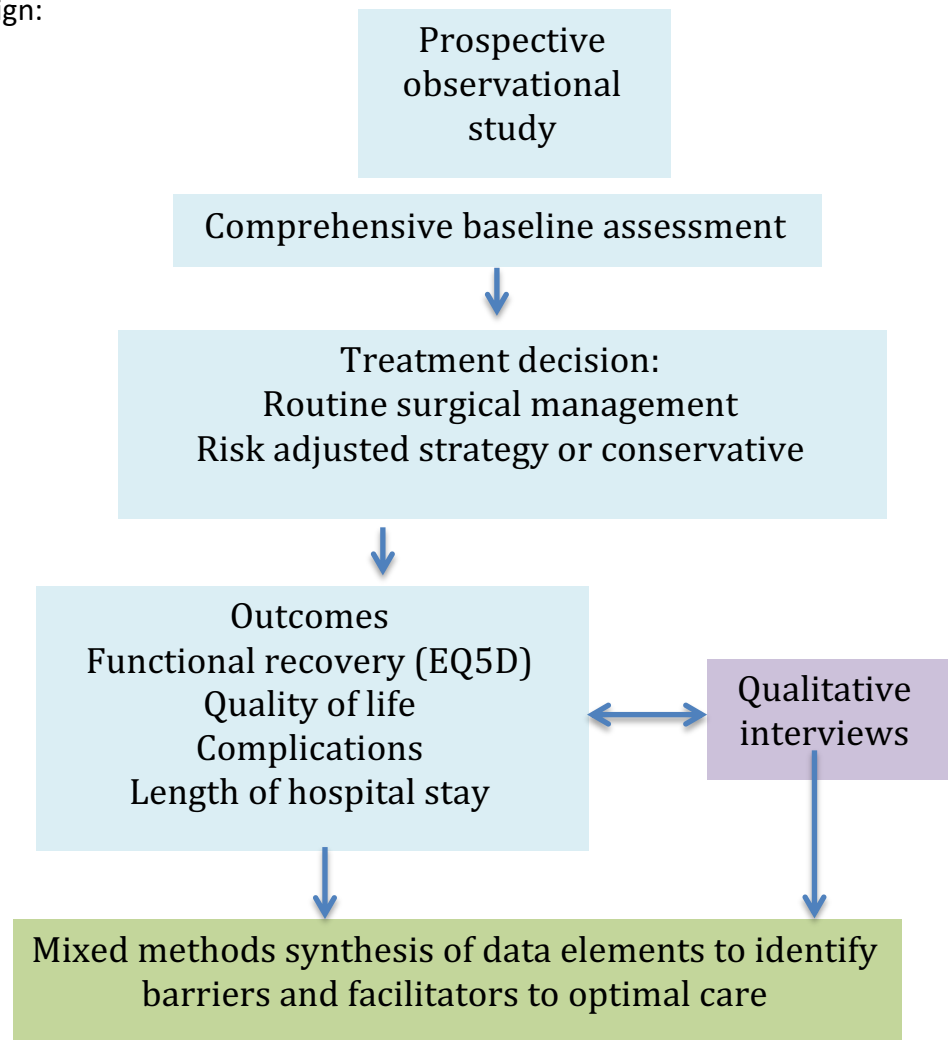
To establish a multi-centre regional observational study across the South Yorkshire region to determine:

- Functional and post-operative morbidity outcomes in older patients undergoing surgery or procedures for GI pathology and correlate outcomes with age, co-morbidity and frailty.
- Whether there are differences in baseline characteristics of patients who are offered major or risk adapted surgery and whether this varies by surgical unit.
- The use of enhanced peri-operative support measures in practice and whether an effect on outcomes can be observed.
- To undertake 20-30 semi-structured interviews with older people with operable GI pathology who have undergone a range of management strategies to determine their views on peri-operative optimisation and fitness assessment. Interviews will take place until there has been saturation of themes.

Mixed methods synthesis of qualitative and quantitative aspects to identify barriers and facilitators to optimal care.

Research Methods

Study Design:



Detailed Methodology.

Stage 1: Observational study

This prospective pragmatic observational multicentre study will observe which baseline characteristics are associated with poor functional outcomes in older patients undergoing major GI surgery. It will also observe what differences in baseline characteristics there are in patients who undergo major surgery compared to risk-adapted procedures or conservative management. The use of enhanced peri-operative support (pre-operative, prehabilitation, peri-operative, post-operative and rehabilitation) will be studied and the effect on outcomes determined if possible. The recruitment target is 120 patients over a 12-month period, however recruitment will continue if this target is met early.

Participants

Inclusion:
Male or female
Aged 65+ years old inclusive
Patients with a diagnosis of gastrointestinal pathology amenable to elective, urgent (unscheduled) or emergency major gastrointestinal surgery who either undergo surgery, a risk-adapted procedure or are managed conservatively (due to patient wishes, co-morbidities or frailty).
Mental capacity to consent

Exclusion:
Patients aged less than 65 years old
Patients with unresectable disease (location, invasion, dissemination)
Lack mental capacity to consent
Unable to understand the information provided (translational issues)
Prisoners
Patients undergoing surgery for major trauma
Patients undergoing surgery for primary gynaecological, vascular or urological disease

Elective	Emergency/ Urgent
Malignant Colon, rectal, gastric, oesophageal and pancreatic cancers, hepatocellular carcinoma, colorectal liver metastases, sarcoma, cholangiocarcinoma **Non-malignant** Complicated diverticular disease, complex abdominal wall hernias, Crohn's disease, ulcerative colitis, complicated gallstone disease (planned open or CBD exploration), reflux disease (fundoplication) **Exclusion** Planned laparoscopic treatment of uncomplicated gallstone disease, uncomplicated groin hernia, laparoscopic appendicectomy	**Malignant** Obstructing/ symptomatic colon, rectal or gastric cancer, reoperations for complications of previous elective surgery (these will be included in elective) **Non-malignant** Adhesional small bowel obstruction, obstructed hernias, bowel ischaemia, gastric/duodenal perforation, colonic perforation, peritonitis, large bowel obstruction, volvulus, complicated diverticulitis, crohn's disease, ulcerative colitis **Exclusion** Trauma, appendicitis, pancreatitis

Table 3. Main surgical indications for inclusion and exclusion

Interventions and Comparator

This observational study will predominantly look at outcomes in patients who have had major GI surgery. It will also compare the outcomes of patients who have undergone major surgery compared to risk adapted procedures or conservative management and with or without elements of enhanced peri-operative support.

Outcomes

Primary outcome

Functional recovery at 6 weeks post-operation/ definitive procedure or from decision not to operate

Secondary outcomes:

Secondary outcomes include:

- Health related quality of life at 6 weeks
- Length of hospital stay
- Treatment related adverse events (including complication rate and severity)
- Overall survival, including cause of and time to death

Other outputs

This study will also look at variation in rates of surgery or risk-adapted procedures by patient baseline characteristics. Variation in treatment strategy will be compared between units in the region to assess whether this is randomly distributed or whether some centres are significant outliers for normal practice.

Recruitment: method used to identify, approach, recruit and consent

Identification

Elective patients with a diagnosis of malignant disease will be identified at the relevant multidisciplinary team meetings when they are identified as having surgically resectable disease (this will include patients with resectable metastatic disease such as colorectal liver metastases). Elective patients with non-malignant diagnoses will be identified in general surgical outpatient clinics. Emergency patients will be identified from General

surgery on call 'take' lists, handover lists or emergency theatre lists. If an elective patient who has not already been approached to participate develops a post-operative complication that requires a return to theatre as an emergency, they will be approached to participate and included in the elective arm of the study.

Patient approach and consent

Potential participants will be approached following the discussion to plan their management (whether surgery, risk adjusted procedure or no intervention) and screened for eligibility.

Emergency Patients:

Emergency patients will be approached as soon as possible after a diagnosis of operable gastrointestinal pathology has been made. Patients can be approached by the PI, delegated clinician, or nursing study team members with the appropriate GCP training. The patient will be given a written information sheet to consider for an appropriate length of time, a letter of invitation and study discussed with the patient. If the patient is willing, they will be consented on the same day that they are approached. This is necessary due to the emergency patient setting.

Elective Patients:

At the patient's diagnosis appointment the patient will be given the patient information sheet and invite letter. If willing, the patient will then be consented at their next clinic appointment (outpatients, pre-op assessment or admission). For those patients that this approach is not appropriate on the day (i.e. cancer diagnosis) or for any missed patients, they may be contacted by phone to introduce the study or posted an invite letter and patient information sheet.

If the patient is contacted by phone and would like to receive more information on the study, then they will be sent an invite letter and patient information sheet. Alternatively, if the patient is willing they may be sent the study pack containing the invite letter, patient information sheet, consent form, questionnaire and pre-paid envelope. The patient will be asked to return the consent form and questionnaire to their local hospital.

For interested patients who prefer not to receive a study pack by post, they will be followed up at their next appointment, and if willing, consented.

The consent form contains an option regarding participation in a semi-structured interview. This is an optional question. If patients do not agree to being interviewed, they can still take part in the study. If patients are willing to take part in the interview, they will be contacted about this on a separate occasion.

Co-recruitment of patients participating in other studies will be allowed as long as the other study also permits co-recruitment. If this is not specified in the protocol, then the decision will be made by the PI.

The consent form will be countersigned by the PI or delegated person. The original consent form will be retained by site in the Investigator Site File. A copy will go in the patient's medical notes and a copy will be given to the patient.

All potentially eligible patients will be recorded on the local screening log. Reason(s) for not consenting will be recorded. Patients will be given a unique study participation number (eg. Sheffield Teaching Hospitals (STH)-001, 002, 003 etc). All patients who consent to take part in the study will be recorded on the enrolment log. The screening log and enrolment log are both retained in the local Investigator Site File.

Recruitment is expected to continue for 12 months with a proposed start date 1st August 2020.

Study visits

Study visits will take place in general surgery outpatient clinics, pre-operative assessment clinics, general surgical wards, HDU and ITU. Study visits will be up to 30 minutes in duration, as this will allow sufficient time for completion of questionnaires. Six-week follow-up and collection of outcome data will be based around routine post-operative follow-up visits or conducted via post or telephone to reduce the burden on patients. 3 and 6 month follow-up questionnaires will be conducted via telephone or post. If the patient prefers to complete the questionnaires by post and they are not returned within 2 weeks, this will be followed up by a phone call. If the patient cannot be contacted by phone on two separate occasions, then the data will be deemed missing and the patient will not be contacted again until their next study timepoint.
See summary table below

	Baseline (first clinic to day 0/operation)	Discharge	6 weeks post-operative or after decision to not operate +/- 2 weeks	3 months post-operation or post decision	6 months Post-operation or post decision
Consent	x				
Demographics	x				
Questionnaires	ADL, IADL, EQ-5D - 5L, frailty score, cognitive test physical activity, WHO DAS	Bespoke questionnaire	EQ5D5L, ADL, WHO DAS	EQ5D5L, ADL, WHO DAS	EQ5D5L, ADL, WHO DAS
CPET/6MWT results (if available)	x				
Optimisation strategies		x			
Operation Details		x			
Post-operative details		x			
Complications		x			
Pathology			x		
Survival		x	x	x	x

Data

Following consent, the following data will be collected using the baseline questionnaires, the CRFs, and the follow-up questionnaires:

Baseline (defined as pre-operative)

Demographic data

Age, sex, postcode, height, weight, smoking status, alcohol intake, ASA, education level

Referral type

Elective - 2 week wait, routine referral, other specialty
Emergency – GP, A&E, clinic admission
Date of referral (elective)
Date of first appointment (elective)
Number of hospital admissions during previous 12 months

Pre-operative assessment

Date of appointment

Admission details

Date and time of admission

Co-morbidity

Charlson Co-morbidity Index
Conditions – Diabetes, renal disease, liver disease, malignancy

Medications

5 or more regular medications
Chemo/radiotherapy within previous 12 months

Pre-operative blood tests

Haemoglobin, ferritin, albumin, creatinine, CRP, lactate

Functional assessment

Frailty level (Rockwood's Clinical Frailty Scale)
Cognitive function – Mini-COG

Nutritional assessment

Mini Nutritional Assessment (MNA)

Fitness assessment

CPET (oxygen consumption at the anaerobic threshold (VO_2 at the AT), peak oxygen consumption (VO_{2peak}), ventilatory efficiency for carbon dioxide (V_E/VCO_2), Respiratory Exchange Ratio at VO_2 peak (RER at VO_{2peak})), baseline heart rate or 6MWT results (where performed)

Baseline questionnaires

These will be for the patient to complete themselves or with assistance from the research team. Questionnaires include:
Functional status: Modified Bartel's ADL, Lawton and Brody's IADL, WHO DAS
Health status: EQ-5D-5L
Physical activity: IPAQ-E
At hospital discharge (elective and emergency):

Optimisation

Bespoke questionnaire with the patient regarding whether they participated in any form of prehabilitation (exercise, nutrition, psychological, geriatric), attended 'surgery school' or attended for transfusion, physiotherapy appointment, dietician review and whether this was self directed or arranged by the hospital

Peri-operative and post-operative optimisation and reviews (geriatric, anaesthetic, dietician, physiotherapy, cardiology, other speciality)

Operative details

Procedure

Operative approach (e.g. laparoscopic or open)

Regional anaesthetic use (epidural, spinal, wound catheters)

Length of hospital stay

Length of hospital stay, length of HDU/ITU stay

Discharge

Destination

Care needs (none, 1-4 calls per day, intermediate care, nursing home)

Post-operative complications:

(Clavien Dindo I-V) specifically including wound infections, chest infections, venous thromboembolism, myocardial infarction, delirium, return to theatre (see Appendix 9)

At 6 weeks, 3 months and 6 months post-operation/procedure or decision not to operate:

Pathology results (6 weeks only)

Survival:

cause of death at any time in follow-up and calculated length of survival from diagnosis to death.

Readmissions (6 weeks only)

Follow-up questionnaires:

Functional recovery: WHO DAS, EQ-5D-5L and ADL

Responses to the questionnaires will be entered into the database (REDCap) locally or posted to the CI depending on local R&D capability.

Statistical considerations

Statistical team members

Statistical analysis is the responsibility of the Chief Investigator with support from Dr Jen Lewis (Study Statistician).

Study design

The study will be a pragmatic cohort study designed to observe normal clinical practice within a region. Data will be reported and presented according to the revised CONSORT guidelines for pragmatic trials(54).

Sample size

We propose to recruit and follow-up eligible patients from between 3 and 5 surgical units. Pre-covid, each unit performed between 70-300 major elective GI resections per year and 114-300 emergency laparotomies per year, of which at least 50% are over the age of 65(40). An opportunistic sample size of 120 has been estimated over the 12-month study recruitment period based on the number of patients undergoing major surgery at each of the units and taking into consideration the impact of Covid-19. At STH in a typical week, approximately 10 patients aged 65 or over will undergo major elective surgery and 5 patients will undergo emergency major surgery. This will give a potential pool of around 390 potentially eligible patients at STH alone. Doncaster Royal Infirmary performs roughly 10 major operations per week on emergency and elective patients aged 65 years and

over, resulting in around 260 potentially eligible patients. We acknowledge that our sample size may not be sufficient to detect a difference in our primary outcome but will give data that may be used to inform the design of a future trial. If we reach the recruitment target, we will continue to recruit patients whilst resources allow.

We expect a high uptake rate from this simple, questionnaire-based study based on a recent study of frailty in emergency laparotomy patients(55) and a post-operative study of quality of life after emergency laparotomy(56). We also anticipate recruiting patients who are deemed to be too frail or to have co-morbidities that preclude curative procedures. These patients may be harder to identify, may have dementia (one of the exclusion criteria) and may decline follow-up so numbers are likely to be small.

Statistical analysis plan

Data analysis for the observational study will focus on two main areas:
Impact of baseline health and fitness on functional outcomes (WHO DAS, EQ-5D-5L, ADL) and surgical outcomes (LOS, mortality, morbidity) (multiple regression)
Criteria for and selection of treatment options stratified according to baseline health and fitness (using multiple regression analysis)

Planned covariates:
Age
Sex
Charlson co-morbidity score
Emergency versus elective presentation
Baseline WHO DAS score
Surgical unit
Baseline characteristic data analysis

Baseline socio-demographic (age, sex, postcode, education level) and individualised baseline scores (EQ5D, ADL, IADL, Mini-COG, Charlson Index, IPAQ-E, WHO DAS) will be summarised and assessed for comparability between the different treatment groups (elective surgery major resection versus risk-adapted management, emergency surgery major resection versus risk-adapted or conservative management). For continuous variables means and standard deviations or medians and interquartile ranges will be calculated depending on the distribution of the data. The number of observations will be presented alongside the summaries.

All baseline summaries will be presented and reported for each treatment group (elective surgery; emergency surgery; major GI surgery; risk-adapted management) and in total. Baseline characteristic imbalances will be descriptively reported and adjusted for if numbers allow.
Since the study is a cohort it is likely that the baseline demographic, clinical and functional characteristics of the patients on the different management pathways will be different and may influence future outcomes. We will therefore use a variety of statistical methods to allow for differences in case-mix between the different management pathways. The main statistical approach that will be used to adjust for baseline imbalances in patient characteristics will be multiple regression.

Primary Endpoint

The primary outcome for both the elective and emergency patients will be WHO DAS score at 6 weeks. It is fully expected that a direct comparison of typical outcome measures between patients who undergo standard surgery compared to risk-adjusted procedures will not be possible as clinicians will select frailer, older patients for non-surgical management, although the relative percentage change from baseline may be of value.

The WHO DAS 2.0(57) will be used as a measure of functional recovery and disability. It will be collected at baseline, 6 weeks, 3 and 6 months post definitive treatment (or post-treatment decision in the case of no surgery/procedure) for all patients. The WHO DAS 2.0 is validated tool for measuring post-operative disability in surgical populations(58) and has been shown to be highly responsive in the post-operative period in patients undergoing radical cystectomy(59).

Planned tables for analysis

Demographics

	Elective presentation			Emergency patients		
	Major surgery	Risk-adapted procedure	Conservative	Major surgery	Risk-adapted procedure	Conservative
n (%)						
Age (mean)						
Sex						
Deprivation						
Comorbidities						
Polypharmacy						
Residential status - Own home - Home with carers - Residential home - Nursing home						

Baseline functional status

	Elective presentation			Emergency patients		
	Major surgery	Risk-adapted procedure	Conservative	Major surgery	Risk-adapted procedure	Conservative
n (%)						
ADL score						
IADL score						
EQ5D5L						
I-PAQ E						
WHO DAS						
Mini-COG						
MNA						
CFS						

Optimisation strategies

	Elective presentation			Emergency patients		
	Major surgery	Risk-adapted procedure	Conservative	Major surgery	Risk-adapted procedure	Conservative
n (%)						

Pre-operative Prehab CGA Specialist Haematinic						
Peri-operative ERAS						
Post-operative Physio/OT Geriatric Haematinic Rehab						

Outcomes

	Elective presentation			Emergency patients		
	Major surgery	Risk-adapted procedure	Conservative	Major surgery	Risk-adapted procedure	Conservative
n (%)						
Primary: WHO DAS						
Secondary: - LOS (median, range) - Complications (mean, SD, severity) - EQ-5D - ADL score - Discharge destination						

	Elective presentation Major Surgery			Emergency patients Major surgery		
Age (years)	65-74	75-84	85+	65-74	75-84	85+
n (%)						
Primary: WHO DAS						

	Elective presentation Major Surgery			Emergency patients Major surgery		
Frailty level	Not frail	At risk	Frail	Not frail	At risk	Frail
n (%)						
Primary: WHO DAS						

Enhanced Peri-operative Support (depending on numbers recruited)

	Elective presentation		Emergency patients	
	Major surgery with EPS (any)	Major surgery without EPS	Major surgery with EPS (any)	Major surgery without EPS
n (%)				
Primary: WHO DAS				
Secondary: - LOS (median, range) - Complications (mean, SD, severity) - Quality of life - ADL score - EQ-5D				

- Discharge destination				

Interim Analysis

There are no statistical criteria for stopping the study early as the study is simply observing normal regional UK practice and therefore very low risk.

Missing data plan

Whilst we will make every effort to minimise missing data, given the different surgical units from which patients will be recruited and range of presentations, it is likely that there will be some missing data. Depending on what data is missing, we may be able to use statistical imputation to give an estimation for missing data points.

Regulatory Approvals

HRA approval and confirmation of capacity and capability (C,C&C) at each participating site will be obtained. All PIs will need to undertake GCP training. All trainees participating in study activities will be logged on a delegation log held at each site and will have to provide evidence of GCP training.

Sites

The study will recruit patients from 3-5 units across the UK. A local Principal Investigator (PI) has been identified at each NHS participating site. They will be asked to identify local trainees to help with identification of participants/ recruitment and may also assist in identification of potential participants.

Subject withdrawal (withdrawal criteria and procedures)

A patient can withdraw from the study at any point, without giving reasons and without prejudicing their treatment. The data collected up to the point of withdrawal will be retained in the study, unless the patient specifically requests removal.

Safety reporting

This is an observational study, therefore we do not anticipate any serious adverse events relating directly to participation in this study.

Data Sources

Data used in this study will come from data entered into the following sources:

The CRFs

Study Questionnaires (baseline and followup)

Case Report Forms

The case report forms will be paper and then transcribed by the study team at each site. Definitions for the elective and emergency CRFs are available.

Questionnaires

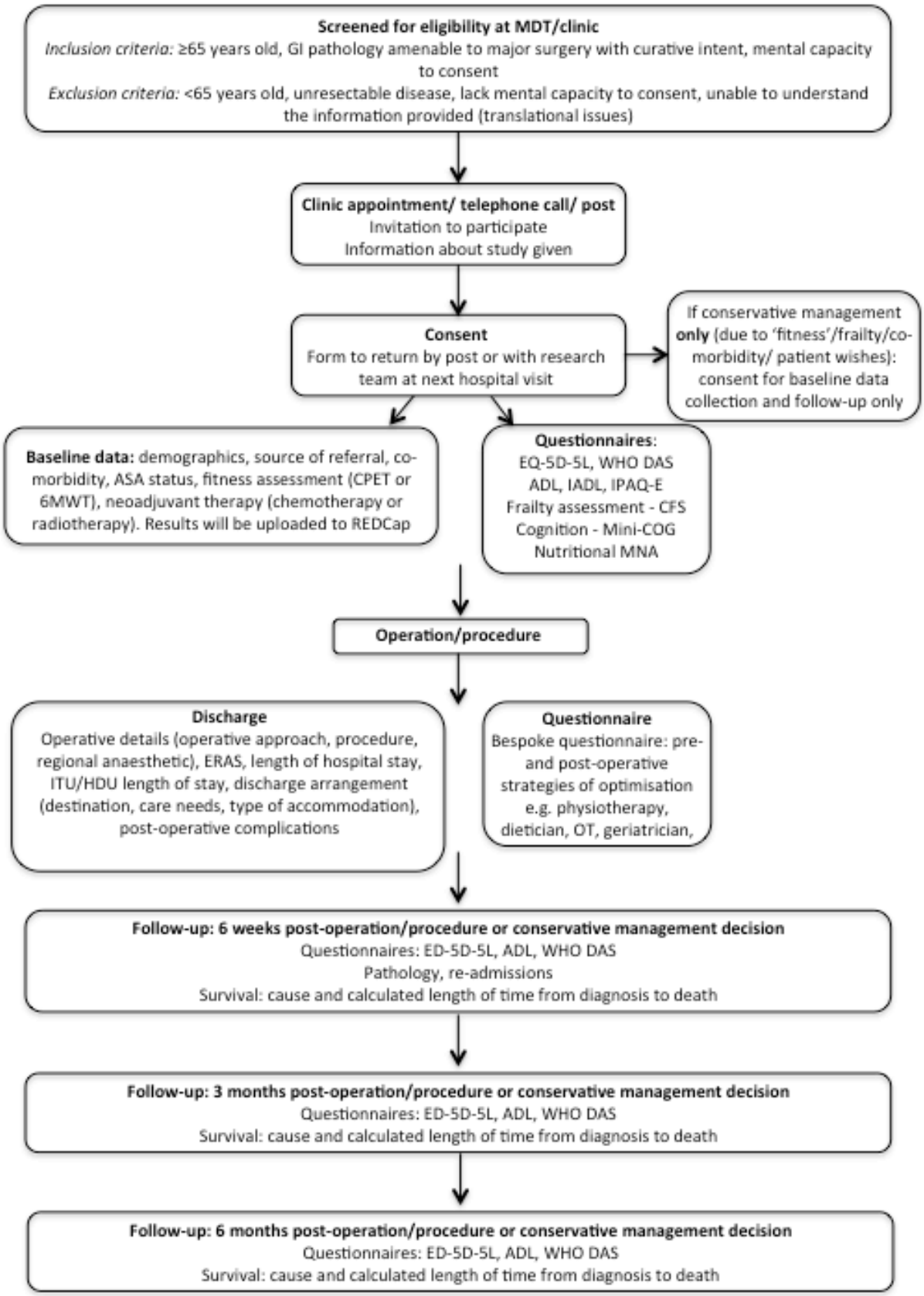
Questionnaires for patients to self-complete are all validated questionnaires designed to be patient facing. However, feedback from the PPI group suggested that patients may want help from the research team to complete the questionnaires, which is why we have given this option. Scoring systems for each of the validated questionnaires are available.

The bespoke questionnaire on peri-operative optimisation strategies has been tested on members of the PPI group for acceptance and understanding.

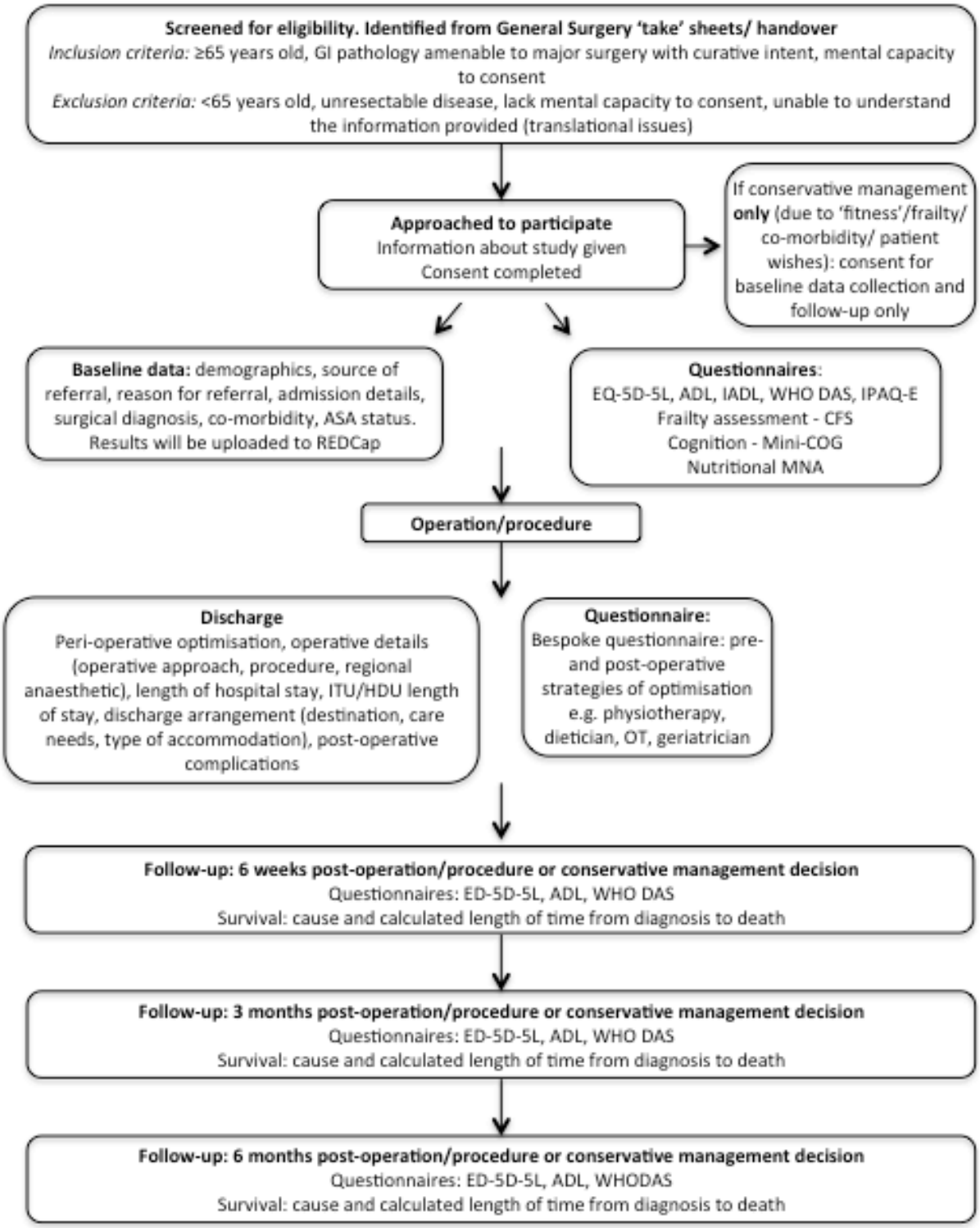
Data Completeness

Reporting data completeness is an integral part of trial reporting. Hence a CONSORT style flow diagram will be used to display data completeness and patient throughput from eligibility screening, invitation, study acceptance and final follow-up visit. The statistical team will also report the number of:
Patients screened per month
Patients recruited per month
Number and percentage of patients who complete each follow up or are lost to follow up
Number of patients who have complete data for each key variable.

Flow chart of elective patient journey through OCTAGON



Flow chart of emergency patient journey through OCTAGON


Screened for eligibility. Identified from General Surgery 'take' sheets/ handover
Inclusion criteria: ≥65 years old, GI pathology amenable to major surgery with curative intent, mental capacity to consent
Exclusion criteria: <65 years old, unresectable disease, lack mental capacity to consent, unable to understand the information provided (translational issues)
Approached to participate
Information about study given
Consent completed
If conservative management only (due to 'fitness'/frailty/ co-morbidity/ patient wishes): consent for baseline data collection and follow-up only
Baseline data: demographics, source of referral, reason for referral, admission details, surgical diagnosis, co-morbidity, ASA status. Results will be uploaded to REDCap
Questionnaires:
EQ-5D-5L, ADL, IADL, WHO DAS, IPAQ-E
Frailty assessment - CFS
Cognition - Mini-COG
Nutritional MNA
Operation/procedure
Discharge
Peri-operative optimisation, operative details (operative approach, procedure, regional anaesthetic), length of hospital stay, ITU/HDU length of stay, discharge arrangement (destination, care needs, type of accommodation), post-operative complications
Questionnaire:
Bespoke questionnaire: pre- and post-operative strategies of optimisation e.g. physiotherapy, dietician, OT, geriatrician
Follow-up: 6 weeks post-operation/procedure or conservative management decision
Questionnaires: ED-5D-5L, ADL, WHO DAS
Survival: cause and calculated length of time from diagnosis to death
Follow-up: 3 months post-operation/procedure or conservative management decision
Questionnaires: ED-5D-5L, ADL, WHO DAS
Survival: cause and calculated length of time from diagnosis to death
Follow-up: 6 months post-operation/procedure or conservative management decision
Questionnaires: ED-5D-5L, ADL, WHODAS
Survival: cause and calculated length of time from diagnosis to death

Database

All data will be handled in accordance with the GDPR 2018 principles. All patients will be given a unique ID number which will be used in the database rather than their NHS number i.e. pseudoanonymised. The key detailing NHS number and study ID will be retained by each site in the Investigator Site File (ISF) to enable data collection at different timepoints. Data will be collected and recorded by hospital staff or members of the hospital research team on paper-based CRFs which will then be entered into a secure server running the Research Electronic Data Capture (REDCap) web application(60). REDCap allows collaborators to enter and store data in a secure system.

All transmission and storage of web by this system is encrypted using 'SSL' connection. System users will be allocated to a data access group for their hospital, allowing them to create and edit records entered by their own team, but not those from other hospitals. Collaborators will be required to set passwords which include letters, numbers and special characters. Passwords will be changed every 30 days. The REDCap servers are encrypted and are hosted in a secure building at the University of Sheffield, and undergo regular back-up. Data from this study will be retained on University of Sheffield servers for 5 years after the study has closed and will not be sent outside the UK.

Sites will be responsible for archiving the source data, case report forms and other essential documents at their own site for a period of 5 years. No patient identifiable data will leave each site.

Data Monitoring

Data will be monitored for quality and completeness by the Study Team. Missing data will be chased until it is received, confirmed as not available, or the study is at analysis.

Stage 2: Qualitative interviews

Qualitative research is extremely helpful when a complex topic is being explored and the analysis is inductive. The additional benefits of qualitative research conducted alongside quantitative research and analysed together, mixed methods research, are well documented. Qualitative research can help to determine how and why certain interventions may or may not work in practice.

The qualitative aspect of this study will establish the views and preferences of a range of patients who have undergone major abdominal surgery (elective or emergency), with or without different methods of peri-operative optimisation and also some patients who choose not to undergo major surgery or undergo a risk adjusted procedure. A particular focus will be on their views on peri-operative support measures, what they feel are the barriers and facilitators to implementing these, what more they feel could be done and how they would like this to be delivered. We will also explore perceptions of fitness and risk assessment and what this means to individuals. Patients will be recruited from the main cohort study if they have indicated on the initial consent form that they are willing to be contacted regarding taking part in a qualitative interview.

Participants

Patients in the observational study who have undergone major surgery with or without enhanced perioperative support measures, risk adapted procedures and conservative management will be approached to participate in the qualitative study. Maximal sampling will be used to ensure breadth of experience is captured.

Aims and Objectives

Aims
To explore the views of older patients (65 years and older) regarding different methods of pre-, peri- and post-operative optimisation
To explore the views of older people on assessment of fitness prior to surgery and how this impacts on shared decision-making.

Objectives
To undertake semi-structured interviews with patients who have undergone major GI surgery, risk-adapted procedures or conservative management in both the elective and emergency settings. Patients will have had different levels of peri-operative support or none and will be recruited from across the South Yorkshire region. Semi-structured interviews will be conducted using a topic guide that enables topics to be explored using a conversational style. It has the flexibility to probe answers and draw on cues to gain more detailed information and discuss issues not previously identified. The interviews will be on a 1:1 basis either face to face or over the phone and will be conducted by the CI; Dr Sarah Daniels (under the supervision of experienced qualitative researchers). Maximal variation sampling will be used to include different types of patients (elective, emergency, major operation, risk-adapted operation, conservative management) and patients managed in different units within the region. Interview data analysis using the Framework

Approach(65) will occur alongside recruitment, and recruitment will cease on achievement of data saturation. From previous work in the field it is anticipated approximately 20-30 interviews will be required.

Conduct of the interviews

Patients who have consented to take part in the interview will be contacted by phone after the 6 weeks visit and a mutually agreed time confirmed. Participants will be contacted again the day before their interviews to ensure they still wish to proceed. They will be given an opportunity to decline if they so wish. All interviewees will be reassured that they may terminate or pause the interview at any point without stating a reason for doing so and that their participation is entirely voluntary. If this happens the information recorded up to that point will be transcribed. All interviews will be conducted by the CI; Dr Sarah Daniels or a delegated member of the study team at the Sponsor site. It is anticipated that the majority of the interviews will be conducted via telephone (all non-STH sites), but face-to-face will also be conducted if requested by the patient (STH patients only). Patients will be encouraged to have a relative or friend present if face-to-face.

Interviews are expected to be around 30 minutes duration. All interviews will be digitally recorded on a dictaphone stored securely and then transcribed verbatim by Dr Sarah Daniels or delegated study team member. All data collected will be pseudonymised, no patient names will be recorded. The transcribed interviews will be stored on NHS password protected computers. Once transcribed the interview will be deleted from the dictaphone and transcription uploaded to the RedCap database.

Interview topic guide and content

An interview topic guide has been developed by the study team with reference to the literature and previous qualitative work by members of the study team. This will enable the interviews to explore key issues but also give opportunity for free expression of views with open questions.

Topic guide for patients who underwent elective major GI surgery

Topic	Questions
Patient pathway	How do you feel about your journey from diagnosis through surgery to now? What do you feel went well? In what ways could things have been improved?
Fitness assessment	Did you undergo exercise testing or other tests to determine whether you were fit to undergo surgery? How did you feel about this? Did you feel that the reasons for doing this were sufficiently explained? What impact did the results of the tests have on you? Reassurance? Incentive to make changes?

Decision-making	Did you feel that you were supported to make decisions regarding your own care? Was there anything or anyone in particular who helped you? Did you understand why different tests were being performed or why you were being told to do different things?
Pre-operative optimisation	Were you advised at any point about lifestyle and behaviour changes that could help you to cope with a major operation better? Who was this from? GP/ surgeon/ specialist nurse/ pre-operative assessment team/ anaesthetist? Did you manage to increase your activity levels before your operation? If so did you feel better for it? If not, what were the challenges? Did you have the opportunity to attend something called Surgery School? Was there anything that you decided to do for yourself before anyone suggested it?
Prehabilitation	If you took part in a formal prehabilitation programme, what was your experience of this? Did you find the time to be able to do it? Did you find it helpful? How did you feel as a result? What did you find most beneficial about it? What did you find hardest about it? E.g. fatigue, time to fit it in, getting to the sessions Did you manage to use some of the techniques you'd learnt at prehabilitation to help you recover after your operation?
Other forms of pre-operative optimisation	Did you make changes to your diet, attend support classes, have an iron infusion, see a geriatrician, stop smoking or reduce your alcohol content? What did you find helpful about this? What were the challenges associated with making changes?
Peri-operative optimisation	Was something called ERAS or enhanced recovery explained to you? Did you feel that you were supported to engage in the different aspects?
Post-operative	How did you find the first few days after your operation? Were you encouraged to mobilise? Was there anything that prevented you from doing this or made it more difficult? E.g. drains, catheters, dizziness, fatigue, help to get out of bed. Did you have many interactions with the physiotherapists, OTs and social work? Did you see a geriatrician? Did you find it helpful? Did they address things that you hadn't necessarily thought to raise before? What do you think could have been done differently to improve your stay in hospital? Is there anything that you feel helped you to recover after your operation?
After discharge	Did you feel ready when you left hospital?

	How did you find the first few weeks being back in your normal environment? Was it easier than expected, harder than expected? Were you given any advice about what to do in the first few weeks after discharge? Did anyone say about when you could return to exercise or other activities? Have you had to modify your diet since your operation? Was this to control bowel motions or to try to regain weight lost? If you now have a stoma, did anyone explain to you ways that you can still exercise with this?
Mental health	How do you feel your mental health has been over the course of your treatment and recovery? Has anything or anyone in particular helped you with the 'ups' and 'downs' of major surgery? What do you think would help another person in your situation? Group sessions? More tailored information? Have feelings of worry or anxiety prevented you from engaging with things like prehabilitation and rehabilitation?

Topic guide for patients who underwent risk-adjusted procedures

Topic	Questions
Patient pathway	How do you feel about your journey from diagnosis through having your procedure to now? What do you feel went well? In what ways could things have been improved?
Fitness assessment	Did you undergo exercise testing or other tests to determine whether you were fit to undergo surgery? How did you feel about this? Did you feel that the reasons for doing this were sufficiently explained? What impact did the results of the tests have on you? Incentive to make changes? Anxiety regarding fitness
Decision-making	Did you feel that you were supported to make decisions regarding your own care? Did you understand what options were available to you? Was there anything or anyone in particular who helped you? Did you understand why different tests were being performed or why you were being told to do different things? Did you understand why it was felt that major surgery would be high risk for you? Did you understand what the benefits of undergoing a risk-adjusted procedure or no intervention were? Reduced length of stay/ short term better quality of life
Pre-operative optimisation	Were you advised at any point about lifestyle and behaviour changes that could help you to cope with your surgical management? Who was this from? GP/ surgeon/ specialist nurse/ pre-operative assessment team/ anaesthetist? Did anyone discuss trying to get you fitter so that you might be able to have major surgery

Other forms of pre-operative optimisation	Did you make changes to your diet, attend support classes, have an iron infusion, see a geriatrician, stop smoking or reduce your alcohol content? What did you find helpful about this? What were the challenges associated with making changes?
Post-procedure	How did you find the first few days after your procedure? Were you encouraged to mobilise? Was there anything that prevented you from doing this or made it more difficult? E.g. catheters, dizziness, fatigue, help to get out of bed. Did you have many interactions with the physiotherapists, OTs and social work? Did you see a geriatrician? Did you find it helpful? Did they address things that you hadn't necessarily thought to raise before? What do you think could have been done differently to improve your stay in hospital? Is there anything that you feel helped you to recover after your procedure?
After discharge	Did you feel ready when you left hospital? How did you find the first few weeks being back in your normal environment? Was it easier than expected, harder than expected? Were you given any advice about what to do in the first few weeks after discharge? Did anyone say about when you could return to exercise or other activities? Have you had to modify your diet since your procedure? Was this to control bowel motions or to try to regain weight lost? If you now have a stoma, did anyone explain to you ways that you can still exercise with this?
Mental health	How do you feel your mental health has been over the course of your treatment and recovery? Has anything or anyone in particular helped you with the 'ups' and 'downs' of hospital investigations and treatment? What do you think would help another person in your situation? Group sessions? More tailored information? Have feelings of worry or anxiety prevented you from engaging with things like rehabilitation?

Topic guide for patients who underwent conservative management

Question	Prompts
Patient pathway	How do you feel about your journey from diagnosis through having investigations to now? What do you feel went well? In what ways could things have been improved?
Fitness assessment	Did you undergo exercise testing or other tests to determine whether you were fit to undergo surgery? How did you feel about this? Did you feel that the reasons for doing this were sufficiently explained? What impact did the results of the tests have on you? Incentive to make changes? Anxiety regarding fitness

Decision-making?	Did you feel that you were supported to make decisions regarding your own care? Did you understand what options were available to you? Was there anything or anyone in particular who helped you? Did you understand why different tests were being performed or why you were being told to do different things? Did you understand why it was felt that major surgery would be high risk for you? Did you understand what the benefits of conservative management were? Reduced length of stay/ short term better quality of life/ more time with family and friends
Long-term planning	Do you feel you know what to expect in the future regarding your health? If you develop problems e.g. symptoms of a bowel blockage do you know who to contact? Have you had the chance to have a talk with your GP and talk about long term care planning?
Mental health	How do you feel your mental health has been over the course of your investigations? Has anything or anyone in particular helped you with the 'ups' and 'downs' of hospital investigations? What do you think would help another person in your situation? Group sessions? More tailored information? Have feelings of worry or anxiety prevented you from engaging with aspects of your care?

Data Analysis

Qualitative interview transcript analysis will follow the National Centre for Social Research "Framework" approach, to identify recurrent themes(61). The Framework approach permits the systematic analysis of large volumes of textual data and permits within and across case and theme comparison. Data coding and analysis will be undertaken by Sarah Daniels with prior training and supervision from two experienced qualitative researchers (MB and LW). A thematic index will be drawn up and applied to the data. Data will be distilled, summarised and entered into thematic charts to allow examination and interpretation of the data and to identify any relationships between themes. Analysis will use NVivo software and Microsoft Excel.

Study organisation

Ethics and Good Clinical Practice

The study will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects, adopted by the 18th World Medical Association General Assembly, Helsinki, Finland, June 1964, amended at the World Medical Association General Assembly, Seoul, Korea, October 2008. Informed written consent will be obtained from the patients prior to participation in the study. The right of a patient to refuse participation without giving reasons will be respected. The study will be submitted to and approved by a National Research Ethics Committee and the appropriate locality site specific R&D approval prior to entering patients into the study. The Study will provide the main Research Ethics Committee with a copy of the final protocol, patient information sheets, consent forms and all other relevant study documentation. The study will be conducted in accordance with the principles of GCP according to the EU Directive 2005/28/EC (GCP Directive), which was implemented in The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006.

Confidentiality

The Study Team will collect patient data that includes some patient identifiers. A subject recruitment log will be maintained in the Investigator Site File to cross-reference subjects against the assigned study subject ID number. The Study Team will handle all data in accordance with the GDPR 2018 principles and the Data Protection Act 2018. Any information that would allow patients to be identified will not be released into the public domain. If a patient withdraws consent from further study participation but not from collection of data, their data will remain on file and will be included in the final study analysis. Quotes from the interviews may be used, but patients will not be identifiable.

Archiving

At the end of the study, data and the site master file will be securely archived at Sheffield Teaching Hospitals for a minimum of 5 years. Following authorisation from the sponsors arrangements for confidential destruction will then be made. If a patient withdraws consent for their data to be used, it will be confidentially destroyed.

Indemnity

This study is sponsored by the Sheffield Teaching Hospitals NHS Foundation Trust (STHNHSFT) which will be liable for negligent harm caused by the design of the study. The NHS has a duty of care to patients treated, whether or not the patient is taking part in a clinical trial, and the NHS remains liable for clinical negligence and other negligent harm to patients under this duty of care.

As this is a clinician-led study there are no arrangements for no-fault compensation.
Study Sponsorship

The study will be sponsored by the Sheffield Teaching Hospitals NHS Foundation Trust (STHNHSFT). This organisation will therefore be responsible for the initiation and management of the trial as defined in the principles of GCP according to the EU Directive 2005/28/EC (GCP Directive), which was implemented in The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006.

Study Organisational Structure

Chief Investigator (CI)

The Chief Investigator is involved in the design, conduct, co-ordination and management of the study.

Study Management Group

The study management group will meet regularly to review progress with meetings annually face to face and by e mail/telephone every 6 months. All collaborators listed above will be invited to attend. They will be involved in the development of the protocol, CRF development, clinical set-up and interpretation of results.

Data Management and Confidentiality

All data will be handled, computerised and stored in accordance with the Data Protection Act 2018. The translated interviews and observational study database will be stored on an encrypted, password protected NHS computer at the Sponsor site and on University of Sheffield computers for analysis. All reply slips containing patient contact information will be sent to the researcher, Sarah Daniels, either in paper form or electronically via secure nhs.net e-mail. All participant identifiers will be removed from interview recordings, transcripts of interviews and questionnaires and replaced with a unique research identification code. The key to this code will be recorded on the enrolment log in the Investigator Site, which will be held in a secure locked research office at the Sponsor site. Consent forms, which are a legal document, will be retained in the Investigator Site File and a copy given to the Sponsor site for monitoring purposes only. Feedback from the research will be offered to all study participants on study completion in the form of a final study report. The results may also be disseminated at appropriate forums/ conferences. At no point will patient names be used. The study will be archived for 5 years and then confidentially destroyed.
If any participant wishes to withdraw consent at any time and for any reason, this will be respected. If they wish for their records to be destroyed (both paper based, digital audio files and on line), this will be done using secure means. The study team will simply keep a numeric record of the number of withdraws for transparency purposes.

The study database will need to be accessed by the study team at the University of Sheffield for data analysis purposes only. The Sponsor and University of Sheffield will act

as joint data controllers. These two institutes operate a joint research office. In addition, regulatory bodies and the Sponsor site may need to access the data for audit purposes.

Regulatory Approvals

Ethical approval for this study will be sought from the NHS Research Ethics Committee, it is anticipated that only proportionate ethical review will be required. Health Research Authority approval will be obtained for this study. Confirmation of Capacity and Capability at each hospital site will be obtained. All PIs will be encouraged to have full GCP training. The study will be conducted in accordance with the principles of GCP according to the EU Directive 2005/28/EC(62). The study will be registered on clinicaltrials.gov. No other approvals or registrations are required.

Responsibilities and Operational Structure.

Lynda Wyld (Professor of Surgical Oncology at the University of Sheffield Medical School and Consultant Surgeon at DRI) will be the research student's primary supervisor and project lead. Statistical advice will be provided for analysis of the observational study data will be by Dr Jen Lewis. Qualitative and mixed methodological expertise will be provided by Dr Maria Burton.

Funding

The day-to-day conduct of the study will be undertaken by the research fellow (during a 24 month research placement). Miss Daniels will be employed by Sheffield Teaching Hospitals NHS Trust for the duration of the project as a Clinical Research Fellow. Salary funding is provided by the STH Trust from a clinical research fellow post. Stationary, postage, printing, transcription costs, transport and funding for statistical support for the study will be supported by an educational grant from Bowel Research UK (BRUK).

Publication Policy

The success of the study depends upon the collaboration of all participants. For this reason, credit for the main results will be given to all those who have collaborated in the study, through authorship and contributorship. Uniform requirements for authorship for manuscripts submitted to medical journals will guide authorship decisions. These state that authorship credit should be based only on substantial contribution to:

- conception and design, or acquisition of data, or analysis and interpretation of data
- drafting the article or revising it critically for important intellectual content
- and final approval of the version to be published
- and that all these conditions must be met (www.icmje.org).

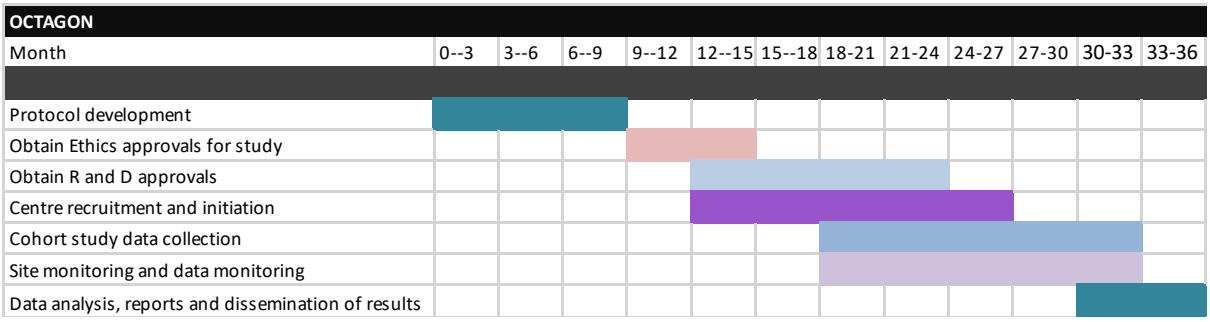
In light of this, the Chief Investigator and co-investigators will be named as authors in any publication. In addition, all collaborators will be listed as contributors for the main study publications, giving details of roles in planning, conducting and reporting the study(63). All publications will acknowledge the depth of gratitude to the patients who have taken part in the study. Full acknowledgement will also be given to the PPI representatives in all publications and presentations.

Sites

The study will be carried out at three to five hospitals to give a range of settings (university versus district general, teaching hospital versus non-teaching hospital, rural versus urban, small, medium and large district general hospital). A local Principal Investigator (PI) will be named at each site and will oversee the running of the study locally.

Study Timeline

GANTT chart of expected timelines



The GANTT chart has been adjusted to reflect the extended timelines as a result of the COVID-19 pandemic.

Expertise of the Research Team:

The project team have extensive experience in this area; L. Wyld conducted the large AGEGAP prospective cohort study that showed significant rates of under-treatment in older patients, C. Mitchell has experience from a primary care perspective of conducting RCTs in community based prehabilitation, S. Brown has experience of complex interventions in colorectal disease trials, T Wilson has experience in quality of life studies in colorectal surgery, M Lee has experience of delivering multi-centre cohort studies in emergency surgery.
Training of the research student in research methodology
The student will be formally mentored by Professor Wyld and Dr Burton throughout her research attachment and will access to research methods lectures run by ScHARR at the University of Sheffield.

Patient and Public Involvement panel (PPI)

Improving outcomes following emergency surgery in the elderly, reducing complications after surgery and improving recovery from surgery in elderly patients have all been identified as priorities by the James Lind Alliance. The PPI panel at Doncaster Royal Infirmary have been involved in the development of the protocol. Lay members from this group have been integrated into the steering group. They will also be involved in the dissemination of findings.

Benefit to the patient and NHS

There will be no direct benefit to the participants as no new intervention is being offered. They will however, be able to contribute to research that will contribute to improved management of older patients with GI pathology

Appendix L: Completed IRAS form for OCTAGON study

IRAS Form | Reference: 20/SC/0076 | IRAS Version 5.13

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Optimising Treatment Pathways for Older Patients Facing GI Surgery

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
(●) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

[x] England
[ ] Scotland

☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◉ England
○ Scotland
○ Wales
○ Northern Ireland
○ This study does not involve the NHS

4. Which applications do you require?

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ Her Majesty's Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

○ Yes ◉ No

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative in all study sites?

Please see information button for further details.

○ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

◉ Yes ○ No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Optimising Treatment Pathways for Older Patients Facing GI Surgery

Please complete these details after you have booked the REC application for review.

REC Name:
Oxford A Committee

REC Reference Number:
20/SC/0076

Submission date:
30/01/2020

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Optimising the Care and Treatment Pathways for Older Patients Facing Major Gastrointestinal Surgery.

A3-1. Chief Investigator:

Title	Forename/Initials	Surname
Dr	Sarah	Daniels

Post	Clinical Research Fellow
Qualifications	MBChB BSc MRCS MSc
ORCID ID	0000 0001 9452 3344
Employer	Sheffield Teaching Hospitals NHS FT
Work Address	Old Nurses Home Northern General Hospital
Post Code	S5 7AU
Work E-mail	sarahdaniels1@nhs.net
* Personal E-mail	sarahdanielsx@gmail.com
Work Telephone	07941605424

* Personal Telephone/Mobile 07941605424
Fax

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Dr	Debby	Hawkins
Address	General surgery		
	2nd Floor, Old Nurses Home, Northern General Hospital		
	Herries Road		
Post Code	S5 7AU		
E-mail	debby.hawkins@nhs.net		
Telephone	01142266210		
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	STH20694
Sponsor's/protocol number:	
Protocol Version:	1.0
Protocol Date:	16/01/2020
Funder's reference number (enter the reference number or state not applicable):	NK
Project website:	

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

The UK population is ageing. Whilst many people remain active and in good health as they get older, getting older is associated with the onset of many common medical conditions, as well as memory and mobility problems. There is a natural decline in heart and lung fitness with age, although this may be slowed by regular exercise. The majority of digestive system problems that require operations (such as bowel cancer) are more common in older people. These operations can lead to long-term disability. In some cases there is a trade-off between major surgery and a smaller operation or procedure with a lower chance of cure, but a faster rate of recovery and fewer problems immediately after the procedure. Some patients may choose not to undergo any form of treatment.
Deciding whether a person is fit enough to undergo a major operation is difficult and depends on patient factors (e.g. other medical conditions, patient choice) and technical factors (e.g. spread of disease, availability of other treatment options). In the outpatient setting there are a number of tests that can be used to try to work out what the risks of a major operation will be for a particular person. These can then guide different approaches to try to lessen these risks. Examples include exercise programmes, dietary supplements and anxiety management programmes before major operations if there is time or early meeting with a physiotherapist and planning for discharge needs after an operation. This study aims to explore whether patients who have poor outcomes after surgery can be identified at the start of their surgical journey, whether similar patients are offered the same treatments and what patients feel about different support measures that may be used to try to improve recovery.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

This is an observational study only and therefore will not affect patient management. The study does involve asking patients to complete standardised questionnaires with the associated burden of completing them. Therefore we have consulted with the PPI representatives and tried to limit the number of questionnaires used.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☐ Qualitative research
- ☑ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

Can we identify older patients at risk of poor outcomes after surgery (such as inability to look after themselves, need to go into a care home) from assessments of their background health and fitness completed before surgery?

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

Are there any differences in the background health and fitness of patients who are offered major surgery compared to risk adapted procedures?
What are the views of patients regarding different strategies to improve their outcomes after surgery (e.g. exercise programmes, counselling, dietician input, geriatrician review) and how do they feel these would be best put into practice?

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Consistently, research has shown that surgical outcomes in older patients are worse than in younger patients. There is evidence that older people are not offered the same treatment options and that chronological age is sometimes used as a substitute for a proper assessment of background health problems and heart and lung fitness. There are a number of different ways to try to improve outcomes that may be before, during or after an operation. These may include supervised exercise programmes, dietician review, psychological counselling, geriatrician review, medication reviews, anaesthetic and surgical techniques, early consultation with a physiotherapy and engagement with social services to facilitate discharge, for example. However, it is not known how often these are used in practice and what patients feel about them. This project will assess patients background health and fitness thoroughly before their operation or procedure and then follow them through their time in hospital and for six months afterwards. It aims to determine whether patients at risk of poor outcomes after their surgical admission can be identified at the beginning of their surgical journey. There is evidence for the use of some of these interventions but older people tend to not be included in research studies, particularly when they present to hospital as an emergency or when there is a decision that they are not fit enough to undergo a big operation.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

This is an observational multicentre study to observe current practice at different hospitals in the South Yorkshire region. The recruitment target is 120 over 6 months. It will involve asking patients to fill in detailed questionnaires when they are first considered for surgery about what they can and can't do around the house (functional abilities), weight loss and diet, physical activity levels and impact of their health conditions on them. A member of the research team will help participants to complete these if needed. The research team will also look through their notes to find information on formal assessment of their fitness, other medical problems and regular medications. The research team will meet with the participant again when they are getting ready to leave hospital after their procedure to find out what procedure they underwent, whether they had any post-operative problems (e.g. infections), how long they stayed in hospital, where they are going home to and with what support and whether any of the strategies to potentially improve outcomes were used (e.g. were they advised to stop smoking, did they see a physiotherapist after their operation). At six weeks the research team will meet with the patient again to help them complete follow-up questionnaires and review their hospital notes for results from any samples taken at their operation. At three months and 6 months, the patient will be contacted by telephone or post to complete the same follow-up questionnaires. Some participants (20-30) will also be contacted at least 6 weeks after their operation to participate in an interview, either in person or by telephone.

We anticipate recruiting a small number of participants who are assessed as being 'unfit' for a major operation and are advised or choose not to undergo any operation or procedure. These patients will only be asked to complete the questionnaires at the time of the decision and then at 6 weeks, 3 months and 6 months after the decision.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [x] Management of the research
- [ ] Undertaking the research

- [x] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Two lay members have been integrated into the study group. They have been involved in reviewing the protocol (in particular the lay summary, patient information sheets and questionnaires) and also in determining how long the questionnaires may take to administer and anticipated burden to participants. The PPI group reviewed the protocol to ensure that the research question was appropriate and of importance.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [x] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [x] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [ ] Neurological
- [x] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 65	Years
Upper age limit:	No upper age limit

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

- Male or female
- Aged 65+ years old inclusive
- Patients with a diagnosis of gastrointestinal pathology amenable to elective, urgent (unscheduled) or emergency major gastrointestinal surgery who either undergo surgery, a risk-adapted procedure or are managed conservatively (due to patient wishes, co-morbidities or frailty).
- Mental capacity to consent

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

- Patients aged less than 65 years old
- Patients with unresectable disease (location, invasion, dissemination)
- Lack mental capacity to consent
- Unable to understand the information provided (translational issues)
- Prisoners
- Patients undergoing surgery for major trauma
- Patients undergoing surgery for primary gynaecological, vascular or urological disease

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Consent	1	0	30	PI or delegated member of the team with GCP training
Baseline questionnaires	1	0	30	PI or delegated member of the team with GCP training
Point of discharge questionnaire	1	0	10	PI or delegated member of the team with GCP training
Follow-up questionnaires	3	0	10	PI or delegated member of the team with GCP training
Semi-structured interviews	1	0	30	PI or delegated member of the team with GCP training

A21. How long do you expect each participant to be in the study in total?

Patients will be in the study for the 6 months following their treatment decision or surgery/procedure. If they wait longer than 9 months from the decision to operate to their operation they will no longer be eligible for the study.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

The main risk of this study is the burden of questionnaires and intrusion at a potentially difficult time for the patient. This has been minimised by trying to limit the number of questionnaires and also by trying to give the study team flexibility for the timing of questionnaire completion and options for completing followup questionnaires by telephone or post. The bespoke questionnaire with patients about what elements of enhanced perioperative support they have received has been designed to try to minimise the burden on the research team and limit the need to access clinical notes.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

○ Yes ◉ No

A24. What is the potential for benefit to research participants?

May benefit older GI patients in the future by standardising methods of assessment and management. Results may be used to inform the design of future studies of interventions in this area.

A26. What are the potential risks for the researchers themselves? *(if any)*

None

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

For the observational study, a local Principal Investigator (PI) and lead trainee will be identified at each site. The PI and trainee will be asked to facilitate identification of potential participants from Multidisciplinary team meetings, outpatient clinic lists, operating lists and emergency admission lists. They will then approach the patient or inform a delegated member of the research team to approach the patient on their behalf.

Patients may also be identified by the direct healthcare team and given the information sheets about the study. Potential participants will then be approached by the study team following discussions with the direct healthcare team re the patient's management plan (i.e. surgery, risk adjusted procedure or no intervention). This may be on the day of diagnosis or afterwards, depending on the urgency and diagnosis.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:
A member of the patient's existing clinical care team will identify potential participants and check whether they meet the inclusion criteria.

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

Potential participants will be approached either by the PI or delegated study team member with the appropriate GCP training, once identified by the direct clinical team.

Emergency participants will be approached as soon as possible after a diagnosis of operable gastrointestinal pathology has been made. The participant will be given a written information sheet to consider for an appropriate length of time and study discussed with the participant. If willing, the patient will be consented on the same day.

Elective participants will be approached at the diagnosis appointment if possible and will be given a written information sheet. If willing, the participant will then be consented on the same day or at their next clinic appointment (outpatients, pre-op assessment or admission). For those patients that this approach is not appropriate on the diagnosis day (i.e. cancer diagnosis) or for any missed patients, they will be posted an invite letter and patient information sheet.

Alternatively, the missed patients will be phoned by the PI or delegated study team member to ask if they may be interested in taking part in the study and if willing, the patent will be sent the invite letter and information sheet. If willing, the patient will be consented at their next clinic appointment by the PI or delegated study team member.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

All participants will be required to give written informed consent. It will be carried out by the PI or delegated study team member. Participants will be asked to consider the information sheet prior to signing the consent form. Emergency participants and elective patients will be consented on the same day that they are approached as this is an observational questionnaire study.

Alternatively for elective patients, they may be posted the information sheet to read prior to their next clinic appointment. At this next appointment the study will be discussed by the PI or study team member and if willing the patient will be consented.

The consent form contains an option regarding participation in a semi-structured interview. This is an optional. If patients do not agree to being interviewed, they can still take part in the main study. If patients are willing to take part in the interview, they will be contacted about this on a separate occasion.

If you are not obtaining consent, please explain why not.

N/A

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

Emergency and elective participants will be given as much time as is practical, but consent for this questionnaire study will be on the same day they are approached. Due to the emergency surgical setting, there is not always the option to give the patient at least 24 hours to consider participation. However, elective patients will be given the additional option of receiving the study information by post and then consented at their next clinic visit. In this case the patient will have more than 24 hours to consider the information.

Elective patients will be given as much time as is practical

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

Participants who lack mental capacity or are unable to understand the information provided (translational issues) are excluded from this study because the nature of the questionnaires to be completed requires a basic understanding of English. It is not feasible to provide translations of the questionnaires in different languages as they are mostly validated questionnaires subject to copyright. If a person has a visual impairment meaning that they cannot read the provided material and questionnaires, a member of the study team may assist by reading the information to them if

local capacity allows.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ◉ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ○ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

This study is an observational study of older patients with gastrointestinal pathology amenable to major surgery. Given the older population studied, it is anticipated that some participants may loose capacity during the study due to complications of the surgery/procedure (e.g. delirium, stroke) or due to their underlying disease or co-morbidities. In this circumstance the patient would be withdrawn from the study and no further data collected. However, all data collected up to the point of withdrawal will be retained and used in the final data analysis.

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

- ☑ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☑ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☑ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☑ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☑ Manual files (includes paper or film)
  - ☑ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers
  - ☑ University computers

☐ Private company computers

☐ Laptop computers

Further details:
All data will be handled in accordance with the GDPR 2018 principles. All patients will be given a unique ID number which will be used in the database rather than their NHS number i.e. pseudoanonymised. The key detailing NHS number and study ID will be retained by each site in the Investigator Site File (ISF) to enable data collection at different timepoints. Data will be collected and recorded by members of the hospital research team on paper-based CRFs which will then be entered into a secure server running the Research Electronic Data Capture (REDCap) web application. REDCap allows collaborators to enter and store data in a secure system.
All transmission and storage of data by this system is encrypted using 'SSL' connection. System users will be allocated to a data access group for their hospital, allowing them to create and edit records entered by their own team, but not those from other hospitals. Collaborators will be required to set passwords which include letters, numbers and special characters. Passwords will be changed every 30 days. The REDCap servers are encrypted and are hosted in a secure building at the University of Sheffield, and undergo regular back-up. Data from this study will be retained on University of Sheffield servers for 5 years after the study has closed and will not be sent outside the UK.

Sites will be responsible for archiving the source data, CFs, CRFs and other essential documents at their own site for a period of 5 years. No patient identifiable data will leave each site.

Patient interviews will be digitally recorded and transcribed verbatim by the study team at each site. No patient names will be recorded. The recording device will be kept securely and files will be transferred onto NHS computers. Transcriptions will be pseudonymised and checked for accuracy, then the digital recordings will be deleted. The transcriptions will be uploaded to RedCap. Patients will not be identifiable from direct quotations used in any publications.

A37. Please describe the physical security arrangements for storage of personal data during the study?

Screening logs, recruitment logs, consent forms and Paper Case Report Forms will be held securely at each hospital site in locked rooms or filling cabinets, accessible to staff only. CRF data will then be entered onto a secure server running the Research Electronic Data Capture (REDCap) web application.

The digital dictaphone will be stored in a locked location when not in use. Digital recordings will be uploaded via a secure server to a registered transcription service. No patient names will be recorded on the Dictaphone.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

All data will be handled in accordance with the GDPR 2018 principles. All patients will be given a unique ID number which will be used in the database rather than their NHS number i.e. pseudoanonymised. The key detailing NHS number and study ID will be retained by each site in the Investigator Site File (ISF) to enable data collection at different timepoints. Data will be collected and recorded by hospital staff or members of the hospital research team on paper-based CRFs which will then be entered into a secure server running the Research Electronic Data Capture (REDCap) web application.
All transcriptions will be pseudonymised and no identifiable information or quotations will be used in any reports or publications arising form this work.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The PI and delegated study team members at each site will have access to the participant's personal data.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

Data generated by the observational part of this study will be analysed by the CI, study statistician and study team at the Sponsor site (STH) and the University of Sheffield.

The interviews from all sites will be transcribed and analysed by the CI and study team at the Sponsor site (STH) and University of Sheffield.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Dr	Sarah	Daniels
Post	Clinical Research Fellow		
Qualifications	MBChB BSc MRCS MSc		
Work Address	General Surgery		
	Herries Road		
	Sheffield		
Post Code	S5 7AU		
Work Email	sarahdaniels1@nhs.net		
Work Telephone	01142266210		
Fax			

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ◉ 6 – 12 months
- ○ 12 months – 3 years
- ○ Over 3 years

A44. For how long will you store research data generated by the study?

Years: 5
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

The study will be archived locally as advised by the local R&D Departments

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

○ Yes ◉ No

Please give details, or justify if not registering the research.
Not a clinical trial. We plan to publish our protocol through an open access publisher.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☑ Internal report
- ☑ Conference presentation
- ☐ Publication on website
- ☐ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- ☐ No plans to report or disseminate the results
- ☐ Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Patients will not be identifiable from observational data or interview quotes.

A53. Will you inform participants of the results?

◉ Yes ○ No

Please give details of how you will inform participants or justify if not doing so.
Any publication(s) arising from this work will be accessible to staff and patients via Pubmed. The website details are provide in the patient information leaflet.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- ☑ Independent external review
- ☐ Review within a company
- ☐ Review within a multi−centre research group
- ☐ Review within the Chief Investigator's institution or host organisation
- ☐ Review within the research team
- ☐ Review by educational supervisor
- ☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
Reviewed by the funders, Bowel Disease Research Foundation

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- ☐ Review by independent statistician commissioned by funder or sponsor
- ☐ Other review by independent statistician
- ☐ Review by company statistician
- ☑ Review by a statistician within the Chief Investigator's institution
- ☐ Review by a statistician within the research team or multi−centre group
- ☐ Review by educational supervisor
- ☐ Other review by individual with relevant statistical expertise
- ☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Dr	Jen	Lewis
Department	Medical Statistics		
Institution	School of Health and Related Research		
Work Address	University of Sheffield		
	Regent Court		
	Sheffield		

Post Code	S1 4DA
Telephone	01142220839
Fax	
Mobile	
E-mail	jen.lewis@sheffield.ac.uk

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

Observational study: Functional recovery at 6 weeks post-operation/ definitive procedure or from decision not to operate

Patient interviews: To determine the views of patients who have undergone surgical management for major gastrointestinal pathology regarding different methods of peri-operative support

A58. What are the secondary outcome measures?*(if any)*

Observational:
- Health related quality of life at 6 weeks
- Length of hospital stay
- Treatment related adverse events (including complication rate and severity)
- Overall survival, including cause of and time to death

Interviews:
To explore patients' experiences of fitness and risk assessment as part of management decisions and the impact of this on shared decision-making.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	120
Total international sample size (including UK):	
Total in European Economic Area:	

Further details:
From this sample size of 120, between 20-30 will be asked to participate in a semi-structured interview.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

We propose to recruit and follow-up eligible patients from up to 5 surgical units within the South Yorkshire region. Each unit performs between 70-300 major elective GI resections per year and 114-300 emergency laparotomies per year, of which at least 50% will be over the age of 65. An opportunistic sample size of 120 has been estimated over the 6-month study recruitment period based on the number of patients undergoing major surgery at each of the units. At STH in a typical week, approximately 10 patients aged 65 or over will undergo major elective surgery and 5 patients will undergo emergency major surgery. This will give a potential pool of around 390 potentially eligible patients at STH alone. Doncaster Royal Infirmary performs roughly 10 major operations per week on emergency and elective patients aged 65 years and over, resulting in around 260 potentially eligible patients. We acknowledge that our sample size may not be sufficient to detect a difference in our primary outcome but will give data that may be used to inform the design of a future trial. If we reach the recruitment target, we will continue to recruit patients whilst resources allow.

Participants from the observational study will also be asked if they are willing to take part in a semi-structured interview. Recruitment will continue until there has been saturation of themes, but from previous experience of the research team, this is anticipated to be between 20-30 participants.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Data analysis for the observational study will focus on two main areas:
1. Impact of baseline health and fitness on functional outcomes (WHO DAS, EQ-5D-5L, ADL) and surgical outcomes (LOS, mortality, morbidity) (multiple regression)
2. Criteria for and selection of treatment options stratified according to baseline health and fitness (using multiple regression analysis)

Planned covariates:
- Age
- Sex
- Charlson co-morbidity score
- Emergency versus elective presentation
- Baseline WHO DAS score
- Surgical unit

Qualitative interview data analysis will be performed using the Framework Approach. It will occur alongside recruitment, and recruitment will cease on achievement of data saturation.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Professor	Lynda	Wyld
Post	Professor of Surgical Oncology		
Qualifications	MBChB PhD FRCS		
Employer	University of Sheffield		
Work Address	Academic Unit of Surgical Oncology		
	Room EU36		
	University of Sheffield Medical School		
Post Code	S10 2JF		
Telephone	01142159066		
Fax			
Mobile			
Work Email	l.wyld@sheffield.ac.uk		

	Title	Forename/Initials	Surname
	Professor	Steven	Brown
Post	Honorary Professor of Colorectal Surgery		
Qualifications	MBChB MD FRCS		
Employer	Sheffield Teaching Hospitals NHS FT		
Work Address	General Surgery, Northern General Hospital		
	Herries Road		
	Sheffield		
Post Code	S5 7AU		
Telephone	01142715279		
Fax			
Mobile			

Work Email	steven.brown13@nhs.net

Title	Forename/Initials	Surname
Mr	Tim	Wilson

Post	Consultant Colorectal Surgeon
Qualifications	MBChB PhD FRCS
Employer	Doncaster Teaching Hospitals NHS FT
Work Address	Doncaster Royal Infirmary Armthorpe Road Doncaster
Post Code	DN2 5LT
Telephone	01302644389
Fax	
Mobile	
Work Email	tim.wilson1@nhs.net

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- (●) NHS or HSC care organisation
- ( ) Academic
- ( ) Pharmaceutical industry
- ( ) Medical device industry
- ( ) Local Authority
- ( ) Other social care provider (including voluntary sector or private organisation)
- ( ) Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	Sheffield Teaching Hospitals NHS FT
Given name	Dipak
Family name	Patel
Address	CRIO, D Floor, Royal Hallamshire Hospital
Town/city	Sheffield
Post code	S10 2JF
Country	UNITED KINGDOM
Telephone	01142265934
Fax	
E-mail	dipak.patek12@nhs.net

A65. Has external funding for the research been secured?

Please tick at least one check box.

- [x] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [ ] No application for external funding will be made

What type of research project is this?

- (•) Standalone project
- ( ) Project that is part of a programme grant
- ( ) Project that is part of a Centre grant
- ( ) Project that is part of a fellowship/ personal award/ research training award
- ( ) Other

Other – please state:

Please give details of funding applications.

Organisation	Bowel Disease Research Foundation
Address	Royal College of Surgeons of England
	35-43 Lincoln's Inn Fields
	London
Post Code	WC2A 3PE
Telephone	02078696946
Fax	
Mobile	
Email	gsaffery@bdrf.org.uk

Funding Application Status: (•) Secured ( ) In progress

Amount: 8647

Duration
Years: 2
Months: 0

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

( ) Yes (•) No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Dr	Modhumita	Harris
Organisation	STH NHS FT		
Address	Clinical Research and Innovation Office		
	D Floor		
	Royal Hallamshire Hospital		
Post Code	S10 2JF		
Work Email	modhumita.harris@nhs.net		
Telephone	01142713570		
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A68-2. Select Local Clinical Research Network for NHS Organisation identified in A68-1:

Yorkshire and Humber

For more information, please refer to the question specific guidance.

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/03/2020
Planned end date: 28/02/2022
Total duration:
Years: 1 Months: 11 Days: 28

A71-1. Is this study?

○ Single centre
◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

☑ England
☐ Scotland
☐ Wales
☐ Northern Ireland
☐ Other countries in European Economic Area

Total UK sites in study 5

Does this trial involve countries outside the EU?

◯ Yes ◉ No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☑ NHS organisations in England	5
☐ NHS organisations in Wales	
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☐ GP practices in England	
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Joint health and social care agencies (eg community mental health teams)	
☐ Local authorities	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent (private or voluntary sector) organisations	
☐ Educational establishments	
☐ Independent research units	
☐ Other (give details)	
Total UK sites in study:	5

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

◯ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

Monitoring is the responsibility of the Sponsor and will be carried out according to SOP of the STH Clinical Research & Innovation Office for Sponsored studies.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes.

Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☑ NHS indemnity scheme will apply (NHS sponsors only)

☐ Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☑ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☐ Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

○ Yes ◉ No ○ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site		Investigator Name	
IN1	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Tim Wilson tim.wilson1@nhs.net
	Organisation name	DONCASTER AND BASSETLAW TEACHING HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)	MBChB PhD FRCS
	Address	DONCASTER ROYAL INFIRMARY ARMTHORPE ROAD DONCASTER SOUTH YORKSHIRE	Country	UNITED KINGDOM
	Post Code	DN2 5LT		
	Country	ENGLAND		
IN2	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Richard Slater richardslater@nhs.net
	Organisation name	THE ROTHERHAM NHS FOUNDATION TRUST	Qualification (MD...)	MBChB MD FRCS
	Address	MOORGATE ROAD ROTHERHAM SOUTH YORKSHIRE	Country	UNITED KINGDOM
	Post Code	S60 2UD		
	Country	ENGLAND		
IN3	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Alison Payne alisonpayne@nhs.net
	Organisation name	BARNSLEY HOSPITAL NHS FOUNDATION TRUST	Qualification (MD...)	MBChB FRCS
	Address	GAWBER ROAD BARNSLEY SOUTH YORKSHIRE	Country	UNITED KINGDOM
	Post Code	S75 2EP		

	Country	ENGLAND

IN4

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	CHESTERFIELD ROYAL HOSPITAL NHS FOUNDATION TRUST
Address	CALOW
	CHESTERFIELD DERBYSHIRE
Post Code	S44 5BL
Country	ENGLAND

Forename	Harjeet
Middle name	
Family name	Narula
Email	harjeet.narula@nhs.net
Qualification (MD...)	MBChB FRCS
Country	UNITED KINGDOM

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.
3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
4. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
5. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
7. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
9. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 2018.
10. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.
11. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 2018.
12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication *(Not applicable for R&D Forms)*

HRA would like to include a contact point with the published summary of the study for those wishing to seek further

information. We would be grateful if you would indicate one of the contact points below.

- (●) Chief Investigator
- ( ) Sponsor
- ( ) Study co-ordinator
- ( ) Student
- ( ) Other – please give details
- ( ) None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Ms Sarah Daniels on 29/01/2020 21:58.

Job Title/Post:	Clinical research fellow
Organisation:	Sheffield teaching hospitals
Email:	Sarahdaniels1@nhs.net

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*
7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.
8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Dr Dipak Patel on 29/01/2020 14:39.

Job Title/Post:	Research Manager
Organisation:	Sheffield Teaching Hospital NHS Foundation Trust
Email:	dipak.patel12@nhs.net

Appendix M: Health Research Authority approval letter OCTAGON study

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Sarah Daniels
Clinical Research Fellow
Sheffield Teaching Hospitals NHS FT
Old Nurses Home
Northern General Hospital
S5 7AU

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

4 May 2020

Dear Dr Daniels

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Optimising the Care and Treatment Pathways for Older Patients Facing Major Gastrointestinal Surgery.**
IRAS project ID:	**277161**
REC reference:	**20/SC/0076**
Sponsor	**Sheffield Teaching Hospitals NHS FT**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **277161**. Please quote this on all correspondence.

Yours sincerely,
Joanna Strickland
Approvals Specialist

Email: oxforda.rec@hra.nhs.uk

Copy to: *Dr Debby Hawkins*

Appendix N: Non-substantial amendments for OCTAGON study

Non substantial amendment number 1

Amendment Tool
v1.2 11 Jun 2020

For office use
QC: No

Section 1: Project information

Short project title*:	OCTAGON
IRAS project ID* (or REC reference if no IRAS project ID is available):	277161
Sponsor amendment reference number*:	Non Substantial Amendment #1
Sponsor amendment date* (enter as DD/MM/YY):	10 September 2020
Summary of amendment including justification*:	Change in PI at Barnsley Hospital NHS Foundation Trust

Project type:	◉ Specific study ○ Research tissue bank ○ Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	◉ Yes	○ No		
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable?:	◉ NHS/HSC REC ○ Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a modified amendment?	○ Yes	◉ No		
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England: ◉	Wales: ○	Scotland: ○	Northern Ireland: ○
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	○ Yes	◉ No		
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	○ Yes	◉ No		
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	○ Yes	◉ No		
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	○ Yes	◉ No		
Did the study involve adults lacking capacity OR does the amendment introduce this?:	○ Yes	◉ No		
Did the study involve access to confidential patient information without consent OR does the amendment introduce this?:	○ Yes	◉ No		
Did the study involve prisoners OR does the amendment introduce this?:	○ Yes	◉ No		
Did the study involve NHS/HSC organisations prior to this amendment?:	◉ Yes	○ No		
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	○ Yes	◉ No		
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	◉	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☑	☐	☐	☐
Which nations will have participating NHS/HSC organisations after this amendment?	☑	☐	☐	☐

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Changes" tab. To add another change, tick the "Add another change" box.

Change 1	
Area of change (select)*:	Researchers
Specific change (select - only available when area of change is selected first)*:	PI - New PI, or temporary arrangements to cover the absence of a PI

Further information (free text):	The PI at Barnsley Hospital has been changed from Alison Payne to Michael Shanaghey, Deputy Associate Director of Nursing. Email: michael.shanaghey@nhs.net

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some?:	○ All		◉ Some	

Add another change: ☐

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

*Name [first name and surname]**:	Modhumita Harris
*Email address**:	modhumita.harris@nhs.net

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a PDF copy of the completed amendment tool that can be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, refer to the "Submission Guidance" tab for further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:			
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:						(Y)				(Y)									B
Overall reviews for the amendment:																			
Full review:						N				N									
Notification only:						Y				Y									
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	B																		

Non substantial amendment number 2

Amendment Tool

v1.2 11 Jun 2020

For office use
QC: No

Section 1: Project information

Short project title*:	OCTAGON
IRAS project ID* (or REC reference if no IRAS project ID is available):	277161
Sponsor amendment reference number*:	Non Substantial Amendment #2
Sponsor amendment date* (enter as DD/MM/YY):	14 December 2020
Summary of amendment including justification*:	6 month recruitment extension until 18th Aug 2021.

Project type:	◉ Specific study ○ Research tissue bank ○ Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	◉ Yes	○ No		
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable?:	◉ NHS/HSC REC ○ Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a modified amendment?	○ Yes	◉ No		
	England	Wales	Scotland	Northern Ireland
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	◉	○	○	○
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	○ Yes	◉ No		
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	○ Yes	◉ No		
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	○ Yes	◉ No		
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	○ Yes	◉ No		
Did the study involve adults lacking capacity OR does the amendment introduce this?:	○ Yes	◉ No		
Did the study involve access to confidential patient information without consent OR does the amendment introduce this?:	○ Yes	◉ No		
Did the study involve prisoners OR does the amendment introduce this?:	○ Yes	◉ No		
Did the study involve NHS/HSC organisations prior to this amendment?:	◉ Yes	○ No		
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	○ Yes	◉ No		
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	◉	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☑	☐	☐	☐
Which nations will have participating NHS/HSC organisations after this amendment?	☑	☐	☐	☐

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Changes" tab. To add another change, tick the "Add another change" box.

Change 1	
Area of change (select)*:	Study Design
Specific change (select - only available when area of change is selected first)*:	Extension to study duration that will have additional resource implications for participating organisations - Please specify in the free text below

Further information (free text):	Recruitment is slower than anticipated at non STH sites due to covid. The recruitment period has therefore been extended from 6 months to 12 months. The actual recruitment start date was 18th Aug 2020 and the new recruitment end date will be the 18th Aug 2021.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some?:	◉ All		○ Some	

Add another change: ☐

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

*Name [first name and surname]**:	Modhumita Harris
*Email address**:	modhumita.harris@nhs.net

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a PDF copy of the completed amendment tool that can be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, refer to the "Submission Guidance" tab for further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:			
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWMA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:						(Y)				(Y)									A
Overall reviews for the amendment:																			
Full review:						N				N									
Notification only:						Y				Y									
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	A																		

Non substantial amendment number 3

Amendment Tool

v1.4 30 Nov 2020

For office use

QC: No

Section 1: Project information

Short project title*:	OCTAGON
IRAS project ID* (or REC reference if no IRAS project ID is available):	277161
Sponsor amendment reference number*:	Non Substantial #3
Sponsor amendment date* (enter as DD/MM/YY):	02 March 2021
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	Addition of 2 new NHS participating sites in England. Protocol, PIS and Invite Letter minor changes which include changes in CI and study team contact details, removal of reference to the GP/consultant letter, removal of appendices, updated recruitment period, change in funder name.

Project type (select):	◉ Specific study ○ Research tissue bank ○ Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	◉ Yes		○ No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	◉ NHS/HSC REC ○ Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	○ Yes		◉ No	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	◉	○	○	○
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	○ Yes		◉ No	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	○ Yes		◉ No	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve prisoners OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve NHS/HSC organisations prior to this amendment?:	◉ Yes		○ No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	○ Yes		◉ No	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	◉	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☑	☐	☐	☐
Which nations will have participating NHS/HSC organisations after this amendment?	☑	☐	☐	☐

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, tick the "Add another change" box.

Change 1	
Area of change (select)*:	Participating Organisations

Specific change (select - only available when area of change is selected first)*:	Addition of sites undertaking the same activities as existing sites
Further information (free text - note that this field will adapt to the amount of text entered):	PI: Mr Arin Saha; Calderdale and Huddersfield NHS Foundation Trust & PI: Mr Janahan Sarveswaran; The Mid Yorkshire Hospitals NHS Trust

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	○ All		◉ Some	

Add another change: ☑

Change 2	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Protocol - Non-substantial changes (e.g. not affecting safety or the scientific value of the trial)
Further information (free text - note that this field will adapt to the amount of text entered):	The patient's GP & consultant will not be informed of their participation in this study as it is an observational cohort study. This was made clear in the original IRAS form but was not updated in the protocol by error. Any reference to appendices has also been removed from the protocol. The name of the funder has changed from BDRF to Bowel Research UK and any reference to regional South Yorkshire hospitals has also been removed. The recruitment period of 12 months as approved in NSAm#2 and the gantt chart has been updated. The new protocol is now version 3, dated 02.03.2021

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	◉ All		○ Some	

Add another change: ☑

Change 3	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Other minor change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information (free text - note that this field will adapt to the amount of text entered):	The name of the funder has changed from BDRF to Bowel Research UK and any reference to regional South Yorkshire hospitals has also been removed from study documents. New study document versions are: PIS v4.0 dated 02.03.2021 and Invite Letter v2.0 dated 02.03.2021

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	◉ All		○ Some	

Add another change: ☑

Change 4	
Area of change (select)*:	Administrative details for the project
Specific change (select - only available when area of change is selected first)*:	Contact details - CI or other project staff
Further information (free text - note that this field will adapt to the amount of text entered):	The CI and study co-ordinator has changed research office address and phone number. This has been updated in the protocol.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	◉ All		○ Some	

Add another change: ☐

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]:*	Modhumita Harris

Email address:*	modhumita.harris@nhs.net

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:			
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:	N					(Y)				(Y)									New site
Change 2:	N					(Y)				(Y)									A
Change 3:	N					(Y)				(Y)									C
Change 4:	(Y)					Y				(Y)									C
Overall reviews for the amendment:																			
Full review:	N					Y				N									
Notification only:	Y					N				Y									
Overall amendment type:	Non-substantial																		
Overall Category:	A																		

For office use:	
Update HARP:	This amendment may involve an update to contact details or other project details. Ensure that HARP is updated with the current details. If this is the only change, no further study-wide review is required.

Non substantial amendment number 4

Amendment Tool

v1.5 25 Mar 2021

For office use

QC: No

Section 1: Project information

Short project title*:	OCTAGON
IRAS project ID* (or REC reference if no IRAS project ID is available):	277161
Sponsor amendment reference number*:	Non Substantial Amendment #4
Sponsor amendment date* (enter as DD/MM/YY):	13 July 2021
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	Change in PI at Huddersfield and recruitment extension until 31st Dec 2021

Project type (select):	◉ Specific study ○ Research tissue bank ○ Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	◉ Yes	○ No		
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	◉ NHS/HSC REC ○ Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	○ Yes	◉ No		
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England: ◉	Wales: ○	Scotland: ○	Northern Ireland: ○
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	○ Yes	◉ No		
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	○ Yes	◉ No		
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	○ Yes	◉ No		
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	○ Yes	◉ No		
Did the study involve adults lacking capacity OR does the amendment introduce this?:	○ Yes	◉ No		
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	○ Yes	◉ No		
Did the study involve prisoners OR does the amendment introduce this?:	○ Yes	◉ No		
Did the study involve children OR does the amendment introduce this?:	○ Yes	◉ No		
Did the study involve NHS/HSC organisations prior to this amendment?:	◉ Yes	○ No		
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	○ Yes	◉ No		
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	◉	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☑	☐	☐	☐
Which nations will have participating NHS/HSC organisations after this amendment?	☑	☐	☐	☐

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, tick the "Add another change" box.

Change 1	
Area of change (select)*:	Researchers

Specific change (select - only available when area of change is selected first)*:	PI - New PI, or temporary arrangements to cover the absence of a PI
Further information (free text - note that this field will adapt to the amount of text entered):	The PI at Calderdale and Huddersfield NHS FT has changed to Miss Tamsyn Grey (Tamsyn.grey@cht.nhs.uk)

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	○ All		◉ Some	

Add another change: ☑

Change 2	
Area of change (select)*:	Study Design
Specific change (select - only available when area of change is selected first)*:	Extension to study duration that will have additional resource implications for participating organisations - Please specify in the free text below
Further information (free text - note that this field will adapt to the amount of text entered):	The recruitment period has been extended until the 31st Dec 2021 due to the impact of Covid. The follow up period remains at 6 months post op.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	◉ All		○ Some	

Add another change: ☐

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

*Name [first name and surname]**:	Modhumita Harris
*Email address**:	modhumita.harris@nhs.net

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:			
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	**UKSW Governance**	REC (MCA)	CAG	HMPPS	**HRA and HCRW Approval**	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:						(Y)				(Y)									B
Change 2:						(Y)				(Y)									A
Overall reviews for the amendment:																			
Full review:						N				N									
Notification only:						Y				Y									
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	A																		

Appendix O: Consent form for Clinician Preferences study

Variation in Clinician Preferences for Treatment of Older patients facing Major GI Surgery
Health Care Professional Consent Form (Interview Study)

Please initial in each box to indicate that you agree with each statement

I confirm that I have read and understood the information leaflet dated 8/10/19 ,version 1.0 for the above study. I have had the opportunity to consider the information and ask questions and have had these answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.	
I give permission for the interview to be audio recorded.	
I understand that quotes from my interview may be used within written reports or publications and that any quotes would be completely anonymous and could not be linked to me in any way.	
I understand that relevant interview data collected during the study may be looked at by individuals from Sheffield Teaching Hospitals NHS Foundation Trust, University of Sheffield, Sheffield Hallam University or from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to these records.	
I agree to take part in the above study	

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

When completed; one copy for participant, original for researcher site file and one for sponsor file

Appendix P: Participant letter of invitation to interview

Dear Colleague,

Clinician Preferences for the Treatment of Older Patients facing Major GI Surgery

We would like to invite you to participate in the above research study that has been funded by the Bowel Disease Research Foundation and the British Association of Surgical Oncologists and is being Sponsored by Sheffield Teaching Hospitals NHS Foundation Trust.

There is wide variation in UK practice relating to the treatment of older patients with both malignant and non-malignant gastrointestinal diseases. Some areas have very high elective resection rates, whereas others are more likely to manage patients with non-resectional surgery, palliative procedures or conservative options. There is little data on which strategy provides optimal outcomes in the frail older patient.

Treatment variation is even more pronounced in the management of older patients presenting as emergencies. In some situations palliative procedures or non-surgical options may be the most appropriate but there is uncertainty about the age, fitness level and disease biology for which they are indicated.

This research project is part of a larger study to define best practice for this age group of patients by helping to define the characteristics of older patients that suggest they may benefit from major surgery and how to optimise their treatment pathways to improve outcomes. We want to establish the views of different health care professionals about their own criteria for different interventions, how they assess fitness/frailty and how they optimise care. This phase of the project will involve conducting semi-structured interviews with a range of health care professionals who undertake some aspect of patient management (whether inpatient, pre-, peri- or post-operative or post discharge). The responses will be used to design a questionnaire to survey the practice of a wider range of health care professionals nationally.

We are writing to ask you to take part in an interview for this study. Please take time to read the information sheet provided. We anticipate that the interview should take about 30 minutes and this can either be by telephone or face to face at your hospital site. For GPs this will be via telephone only. If you wish to take part in the study, then please complete the reply slip and return it to Sarah Daniels in the FREEPOST envelope provided or confirm by email (sarahdaniels1@nhs.net). I will then contact you to schedule the interview.

If you would like to find out more about the study before deciding whether or not to take part please contact a member of the study team:
Sarah Daniels, Research Fellow, Sheffield Teaching Hospitals sarahdaniels1@nhs.net

Many thanks for considering taking part.
Yours faithfully,

Appendix Q: Participant letter of invitation to clinician preferences study questionnaire

Dear Colleague,

Clinician Preferences for the Treatment of Older Patients facing Major GI Surgery

We would like to invite you to participate in the above research study that has been funded by the Bowel Disease Research Foundation and the British Association of Surgical Oncologists.

There is wide variation in UK practice relating to the treatment of older patients (aged 65 years and older) with both malignant and non-malignant gastrointestinal diseases. Major surgery rates vary between regions and clinicians. Treatment variation is even more pronounced in older patients presenting as emergencies. In some situations non-resectional surgery or conservative management may be the most appropriate option but there is uncertainty about the age, fitness level and disease biology for which they are indicated.

We want to establish the practice of different UK surgeons in how they assess suitability for major surgery, how they optimise care and the importance of different factors in decision-making.

The questionnaire consists of five sections:

- Section 1 asks about your background
- Section 2 asks how you routinely assess patients in practice
- Section 3 asks how you routinely optimise patient pathways
- Section 4 asks about the importance you place on different risk factors for major surgery
- Section 5 presents 18 hypothetical patient scenarios and asks how you would manage them

We are writing to ask you to complete a web-based questionnaire on Google Forms. The information will be anonymous. If you would like to find out more about the study, please contact Dr Sarah Daniels: sarahdaniels1@nhs.net

Appendix R: Consent form for OCTAGON study

Optimising the Care and Treatment Pathways for Older Patients facing Major GastroIntestinal Surgery (OCTAGON)

PATIENT CONSENT FORM

Please initial in each box to indicate that you agree with each statement

I confirm that I have read and understood the patient information leaflet Version 2 dated 08/02/2020 for the above study. I have had the opportunity to consider the information and ask questions and have had these answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.	
I understand that the study data collected will be entered into a secure research database stored by the University of Sheffield and the database will not contain my name.	
I give permission for my questionnaires, study data and database to be stored for 5 years after the study has ended.	
I agree for my contact details to be shared with the sponsor to enable me to be contacted and interviewed about my treatment at a later date **(optional)**	
I understand that my research data collected during the study may be looked at by individuals from the NHS Trust where I am participating in the research, Sheffield Teaching Hospitals NHS Foundation Trust (Sponsor), the University of Sheffield, Sheffield Hallam University or from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to these records.	
I agree to take part in the above study	

Name of Participant_____Date __/__ /____
Signature_____

Name of Person _____Date __/__ /____
Signature_____
Taking Consent

One copy of the CF for the patient, one for the ISF and one for the patient's medical notes

Appendix S: Participant letter of invitation for OCTAGON study

Dear Sir or Madam

Optimising the Care and Treatment Pathways for Older Patients facing Major GastroIntestinal Surgery (OCTAGON)

I would like to invite you to participate in the OCTAGON study, as you have had a recent diagnosis which will require medical attention, possibly surgery. This study will assess the suitability of older patients for surgery, so that we can improve care in the future. Patients from different hospitals in the UK will be taking part in this study. It is funded by Bowel Research UK and Sponsored by Sheffield Teaching Hospitals NHS Foundation Trust.

Before you decide if you would like to take part, it is important for you to understand why the project is being done and what it will involve. Please take the time to read the Participant Information Sheet carefully.

If this is the first time you have been made aware of this study, then a member of the study team will discuss the study with you further when you next visit the hospital. If after this discussion you think you may be interested in taking part, we will ask you to sign a consent form.

Please do not hesitate to contact me if you have any questions.

Yours faithfully,

Insert PI Name or Research Nurse Name
Insert Position
Insert Contact Details

Appendix T: Participant information sheet for OCTAGON study

Optimising the Care and Treatment Pathways for Older Patients facing Major GastroIntestinal Surgery (OCTAGON)

Participant Information Sheet

Invitation to participate in the study

We would like to invite you to take part in our research study Sponsored by Sheffield Teaching Hospitals NHS Foundation Trust and funded by Bowel Research UK (formerly Bowel Disease Research Foundation). Before you decide, it's important that you understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

We are interested in improving outcomes for older people who have digestive problems that might be treated by major surgery (e.g. bowel, stomach, liver, oesophagus problems). We know that there are big differences in the health and fitness of people over the age of 65 years. We also know that not everyone is offered the same treatment options for the same problem. Sometimes there may be smaller operations or procedures that might be suggested if it is felt that a major operation is too risky. There are lots of different things that your surgeon and nursing team may suggest or organise to help to prepare you for surgery and recover afterwards but these are not available in every hospital. For example, seeing a dietician before your operation or attending an exercise programme. We want to look at your fitness levels, other medical problems and social situation before any treatments, see what treatment(s) you undergo and then look at how these affect you afterwards. We also want to study some people who chose not to undergo surgery. We also want to know what you feel about your experiences, particularly things that you feel would help you to recover.

Why have I been invited?

You have been invited because you have a health condition that might be treated by major surgery and are 65 years or older.

Do I have to take part?

No, taking part is entirely voluntary. If you decide you don't want to take part, you don't need to give a reason. If you agree to take part and later change your mind, you can withdraw (leave the study) at any point without giving a reason. Withdrawal from the study will not affect your clinical care.

What will happen to me if I decide to take part?

Taking part will involve completing some simple questionnaires about yourself, what you can do normally and how your health effects you before any surgical treatment. We will contact you again to fill in another questionnaire when you are getting ready to leave hospital (if you have inpatient treatment) and three times after you return home over the next 6 months. The questionnaires will usually take 10-20 minutes to complete. We will also look at your hospital records to collect information related to your surgical care and other health problems. All this recorded information is research data. All face-to-face contacts with the research team will take place when you come to hospital for appointments anyway, everything else can be done either by post or telephone.

We would also like to know whether you are willing to take part in an interview after you return home to discuss your experiences. This will be with either Dr Sarah Daniels or a member of the study team at Sheffield Teaching Hospitals. This can either be done over the telephone or at your next clinic appointment. Being interviewed is optional. If you prefer not to be interviewed, you can still be involved in the main study.

What should I consider?

If you are already taking part in another study, you can still take part in this study as taking part will not affect your care now or in the future. Your clinical team will not be told any of your responses to the questionnaires or from the interview.

Are there any possible disadvantages or risks from taking part?

Occasionally people struggle to answer all the questions in questionnaire-based studies, particularly if you are tired from your illness or treatments. If you find that you're struggling, just let the research team know and we can help.

What are the possible benefits of taking part?

Taking part in the study will not benefit you directly but may help to improve care for patients with similar problems to you in the future.

Will I be reimbursed for taking part?

No, we are not able to offer any payment for taking part in this study.

Will my taking part in the study be kept confidential?

The local research team will need to know your name and contact details to arrange for completion of the questionnaires. They will also store a copy of the consent form that you sign. If you agree to take part in an interview, your contact details will also be shared with the sponsor to enable us to arrange this. Any other information that we gather from you, including the questionnaires and information from your medical notes, will be stored using a code number rather than your name. This means that it can be matched up with the rest of the data relating to you by the code number and means that most members of the research team will not need to know your name. We will also make sure that other information that could identify you, such as your date of birth, is removed. This is in line with the current GDPR rules.

If you agree to take part in an interview, these will be recorded and typed into a document stored on a password protected NHS computer. This will then be added to the research database. You will not be identifiable by any quotes from your interview. The original recording will be deleted.

Where will my data go?

We will be using information from you and your medical records in order to undertake this study. Research is a task that we perform in the public interest. Sheffield Teaching Hospitals NHS Foundation Trust, as sponsor, is the joint data controller with the

University of Sheffield. This means that we are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible. We will store the anonymised research data and any research documents with personal information (such as consent forms), securely for 5 years after the end of the study.

What are my choices about my patient data?

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at https://www.sth.nhs.uk/about-us/general-data-protection-regulations and/or by contacting:

Peter Wilson, Data Protection Officer, Sheffield Teaching Hospitals NHS Foundation Trust, 2 Claremont Place, Sheffield, S10 2TB Tel: 0114 226 5151 Email: infogov@nhs.net

What happens at the end of the study?

Once the study has finished we will write up a report of our findings. This will be presented at conferences, published in scientific journals and shared with the different surgical units taking part. Some of the research being undertaken will also contribute to the fulfilment of an educational requirement for the Chief Investigator.

You will not be identified from any report or publication arising from this study.

What if there is a problem during the study?

If you have any concerns or questions about this study, please contact Sarah Daniels (sarahdaniels1@nhs.net).

If you have concerns about the way you have been treated during the study or wish to make a formal complaint, you may wish to contact your local Patient Service Team. Insert local contact details.

How have patients and the public been involved in this study?

Service users helped develop the research topic and were involved in deciding the frequency and number of questionnaires that we will carry out.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by the Research Ethics Committee.

What do I need to do now?

A member of the study team will be in touch to answer any questions, check whether you are happy to take part and arrange to meet you to fill in some of the questionnaires. You may have already received some of the questionnaires with the consent form, if you are happy to, you can complete these yourself and return them in the envelope provided. We will need to meet with you anyway to complete a couple more questionnaires in person, so if you don't feel comfortable completing the questionnaires we can assist you when we meet with you.

If you are happy to be contacted about taking part in an interview, Dr Sarah Daniels will contact you about arranging this separately after you have returned home from hospital.

Contact for further information

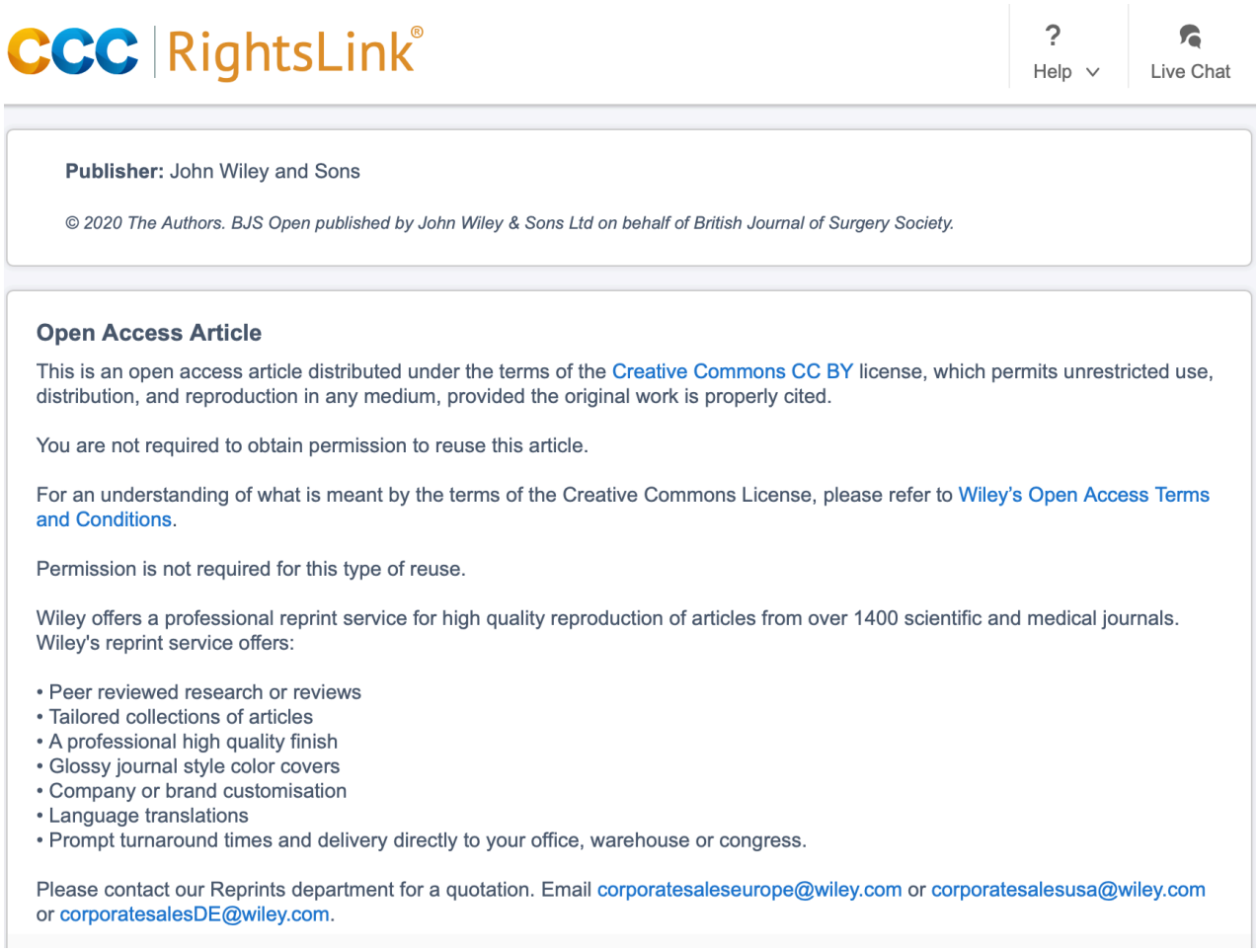
If you would like any further information, or have any questions concerning this study, please contact a member of the study team:

Sarah Daniels, Research Fellow sarahdaniels1@nhs.net

Please keep this information leaflet for future reference. Thank you for reading this information sheet and for taking an interest in this research study.

Appendix U: Copyright permissions for reproduction of papers

Daniels SL, Lee MJ, George J, Kerr K, Moug S, Wilson TR, Brown SR, Wyld L. Prehabilitation in elective abdominal cancer surgery in older patients: a systematic review and meta-analysis. 22/9/20 BJS Open DOI:10.1002/bjs5.50347



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Daniels SL, Lee MJ, Moug S, Wilson TR, Burton M, George J, Brown SR, Wyld L. Protocol for a multi-centre observational and mixed methods pilot study to identify factors predictive of poor functional recovery after major gastrointestinal surgery and strategies to enhance uptake of peri-operative optimisation: Optimising the Care and Treatment pAthways for older patients facing major GastrOiNtestinal surgery (OCTAGON). Colorectal diseases DOI:10.1111/CODI.15603

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Appendix V: Confirmation of permission to reproduce papers in thesis from co-authors

Sarah Daniels <sarahdanielsx@gmail.com> Wed, 18 Aug, 10:20 (1 day ago)
to Matt

Dear Matt

Please could you confirm by reply to this email that you are happy for the three papers that you have co-authored with me detailed below to be reproduced in my MD thesis.

Best wishes

Sarah

1. **Daniels SL**, Lee MJ, George J, Kerr K, Moug S, Wilson TR, Brown SR, Wyld L. Prehabilitation in elective abdominal cancer surgery in older patients: a systematic review and meta-analysis. 22/9/20 BJS Open DOI:10.1002/bjs5.50347
2. **Daniels SL,** Lee MJ, Moug S, Wilson TR, Burton M, George J, Brown SR, Wyld L. Protocol for a multi-centre observational and mixed methods pilot study to identify factors predictive of poor functional recovery after major gastrointestinal surgery and strategies to enhance uptake of peri-operative optimisation: Optimising the Care and Treatment pAthways for older patients facing major GastrOiNtestinal surgery (OCTAGON). Colorectal diseases DOI:10.1111/CODI.15603
3. **Daniels SL,** Burton M, Lee MJ, Moug S, Kerr K, Wilson TR, Brown SR, Wyld L. Healthcare professional preferences in the health and fitness assessment and optimisation of older patients facing colorectal cancer surgery. Colorectal Disease 2021;00:1-10. DOI: 10.1111/codi.15758

Matt Lee Wed, 18 Aug, 10:22 (1 day ago)
to me

Dear Sarah

Happy for them to be included in your thesis.

Matt

Sarah Daniels <sarahdanielsx@gmail.com> Wed, 18 Aug, 10:23 (1 day ago)
to Lynda

Dear Lynda

Please could you confirm by reply to this email that you are happy for the three papers that you have co-authored with me detailed below to be reproduced in my MD thesis.

Best wishes

Sarah

1. **Daniels SL**, Lee MJ, George J, Kerr K, Moug S, Wilson TR, Brown SR, Wyld L. Prehabilitation in elective abdominal cancer surgery in older patients: a systematic review and meta-analysis. 22/9/20 BJS Open DOI:10.1002/bjs5.50347
2. **Daniels SL,** Lee MJ, Moug S, Wilson TR, Burton M, George J, Brown SR, Wyld L. Protocol for a multi-centre observational and mixed methods pilot study to identify factors predictive of poor functional recovery after major gastrointestinal surgery and strategies to enhance uptake of peri-operative optimisation: Optimising the Care and Treatment pAthways for older patients facing major GastrOiNtestinal surgery (OCTAGON). Colorectal diseases DOI:10.1111/CODI.15603
3. **Daniels SL,** Burton M, Lee MJ, Moug S, Kerr K, Wilson TR, Brown SR, Wyld L. Healthcare professional preferences in the health and fitness assessment and optimisation of older patients facing colorectal cancer surgery. Colorectal Disease 2021;00:1-10. DOI: 10.1111/codi.15758

Lynda Wyld Wed, 18 Aug, 10:28 (1 day ago)
to me

Yes of course.

Bw

Lynda

Sarah Daniels <sarahdanielsx@gmail.com> Wed, 18 Aug, 10:23 (1 day ago)
to Steven

Dear Steve

Please could you confirm by reply to this email that you are happy for the three papers that you have co-authored with me detailed below to be reproduced in my MD thesis.

Best wishes

Sarah

1. **Daniels SL**, Lee MJ, George J, Kerr K, Moug S, Wilson TR, Brown SR, Wyld L. Prehabilitation in elective abdominal cancer surgery in older patients: a systematic review and meta-analysis. 22/9/20 BJS Open DOI:10.1002/bjs5.50347
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3. **Daniels SL,** Burton M, Lee MJ, Moug S, Kerr K, Wilson TR, Brown SR, Wyld L. Healthcare professional preferences in the health and fitness assessment and optimisation of older patients facing colorectal cancer surgery. Colorectal Disease 2021;00:1-10. DOI: 10.1111/codi.15758

BROWN, Steven (SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST) Wed, 18 Aug, 10:28 (1 day ago)
to me

OK

Sarah Daniels <sarahdanielsx@gmail.com> Wed, 18 Aug, 10:20 (1 day ago)
to Jayan

Dear Jayan

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Best wishes

Sarah

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Jayan 'G' George Wed, 18 Aug, 10:30 (1 day ago)
to me

Dear Sarah,

Very happy.

With warm regards,

Yours sincerely

G

Sarah Daniels <sarahdanielsx@gmail.com> Wed, 18 Aug, 10:21 (1 day ago)
to Susan

Hi Susan

Please could you confirm by reply to this email that you are happy for the three papers that you have co-authored with me detailed below to be reproduced in my MD thesis.

Best wishes

Sarah

1. **Daniels SL**, Lee MJ, George J, Kerr K, Moug S, Wilson TR, Brown SR, Wyld L. Prehabilitation in elective abdominal cancer surgery in older patients: a systematic review and meta-analysis. 22/9/20 BJS Open DOI:10.1002/bjs5.50347
2. **Daniels SL,** Lee MJ, Moug S, Wilson TR, Burton M, George J, Brown SR, Wyld L. Protocol for a multi-centre observational and mixed methods pilot study to identify factors predictive of poor functional recovery after major gastrointestinal surgery and strategies to enhance uptake of peri-operative optimisation: Optimising the Care and Treatment pAthways for older patients facing major GastrOiNtestinal surgery (OCTAGON). Colorectal diseases DOI:10.1111/CODI.15603
3. **Daniels SL,** Burton M, Lee MJ, Moug S, Kerr K, Wilson TR, Brown SR, Wyld L. Healthcare professional preferences in the health and fitness assessment and optimisation of older patients facing colorectal cancer surgery. Colorectal Disease 2021;00:1-10. DOI: 10.1111/codi.15758

Moug, Susan Wed, 18 Aug, 10:43 (1 day ago)
to me

very happy

S

Professor Susan J Moug

Consultant General and Colorectal Surgeon,

Sarah Daniels <sarahdanielsx@gmail.com> Wed, 18 Aug, 10:22 (1 day ago)
to Karen

Dear Karen

Please could you confirm by reply to this email that you are happy for the two papers that you have co-authored with me detailed below to be reproduced in my MD thesis.

Best wishes

Sarah

1. **Daniels SL**, Lee MJ, George J, Kerr K, Moug S, Wilson TR, Brown SR, Wyld L. Prehabilitation in elective abdominal cancer surgery in older patients: a systematic review and meta-analysis. 22/9/20 BJS Open DOI:10.1002/bjs5.50347
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KERR, Karen (SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST) 09:44 (1 hour ago)
to me

Dear Sarah

More than happy to have those two papers reproduced within your MD thesis.

Hope all is well.
Good luck with your thesis.

Bws
Karen

Sarah Daniels <sarahdanielsx@gmail.com> 18 Aug 2021, 11:00 (1 day ago)
to rmbapril2017

Dear Maria

Please could you confirm by reply to this email that you are happy for the two papers that you have co-authored with me detailed below to be reproduced in my MD thesis.

Best wishes

Sarah

1. **Daniels SL,** Lee MJ, Moug S, Wilson TR, Burton M, George J, Brown SR, Wyld L. Protocol for a multi-centre observational and mixed methods pilot study to identify factors predictive of poor functional recovery after major gastrointestinal surgery and strategies to enhance uptake of peri-operative optimisation: Optimising the Care and Treatment pAthways for older patients facing major GastrOiNtestinal surgery (OCTAGON). Colorectal diseases DOI:10.1111/CODI.15603
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Maria Burton 18 Aug 2021, 11:02 (1 day ago)
to me

Dear Sarah,
I am happy for the two co-authored articles
To be reproduced in your MD.
Best wishes
Maria

Sarah Daniels <sarahdanielsx@gmail.com> Wed, 18 Aug, 10:22 (1 day ago)
to Tim

Dear Tim

Please could you confirm by reply to this email that you are happy for the three papers that you have co-authored with me detailed below to be reproduced in my MD thesis.

Best wishes

Sarah

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WILSON, Tim (DONCASTER AND BASSETLAW TEACHING HOSPITALS NHS FOUNDA... 11:41 (58 minutes ago)
to me

Dear Sarah,

I am very happy for you to reproduce the papers that you have outlined below into your PhD thesis.

Best Wishes

Tim Wilson

Appendix W: Systematic review sample search strategy

Search strategy
MEDLINE search

1. Perioperative.mp
2. peri-operative.mp
3. pre-operative.mp
4. preoperative care/exp
5. pre-hab*.mp
6. prehab*.mp
7. pre hab*mp
8. 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7
9. exercise/exp
10. physiotherapy.mp
11. preconditioning.mp
12. exercise therapy/exp
13. circuit-based exercise/exp
14. 9 OR 10 OR 11 OR 12 OR 13
15. nutrition therapy/exp
16. diet therapy.mp
17. nutrition assessment/exp
18. dietician assessment
19. 15 OR 16 OR 17 OR 18
20. smoking cess*.mp
21. nicotine replacement.mp
22. 20 OR 21
23. alcohol cessation.mp
24. alcohol reduction.mp
25. 23 OR 24
26. comprehensive geriatric assessment.mp
27. geriatric optimi*.mp
28. geriatric intervention.mp
29. 26 OR 27 OR 28
30. psychological*.mp
31. cognitive therap*.mp
32. psychotherapy*.mp
33. 30 OR 31 OR 32
34. abdominal surgery.mp
35. gastrointestinal surgery/exp
36. Digestive system Surgical Procedures/exp
37. gynecological surgical procedures/exp OR gynaecological surgery.mp
38. urological surgical procedures/exp OR urological surgery.mp
39. gastrointestinal neoplasms/exp
40. oncolog*.mp
41. malign*.mp
42. 34 OR 35 OR 36 OR 37 OR 38 OR 39 OR 40 OR 41
43. 14 OR 19 OR 22 OR 25 OR 29 OR 33
44. 8 AND 42 AND 43

Appendix X: Sample interview transcript

We'll start with your professional background and how long you've been working in Doncaster.

I've been working in Doncaster since 1989 when I started nurse training. And when I qualified in '92, I worked in neurology, followed by breast and thyroid and a lot of general surgery mixed in. I then worked on a day surgery unit due to family reasons. And then I moved back to, because that was at Mexborough, then I moved back to Doncaster onto a male colorectal ward, where somebody approached me and asked me to do a secondment and I've been in colorectal nursing since. So that was 2002. So I've been here for a long time.

And you were talking a minute ago about you decide whether someone's fit for surgery or not and in your practice what do you currently do?

Yeah. We meet up with the patient and speak to the patient, ideally with someone with them. In my experience, patients are not always truthful about how fit they are or unfit they are because they're guided by the worry that somebody's going to say they're not going to do something. So we need to sometimes tease out a bit of truth about fitness and does somebody work, does somebody look after anybody else, do they function normally, who does the shopping, who does the cooking, cleaning and washing, are they able to manage their daily living activities without somebody else's input. If it's somebody extremely old or looks extremely frail regardless of age, we tend to ask about, well, one of the consultants asks about squeezing their hand and how far they can walk. Most of them ask them how far they can walk, are they breathless, can they manage a flight of stairs. They're the kind of things that are asked to try and assess fitness. And then we do heavily rely on pre-op assessment to assess the fitness for an anaesthetic and surgery.

And is that delivered by nurses or anaesthetists?

The pre-op assessment, the pre-op assessment is nurses. The process has recently changed. We used to have two very experienced nurses that worked on a colorectal ward. So they understood the implications of surgery. But they've now changed the pre-op assessment process to a very generic process where it's more like a tick-box exercise and there's no physical assessment other than blood pressure, pulse,

temperature, weight, height, that kind of assessment. But it's not very hands-on and no sort of fitness test or assessment that I'm aware of.

And if you have particular concerns about someone, what would you do if you were thinking right, they're really borderline, whether because they've got comorbidities or?

Recently, I saw a patient that was in clinic on her own, elderly, admitted to having a car accident last year caused by herself because she was driving. She sustained a head injury, almost had a leg amputated and had a shoulder injury. She walked into clinic, denied any problems with mobility, but when we delved further, she didn't do her own shopping, she was reliant on neighbours, her family lived afar and did keep repeating herself, so obviously had memory issues. So it was quite difficult. And from the surgeon's point of view I think the perspective was that she could get her through an operation; however, I suggested that a pre-op assessment/anaesthetic assessment might be the better way to go because the anaesthetic assessment would then at least give us statistical possibilities about complications and risk involved. And that's the way that that outcome went.

And do you find that you quite often pick up on things that haven't necessarily been picked up by the consultant, because you see them separately, don't you?

Yes. Because we see them with the consultant at the same time, but the consultant then leaves after the plan is put in place. So then we actually tease out much more information about who looks after people, who do the activities really and how often do they do things. And usually people divulge much more because we're having the informal, friendly chat and nurses tend to tease out quite a bit from the patient that, for whatever reason, the doctor's not managed to get out of the patient, or sometimes it's just the white coat syndrome, even though they might not have a white coat on. But it is just the status that scares them to say I don't actually do anything. And we currently have a patient that came in as an emergency, who we've been trying to promote independence, but the lady actually then after several weeks in hospital has admitted to the fact that she did nothing in life: she just sat in a chair and her husband does absolutely everything. So we're not going to actually be able to introduce that behaviour when it's never been there, but that was never picked up for her obviously. She was an emergency.

And like you mentioned the lady who kept repeating herself, would you then do a cognitive assessment or would you then ask the consultant to arrange one or do you refer to a geriatrician?

I relayed that information back to the colorectal consultant, who added that into the letter for the anaesthetic assessment so that they'd take that into account that there are cognitive issues. And that lady, because it was quite difficult to get history from her, she couldn't quite remember things. And she'd had a previous bowel cancer, but couldn't quite remember when it was. I remembered her from the previous bowel cancer, but I couldn't remember, I couldn't recall, who'd seen her. I see lots of people. But I suggested that she pass on our contact details to her daughters that live afar so that at least we could speak to her family and highlight the fact that this lady possibly has a bowel cancer and possibly needs to have care, whether it be in the form of surgery or not, and that the decision-making process should be in partnership with the next of kin ideally in this setting. This lady was adamant that she thought she was fit enough and that is quite difficult to manage because you kind of get, I'll not say lies, but untruths about the fitness because they're trying to persuade you that that's what should be done, but of course if she dies from her treatment then that's not a great outcome for her or her family.

And do you think if we could actually in Doncaster do more like an actual exercise test on a bike or something then you can demonstrate look actually...

Yes, absolutely. Yeah. I think the whole pathway is influenced by the patient's fitness. In my role, we run the cancer follow-up service. Cancer follow-up, as you're probably aware, is changing nationally and we're looking at stratified pathways and where people should be at what time and how long we should be following people up for. Rightly so, I think. We've not got an unlimited resource and an unlimited pot of cash to sustain these services; however, I do find that in these clinics we are following people up that even if we found metastatic disease or recurrence, they're not fit enough. So I don't think it should be a one-off assessment. I think it should be an ongoing assessment so that we, I'm not saying performance status is the right tool, but something like a status similar to that would be a measure that we could quantify and justify why we're making those decisions. And I think from an ethical/legal point of view we are looking at what sort of level somebody's at prior to having any treatment.

It should be reassessed after the treatment and then suitability for follow-up would be easier because we've got some tool saying actually they did badly from the treatment and I really don't think they could go through that kind of thing again. Or worse, so maybe something like a liver resection in the future that we wouldn't be able to get them through that. And the answer to the patients coming back with a poor outcome from surgery is probably no. And even going onto oncological treatments, I think that would limit their options and we should be honest with people and say you did badly. I'm not saying to write the patient off at that point, but that could always be repeated by a GP or somebody in community and say well actually this patient's become extremely fit again and they've changed their lifestyle: they've stopped smoking and drinking and taken up exercise and they've become extremely fit, so we feel that they would be suitable and come back for follow-up. So I don't think it should be sort of carbon copied for every patient because we've got individuals and we're not robots and machines.

Do you very often find if you've got a patient that you think is either extreme of age, frailty or loads of comorbidities, if there is another option, so a defunctioning stoma or a stent, will you try and guide them towards that decision rather than...?

Yes. For example, we may have somebody who's got a sigmoid cancer, but actually the risks are higher. We've got somebody that's not quite a cancer. It's been re-biopsied several times, but the comorbidities stack against going straight into have major surgery. We would revisit that. So we would adopt a watch-and-wait policy and say right we'll see you back in a couple of months' time, maybe do a re-scope in three months or something just to re-biopsy, see if something else has changed, have a look at the area. Also talk about function and has function changed and does somebody look less well or does somebody say actually I'm absolutely fine and I don't want to keep being rescanned and rescoped, thank you very much; I'll flag it up when I've got a problem. I think we should empower people in saying we've got this grey situation; we've not got a clear-cut problem, but we're giving you ownership.

But I think the frightening part for patients is they may have struggled to get through the GP process originally, so we maybe need to adopt something like an open-door policy for these kinds of patients that say well, I do know Mr X, my surgeon, and I'd like to come back to him because he knows my story. Because I think patients do find it is quite repetitive when they see a different doctor every time and they've got to go through the whole story and perhaps don't relay the right story.

Because they might not quite get the intricacies of what's suspicious.

Yes, exactly.

A high-risk patient and all that, because it doesn't necessarily get documented fully, does it?

Exactly and I think somewhere like Doncaster, we have a huge geographical area, so people have to travel a long way sometimes to come and see somebody. So they wouldn't particularly want to come back to say I'm all right actually. They might just want an access in if something changes to be assessed. And then if it's still something that is not operable, we look at stent and stoma, probably stent as a first line and see if we can alleviate symptoms. But it depends where it is. So if it's high enough up to put a stent in, that's fine. But if it's rectal, you're probably looking at stoma and we would usually have given that information at the first contact so that people know this is an option for the future. So you're pre-educating with we give them a stoma pack. It's got a model stoma in there and a bag that shows them what it is so that they're not frightened to come forward and say actually I think that would help me; it would alleviate some symptoms. It might not get rid of them all if it's [unclear 0:13:39] kind of thing. But it would alleviate some of the symptoms and help with function and quality of life.

Do you find sometimes, because sometimes you get patients and they just say I just want the cancer out.

Yeah.

And do you find maybe the older ones, are they more accepting of the idea of a procedure to get them out of trouble more than the younger ones maybe?

Yes. Yeah. The younger ones feel cheated, so you kind of think, there's a locally advanced disease that we think ooh you've had a cardiac event last year, we really don't want to give you a, or you've had a stroke and we're trying to recover you from that. We've got to delay things. We had an episode last year where we had someone diagnosed with cancer, but then had a deep vein thrombosis and PE and really was quite unwell and he was only young. And he couldn't accept that the cancer was still in. He was like oh my god, this cancer's still in. He did actually do really well when he

got to the surgery, but he had a more or less six month delay in getting from diagnosis to treatment. It wasn't easy for him. He was too ill. So accepting that was quite difficult and his psychological state was really difficult to manage because he was I've still got cancer, what if it's spreading. And the reality is it could have and his staging may have been worse because of the delay, but he understood the risks. But that's an extreme really. Most people in a normal setting, if they're older, will accept that I'm not going to have anything done because I'm too old to do that. Whereas, the patient yesterday that I saw was adamant that she felt she was fine for surgery and I was really concerned more about the decision-making and the right thing to do.

Do you end up doing much operating on, because I think most people will say mild dementia, if they're coping, OK, have you ended up caring for people at the more moderate or severe dementia end?

Yeah, usually as an emergency, we kind of have a best interests meeting for the ones that we think are in that category preoperatively. And you often find families will say their opinion and that's what should guide it. We often have a discussion and we'll say well actually this patient's going to run into problems and their life could end in a few months if this obstructs the bowel and we don't do anything about it. So we've had decisions before where family have absolutely pushed for not having treatment and a patient's incapable of making their own decisions and then patients have run into problems a few months later and it's all alarm bells and worries and drama because we've not done anything. So we've had those kinds of situations when people have come in for urgent care as emergency and then they want everything doing. You kind of have to counsel the family, you know, we did have this decision-making in the beginning and this is where we were going. But because of some of the issues I do give that scenario to families and say look, if in a few months' time we're sitting here and we're saying this patient's bowel's blocked, you can't then change your mind to say we want to something radical because it may be too big of a procedure for that patient to undergo at that time.

So it's tricky sometimes. It is tricky. And I think you just have to document well, make sure that everything's minuted from any best interests meeting and that it is the right decision. It shouldn't just be family that make that decision. Professionals should give their opinion because we do kind of get a little bit coerced sometimes by people into making the wrong decision. And you've got to justify that. Sometimes there's no right and wrong decision and you just have to keep speaking to people. Sometimes we've had more than one meeting and said we'll give you the facts, we want you to talk

about it as a family and come back and revisit there. And I've done that three or four times with people so we've actually reached a conclusion that we're all happy with. But sometimes you do defer your opinion to somebody else. So we try to tease out the right thing to do. Sometimes you've not got the beauty of that if somebody's unwell.

And sometimes we do something in emergency, don't we, and then all the rest of the collateral history comes out and you think oh why did we do that one?

Absolutely and it is a really tricky one. And it's the same, not particularly with dementia. We've had quite a lot with learning disability where the patient's not got the full capacity but has some capacity and is the one that's pleading for you to do something, which is really difficult. It's really a tough call as a professional, but also as a human being. You're seeing somebody suffering and think well, we could make that a lot better. And in a care profession we've all got a thread of we do want to do something about something to make it better for somebody. So it is hard to think you can fix every problem. You can't always, but as long as you put the right support network in, you can always give them something back.

And have you had many patients that you think oh, you're really just, either they're really unfit or deconditioned or that you think right, you've got three weeks till your operation, you could get fitter?

Mm.

I know Mr Keaton was saying he gives them a…

Mr Keaton in particular, he says to patients right, your operation date is on whatever date. And he then says to them in the meantime, I want you to eat healthily. If they don't understand what eat healthily is, I reiterate that after he's left. So I say well, what's your normal diet like, what do you eat. You know, not fast food and rubbish. Let's eat fruit and vegetables. Unless they've got a low residue diet and then that changes that. So dependent on what their situation is, we would talk about healthy eating and give them written information about healthy eating, guide them a little bit by saying right, do you get out and about. Oh no, I always go everywhere in my car. Well, have a little walk: walk to the gate and back every day, walk round the block, walk around the supermarket, walk around. So we kind of set them tasks. So we want

them to walk a set amount every day. He usually says 100 yards, increase it to 150. Patients don't always have that concept, so we can't justify that. I say where do you live. Do you have a big garden? Have a walk around the garden. For the first week I want you to talk round it once a day. For the next week I want you to walk round it three times a day because we're going to increase your abilities.

I'm not sure it makes much difference in the timespan that we prepare them. Sometimes we're not giving them much of a time before the operation date. But patients do have an expectation set them that post-surgery we're going to still expect them to do something. So I say gone are the days that you can have a laparotomy and lie in bed with your tube drains and your nasogastric tube and whatever else anchoring you to your bed. We get everything out pretty quickly regardless of what's put in and we get you up and about and get you eating and drinking and we get you out of here because we don't want you to sit in hospital having post-op complications so we have better outcomes. I do think that is true. I do think we have better outcomes. And we do most surgeries laparoscopically, which I think again helps with the outcome.

Preoperatively, I do think there's a big reliance on the pre-op nurses to give information, but I have been told recently with the changes here that patients are going to be assessed for fitness for anaesthetic only, not supported. So I do find it's quite bizarre. They've tried to offload the anticoagulation bridging and bowel prep onto my team, which I've told them we're not taking on – we can't do that. I think it's losing its holistic approach. There was a shuffle around in the pre-op services probably about 18 months since now and it's lost the patient care touch, I feel. And that's just my opinion, but it's a battle. It is a battle all the time. It's more like an appointing system rather than a care system.

Yeah, you mentioned this.

Yeah, it feels like a production line. And I feel that's quite sad because when we've seen somebody in the past, if I've said right, you need to eat healthily, try and cut down on your smoking and there are smoking cessation support teams and we give them information and so do pre-op assessment, I do think it reiterates your information. But if you're just ticking a box and doing their obs and not really fully assessing somebody, I think you lose that touch. And two of the really experienced pre-op nurses have got the same opinion as me because they're old-school. They've seen the good service and now the service has been torn apart.

And do any of your patients actually come to you and say I want to do an exercise programme pre...?

Sometimes, sometimes patients do say what can I do to make myself fitter? Some patients will go I'm not doing that. So I'm sure even if we put some wonderful exercise programme in place, not a lot, but some will say no chance, I'm not doing that. But I think if we were on the borderline patients, we're not really sure if you're fit enough for surgery; however, if you undertake this, we can reassess that situation and see if you've improved. If we've put somebody through some kind of a programme, we've at least again got a measure as to whether with a little bit of input and guidance they do improve. If they don't improve, you know, we've kind of got the answer that it was the right decision to delay or put them through some kind of programme. But I really don't think for the outcome side it would hurt the outcome. I think a little bit of investment pre-treatment would certainly be a good thing.

Yeah, because you wonder whether actually obviously they've got more invested if it's a I need to get myself fitter for my operation, which I might not get if I don't make an effort.

Yeah.

But also it is those borderline ones.

Yeah. And I think the focus on NHS healthcare now should be on empowering patients and saying this is your body, this is your cancer, this is your treatment plan, if we can get you fit enough for it. And it has to be a two-way situation. We've not got any magic solution in a drawer saying yeah, drink that and we'll get you fit enough to get through this. Because if somebody dies we all feel burdened by that did we do the right thing, did we counsel them enough? You know, did they give informed consent or were they just frightened by the disease. So I do think we should let people own their own problems and not take those problems away. We share the problem and we say this is what we possibly could do about it, but it's not without risk. Whatever it is, whether it's oncology treatment or surgery or any invasive procedure, it still has a risk.

I think it's a tricky one, isn't it, because if you're saying you need to get yourself better then we need to help them, don't we?

Yes.

Because I think...

Absolutely, yeah, there needs to be something there. So it's pointless assessing somebody and saying oh yeah, we need to get you fitter and then saying actually, get yourself fitter, it's not our problem. So we need to put some kind of service in place to help them to get fitter and guide them to get fitter. And a lot of the, I mean, obviously we work in stoma care. A lot of the stoma companies are putting out booklets for post-surgery fitness. Doncaster Council for cancer patients will give a fitness programme post-treatment. So they will help them with reduced subsidised fees for the gym, for the swimming pool. It's Doncaster culture and leisure team. There's a network of leisure centres that will support patients post-surgery after cancer. So they get I think something like six sessions free and then they'll give them a cut-price if they want to continue, which is good in making the society healthier, but they've actually gone through the treatment and survived it to get to there; whereas, we could actually do with turning that on its head and saying right, we need to try and encourage you to be fit and then once you're fit, you're going to have less risk involved in your surgery and treatment.

It's an interesting one, isn't it, because I think a lot of patients, they've never been to a gym. They find gyms really intimidating and they don't want to go to a gym.

Yeah. No. I'm one of them.

We all feel intimidated when we go to a gym.

Yeah.

And actually that's in some ways where exercise testing people I think has a role just because you're saying right, this is a cycle-

Yeah, a bike or something, yeah.

-a bike, you can do this. And it's in a safe environment. So then maybe I wonder whether those patients then feel slightly better about going to a gym

because they're like oh well, I've been on the exercise bike and I know what feels like.

Yes. Yeah. Yeah. So from a personal point of view my husband started spinning.

Oh, did he?

And trying to get me to go and I was like no, I'm not going because everybody will be really good and I don't know what to do. And he was like well, you can come with me. So I'm not a patient, but I can share their fear. But I would prefer to walk round the block because I'm just a person walking round a block and everybody's walking round a block or walking somewhere. So I can understand that. So I just think of simple things for patients. I say do you lift your own shopping, do you do your own shopping, do you walk around the supermarket? Because we presume when somebody walks into clinic that they do things, but often people don't. They don't do much. There's too much ease of convenience now with online shopping or online everything.

Because actually if someone can get from their house, they can walk to the shops, walk round the shops and carry their shopping home, they're doing pretty well.

They're doing all right, yeah exactly. They're doing all right.

The number of times you go into it and they're like well, my daughter picks me up, she takes me to the shop and then I walk around the shop.

I sit in the café. They do my shopping. They come back, pick me up in the café and take me back home again.

But I do my own shopping.

Yes.

Do you have any access to dieticians in terms of pre-op?

Not pre-operatively, no. There's a big deal and it's quite irritating. You know, when you know somebody needs some nutritional support, you think it would be so easy to just do a referral: can this patient have some support, we're trying to optimise for

surgery. It's often no. We've had instances where we've brought patients into hospital to build them up. I can think of two patients that had better outcomes because we'd brought them into hospital, but obviously that was blocking a bed in hospital. So one had a nasogastric feed. Just because they were so malnourished, we optimised them. We had another one that had long-course chemo and radiotherapy. I've never seen anybody do as badly from it. He looked like he was going to die. We brought him up to talk about suitability to move on to have an AP resection and he looked like he was emaciated, like he'd withered away.

He was in the phase of post-treatment, waiting for his scans, had his scans. Nobody had seen him in that part - that's in the part where he deteriorated. But in all the years in my experience, I've never seen anybody deteriorate badly. His wife never flagged it up to anyone. Nobody actually had stepped in. And it did actually highlight that there is a gap in the pathway there, you know, there's no district nurses, no GP has gone in. Nobody had seen him. Nobody had picked this issue up that he'd had some severe reaction, for want of a better word, but some severe outcome from his long-course treatment. And so he'd got the delay. He'd been for the scans. Nobody had picked up that he'd lost lots and lots of weight. The man turned up. His respiratory rate wasn't very great. When he came, he had quite a grey pallor. And we were in a darkish room anyway and I kept thinking does he look poorly or am I just thinking he looks poorly in this light.

So I asked him loads of questions about nutrition. Well, I've not been eating nurse since my treatment stopped, I've been really anxious, but also I've felt unwell, didn't think to contact anybody, my wife didn't think to contact anybody. And I kind of felt like we'd let him down. I thought I feel like we've got a gap here that nobody has seen this man. It doesn't happen mostly. Most people are fine and actually feel better because they've had the treatment and start picking up again. But he looked dreadful. We brought him into hospital for two weeks and built him up and then his consultant monitored him for some time and his bloods recovered and he looks a lot better. Then he came back and he had a pre-op assessment and an anaesthetic assessment just to see if we were doing the right thing. And that was the only measure that we'd got, which is a shame because he possibly would have benefited from some dietetic input and some activity.

And some psychological support.

And psychological support, yeah.

Because you guys provide a lot of psychological support, don't you?

We do, but we've got a counselling team as well.

Have you?

Yes.

Ooh.

So we've got in Doncaster itself, we have a counselling service specific for cancer patients. We also have one in Bassetlaw. So obviously there's two CCGs that are a similar kind of setup. They have a benefits advice and counselling. There's no psychology support, but there's a good counselling team and they're quite quick at seeing people.

And how do you screen people to see whether they need them?

Yeah. They have a holistic needs assessment. We used to use the SPARC tool, but it is quite lengthy and now the new role that I spoke to you about earlier, the cancer care coordinator, that's her role. So she's doing all the holistic needs assessments. She started in September. But I'm kind of trying to integrate her into all aspects. So I took her to clinic yesterday to look at patients that were pre-treatment, so we could get some assessment in place, look at psychological support. Do we need to think about contacting the Doncaster culture and leisure team and saying is there any kind of programme we could put on pre-treatment, you know, optimising patient fitness? It might not be a lot of patients, but if there's a few and they're only scattered across several leisure centres, it might be something that's good and an improvement. Smoking cessation, we talk about. Sometimes it's alcohol, but we advise. We don't refer anywhere for that, if people are on a lot of alcohol.

Do you ever refer to a geriatrician if you notice someone's had lots of falls or their memory's an issue?

Yeah, sometimes the surgeons do. We don't. We'd flag it up and say this patient's now saying they've been having falls and family have said they're having memory issues. We look at memory clinic and things like that. I do think that we should give patients

some kind of a generic handout because we're not all the same all the time. Sometimes you're weaker than others. And we do go through chapters in life where you think actually I do need a bit of psychological support because there's other factors burdening you. But I think for the patient journey, we should be giving them something that we can clip into that's their personal story that we can say actually this patient is borderline fitness. We could give them a booklet that says walk around the block three times a day, tick this box. Because obviously it's like you self-reward: oh, I can tick that box, I've done that today. You can see you've made progress and you can see you've done something.

So I've gone and put myself on the steering group for prehabilitation so that we can look at what we can do. And it might be simple things. We don't have to make massive changes. We can just empower patients into doing stuff for themselves, because I think we're very much guilty in healthcare in thinking that we can fix it all. But actually you can do all you want. You can't make them turn up to any exercise programme or whatever. You can't make them do anything. If they don't want to do it, they'll not do it.

I find it fascinating because it's almost like people can say right, I want surgery, but I don't want to engage in this.

Yeah.

And on the one hand, yes, it's their own body, it's their own choice, but equally when you know that the surgery will be very high risk, very difficult.

Yeah, you do everything you could.

And you're kind of like sometimes it doesn't seem fair that they can just say no to actually getting fit or losing weight.

Yeah. I don't think people should have too much choice. I think the problem is we give too much choice now. We've got different aspects of referral in, so we have a straight-to-test service here. We've got a bowel screening. We've got the usual two-week wait. We've got the routine. We've got lots of different arms coming in and unfortunately I don't think that's a good thing because I don't think the service is set up to support all the referrals in. So somebody may look fantastic on a piece of paper on a GP letter and go through a straight-to-test system, but actually nobody's spoken to the patient

in-depth and highlighted that they've got massive psychological issues. So they don't meet anybody in straight-to-test. They go straight for a colonoscopy after screening via the colonoscopy team and that screening over a telephone.

So they've not actually met anybody. Somebody sticks a scope in their bowel, identifies the problem, tells them the problem on the day and sends them off. They refer them to our team. I or one of the team phone them 24 hours after scope to make sure that they understand the staging process and MDT. That is the theory. In reality, what does happen is I phone the patient say hello Mrs Whoever. She cries for half an hour and then I unpick all the problems by telephone, which I feel is really awful because who wants to sit with the phone in their ear when they're crying their eyes out, trying to wipe their nose and their eyes and…

With someone they've never met.

With somebody they can't even put a face to. Whereas, if you were sat by somebody's side and said actually it's lovely to meet you, we have got this situation, but this is what we want to do about it and we're going to work together and I'm going to support you and here's my card so you've got somebody to contact. It does feel much better. And if it were me, and I try to put myself in their chair, I would feel very much like I was on a production line if I'd seen a GP, who I'd seen five times before, they'd not put a finger in my bottom and they've not told me I've got rectal cancer at that time. So the problem bounces from the first contact and on and on and on until they've actually gone through an MRI, a CT, a colonoscopy, biopsy, a phone call or two and then they've gone through MDT and then we meet them. Yeah. So it's way down the line.

So they've got, I pick up a lot of psychological problems on the support call post-colonoscopy and I often phone them back if I think it's a serious issue. I offer to meet them. I bring them up to people if I think they've not had their scans, but I really need them to see somebody if it’s an extreme. The beauty of having a cancer care coordinator is what I do now, I've added into the system, is that once I've done the support call I pass that on to Becky so she does a follow-up call for all of them, whether they want it or not. And they can always say thanks a lot, I'm all right, I've had my scan or I've got my data, or whatever. That's fine. It's not a big waste, I don't feel. I think it's adding another layer, but they'd feel like somebody cares and there's something happening. So I've told her to look for the scan dates and which part of the trust it's at, whether it's at Doncaster or Bassetlaw, have they got transport? Will

somebody be going with them? What will happen when they have that test? And so she uses that almost as an excuse to have another point of contact. And up to now, everybody's liked that. And I think it has dampened down the distance between this bringing people in, whizzing them through, sending them off. It feels almost like they're in a factory.

Because another thing with prehab is everyone says we should try and do it as early as possible in the pathway, but if you're not meeting them until after they've been to MDT -

After the, exactly.

Then there is a very short window, isn't there?

Exactly.

Whereas, I know one of the upper GI surgeons in Sheffield, he says he will meet with them on the day of their scope and if a lesion is picked up he will sit with them and explain and get the specialist nurse on that day.

Yes.

Which then you can say you don't look very fit, do you?

That's what we used to do. We were well staffed with three surgeons once upon a time. We had a well-staffed nursing team and three surgeons. It was a breeze. Now we've got seven surgeons and we've got three CNSs that are NHS funded and two externally funded CNSs. And as much as it sounds a lot, we have three sites of the trust in community to cover. We see colorectal, stoma care and fistula management and urostomies. So we have the whole shebang, whether they've got cancer or not. So we've got the benign, we've got the traumas, we've got everything. And it's a real big chunk to take on. I'm not moaning about that. I just think we could do it better if we'd got more staff. We used to go and meet the patient on the day of suspicion. We used to go down to endoscopy. It was a pain. We were up and down the hospital, back and forth to endoscopy: oh we've got another patient, oh we've got another patient – that's fine because I think it added value to that. We used to help the patient understand what tests were being done. And I'm trying to do that now remotely using the cancer care coordinator, just because we've not got the manpower to do the face-

to-face stuff. And as you say, we're not picking up what somebody actually looks like. Do they smell of nicotine? Do they look like they heavily smoke? Do they look like they're unkempt and not looked after and malnourished? You can't see that by phone.

Because a lot of people still rely very much on the end-of-the-bed test, don't they?

Yeah.

And if it's done by phone...

Yeah, exactly. And, as I say, I've been a nurse since 1989, well, I started nursing in 1989 and I know we have early warning scores and all this malarkey on the wards, but we never needed that or had that when I was on a ward. I could just use my eyes and look at somebody and think they're not good, I need to do this, I need to do that. And I knew from instinct and experience what I needed to do. I didn't need a piece of paper to tell me to do it. And I think the sadness is the more we're moving away from the face-to-face support with these patients, there's more risk involved. There is more risk and there's more pressure from government targets. And we've got all these targets to meet, cancer targets, so people are juggling patients around trying to make sure we've met the target. It irritates the life out of me because we're people at the end of the day. If you've got rectal cancer, you don't really care if you're going to breach. You just want the right care in the right place at the right time.

So it is difficult, but I think patients are pretty much supported. This new cancer care coordinator role, I have suggested that we do a baseline. I called it a patient party, but not exactly having a bottle of champagne or anything. It was more a patient event where we just ask patients for some feedback, put tea and coffee and biscuits on and say can you tell us what you feel about your cancer journey, what happened to you. Give them a pad of post-it notes, stick some boards around the room and let them put their honest views on and stick them on anonymously so that we actually understand what people's perception of their journey was. Invite, I don't know, probably 50 patients. You'll maybe get 30, if you're lucky, turn up. But let them come. Let them stick the stickers around. Did we support you with your psychological needs, what did you feel was the best part of your journey, what was the worst part of your journey, how are you left feeling after that journey, these kinds of things. Because I do feel that we do things because we think it's right, but are we doing the right thing? Are we doing what patients really want us to do and families? And the resources are not

unlimited, but could we do things better? Rather than doing some of the things that we do do badly, we could do the things that really matter better. So I've suggested we do that as a baseline and then repeat it in two years' time when Becky is fully integrated into the team and see if we've made a difference. Yeah. Sorry, I've digressed.

No, I was just thinking. In terms of you were saying they can get rehab, exercise rehab, at the leisure centres post-surgery, post-treatment. Do many patients take that up?

No. The only one, there's one patient that I know, yeah, one in the whole shebang. She took it seriously because she was really struggling with lymphedema. She was a patient that had anal cancer and had anal cancer treatment and she had a horrid lower-limb lymphedema and some of it, she was obese and she admitted that she said her lifestyle was poor and she wanted to make some drastic changes. So she started healthy eating and she supported that with going to Slimming World, so she had a network of friends that were healthy eating as well. And she wanted to join a gym. But she lived somewhere, I can't remember, but it was somewhere that was in-between CCGs, somewhere like, let's say [unclear 0:48:15]. So it wasn't particularly Rotherham. There was nothing at Mexborough. So she had to come to come to Doncaster, but then she'd not got a Doncaster postcode, so there was a battle to get her into the system with this free six-course thing. It was a nightmare. And I know she works at Barnsley. So I did see her in a shop in Barnsley where she works and she said to me I gave it up because it just wasn't worth it; it was just so much hassle. And I thought ah.

It's such a shame, isn't it?

Yeah, I think if you've got a Doncaster postcode, you're probably all right, but other than that it would have failed.

Yeah. Because actually by the time she's paid for transport, she could have probably just got something...

She could have just bought herself a pedal bike at home and done it herself.

I think that's one of the big things, isn't it? They've got all these other appointments and if you then say right, I want you to go to the gym three times a week as well, people will just say well, I can't.

Yeah, exactly, yeah. I'm trying to work. I'm trying to get myself back to surviving this cancer, yeah. So I'm not sure that it's a big deal, the support that the council give, but at least it's there if anybody needs it or wants it. Most don't. Like I say, most don't want it. The ones that probably would use it are the ones that have said well, I've had so much time off work I'm going back; thanks very much, I'm fit; I'm all right.

Yeah and I'll get back to it.

So it's a bit of a Catch-22 that one. But I think if we educated and sowed the seed of healthy living more, pre-operatively or pre-treatment, then I think we would get people more engaged to carry that on and think ooh, I've had a cancer; I definitely need to change my lifestyle because they blame themselves for it. Well, that's if they don't blame us for it.

I think we'll finish here.

END OF INTERVIEW

Appendix Y: Sample of coding table for framework analysis

	Assessment	
Clinician ID	2. How do you assess elective patients?	3. How do you assess emergency patients?
B7	CPET test all patients going for elective major surgery, Risk scoring for patients not undergoing major resection. All patients are seen in nurse-led pre-operative assessment and those that meet certain criteria are referred for anaesthetic review or further investigations.	Carry out anaesthetic assessment prior to surgery, including risk assessment, although more frequently now this is being performed by the surgeons359-361.
C4	Consultant anaesthetist usually involved pre- and intra-operatively whereas intensivists will take over afterwards.	Involved in the ITU care of emergency GI patients. Wouldn't usually admit the patient to ITU pre-operatively as there isn't the time or really much additional that they could do 29-30.
A4	Pre-operative assessment to identify specific risk factors - frailty(mandatory), anaemia, medical co-morbidities, hypertension. For high risk surgery… If concerns on pre-op assessment will suggest that the surgeon books a CPET148-50. Slightly more time in pre-op assessment to delve into functional capacity, what the proposed surgery involves, risks etc... find out more information becasue the emphasis of the appointment is different173-176 Pre-operative assessment nurses, pre-op anaesthetists	
B6	CPET test all patients going for elective major GI surgery. If a patient performs very badly on CPET they will usually discuss personally with the surgeon at the end of the clinic and make a plan 128.	Involved as an on call anaesthetist but often role is just in anaesthetising, often decision to operate has already been made351. Even if there has been a decision not to perform an elective operation, need to reassess if the patient presents as an emergency 366-7.

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Case Report Forms

Elective

Version 1

OCTAGON Case Report Form
Baseline Assessment - Elective

Hospital ID ☐☐☐ Study ID ☐☐☐

Page 1

Age ☐☐☐ Years

Postcode ☐☐☐ ☐☐☐

Sex ☐Male ☐Female

Height ☐.☐☐ metres Weight ☐☐☐ kg

Date of 1st appointment ☐☐/☐☐/☐☐

Date of referral ☐☐/☐☐/☐☐

Source of referral
☐ GP
☐ Gastroenterology
☐ General medicine
☐ Other.....
☐Follow-up (emergency surgical admission)
☐Geriatrics
☐Oncology

Type of referral ☐ Routine ☐Straight to test ☐ Urgent ☐2 week wait

Surgical diagnosis _____

Number of hospital admissions or A&E attendances in 12 months prior to appointment ☐☐

Date of pre-operative assessment appointment ☐☐/☐☐/☐☐

Does the patient have

AIDS	☐Yes	☐No	Hemiplegia	☐Yes	☐No
Cerebrovascular disease	☐Yes	☐No	Leukaemia	☐Yes	☐No
Chronic pulmonary disease	☐Yes	☐No	Malignant lymphoma	☐Yes	☐No
Congestive heart failure	☐Yes	☐No	Myocardial infarction	☐Yes	☐No
Connective tissue disease	☐Yes	☐No	Peripheral vascular disease	☐Yes	☐No
Dementia	☐Yes	☐No	Ulcer disease (GI)	☐Yes	☐No

Conditions (please tick one answer per row)

Diabetes mellitus	☐None	☐Without end organ damage	☐With end organ damage	
Liver disease	☐None	☐Mild	☐Moderate	☐Severe
Renal disease	☐None	☐Mild	☐Moderate	☐Severe
Malignant solid tumour	☐None	☐Non-metastatic	☐Metastatic	

Polypharmacy (≥ 5 oral medications) ☐Yes ☐No

Chemo/radiotherapy in previous 12 months ☐No ☐Yes chemotherapy ☐Yes radiotherapy

Alcohol use ☐Yes ☐No ☐☐ Units/week Smoker ☐Yes ☐No ☐Ex-smoker >2 weeks

Pre-operative blood test results Hb ☐☐☐ Albumin ☐☐ Creatinine ☐☐☐ Ferritin ☐☐☐

Assistance level prior to clinic
☐Own home (no assistance)
☐Own home with informal carers (family/friends)
☐Own home (with assistance/carers .....times/day)
☐Residential home
☐Nursing home
☐Intermediate care/ respite care

Functional Assessment

ASA score I II III IV V

Activities of Daily Living score ☐☐

Instrumental Activities of Daily Living Score ☐☐

Frailty score CFS ☐

Cognitive function (Mini-COG) score ☐

Nutritional Assessment BMI ☐☐

MNA score ☐☐

EQ-5D-5L: Mobility ☐ Self-care ☐ Usual activities ☐ Pain ☐ Mood ☐

Visual analogue score ☐☐

Physical activity IPAQ-E ☐☐☐☐ MET-minutes/week

WHO DAS S1 ☐ S2 ☐ S3 ☐ S4 ☐ S5 ☐ S6 ☐ S7 ☐ S8 ☐ S9 ☐ S10 ☐

S11 ☐ S12 ☐ H1 ☐ H2 ☐ H3 ☐

Fitness Assessment

CPET performed Yes ☐ No ☐ Date of test ☐☐/☐☐/☐☐

VO_2 at AT ☐☐.☐☐ ml/kg/min VO_{2peak} ☐☐.☐☐

V_E/VCO_2 ☐☐.☐☐ RER at VO_{2peak} ☐.☐☐

Resting heart rate ☐☐☐

Recommendation on CPET_____

6MWT performed Yes ☐ No ☐ Date of test ☐☐/☐☐/☐☐

Distance achieved ☐☐☐ metres

ASA classification	Description
ASA I	Normal, healthy individual
ASA II	Mild systemic disease or impairment
ASA III	Moderate to severe systemic disease that is well compensated/ controlled by treatment
ASA IV	Severe systemic disease which is a constant threat to life
ASA V	Moribund, unlikely to survive 24 hours

Canadian Study of Health and Ageing (CSHA) Frailty scale (Rockwood)

Date / /

Circle which description best fits the patient

Score	Description
1 – very fit	Robust, active, energetic, well-motivated and fit; these people commonly exercise regularly and are in the most fit group for their age
2 - well	Without active disease, but less fit than people in category 1.
3 – Well, with treated comorbid disease	Disease symptoms are well controlled compared with those in category 4.
4 – Apparently vulnerable	Although not frankly dependent, these people commonly complain of being "slowed up" or have disease symptoms
5 – Mildly frail	With limited dependence on others for instrumental* activities of daily living
6 – Moderately frail	Help is needed with both instrumental* and non-instrumental activities of daily living
7 – Severely frail	Completely dependent on others for activities of daily living, or terminally ill.

*Non-instrumental activities of daily living are basic everyday tasks such as walking, bathing, dressing, toileting, brushing teeth and eating. Instrumental activities of daily living are further tasks such as cooking, shopping, driving etc.

Cognitive assessment (Mini-COG)

Date / /

Make sure that the patient is paying attention.

Step 1: Three word Registration

"Please listen carefully. I am going to say three words that I want you to repeat back to me now and try to remember. The words are Captain, Garden, Picture. Please say them for me now." If the person is unable to repeat the words after three attempts, move on to step 2.

Step 2: Clock drawing

"Next, I want you to draw a clock for me. First, put in all of the numbers where they go." When that is completed, say "Now, set the hands to 10 past 11."

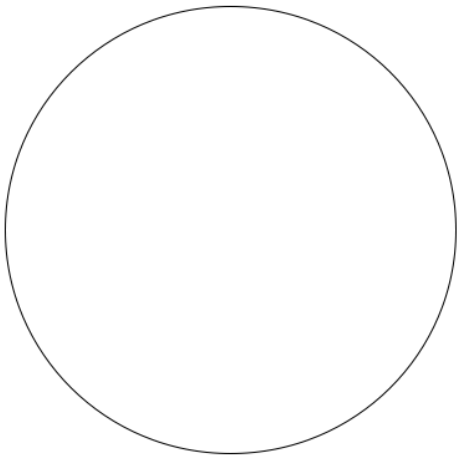
Step 3: Three word recall

Ask the person to recall the three words you stated in Step 1. Say "what were the three words I asked you to remember?" Record the person's answers below

Word recall: _____ (0-3 points)	1 point for each word spontaneously recalled without cueing
Clock draw: _____(0 or 2 points)	Normal clock = 2 points. A normal clock has all numbers placed in the correct sequence and approximately correct position with no missing or duplicate numbers. Hands are pointing to the 11 and 2. Hand length is not scored. Inability or refusal to draw a clock (abnormal) = 0 points
Total score: _____(0-5 points)	Total score = word recall + clock draw score

Cognitive assessment (Mini-COG)

Date ☐☐ / ☐☐ / ☐☐



Mini Nutritional Assessment (MNA) screening

Date ☐☐ / ☐☐ / ☐☐

Screening Questionnaire (circle one from each group and then calculate score)

Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties?
- 0 = severe decrease in food intake
- 1 = moderate decrease in food intake
- 2 = no decrease in food intake

Weight loss during the last 3 months
- 0 = weight loss greater than 3 kg (6.6lbs)
- 1 = does not know
- 2 = weight loss between 1 and 3 kg (2.2 and 6.6lbs)
- 3 = no weight loss

Mobility
- 0 = chair or bedbound
- 1 = able to get out of bed/ chair but does not go out
- 2 = goes out

Has suffered psychological distress or acute disease in the past 3 months
- 0 = yes
- 2 = no

Neuropsychological problems
- 0 = severe dementia or depression
- 1 = mild dementia
- 2 = no psychological problems

Body Mass Index
- 0 = BMI less than 19
- 1 = BMI 19 to less than 21
- 2 = BMI 21 to less than 23
- 3 = BMI 23 or greater

Screening score (subtotal max. 14 points) ☐☐
12-14 points: Normal nutritional status
8-11 points: At risk of malnutrition
0-7 points: Malnourished

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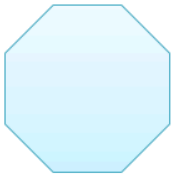


At discharge data collection

Elective

Hospital ID | Study ID

Peri-operative

Date of admission ☐☐ / ☐☐ / ☐☐

Was there any inpatient pre-operative optimisation? ☐Yes ☐No
If yes, was this: ☐Geriatric ☐Anaesthetic ☐Cardiology ☐Respiratory
☐Dietician ☐Physiotherapy ☐Specialist nurse ☐Other_____

Transfusion ☐Yes ☐No No. of units red cells ☐☐ ☐Iron infusion

Procedure Did the patient undergo a procedure/operation ☐Yes ☐No

Date of procedure ☐☐ / ☐☐ / ☐☐ Major operation ☐Yes ☐No

Procedure _____

_____

Operative approach ☐Laparoscopic ☐Laparoscopic assisted ☐Open
Stoma ☐Yes ☐No
ERAS protocol components ☐Fasting/carb loading ☐Intra-operative ☐Post-op
Anaesthetic analgesia ☐Epidural ☐Spinal ☐PCA ☐Wound catheters
Post-operative destination ☐ITU ☐HDU ☐ERB ☐Ward

Discharge

Did the patient survive to hospital discharge? ☐Yes ☐No

Length of hospital stay ☐☐ days Length of ITU/HDU stay ☐☐ days

Date medically fit for discharge (if known) ☐☐ / ☐☐ / ☐☐ Date of discharge ☐☐ / ☐☐ / ☐☐

Discharge destination ☐Own home ☐Intermediate care ☐Sheltered ☐Nursing home
☐Hospice ☐Deceased

Care needs ☐None ☐Calls per day 1 2 3 4 ☐24hr care

Bespoke questionnaire for patients

Preparation

What treatment options were discussed with you after being told your diagnosis? (tick all that apply)

- ☐Major operation
- ☐Risk-adapted/minor operation or procedure
- ☐Conservative management e.g. antibiotics/ watch and wait / no operation

Sometimes, patients are advised to try to make some changes to their lifestyle before their operation/procedure. Do you remember being advised about any of the following:

To improve your fitness e.g. exercise or walking more	☐Yes	☐No	
To improve your diet	☐Yes	☐No	
To stop smoking	☐Yes	☐No	☐N/A
To reduce alcohol consumption	☐Yes	☐No	☐N/A

Occasionally, patients may take part in a formal programme to help them prepare for surgery

Did you take part in an exercise programme?	☐Yes	☐No	
Who was this organised by?	☐Hospital	☐GP	☐Myself/family
Were you prescribed dietary supplements e.g. fortisips?	☐Yes	☐No	
Did you have support to reduce anxiety or stress?	☐Yes	☐No	

Occasionally, patients may also see other healthcare professionals before their operation/procedure. Do you remember seeing any of the following:

Physiotherapist	☐Yes	☐No	Don't know ☐
Dietician	☐Yes	☐No	Don't know ☐
Geriatrician/ older adult team	☐Yes	☐No	Don't know ☐
Stoma/colorectal specialist nurse	☐Yes	☐No	Don't know ☐
Pain team	☐Yes	☐No	Don't know ☐
Palliative care team	☐Yes	☐No	Don't know ☐

Did you attend a 'Surgery School' prior to your operation (if relevant)? ☐Yes ☐No

Were you told that you were on a 'fast-track' or 'enhanced recovery programme'? ☐Yes ☐No

After your operation/ procedure

Do you remember seeing any of the following professionals after your operation?

Physiotherapist	☐Yes	☐No	Don't know ☐
Occupational therapist	☐Yes	☐No	Don't know ☐
Dietician	☐Yes	☐No	Don't know ☐
Geriatrician/ older adult team	☐Yes	☐No	Don't know ☐
Social worker	☐Yes	☐No	Don't know ☐
Pain team	☐Yes	☐No	Don't know ☐
Palliative care team	☐Yes	☐No	Don't know ☐

Are you going to undertake a rehabilitation programme after discharge? ☐Yes ☐No
Who has organised this? ☐Hospital ☐GP ☐Myself/ family

Post-operative complications at discharge

Clavien Dindo Classification

Degree	Definition
1	Any deviation from the normal postoperative course without need of intervention beyond the administration of antiemetics, antipyretics, analgesics, diuretics, electrolytes and physiotherapy
2	Complication requiring pharmacological treatment with other medicines beyond the ones used for the complications of degree I
3 3a 3b	Complication requiring surgical, endoscopic or radiological intervention Intervention without general anaesthesia Intervention under general anaesthesia
4 4a 4b	Life-threatening complication requiring admission to intensive care unit Uni-organ dysfunction (including dialysis) Multi-organ dysfunction
5	Death

Abdominal wall dehiscence ☐Yes ☐No Clavien Dindo grade 1 2 3a 3b 4a 4b

Anastamotic leakage ☐Yes ☐No Clavien Dindo grade 1 2 3a 3b 4a 4b

Superficial surgical site infection ☐Yes ☐No Clavien Dindo grade 1 2 3a 3b 4a 4b

Deep (intra-abdominal) infection ☐Yes ☐No Clavien Dindo grade 1 2 3a 3b 4a 4b

Urinary tract infection ☐Yes ☐No Clavien Dindo grade 1 2 3a 3b 4a 4b

Pneumonia ☐Yes ☐No Clavien Dindo grade 1 2 3a 3b 4a 4b

Cardiac ☐Yes ☐No Clavien Dindo grade 1 2 3a 3b 4a 4b

DVT/PE ☐Yes ☐No Clavien Dindo grade 1 2 3a 3b 4a 4b

Delirium ☐Yes ☐No Clavien Dindo grade 1 2 3a 3b 4a 4b

Radiological drain ☐Yes ☐No

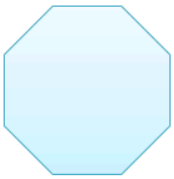
Reoperation ☐Yes ☐No Number of re-operations ☐

Unplanned HDU/ITU admission ☐No ☐Yes – HDU ☐Yes - ITU

If patient died during admission: Date of death ☐☐ / ☐☐ / ☐☐

Cause of death_____

OCTAGON



Follow-up data collection

Elective

Hospital ID | | | | Study ID | | | |

6 weeks post-operation/ procedure

Pathology Malignant ☐Yes ☐No

Site Grade T____N____M____

Non malignant pathology

Re-admission within 30 days of discharge ☐Yes ☐No

EQ-5D Date of assessment ☐☐ / ☐☐ / ☐☐ Visual analogue scale ☐☐

Mobility ☐ Self-care ☐ Usual activities ☐ Pain ☐ Mood ☐

ADL Overall score ☐☐

WHO DAS S1 ☐ S2 ☐ S3 ☐ S4 ☐ S5 ☐ S6 ☐ S7 ☐ S8 ☐ S9 ☐ S10 ☐

S11 ☐ S12 ☐ H1 ☐ H2 ☐ H3 ☐

3 months post-operation/procedure

EQ-5D Date of assessment ☐☐ / ☐☐ / ☐☐ Visual analogue scale ☐☐

Mobility ☐ Self-care ☐ Usual activities ☐ Pain ☐ Mood ☐

ADL Overall score ☐☐

WHO DAS S1 ☐ S2 ☐ S3 ☐ S4 ☐ S5 ☐ S6 ☐ S7 ☐ S8 ☐ S9 ☐ S10 ☐

S11 ☐ S12 ☐ H1 ☐ H2 ☐ H3 ☐

6 months post-operation/procedure

EQ-5D Date of assessment ☐☐ / ☐☐ / ☐☐ Visual analogue scale ☐☐

Mobility ☐ Self-care ☐ Usual activities ☐ Pain ☐ Mood ☐

ADL Overall score

WHO DAS S1 ☐ S2 ☐ S3 ☐ S4 ☐ S5 ☐ S6 ☐ S7 ☐ S8 ☐ S9 ☐ S10 ☐

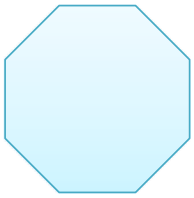
S11 ☐ S12 ☐ H1 ☐ H2 ☐ H3 ☐

If patient died after discharge from hospital Date of death ☐☐ / ☐☐ / ☐☐

Cause of death if known

Emergency CRF (only the pages that are different to the elective CRF are shown)

OCTAGON



Case Report Forms

Emergency

Hospital ID | Study ID

Version 1

OCTAGON Case Report Form
Baseline Assessment - Emergency

Hospital ID ☐☐☐ Study ID ☐☐☐

Age ☐☐☐ Years

Postcode ☐☐☐ ☐☐☐

Sex ☐Male ☐Female

Height ☐.☐☐ metres Weight ☐☐☐ kg

Source of referral ☐GP ☐A&E ☐Clinic

Specialty admitted under ☐General surgery ☐Gastroenterology ☐Geriatrics ☐General medicine ☐Oncology ☐Other_____

Number of hospital admissions or A&E attendances in 12 months prior to admission ☐☐

Does the patient have

AIDS	☐Yes	☐No	Hemiplegia	☐Yes	☐No
Cerebrovascular disease	☐Yes	☐No	Leukaemia	☐Yes	☐No
Chronic pulmonary disease	☐Yes	☐No	Malignant lymphoma	☐Yes	☐No
Congestive heart failure	☐Yes	☐No	Myocardial infarction	☐Yes	☐No
Connective tissue disease	☐Yes	☐No	Peripheral vascular disease	☐Yes	☐No
Dementia	☐Yes	☐No	Ulcer disease (GI)	☐Yes	☐No

Conditions (please tick one answer per row)

Diabetes mellitus	☐None	☐Without end organ damage	☐With end organ damage	
Liver disease	☐None	☐Mild	☐Moderate	☐Severe
Renal disease	☐None	☐Mild	☐Moderate	☐Severe
Malignant solid tumour	☐None	☐Non-metastatic		☐Metastatic

Polypharmacy (≥ 5 oral medications) ☐Yes ☐No

Chemo/radiotherapy in previous 12 months ☐No ☐Yes chemotherapy ☐Yes radiotherapy

Alcohol use ☐Yes ☐No ☐☐ Units/week Smoker ☐Yes ☐No ☐Ex-smoker >2 weeks

Pre-operative blood test results Hb ☐☐☐ Albumin ☐☐ Creatinine ☐☐☐

Ferritin ☐☐☐ CRP ☐☐☐ Lactate ☐☐☐

Assistance level prior to admission
☐Own home (no assistance)
☐Own home with informal carers (family/ friends)
☐Own home (with assistance/carers.....times/day)
☐Residential home
☐Nursing home
☐Intermediate care/ respite care

Functional Assessment

ASA score I II III IV V

Activities of Daily Living score ☐☐

Instrumental Activities of Daily Living Score ☐☐

Frailty score (CFS) ☐

Cognitive function (Mini-COG) score ☐

Nutritional Assessment BMI ☐☐ MNA score ☐☐

EQ-5D-5L: Mobility ☐ Self-care ☐ Usual activities ☐ Pain ☐ Mood ☐

Visual analogue score ☐☐

Physical activity IPAQ-E ☐☐☐☐ MET-minutes/week

WHO DAS S1 ☐ S2 ☐ S3 ☐ S4 ☐ S5 ☐ S6 ☐ S7 ☐ S8 ☐ S9 ☐ S10 ☐

S11 ☐ S12 ☐ H1 ☐ H2 ☐ H3 ☐

Risk Assessment

Pre-operative risk score ☐NELA ☐P-POSSUM ☐Other_____☐Not documented

Mortality ☐☐ % Morbidity ☐☐ %

Operative urgency (CEPOD)

☐1.	Immediate	<2hrs
☐2a.	Urgent	2-6hrs
☐2b.	Urgent	6-18hrs
☐3.	Expedited	>18hrs

Operative indication

☐Peritonitis
☐Abdominal abscess
☐Intestinal fistula
☐Intestinal obstruction
☐Ischaemia
☐Perforation
☐Anastamotic leak
☐Sepsis (other)
☐Haemorrhage
☐Colitis
☐Other_____

ASA classification	Description
ASA I	Normal, healthy individual
ASA II	Mild systemic disease or impairment
ASA III	Moderate to severe systemic disease that is well compensated/ controlled by treatment
ASA IV	Severe systemic disease which is a constant threat to life
ASA V	Moribund, unlikely to survive 24 hours

Appendix AA: Definitions of complications for OCTAGON

In-hospital mortality: Death occurring in the index hospital admission

Urinary Tract Infection: Patient has at least one of the following signs or symptoms: fever (>38.0°C); suprapubic tenderness; costovertebral angle pain or tenderness; urinary urgency; urinary frequency; dysuria AND Patient has a urine culture with no more than two species of organisms identified, at least one of which is a bacterium of $\geq 10^5$ CFU/ml.

Pneumonia must meet one of the criteria (1) Rales or dullness to percussion on physical examination of chest and any of the following: new onset of purulent sputum or change in character of sputum; organism isolated from blood culture; isolation of pathogen from specimen obtained by transtracheal aspirate, bronchial brushing or biopsy. (2) Chest radiographic examination shows new or progressive infiltrate, consolidation, cavitation or pleural effusion and any of the following: new onset of purulent sputum or change in character of sputum; organism isolated from blood culture; isolation of pathogen from specimen obtained by transtracheal aspirate, bronchial brushing or biopsy; isolation of virus or detection of viral antigen in respiratory secretions; diagnostic single antibody titre (IgM) or four-fold increase in paired serum samples (IgG) for pathogen.

Cardiac: All complications newly diagnosed whilst inpatient (e.g. AF, MI, etc).

DVT/PE – Radiologically confirmed pulmonary embolus or deep vein thrombosis whilst inpatient.

Delirium – acute confusional state with change from the patient's normal cognitive baseline, defined by clinical team.

Superficial surgical site infection: (1) Purulent drainage from the incision; OR (2) At least two of: pain or tenderness; localised swelling; redness; heat; fever; AND incision opened deliberately to manage infection or the clinician diagnoses a SSI; OR (3) Wound organisms AND pus cells from aspirate/ swab.

Deep (intra-abdominal) surgical site infection: (1) A clinical diagnosis of wound infection with dehiscence of mass closure or any layer below fat/Scarpa's fascia; (2) A clinical diagnosis of intra-abdominal collection (fever/abdominal pain) with operative/radiological evidence of a collection.

Abdominal Wall Dehiscence: Full thickness dehiscence of laparotomy wound whilst inpatient.

Anastomotic leakage: A clinical diagnosis will require symptoms related to leakage (gas, pus or faecal discharge from the drainage site, peritonitis or discharge of pus from the rectum). In the event of a clinically suspicious leak (fever or abdominal pain) the diagnosis can be established by operative or radiological diagnosis. When an anastomosis is defunctioned the presence or absence of a leak will be established by contrast radiology.

Radiological drain: Any additional procedure after operation, including imaging guided aspiration of collection or placement of a drain.

Reoperation: Any return to theatre for a general surgical cause whilst inpatient.

Unplanned HDU/ITU admission: any unplanned episodes of level 2 or 3 care due to deterioration on the ward. Does not include patients admitted directly from operating theatre.

Any additional in-hospital complications (as diagnosed by clinical team) will also be recorded e.g. hyponatraemia

Appendix AB: Baseline questionnaires for OCTAGON study

OCTAGON

Baseline Questionnaires

(Self complete or with assistance from research team)

Elective and emergency

Hospital ID | Study ID

Version 1

Activities of Daily Living

Date ☐☐/☐☐/☐☐

Select one statement from each group that best describes you

Feeding	Independent	☐
	Food needs to be cut, help with spreading butter	☐
	Dependent	☐
Transfer bed to chair	Independent	☐
	With minimal help	☐
	Able to sit but maximum assistance to transfer	☐
	Unable – no sitting balance	☐
Personal grooming	Independent	☐
	Needs help face/hair/teeth/shaving	☐
Toilet use	Independent	☐
	Needs help	☐
	Unable	☐
Bathing/shower self	Independent	☐
	Needs help	☐
Mobility	Independent but may use any aid e.g. stick	☐
	Walks with help of one person	☐
	Wheelchair independent including corners etc	☐
	Unable/immobile	☐
Stairs	Independent up and down	☐
	With help	☐
	Unable	☐
Dressing	Independent	☐
	With help but can do about half unaided	☐
	Dependent	☐
Controlling bowels	No accidents	☐
	Occasional accidents	☐
	Incontinent	☐
Controlling bladder	No accidents	☐
	Occasional accidents	☐
	Incontinent	☐

Instrumental Activities of Daily Living (please select one from each group)

Date ☐☐/☐☐/☐☐

Ability to use telephone

- ☐Operates telephone on own initiative, looks up and dials numbers etc.
- ☐Dials a few well known numbers
- ☐Answers telephone but does not dial
- ☐Does not use telephone at all

Shopping

- ☐Takes care of all shopping needs independently
- ☐Shops independently for small purchases
- ☐Needs to be accompanied on any shopping trips
- ☐Completely unable to shop

Food preparation

- ☐Plans, prepares and serves adequate meals independently
- ☐Prepares adequate meals if supplied with ingredients
- ☐Heats, serves and prepares meals but does not maintain adequate diet
- ☐Needs to have meals prepared and served

Housekeeping

- ☐Maintains house alone or with occasional assistance (e.g. domestic help)
- ☐Performs light daily tasks such as dishwashing, bed-making
- ☐Performs light daily tasks but cannot maintain acceptable level of cleanliness
- ☐Needs help with all home maintenance tasks
- ☐Does not participate in any housekeeping tasks

Laundry

- ☐Does personal laundry completely
- ☐Launders small item – rinses stockings etc.
- ☐All laundry must be done by others

Mode of transportation

- ☐Travels independently on public transport/ drives own car
- ☐Arranges own transport via taxi but does not otherwise use public transport
- ☐Travels on public transport when accompanied by others
- ☐Travel limited to taxi/automobile with assistance of others
- ☐Does not travel at all

Responsibility for medication

- ☐Is responsible for taking medication in correct dosages at correct time
- ☐Takes responsibility if medication is prepared in advance in separate
- ☐Is not capable of dispensing own medication

Ability to handle finances

- ☐Manages financial matters independently
- ☐Manages day-to-day purchases, but needs help with banking, major purchases
- ☐Incapable of handling money

EQ-5D Your own health today

Date ☐☐/☐☐/☐☐

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today

Mobility

- ☐I have no problems in walking about
- ☐I have slight problems in walking about
- ☐I have moderate problems in walking about
- ☐I have severe problems in walking about
- ☐I am unable to walk about

Self-care

- ☐I have no problems washing or dressing myself
- ☐I have slight problems washing or dressing myself
- ☐I have moderate problems washing or dressing myself
- ☐I have severe problems washing or dressing myself
- ☐I am unable to wash or dress myself

Usual activities (e.g. work, study, housework, family or leisure activities)

- ☐I have no problems doing my usual activities
- ☐I have slight problems doing my usual activities
- ☐I have moderate problems doing my usual activities
- ☐I have severe problems doing my usual activities
- ☐I am unable to do my usual activities

Pain/ discomfort

- ☐I have no pain or discomfort
- ☐I have slight pain or discomfort
- ☐I have moderate pain or discomfort
- ☐I have severe pain or discomfort
- ☐I have extreme pain or discomfort

Anxiety/ Depression

- ☐I am not anxious or depressed
- ☐I am slightly anxious or depressed
- ☐I am moderately anxious or depressed
- ☐I am severely anxious or depressed
- ☐I am extremely anxious or depressed

EQ-5D Continued

We would like to know how good or bad your health is TODAY

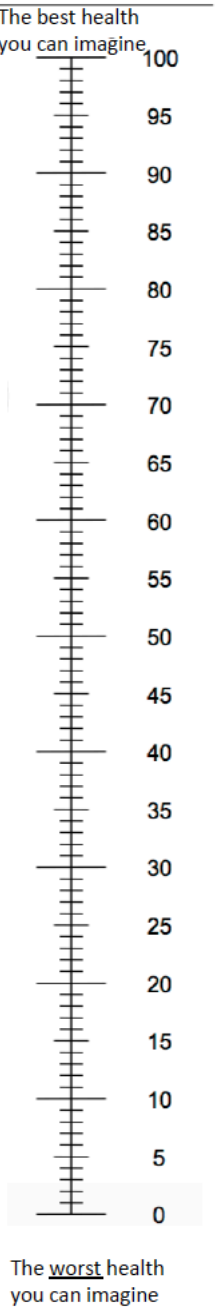
This scale is numbered from 0 to 100.

100 means the best health you can imagine
0 means the worst health you can imagine

Mark an X on the scale to indicate how your health is today

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Date ☐☐/☐☐/☐☐

International Physical Activity Questionnaire –(IPAQ-E)

1. The first question is about the time you spent sitting during the last 7 days. Include time spent at work, at home, whilst doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

During the last 7 days, how much time did you spend sitting during a day?
_____hours _____minutes

2. Think about the time you spent walking in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise or leisure.

During the last 7 days, on how many days did you walk for at least 10 minutes at a time?

_____ Days — How much time did you actually spend walking on one of those days?
Or
☐No day — _____hours_____minutes

3. During the last 7 days, on how many days did you do moderate physical activities like gardening, cleaning, bicycling at a regular pace, swimming or other fitness activities?

Think **only** about those physical activities that you did for at least 10 minutes at a time. Do not include walking.

_____ Days — How much time did you actually spend doing moderate physical activity on one of those days?
Or
☐No day — _____hours_____minutes

4. During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, heavier garden or construction work, chopping wood, aerobics, jogging/running or fast bicycling?

Think **only** about those physical activities that you did for at least 10 minutes at a time.

_____ Days — How much time did you actually spend doing vigorous physical activity on one of those days?
Or
☐No day — _____hours_____minutes

WHODAS 2.0 World Health Organization
Disability Assessment Schedule 2.0

Date / /

12- item version, self administered

This questionnaire asks about difficulties due to health conditions. Health conditions include diseases or illnesses, other health problems that may be short or long lasting, injuries, mental or emotional problems, and problems with alcohol or drugs.

Think back over the past 30 days and answer these questions, thinking about how much difficulty you had doing the following activities. For each question, please circle only one response.

In the past 30 days, how much difficulty did you have in:						
S1	Standing for long periods such as 30 minutes?	None	Mild	Moderate	Severe	Extreme or cannot do
S2	Taking care of your household responsibilities?	None	Mild	Moderate	Severe	Extreme or cannot do
S3	Learning a new task, for example, learning how to get to a new place?	None	Mild	Moderate	Severe	Extreme or cannot do
S4	How much of a problem did you have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?	None	Mild	Moderate	Severe	Extreme or cannot do
S5	How much have you been emotionally affected by your health problems?	None	Mild	Moderate	Severe	Extreme or cannot do

Please continue to next page...

WHODAS 2.0 continued

Date / /

In the past 30 days, how much difficulty did you have in:						
S6	Concentrating on doing something for ten minutes?	None	Mild	Moderate	Severe	Extreme or cannot do
S7	Walking a long distance such as a kilometre (or equivalent)?	None	Mild	Moderate	Severe	Extreme or cannot do
S8	Washing your whole body?	None	Mild	Moderate	Severe	Extreme or cannot do
S9	Getting dressed?	None	Mild	Moderate	Severe	Extreme or cannot do
S10	Dealing with people you do not know?	None	Mild	Moderate	Severe	Extreme or cannot do
S11	Maintaining a friendship?	None	Mild	Moderate	Severe	Extreme or cannot do
S12	Your day-to-day work?	None	Mild	Moderate	Severe	Extreme or cannot do

H1	Overall, in the past 30 days, how many days were these difficulties present?	**Record number of days .....**
H2	In the past 30 days, for how many days were you totally unable to carry out your usual activities or work because of any health condition?	**Record number of days .....**
H3	In the past 30 days, not counting the days that you were unable, for how many days did you cut back or reduce your usual activities or work because of any health condition?	**Record number of days .....**

This completes the questionnaires. Thank you.

Appendix AC: Approval for use of validated questionnaires

Re: Mini-Cog Permission Form

Soo Borson <soo.borson@gmail.com>
Wed 06/11/2019 15:49
To: DANIELS, Sarah (SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST) <sarahdaniels1@nhs.net>

Permission granted. Best wishes for the success of your important work.

On Wed, Nov 6, 2019 at 1:44 AM Sarah Daniels <wordpress@mini-cog.com> wrote:

> From: Sarah Daniels <sarahdaniels1@nhs.net>
> Institution: Sheffield Teaching Hospitals/ University of Sheffield
> Country: UK
> State:
>
> Study Title:
> Optimising the care and treatment pathways for older patients undergoing major GI surgery
>
> Study Objectives:
> To establish a multi-centre regional observational study across the South Yorkshire region to determine:
> • Whether there are differences across the region in who is offered major surgery or risk adapted procedures for GI pathology.
> • Whether older patients who are at risk of poor post-operative outcomes (complications, adverse events and functional decline) and who might benefit from enhanced peri-operative support can be identified and correlate outcomes with age, frailty and co-morbidity
> • To determine post-operative complications and adverse events (AEs) and their severity in older patients undergoing surgery or procedures and correlate these with patient age, co-morbidity and frailty
> • To determine functional outcomes in older patients undergoing surgery or procedures for GI pathology and correlate outcomes with age, co-morbidity and frailty.
> • Whether the use of targeted enhanced peri-operative support in practice improves post-operative outcomes and functional recovery at 6 weeks after surgery/ definitive treatment
>
> Source of Funding:
> Educational grant from Bowel Disease Research Foundation
>
> Name of PI:
> Sarah Daniels
>
> --
> This e-mail was sent from a contact form on Mini-Cog (http://mini-cog.com)

--
Soo Borson MD
Professor (Emerita), University of Washington
Dementia Care Research and Consulting

General conditions for the registration ID : 32654

EuroQol - Registration <registration@euroqol.org>
Mon 04/11/2019 14:17
To: DANIELS, Sarah (SHEFFIELD [illegible] sarahdaniels1@nhs.net>
Cc: registration@euroqol.org <mailto:registration@euroqol.org

EQ-5D

Dear Dr. Sarah Daniels ,

Thank you for your registration.
The study / project titled "Optimising the Care and Treatment pathways for older patients facing major GI surgery" you registered fulfils the conditions for you to use the requested version(s) free of charge.

Below you find our Terms of Use. We will provide you with the requested versions free of charge once we have received your agreement with our Terms of Use. You can indicate your agreement by pressing the green "Agree" button below. If you do not agree, please press "Disagree".

If you have any questions please contact us by sending an email to userinformationservice@euroqol.org.

Thank you in advance.

Kind regards,

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   - A maximum of 100,000 unique respondents when used in a ROM/PROMs Project;
   - 5 years from the date of acceptance of the Terms of Use when used in a ROM/PROMs project or Registry.
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Bernhard Slaap
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Appendix AD: Bespoke questionnaires

OCTAGON Case Report Form
At discharge – Elective

Version 1 Hospital ID ☐☐☐ Study ID ☐☐☐

Bespoke questionnaire for elective patients

Preparation

What treatment options were discussed with you after being told your diagnosis? (tick all that apply)

- ☐Major operation
- ☐Risk-adapted/minor operation or procedure
- ☐Conservative management e.g. antibiotics/ watch and wait / no operation

Sometimes, patients are advised to try to make some changes to their lifestyle before their operation/procedure. Do you remember being advised about any of the following:

To improve your fitness e.g. exercise or walking more	☐Yes ☐No
To improve your diet	☐Yes ☐No
To stop smoking	☐Yes ☐No ☐N/A
To reduce alcohol consumption	☐Yes ☐No ☐N/A

Occasionally, patients may take part in a formal programme to help them prepare for surgery

Did you take part in an exercise programme?	☐Yes ☐No
Who was this organised by?	☐Hospital ☐GP ☐Myself/family
Were you prescribed dietary supplements e.g. fortisips?	☐Yes ☐No
Did you have support to reduce anxiety or stress?	☐Yes ☐No

Occasionally, patients may also see other healthcare professionals before their operation/procedure. Do you remember seeing any of the following:

Physiotherapist	☐Yes ☐No Don't know ☐
Dietician	☐Yes ☐No Don't know ☐
Geriatrician/ older adult team	☐Yes ☐No Don't know ☐
Stoma/colorectal specialist nurse	☐Yes ☐No Don't know ☐ N/A☐
Pain team	☐Yes ☐No Don't know ☐
Palliative care team	☐Yes ☐No Don't know ☐

Did you attend a 'Surgery School' prior to your operation (if relevant)? ☐Yes ☐No

Were you told that you were on a 'fast-track' or 'enhanced recovery programme'? ☐Yes ☐No

After your operation/ procedure

Do you remember seeing any of the following professionals after your operation?

Physiotherapist	☐Yes ☐No Don't know ☐
Occupational therapist	☐Yes ☐No Don't know ☐
Dietician	☐Yes ☐No Don't know ☐
Geriatrician/ older adult team	☐Yes ☐No Don't know ☐
Social worker	☐Yes ☐No Don't know ☐
Pain team	☐Yes ☐No Don't know ☐
Palliative care team	☐Yes ☐No Don't know ☐

Are you going to undertake a rehabilitation programme after discharge? ☐Yes ☐No

Who was this organised by? ☐Hospital ☐GP ☐Myself/ family

Bespoke questionnaire for emergency patients

Preparation

What management options were discussed with you before your operation/ procedure? (tick all that apply)

☐Major operation
☐Risk-adapted/minor operation or procedure
☐Conservative management e.g. antibiotics/ watch and wait/ no operation

Occasionally patients may see other professionals to help prepare them before their operation/ procedure or to help with decision making. Do you remember seeing any of the following:

Physiotherapist	☐Yes	☐No	Don't know ☐	
Dietician	☐Yes	☐No	Don't know ☐	
Geriatrician	☐Yes	☐No	Don't know ☐	
Stoma/colorectal specialist nurse	☐Yes	☐No	Don't know ☐	N/A☐
Pain team	☐Yes	☐No	Don't know ☐	
Palliative care team	☐Yes	☐No	Don't know ☐	

After your operation/procedure

Did you see any of the following professionals after your operation

Physiotherapist	☐Yes	☐No	Don't know ☐
Occupational therapist	☐Yes	☐No	Don't know ☐
Dietician	☐Yes	☐No	Don't know ☐
Geriatrician/ older adult team	☐Yes	☐No	Don't know ☐
Social worker	☐Yes	☐No	Don't know ☐
Pain team	☐Yes	☐No	Don't know ☐
Palliative care team	☐Yes	☐No	Don't know ☐

At discharge from hospital

Are you going to undertake a rehabilitation programme after discharge? ☐Yes ☐No

Who has organised this? ☐Hospital ☐GP ☐Myself/family

Appendix AE: Follow-up questionnaires

OCTAGON

Follow-up Questionnaires

Elective and Emergency

Hospital ID | | | | Study ID | | | | |

Version 1

EQ-5D Your own health today

Date ☐☐/☐☐/☐☐

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today

Mobility

- ☐I have no problems in walking about
- ☐I have slight problems in walking about
- ☐I have moderate problems in walking about
- ☐I have severe problems in walking about
- ☐I am unable to walk about

Self-care

- ☐I have no problems washing or dressing myself
- ☐I have slight problems washing or dressing myself
- ☐I have moderate problems washing or dressing myself
- ☐I have severe problems washing or dressing myself
- ☐I am unable to wash or dress myself

Usual activities (e.g. work, study, housework, family or leisure activities)

- ☐I have no problems doing my usual activities
- ☐I have slight problems doing my usual activities
- ☐I have moderate problems doing my usual activities
- ☐I have severe problems doing my usual activities
- ☐I am unable to do my usual activities

Pain/ discomfort

- ☐I have no pain or discomfort
- ☐I have slight pain or discomfort
- ☐I have moderate pain or discomfort
- ☐I have severe pain or discomfort
- ☐I have extreme pain or discomfort

Anxiety/ Depression

- ☐I am not anxious or depressed
- ☐I am slightly anxious or depressed
- ☐I am moderately anxious or depressed
- ☐I am severely anxious or depressed
- ☐I am extremely anxious or depressed

EQ-5D Continued

We would like to know how good or bad your health is TODAY

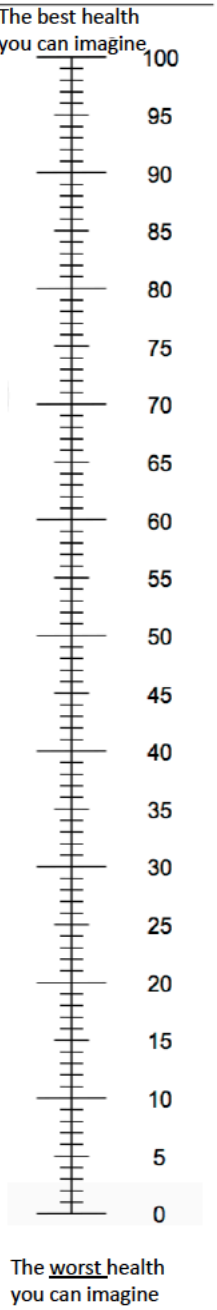
This scale is numbered from 0 to 100.

100 means the best health you can imagine
0 means the worst health you can imagine

Mark an X on the scale to indicate how your health is today

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Activities of Daily Living Index (select one from each group)

Date ☐☐/☐☐/☐☐

Feeding	Independent	☐
	Food needs to be cut, help with spreading butter	☐
	Dependent	☐
Transfer bed to chair	Independent	☐
	With minimal help	☐
	Able to sit but maximum assistance to transfer	☐
	Unable – no sitting balance	☐
Personal grooming	Independent	☐
	Needs help face/hair/teeth/shaving	☐
Toilet use	Independent	☐
	Needs help	☐
	Unable	☐
Bathing/shower self	Independent	☐
	Needs help	☐
Mobility	Independent but may use any aid e.g. stick	☐
	Walks with help of one person	☐
	Wheelchair independent including corners etc	☐
	Unable/immobile	☐
Stairs	Independent up and down	☐
	With help	☐
	Unable	☐
Dressing	Independent	☐
	With help but can do about half unaided	☐
	Dependent	☐
Controlling bowels	No accidents	☐
	Occasional accidents	☐
	Incontinent	☐
Controlling bladder	No accidents	☐
	Occasional accidents	☐
	Incontinent	☐

WHODAS 2.0 World Health Organization
Disability Assessment Schedule 2.0

Date ☐☐/☐☐/☐☐

12- item version, self administered

This questionnaire asks about difficulties due to health conditions. Health conditions include diseases or illnesses, other health problems that may be short or long lasting, injuries, mental or emotional problems, and problems with alcohol or drugs.

Think back over the past 30 days and answer these questions, thinking about how much difficulty you had doing the following activities. For each question, please circle only one response.

In the past 30 days, how much difficulty did you have in:						
S1	Standing for long periods such as 30 minutes?	None	Mild	Moderate	Severe	Extreme or cannot do
S2	Taking care of your household responsibilities?	None	Mild	Moderate	Severe	Extreme or cannot do
S3	Learning a new task, for example, learning how to get to a new place?	None	Mild	Moderate	Severe	Extreme or cannot do
S4	How much of a problem did you have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?	None	Mild	Moderate	Severe	Extreme or cannot do
S5	How much have you been emotionally affected by your health problems?	None	Mild	Moderate	Severe	Extreme or cannot do

Please continue to next page…

WHODAS 2.0 continued

Date ☐☐/☐☐/☐☐

In the past 30 days, how much difficulty did you have in:						
S6	Concentrating on doing something for ten minutes?	None	Mild	Moderate	Severe	Extreme or cannot do
S7	Walking a long distance such as a kilometre (or equivalent)?	None	Mild	Moderate	Severe	Extreme or cannot do
S8	Washing your whole body?	None	Mild	Moderate	Severe	Extreme or cannot do
S9	Getting dressed?	None	Mild	Moderate	Severe	Extreme or cannot do
S10	Dealing with people you do not know?	None	Mild	Moderate	Severe	Extreme or cannot do
S11	Maintaining a friendship?	None	Mild	Moderate	Severe	Extreme or cannot do
S12	Your day-to-day work?	None	Mild	Moderate	Severe	Extreme or cannot do

H1	Overall, in the past 30 days, how many days were these difficulties present?	**Record number of days .....**
H2	In the past 30 days, for how many days were you totally unable to carry out your usual activities or work because of any health condition?	**Record number of days .....**
H3	In the past 30 days, not counting the days that you were unable, for how many days did you cut back or reduce your usual activities or work because of any health condition?	**Record number of days .....**

This completes the questionnaires. Thank you.

Appendix AF: Guidelines for scoring validated questionnaires

Barthel's Activities of Daily Living Questionnaire scoring

Sum the patient's scores for each item. Total possible scores range from 1 – 20, with lower scores indicating increased disability. Input the total score into RedCap. Responses should reflect what the patient does, not what they could do.

Activities of Daily Living questionnaire with scoring

Feeding	2= Independent	☐
	1= Food needs to be cut, help with spreading butter	☐
	0= Dependent	
☐		
Transfer bed to chair	3= Independent	☐
	2= With minimal help	
☐		
	1= Able to sit but maximum assistance to transfer	
☐		
	0= Unable – no sitting balance	☐
Personal grooming	1= Independent	☐
	0= Needs help face/hair/teeth/shaving	☐
Toilet use	2= Independent	☐
	1= Needs help	
☐		
	0= Unable	☐
Bathing/shower self	1= Independent	☐
	0= Needs help	
☐		
Mobility	3= Independent but may use any aid e.g. stick	☐
	2= Walks with help of one person	☐
	1= Wheelchair independent including corners etc	
☐		
	0= Unable/immobile	☐
Stairs	2= Independent up and down	☐
	1= With help	☐
	0= Unable	☐
Dressing	2= Independent	☐
	1= With help but can do about half unaided	
☐		
	0= Dependent	
☐		
Controlling bowels	2= No accidents	☐
	1= Occasional accidents	☐
	0= Incontinent	
☐		
Controlling bladder	2= No accidents	☐
	1= Occasional accidents	☐
	0= Incontinent	
☐		

Guidelines for the Barthel Index of Activities of Daily Living

General

- The Index should be used as a record of what a patient ***does***, NOT as a record of what a patient ***could do***.
- The main aim is to establish degree of independence from any help, physical or verbal, however minor and for whatever reason.
- The need for supervision renders the patient not independent.
- A patient's performance should be established using the best available evidence. Asking the patient, friends/relatives, and nurses will be the usual source, but direct observation and common sense are also important. However, direct testing is not needed.
- Usually the performance over the preceding 24 – 48 hours is important, but occasionally longer periods will be relevant.
- Unconscious patients should score '0' throughout, even if not yet incontinent.
- Middle categories imply that the patient supplies over 50% of the effort.
- Use of aids to be independent is allowed.

Bowels (preceding week)

- If needs enema from nurse, then 'incontinent.'
- 'Occasional' = once a week.

Bladder (preceding week)

- 'Occasional' = less than once a day.
- A catheterized patient who can completely manage the catheter alone is registered as 'continent.'

Grooming (preceding 24 – 48 hours)

- Refers to personal hygiene: doing teeth, fitting false teeth, doing hair, shaving, washing face. Implements can be provided by helper.

Toilet use

- Should be able to reach toilet/commode, undress sufficiently, clean self, dress, and leave.
- 'With help' = can wipe self and do some other of above.

Feeding

- Able to eat any normal food (not only soft food). Food cooked and served by others, but not cut up.
- 'Help' = food cut up, patient feeds self.

Transfer

- From bed to chair and back.
- 'Dependent' = NO sitting balance (unable to sit); two people to lift.
- 'Major help' = one strong/skilled, or two normal people. Can sit up.
- 'Minor help' = one person easily, OR needs any supervision for safety.

Mobility

- Refers to mobility about house or ward, indoors. May use aid. If in wheelchair, must negotiate corners/doors unaided.
- 'Help' = by one untrained person, including supervision/moral support.

Dressing

- Should be able to select and put on all clothes, which may be adapted.
- 'Half' = help with buttons, zips, etc. (*check!*), but can put on some garments alone.

Stairs

- Must carry any walking aid used to be independent.

Bathing

- Usually the most difficult activity.
- Must get in and out unsupervised, and wash self.
- Independent in shower = 'independent' if unsupervised/unaided.

(Collin et al., 1988)

Instrumental Activities of Daily Living scoring
Input the total score into RedCap. Maximum score = 8

Ability to use telephone

1=☐Operates telephone on own initiative, looks up and dials numbers etc.
1=☐Dials a few well known numbers
1=☐Answers telephone but does not dial
0=☐Does not use telephone at all

Shopping

1=☐Takes care of all shopping needs independently
0=☐Shops independently for small purchases
0=☐Needs to be accompanied on any shopping trips
0=☐Completely unable to shop

Food preparation

1=☐Plans, prepares and serves adequate meals independently
0=☐Prepares adequate meals if supplied with ingredients
0=☐Heats, serves and prepares meals but does not maintain adequate diet
0=☐Needs to have meals prepared and served

Housekeeping

1=☐Maintains house alone or with occasional assistance (e.g. domestic help)
1=☐Performs light daily tasks such as dishwashing, bed-making
1=☐Performs light daily tasks but cannot maintain acceptable level of cleanliness
1=☐Needs help with all home maintenance tasks
0=☐Does not participate in any housekeeping tasks

Laundry

1=☐Does personal laundry completely
1=☐Launders small item – rinses stockings etc.
0=☐All laundry must be done by others

Mode of transportation

1=☐Travels independently on public transport/ drives own car
1=☐Arranges own transport via taxi but does not otherwise use public transport
1=☐Travels on public transport when accompanied by others
0=☐Travel limited to taxi/automobile with assistance of others
0=☐Does not travel at all

Responsibility for medication

1=☐Is responsible for taking medication in correct dosages at correct time
0=☐Takes responsibility if medication is prepared in advance in separate
0=☐Is not capable of dispensing own medication

Ability to handle finances

1=☐Manages financial matters independently
1=☐Manages day-to-day purchases, but needs help with banking, major purchases
0=☐Incapable of handling money

EQ5D Questionnaire scoring

Input the score from each question into RedCap as well as the Visual Analogue Score. A total score is not needed

EQ-5D

Mobility

1=☐I have no problems in walking about
2=☐I have slight problems in walking about
3=☐I have moderate problems in walking about
4=☐I have severe problems in walking about
5=☐I am unable to walk about

Self-care

1=☐I have no problems washing or dressing myself
2=☐I have slight problems washing or dressing myself
3=☐I have moderate problems washing or dressing myself
4=☐I have severe problems washing or dressing myself
5=☐I am unable to wash or dress myself

Usual activities (e.g. work, study, housework, family or leisure activities)

1=☐I have no problems doing my usual activities
2=☐I have slight problems doing my usual activities
3=☐I have moderate problems doing my usual activities
4=☐I have severe problems doing my usual activities
5=☐I am unable to do my usual activities

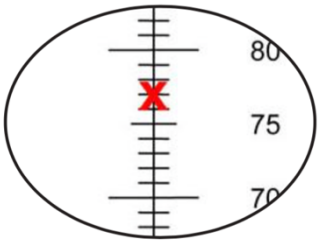
Pain/ discomfort

1=☐I have no pain or discomfort
2=☐I have slight pain or discomfort
3=☐I have moderate pain or discomfort
4=☐I have severe pain or discomfort
5=☐I have extreme pain or discomfort

Anxiety/ Depression

1=☐I am not anxious or depressed
2=☐I am slightly anxious or depressed
3=☐I am moderately anxious or depressed
4=☐I am severely anxious or depressed
5=☐I am extremely anxious or depressed

Visual analogue scale coding



For example,
the response above
should be coded as 77

International Physical Activity Questionnaire – Elderly (IPAQ-E) Protocol for scoring

Continuous score for entering into RedCap:

Ignore the response to question 1
Question 2 = walk, Question 3 = moderate activities, Question 4 = vigorous activities
Convert the times from hours into minutes
Carry out the calculation below
Input the final figure into RedCap

Equation

Total MET-minutes/week = Walk (3.3 x no. of minutes x no. of days) + moderate(4.0 x no. of minutes x no. of days) + vigorous (8.0 x no. of minutes x no. of days)
e.g. walking for 30 minutes per day for 5 days, moderate activity for 30 minutes per day for 5 days and vigorous activity for 30 minutes per day for 5 days

Walking = 3.3 METs	3.3 x 30 x 5 = 495 MET-minutes/week
Moderate = 4.0 METs	4.0 x 30 x 5 = 600 MET-minutes/week
Vigorous = 8.0 METs	8.0 x 30 x 5 = 1,200 MET-minutes/week
	TOTAL = 2,295 MET-minutes/week

Input this figure into RedCap (e.g. 2,295 MET-minutes/week)

WHODAS 2.0 scoring

Input the score for each individual question into RedCap

PLEASE NOTE: When scoring WHODAS, the following numbers are assigned to responses:

0 = No Difficulty
1 = Mild Difficulty
2 = Moderate Difficulty
3 = Severe Difficulty
4 = Extreme Difficulty or Cannot Do

		Score
S1	Standing for long periods such as 30 minutes?	0
S2	Taking care of your household responsibilities?	0
S3	Learning a new task, for example, learning how to get to a new place?	0
S4	How much of a problem did you have in joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?	0
S5	How much have you been emotionally affected by your health problems?	0
S6	Concentrating on doing something for ten minutes?	0
S7	Walking a long distance such as a kilometre [or equivalent]?	0
S8	Washing your whole body?	0
S9	Getting dressed?	0
S10	Dealing with people you do not know?	0
S11	Maintaining a friendship?	0
S12	Your day-to-day work/school?	0
	Overall Score	0.00%
H1	Overall, in the past 30 days, how many days were these difficulties present?	0
H2	In the past 30 days, for how many days were you totally unable to carry out your usual activities or work because of any health condition?	0
H3	In the past 30 days, not counting the days that you were totally unable, for how many days did you cut back or reduce your usual activities or work because of any health condition?	0