Routine self-reporting of symptoms and side effects during cancer treatment: The patient's perspective

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The candidate confirms that the work submitted is her own, except where work which has formed part of jointly authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

Publications

Warrington, L, K. Absolom, M. Conner, I. Kellar, B. Clayton, M. Ayres and G. Velikova (2019). "Electronic Systems for Patients to Report and Manage Side Effects of Cancer Treatment: Systematic Review". Journal of Medical Internet Research 2019;21(1):e10875.

This publication reports on the systematic review described in Chapter 5 of this thesis.

I was responsible for all aspects of planning and executing the review and preparing the manuscript. Other authors advised on the review topic, assisted with study selection and data extraction and contributed to the manuscript.

Warrington, L, K. Absolom, P. Holch, A. Gibson, B. Clayton and G. Velikova (2019). "Online tool for monitoring adverse events in cancer patients during treatment (eRAPID): Field testing in a clinical setting". BMJ Open. 2019;9.

This paper gives a full report of the field usability testing of eRAPID in a breast cancer clinic described in Chapter 4 of this thesis. I had a lead role in the study design, data collection and analysis of this study. I prepared the manuscript for publication. Other authors contributed to study design, data collection and analysis and contributed to the manuscript.

Warrington, L., P. Holch, L. Kenyon, C. Hector, K. Kozlowska, A. M. Kenny, L. Ziegler and G. Velikova (2016). "An audit of acute oncology services: patient experiences of admission

procedures and staff utilisation of a new telephone triage system."Supportive Care in Cancer 24(12): 5041-5048.

This paper describes an audit of the acute oncology services undertaken at St James Hospital, Leeds from 2011 to 2013. Results from this audit are described in Chapter 3 of this thesis. I was responsible for data collection, analysis and preparation of the manuscript. Other authors were involved in the design of the study and contributed to the manuscript.

Warrington, L., K. Absolom and G. Velikova (2015). "Integrated care pathways for cancer survivors - a role for patient-reported outcome measures and health informatics." Acta Oncologica 54(5): 600-608.

This paper describes how the eRAPID model of care could potentially be applied to cancer survivorship, and briefly describes findings from two previous studies undertaken in the Patient Centred Outcomes Research group. One of these studies is the field usability testing of eRAPID in breast cancer described in Chapter 4 of this thesis. I had a lead role in the study design, data collection and analysis of this study. I prepared the manuscript for publication. Other authors contributed to study design, data collection and analysis and contributed to the manuscript.

Holch, P., L. Warrington, L. C. A. Bamforth, A. Keding, L. E. Ziegler, K. Absolom, C. Hector, C. Harley, O. Johnson, G. Hall, C. Morris and G. Velikova (2017). "Development of an integrated electronic platform for patient self-report and management of adverse events during cancer treatment." Annals of Oncology 28(9): 2305-2311.

This paper describes some of the early IT work undertaken to develop the eRAPID intervention, focusing on the usability testing with patients. Some of this work is briefly described in Chapter 2 of this thesis. I had a lead role in the development of the usability

testing, data collection and analysis and contributed to the manuscript. Other authors contributed to the data collection and analysis, and preparation of the manuscript.

Absolom, K., P. Holch, L. Warrington, F. Samy, C. Hulme, J. Hewison, C. Morris, L. Bamforth, M. Conner, J. Brown and G. Velikova (2017). "Electronic patient self-Reporting of Adverse-events: Patient Information and aDvice (eRAPID): a randomised controlled trial in systemic cancer treatment." BMC Cancer 17(1): 318.

This paper describes the methodology of the eRAPID RCT in systemic therapy outlined in Chapter 2 of this thesis. I was involved in the design of the clinical trial and development of the intervention, in addition to sharing responsibility for implementation of the trial. I developed aspects of the trial for the purposes of this PhD, specifically the inclusion of self-efficacy and patient activation outcome measures, in addition to the schedules for end of study interviews. I also contributed to the manuscript. Other authors were involved in the design of the trial, the development of the intervention, obtaining study funding, implementing the trial and contributing to the manuscript.

Holch, P., L. Warrington, B. Potrata, L. Ziegler, C. Hector, A. Keding, C. Harley, K. Absolom, C. Morris, L. Bamforth and G. Velikova (2016). "Asking the right questions to get the right answers: using cognitive interviews to review the acceptability, comprehension and clinical meaningfulness of patient self-report adverse event items in oncology patients." Acta Oncologica 55(9-10): 1220-1226.

This paper describes a cognitive interview study undertaken as part of the development work for eRAPID. This work is briefly described in Chapter 2 of this thesis. Chapter 3 also includes secondary analysis from these interviews. I was involved in the design of the study, had a joint lead role in data collection and analysis and contributed to the manuscript. Other authors

were involved in the design of the study, contributed to data collection and analysis, and preparation of the manuscript.

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Abstract

Introduction

There has been a dramatic increase in web-based systems developed to support patients to report/manage cancer treatment side effects (ePROM systems). However, little is known about processes underpinning patient engagement and impact on experience.

Aims

To explore the patient perspective on using ePROM systems during chemotherapy.

Mixed methods

Preliminary work

Interviews (n=27) and questionnaires (n=40) explored patient experience of chemotherapy and indicated that difficulty deciding when to seek medical support during treatment was common. Field usability testing of eRAPID (n=12) indicated potential to support patients but variable engagement. A systematic review of ePROM systems (n=41) indicated a scarcity of robust evidence with few RCTs, with patient engagement and psychosocial outcomes such as self-efficacy not routinely explored or assessed.

Main studies

Qualitative and quantitative evaluation of patient engagement/experience was integrated into an RCT to evaluate eRAPID (n=354). Engagement was evaluated by weekly symptom reports and use of website. Validated measures assessed impact of eRAPID on self-efficacy to manage side effects (CSES) and cope with cancer (CBI-B), and patient activation (PAM). Relationships between outcomes and engagement were explored. A subset of patients were interviewed (n=23) to explore patient engagement/experience. Triangulation techniques were used to compare and contrast findings.

Results

Engagement was generally high with few barriers to use reported. One of the main motivators for sustained patient engagement was providing information to clinicians for use in consultations. Patients reported eRAPID provided psychological benefits and improved care. There was a positive impact of eRAPID on CSES ($p=.015$) but not CBI-B or PAM. Engagement was a significant predictor of improvement in CSES ($p<.001$) and CBI-B ($p<.01$) but not PAM.

Conclusion

ePROM systems have potential to improve patient's experience of chemotherapy. Further exploration using qualitative and quantitative assessments is needed to provide insights into motivators and barriers. Clinician engagement is intertwined with patient engagement and requires ongoing assessment to inform future development and implementation.

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List of abbreviations

AE	Adverse Event
AOS	Acute Oncology Service
CBI	Cancer Behaviour Inventory
CBI-B	Cancer Behaviour Inventory - Brief
CNS	Clinical Nurse Specialist
CSES	Chronic disease Self efficacy Scale
CTCAE	Common Terminology Criteria for Adverse Events
CTRU	Cancer Trials Research Unit
DPA	Data Protection Act
EORTC-QLQ-C30	European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire- Core 30
EPR	Electronic Patient Record
ePROMs	Electronic or web-based Patient Reported Outcome Measures
EQ-5D-5L	EuroQol Group -5 Dimension - 5 Levels
eRAPID	electronic patient self-Reporting of Adverse-events: Patient Information and aDvice
ESRC	Economic and Social Research Council
FACT-G	Functional Assessment of Cancer Therapy- General
GCP	Good Clinical Practice
GP	General Practitioner
HRQoL	Health Related Quality of Life
NHS	National Health Service
PA	Patient Activation
PAM	Patient Activation Measure
PCOR	Patient Centred Outcomes Research
PICOS	Population, Intervention, Comparator, Outcome, Study design
PPM	Patient Pathway Manager
PROMs	Patient Reported Outcome Measures
PROSPERO	International prospective register of systematic reviews
QoL	Quality of Life
RCP	Royal College of Practitioners
RCT	Randomised Controlled Trial
SRDR	Systematic Review Data Repository
SUS	System Usability Scale

Chapter 1 Introduction

1.1 Background

A growing and aging population coupled with increasingly successful cancer treatments has led to a dramatic increase in the number of people living with and beyond cancer. Approximately 2 million people in the United Kingdom have had a cancer diagnosis at some point in their lives and this is expected to rise to 4 million by 2030 [1]. The number of new diagnoses of cancer continues to rise. 303,135 people were registered with new cases of cancer in England in 2016, the equivalent of 828 new cases per day. This is comparison to 268,758 cases registered in 2010 [2]. However, cancer mortality rates continue to decrease each year, reflecting improvements in cancer treatment cancer care [3].

The common treatments available for cancer include chemotherapy, surgery, radiotherapy, hormone therapies and immunotherapies. The type of treatment used is dependent on the type and stage of cancer with many patients receiving multiple treatments or a combination of therapies. Treatment can be delivered with curative intent, where the goal is to eradicate disease altogether, or with non-curative intent, where the goal is to control symptoms, improve quality of life (QoL) and slow disease progression.

1.1.1 The costs and benefits of chemotherapy

An increasing number of cancer patients are treated with chemotherapy in the United Kingdom [4]. Chemotherapy can slow disease progression, ease symptoms of the disease and in some cases cure disease altogether. However, the treatment is not without costs and many patients experience a vast array of side effects such as nausea, pain, fatigue, constipation and diarrhoea, in addition to being at increased risk of infection due to a compromised immune

system [5-8]. These side effects can have a detrimental impact on QoL for patients both during and after chemotherapy [9-12], and can have a huge impact on patients emotionally, psychologically and socially [10, 13, 14].

Although some side effects are unavoidable with chemotherapy, many can be treated effectively with early intervention through supportive medication or self-management techniques [14]. However where side effects are poorly controlled, patients can require emergency assessment and admissions [15, 16]. Furthermore, untreated side effects such as febrile neutropenia can escalate and become life-threatening in a relatively short amount of time [17].

1.1.2 Challenges of managing chemotherapy side effects

It has become increasingly common for chemotherapy to be delivered in an ambulatory setting. Patients typically receive chemotherapy as a day case and are discharged home on the same day, with information and advice on expected and possible side effects and are advised to seek help if symptoms become a cause for concern. The next scheduled contact with their healthcare team will be arranged for a couple of days before their next treatment is due (often three weeks later). These pre-assessment appointments with a clinician (usually an oncologist or specially trained nurse) assess whether the patient is fit and well enough for their next cycle of treatment.

This method of treatment delivery places a demand on patients to play a significant role in the management of their own care [18]. However, evidence suggests that patients do not always feel equipped for this role. The beginning of cancer treatment can be a very distressing time and patients may not always be able to absorb the information they are given [19]. They often report being feeling overwhelmed by the amount of written information they receive, which impacts on confidence in making decisions about when to access support, and when self-management is appropriate [20-22]. Previous research has found that patients often wait

several days before contacting the hospital about problematic symptoms arising from chemotherapy which may result in symptoms escalating [23]. These decisions can be influenced by a number of psychosocial factors, including their perception of the accessibility of hospital advice and support, and their expectations and beliefs about being able to control symptoms [24]. Patients have also expressed a reluctance to 'bother' healthcare staff, particularly if they are uncertain about the relevance of certain symptoms and believe that they are a normal part of cancer and cancer treatment [24-27]. Patients also may delay contacting the hospital if they have an upcoming hospital appointment or even to purposively try to avoid a hospital admission [21, 25, 28]. Patients are also much less likely to seek out advice or follow self-management advice given by clinicians (e.g. taking prescribed or over the counter supportive medications, or making lifestyle changes) if they have low expectations about the influence that these behaviours can have on symptoms [29]. Escalation of symptoms and side effects can impact on patient's confidence to manage during chemotherapy and subsequently they may be less likely to engage in self-management behaviours or contact the hospital in the future [30]. Conversely, patients may contact the hospital frequently about mild side effects because they are worried, and simply need reassurance that their side effects are a normal part of the treatment trajectory. Unnecessary contacts place a burden on already stretched services in busy oncology units, and there is a need to develop more sustainable ways to support patients to manage at home and aid decision-making about contacting the hospital.

When patients attend for pre-assessment appointments prior to each cycle of chemotherapy, clinicians are required to make treatment decisions based on the level of side effects and toxicity experienced. For example, they may need to reduce or delay chemotherapy while the patient recovers, in addition to providing supportive medication to manage side effects [31]. While some objective measures such as blood tests can assess how well patients are tolerating treatment, clinicians are also very reliant on patient reports of the side effects they have been

experiencing between treatments. The level of side effects experienced by patients is typically cyclic in nature, sometimes referred to as the 'rollercoaster effect' [24, 32]. Patients usually experience the greatest burden in the week immediately following chemotherapy and feel most well just before their next treatment, which is generally when a clinic appointment takes place. Although their health and well-being at this point is most relevant for clinicians prescribing the next cycle of chemotherapy, it may not always provide the most accurate picture of symptom experience during the preceding weeks. Patients may have difficulty remembering symptoms when reporting retrospectively and may be unsure of the relevance of side effects, or the acceptable level of severity [20, 33, 34]. Clinicians often underestimate the prevalence and impact of side effects, resulting in poor documentation and ineffective management, despite the availability of supportive medications [14, 35, 36].

1.1.3 Use of Patient Reported Outcome Measures (PROMs) in clinical practice

PROMs are defined as 'any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else' [37]. As the focus on effective cancer treatments shifts from survival alone to improved health related quality of life (HRQoL), PROMs have become an increasingly important tool for understanding outcomes in cancer populations and assisting in patient monitoring during cancer care and treatment. PROMs can have a direct impact on care during cancer treatment by facilitating the identification of issues to clinicians, theoretically leading to better intervention and care. For example, if a patient completes a PROMs assessment prior to a consultation, this may highlight to the clinician that the patient is experiencing particular problems with nausea, which might result in the clinician prescribing a stronger antiemetic. The evidence for the benefits of integrating PROMs data into clinical practice to assess HRQoL and support clinical assessments during cancer treatment is growing [38-40]. Provision of PROMs data to clinicians can increase clinicians awareness of issues and facilitate the

identification, discussion and documentation of symptoms and HRQoL. There is some evidence for improved HRQoL, symptom control and even survival but this evidence is mixed [41-52]. It has been suggested that differences in efficacy may be in part due to methodological issues related to the many challenges associated with implementing PROMs into clinical practice, which have been well documented [49, 53-55]. Considerations include what measures to choose, method of collection, frequency of completion, presentation to clinicians and training of clinicians [56-59].

Engaging clinicians to use PROMs data in consultations has proven to be challenging. Clinicians generally report finding PROMs data useful but are often concerned that reviewing data during consultations may increase their workload and make consultations longer, despite evidence to suggest that this is not the case [42-44, 60]. Other barriers to effective clinician use of PROMs data include concerns about a negative impact on communication and a belief that patients do not require PROMs to raise issues they are concerned about [61-65]. However, research suggests that patients often do not raise issues without probing, even when they are experiencing substantial difficulties [36, 66, 67]. In addition, some clinicians express concerns that PROMs create an expectation of intervention for patients, when there is not always a clear management strategy, particularly for difficult to manage symptoms such as fatigue [62, 63, 68, 69]. Engaging clinicians in the selection of measures and training in the interpretation and use of PROMs in consultations has shown good promise in overcoming some of these barriers [70].

Early research has relied on patients completing PROMs in clinic waiting rooms prior to consultations, initially using pen and paper methods, and later using touch screen devices [42-45, 49]. However, completion of PROMs data immediately prior to clinic appointments has some limitations. In this scenario, patients are still required to provide accounts of symptoms retrospectively, at a time point when they generally feel most well, which may impact on the value of data provided. A new wave of research has focused on using technological

developments to support patients to complete PROMs data from home, and integrate this data into clinical practice in real-time.

1.1.4 Web-based reporting of PROMs data (ePROM systems)

Technological developments have made it possible for patients to report PROMs data from home in real-time in the interim period between hospital appointments. Web-based or electronic ePROM systems can be accessed from patients own devices such as laptops or smartphones, or specially developed devices can be provided. Feasibility studies indicate that web-based reporting is generally acceptable to patients, although patient use of systems is often variable [71-75]. Patients report higher frequency and severity of symptoms using real-time reporting in comparison to retrospective reporting before clinic appointments. As patients commonly report difficulty remembering symptoms, this would suggest that real-time reporting provides a more accurate picture of patient symptoms and side effects [33, 76]. Although this wave of research is still in it's infancy, evidence for the benefits of this approach are encouraging. Use of ePROM systems can improve symptom control and HRQoL, reduce healthcare utilisation, improve safe delivery of cancer treatment and even impact on survival [51, 77-83]. However, different approaches to design, implementation and evaluation make comparison difficult [79, 84-86]. While some ePROM systems focus on collection of PROMs data for clinical review [51, 87, 88], some have argued that there is an ethical responsibility to develop strategies to guide patients to deal with severe symptoms and side effects and alert clinicians in real-time [89]. A number of ePROM systems are now utilising PROMs data to support patients to self-manage in the interim period between hospital appointments by utilising algorithms to provide automated tailored advice on how to manage side effects [90-94]. There is evidence to suggest that incorporating these self-management and real-time monitoring elements into ePROM systems has benefits over and above simply providing PROMs data to clinicians for use in consultations [95, 96].

This new era of research reflects a general shift towards supported self-management in healthcare [97]. There are many different factors contributing towards this shift such as a growing and aging population, a rise in the incidence of chronic illness and a lack of sustainability of traditional models of healthcare [98-100]. The fast-paced advance of the internet and technology has led to a changing environment in which self-management interventions can be integrated into routine care [101, 102]. Research in other chronic illnesses such as diabetes, asthma and hypertension has made advances in developing more sophisticated telehealth and telecare interventions (interventions which allow patients to measure and report physical markers such as bloods from home) to support self-management for people living with a chronic illness by integrating objective physical markers into ePROM systems [103]. Systems have demonstrated promising benefits both on an individual patient level, and at a wider social level, such as improved HRQoL, reduced healthcare utilisation, and even a significant reduction in mortality [97, 104].

1.1.5 The patient perspective

It is important to recognise that ePROM systems are complex interventions which usually require behaviour change from both patients and clinicians [105]. However, the complexities underpinning how patients interact with them are still largely unknown. Until recently, PROMs data was collected from patients in clinic waiting rooms prior to routine appointments, meaning that patient engagement was relatively straightforward [42-45, 49]. Little is known about the processes of how patients interact and engage with ePROM systems in their own home environments.

The term patient engagement is sometimes used in healthcare research to describe patient's autonomous engagement in their own health and care [106], in addition to describing engagement with specific services or care. For the purposes of this thesis, I refer to patient engagement in a broad sense of patient interaction with ePROM systems. The term

'engagement' is often used interchangeably in this context with terms like 'adherence' and 'usage'. However, adherence suggests an evidence-based optimal way to use a technology and this is something that is rarely easy to define [107]. Studies vary in the frequency they ask patients to complete ePROMs, and there is little evidence to indicate what the most beneficial frequency of completion, if any, may be. While the term 'usage' is broader, it doesn't take into account the nuances of how and why patients interact with systems. Studies evaluating adherence or usage have tended to focus on 'if' patients use systems, and much less is known about 'how' or 'why' they use them, or conversely why they may not use them.

Better understanding about how patients engage with ePROM systems, and the impact that this has on individuals' experience of self-management, is essential to inform implementation and continuing development. This field of research is still in it's infancy, and there is not yet enough of an evidence base to build theories to try and conceptualise patient engagement. There is a range of literature and evidence based theory on adherence to medications in healthcare research, and there may be something to be learned from these. This literature suggests that there are broadly two categories of non-adherence behaviours: intentional and non-intentional [108, 109]. Non-intentional non-adherence in the context of ePROM systems may occur simply because a patient forgets to complete symptom assessments, or may be due to technical issues accessing the system. Intentional non-adherence on the other hand, can be much more complex. The Necessity-Concerns Framework (NCF) postulates that intentional non-adherence to medication regimes is influenced by patients' perception of their personal need for treatment, and of their concerns about potential adverse consequences of treatment and there is strong evidence to support this theory by assessment of these perceptions using the validated Beliefs about Medicines questionnaire [110, 111]. Similarly, illness perceptions, a central component of Leventhal's self-regulatory model [112] have been demonstrated to be strongly related to patient medication adherence. For example, illness perceptions (measured

using the Illness Perception Questionnaire (IPQ)) [113] have been shown to have better predictive value than clinical or demographic variables [114].

Broadly, we can apply some of this theory to patient engagement with ePROM systems in that patient engagement is likely to be highly related to their perceived motivations and perceived barriers to using the system. For example, do they perceive ePROM systems are easy to use? Is it something they think would be useful for them? However, there are some very important differences which limit the application of these theories. Most importantly, ePROM systems are not a treatment for cancer. Studies on adherence to medication are usually in reference to treatments which have a strong evidence base for their efficacy, and where evidence on potential consequences such as side effects are relatively well established. ePROM systems on the other hand are generally complex interventions which aim to improve patient care in some way. However, the evidence for their efficacy to actually do this is still limited, as many systems are still in early phases, and much less the processes by the which they might improve care are complex and still somewhat unknown.

In addition, little is known about what specific motivations and barriers to patient engagement with systems might be. Although systems appear to be well received by patients, engagement is often variable [74, 75, 115, 116]. There is evidence to suggest that engagement may be related to socio-demographic factors such as age or socioeconomic status, with many criticising ePROM and other eHealth systems for creating a 'digital divide' in healthcare [117, 118]. However, others have contested the current magnitude of the divide with use of the internet becoming increasingly widespread [119].

Patients' beliefs about how important their role is in their care during chemotherapy may also impact on how they engage with ePROM systems [30, 120]. While some patients view their role as equally important to that of the clinician, and feel confident in their ability to learn about their disease and treatment, others prefer to take a more passive role during treatment

[34, 121-124]. These beliefs are likely to impact on how patients perceive the use of ePROMs in clinical care and about self-management more generally.

However, there is also some evidence to suggest that ePROM systems may have the potential to actually influence patients' confidence and beliefs about taking a more active role in managing their health [81, 91, 92, 96]. Although heterogeneity in system designs and evaluation methods makes comparison difficult [78-80, 84-86], it seems logical that equipping patients with the knowledge, skills and confidence to successfully self-manage during chemotherapy may foster a sense of empowerment and control over their own care [125, 126].

1.2 Context of thesis

Since 2010, I have worked as a research assistant in the section of Patient Centred Outcomes Research (PCOR) led by Professor Galina Velikova based at St. James University Hospital in Leeds. This section specialises in the use of PROMs in oncology clinical practice, and more recently, the development and evaluation of ePROM systems. In 2011, the group were awarded an 18 month grant to develop eRAPID (electronic patient self-Reporting of Adverse-events: Patient Information and aDvice) funded by an NIHR PDG scheme RP-DG-1209-10031. eRAPID is an online system for patients to report and manage symptoms and side effects during and after cancer treatments. Following the successful development of eRAPID, a further 5 year NIHR programme grant was awarded, which commenced in July 2013 (Grant Reference Number RP-PG-0611-20,008). The programme grant aimed to evaluate eRAPID in a large scale Randomised Controlled Trial (RCT) in systemic therapy, and to develop eRAPID for use in radiotherapy and surgical practice.

I was employed as a research assistant both on the eRAPID development grant, and the subsequent programme grant. This experience provided me with a good understanding and overview of the potential benefits and limitations of eRAPID and other ePROM systems.

Patients' experiences of cancer and cancer treatment vary dramatically. The actual treatment pathway is largely variable dependent on disease, however, even patients receiving exactly the same treatment may have completely different experiences. Patients have different physical reactions to treatments, but in addition individual differences mean they vary hugely in their approaches to managing and coping with cancer and treatment, and in the support that they have available to them. The processes involved in patient decision-making about managing and reporting side effects during treatment are complex and I was interested in exploring how eRAPID would impact on this.

In January 2014, I began a part-time PhD, undertaken alongside my work as a research assistant to explore the patient perspective of using ePROM systems to report and manage side effects of cancer treatment. Specifically, I was interested in how patients engage with systems, and also the impact that systems have on patients' experience of cancer treatment. I felt that this was work which could make a valuable contribution to the field. This is an area of research which is rapidly growing. In recent years, there have been many exciting new developments which illustrate that ePROMs and telehealth if implemented and used well, can not only dramatically decrease hospital usage but even reduce mortality rates [97]. However, there is an acknowledged need to develop evidence-based theory to inform implementation [127] and understanding patient engagement and experience is a vital part of this [128].

1.3 Aims

The overall aim of this thesis is to explore the patient perspective of using ePROM systems to report and manage symptoms and side effects during chemotherapy. Specifically to explore:

1) The main challenges that patients face managing symptoms and side effects of chemotherapy in standard practice.

2) The potential for ePROM systems to support patients to overcome some of these challenges.
3) How patients engage with eRAPID over the course of chemotherapy treatment.
4) How eRAPID impacts on patient experience of chemotherapy.

1.4 Structure of the thesis

Chapter 2 gives an overview of the methodology of the thesis. The eRAPID intervention is described in detail in this chapter, in addition to the main work undertaken for development and evaluation. Information on the specific methodology used is provided in addition to a summary of how this was integrated into the eRAPID programme.

Chapter 3 summarises qualitative and quantitative data from two strands of work to explore factors that influence how patients manage and report symptoms and side effects during chemotherapy in routine care, and the impact that this can have on their chemotherapy experience (Aim 1).

Chapter 4 describes the clinical field usability testing of eRAPID in a breast cancer clinic, focusing on patient experiences of eRAPID, both in terms of how patients engaged with the system and the impact that it had on their experience of chemotherapy (Aims 3 and 4).

Chapter 5 describes a systematic review of online systems to support patients to report and manage side effects of chemotherapy. An inclusive approach is taken to identify and characterise existing systems and evidence for engagement and outcomes is synthesised (Aim 2).

Chapter 6 describes quantitative work to explore patient engagement with eRAPID, and the impact of eRAPID on colorectal, gynae and breast patients' experiences of chemotherapy over an 18 week study period during a large scale RCT to evaluate the system (Aims 3 and 4).

Chapter 7 describes qualitative work undertaken with participants following their participation in the eRAPID RCT to further explore motivations and barriers for engagement with the system, and their perception of its impact on their care (Aims 3 and 4).

Chapter 8 summarises and discusses the work in the preceding chapters. Strengths and limitations of the thesis are outlined and recommendations for future research are made.

Chapter 2 Methodology and overview of eRAPID

2.1 Overview

The purpose of this Chapter is to give an overview of the methodology of this thesis (more detailed descriptions of methodology are provided in individual Chapters). Much of the work undertaken for this thesis was integrated into the main eRAPID development and evaluation work. The Principal Investigator (Professor Galina Velikova) and the Senior Research Fellow (Dr Kate Absolom) for the eRAPID programme grant were also supervisors for this thesis. As such, I was able to work with them, and my other supervisors to develop my own original ideas and integrate these into the eRAPID study design. The first three sections of this chapter describe the eRAPID intervention, and the main work undertaken for its development and evaluation. The final section focuses on the methodology for this thesis and how this was integrated into the planned RCT to evaluate eRAPID.

The Chapter is comprised of four sections outlined below:

- Section 2.2 Description of eRAPID. This section describes the eRAPID system on a functional level and describes how it works in practice from both patient and staff points of view.
- Section 2.3 eRAPID development work overview provides a brief overview of the work undertaken to develop eRAPID. In addition, a small field usability study of eRAPID is described, which was undertaken prior to the commencement of the RCT with an internal pilot. Some of the findings from this work were integral in forming some of the initial ideas for this PhD, and are described in greater detail in Chapters 3 and 4.
- Section 2.4 eRAPID RCT with internal pilot. The eRAPID programme grant aimed to evaluate the intervention in a large scale RCT in systemic therapy, and to develop

eRAPID in radiotherapy and surgery. This section focuses only on the evaluation of eRAPID in systemic therapy. The protocol for this study has been published [94].

- Section 2.5 The role of this thesis. This final section briefly gives an overview of the methodology used in this thesis and describes how it was integrated into the main eRAPID trial.

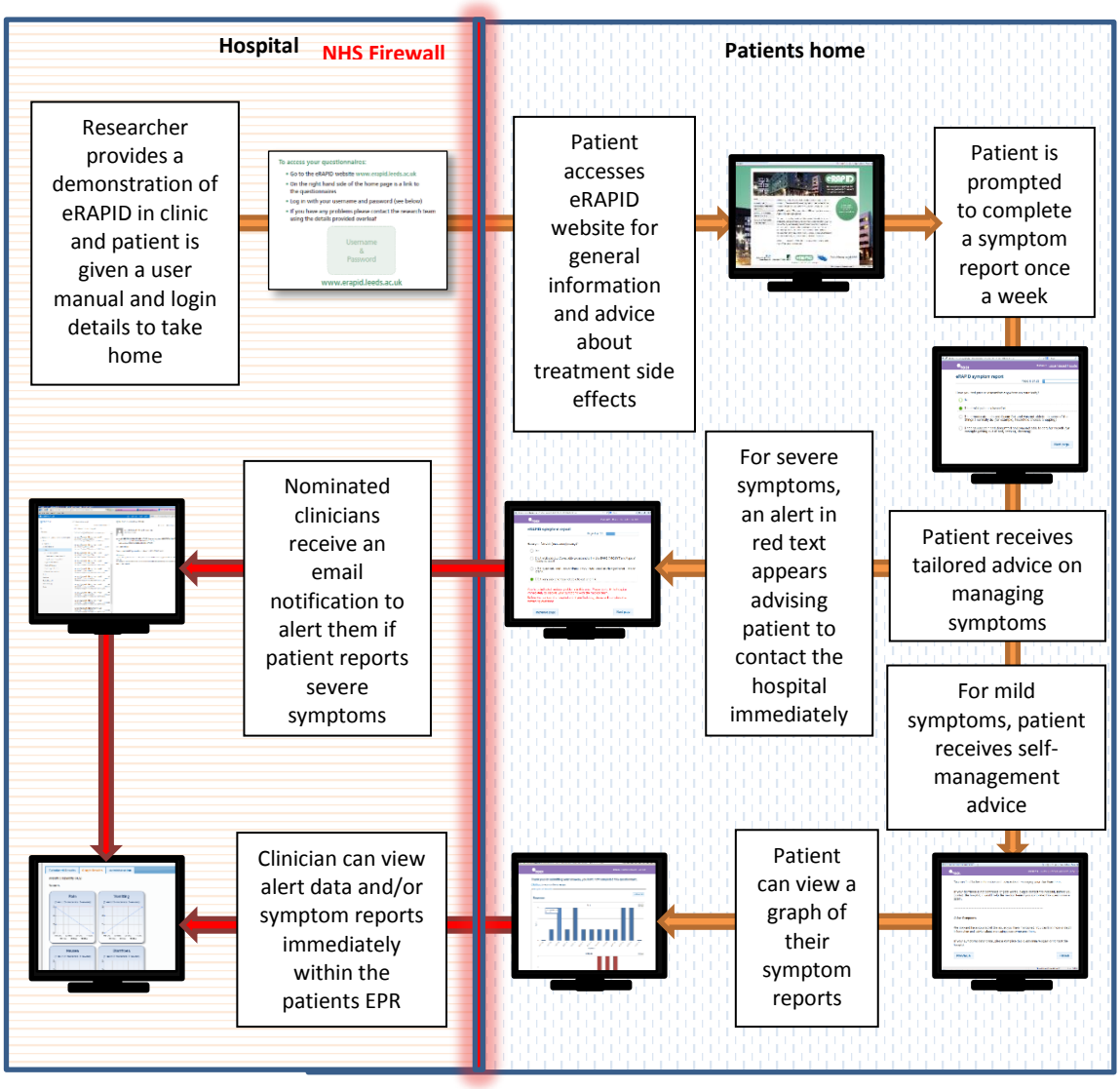
2.2 eRAPID intervention

eRAPID is an online system for patients to report and manage symptoms and side effects during and after cancer treatments. Patients can log onto the eRAPID website from any web-enabled device from their own homes and access information and self-management advice on treatment side effects. At any time, patients can click a button on the website to complete a short symptom assessment which takes approximately 5-10 minutes to complete. The patient then receives advice on how to manage reported symptoms and side effects. The advice patients receive is targeted to the severity of the symptoms reported. For example, if patients report mild symptoms, and self-management is appropriate, they will receive brief automated advice on how to self-manage their reported symptoms (e.g. over the counter medications or diet tips). If the symptoms they report are more serious, and medical intervention is required, the patient will receive a standard alert to contact the hospital immediately and a number for the local acute oncology service is provided.

In addition to this, an email notification is also sent to the key clinical staff in the patient's medical team to inform them. However clinicians are not required to take any action in response to the notification, and patients are not informed of the notifications, to ensure that there is no expectation that they will be contacted by clinicians and that the focus remains on self-management.

All patient reported data is transferred in real-time into patients' individual electronic medical records in the hospital, and is available for clinical staff to view at any time. Figure 2.1 illustrates the process of eRAPID for patients and staff.

Figure 2.1 Overview of eRAPID system



2.2.1 eRAPID from the patient's point of view

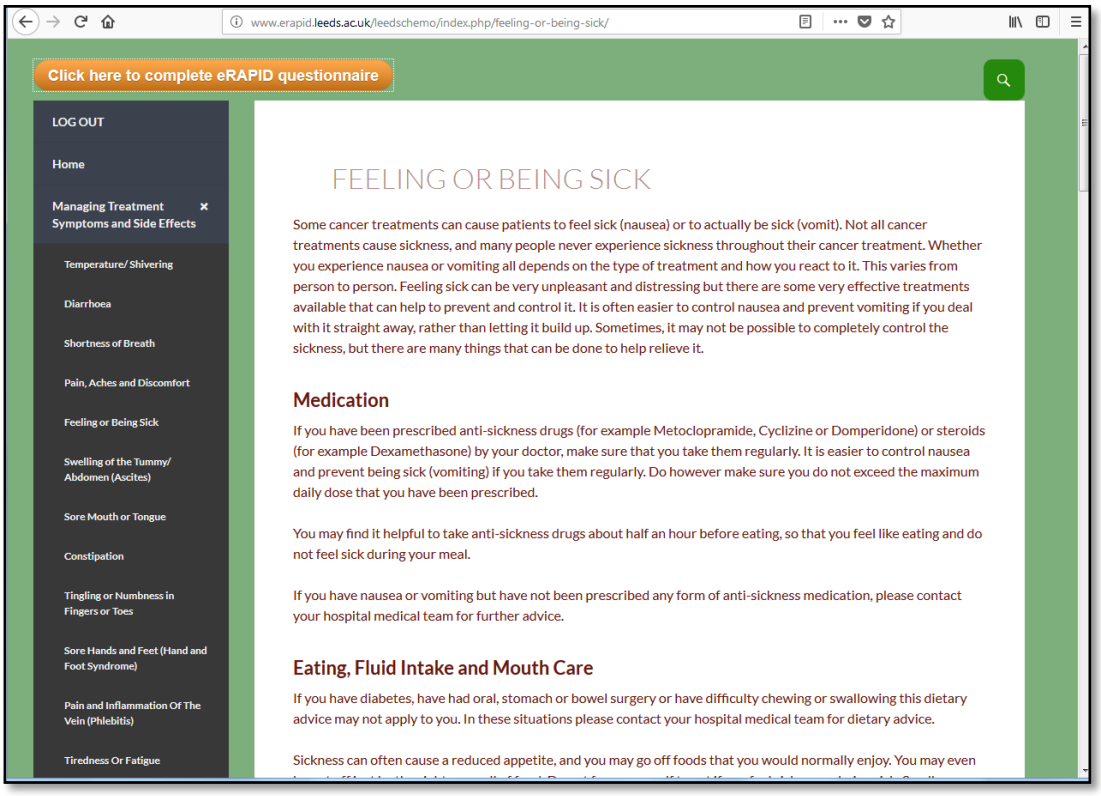
On the day of their first chemotherapy appointment, patients are given a brief demonstration of the system and are provided with a A5 postcard with their unique logon details and a detailed user manual with instructions on how to access the eRAPID website and complete the symptom reports.

2.2.1.1 The eRAPID website

Patients can log on to the eRAPID website (see Figure 2.2) from any web-enabled device using the unique username provided. They can then access self-management advice and information

on common treatment side effects. The website also comprises of helpful information on emotional coping with cancer and treatment, in addition to practical information on local services that are available. All information has been collated from standard medical information provided to patients and from reputable websites.

Figure 2.2 The eRAPID website – self-management advice page

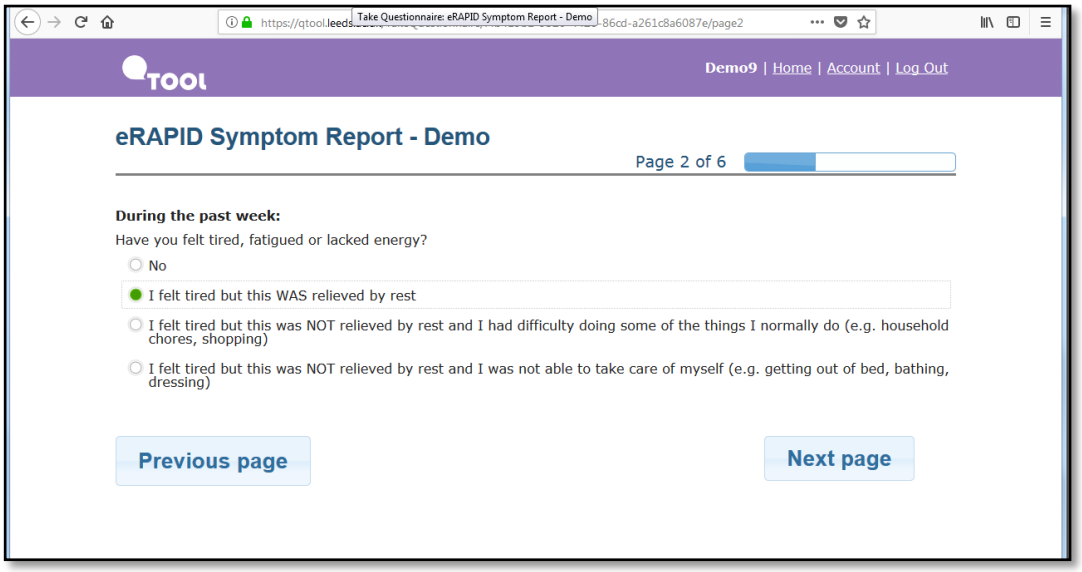


2.2.1.2 The eRAPID symptom report

Patients are asked to complete the eRAPID symptom report at least once a week and receive a weekly reminder by text, email or both. However, the symptom report is accessible at any time, and patients are advised to complete it any time they feel unwell. To access the symptom report, patients click the orange button in the top left of the page (see Figure 2.2) and are taken to QTool, a questionnaire management system, where they are asked to enter their eRAPID password. Patients complete a symptom assessment comprising of 10-14 questions (dependent on cancer type). The questions are multiple choice and are based on

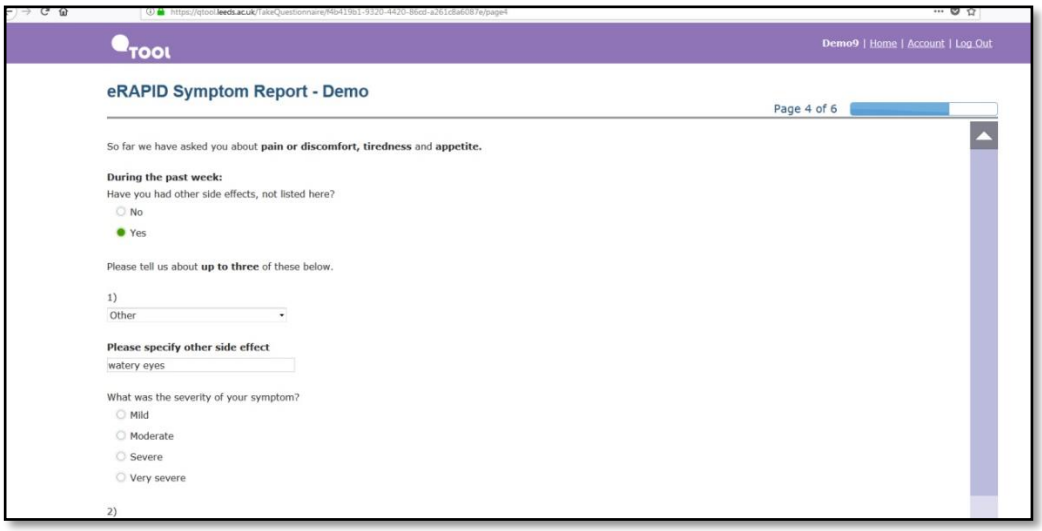
specific grading criteria commonly used by oncology clinicians [129] (see section 1.3.2). An example of a symptom report question is illustrated in Figure 2.3.

Figure 2.3 Example of eRAPID symptom report question



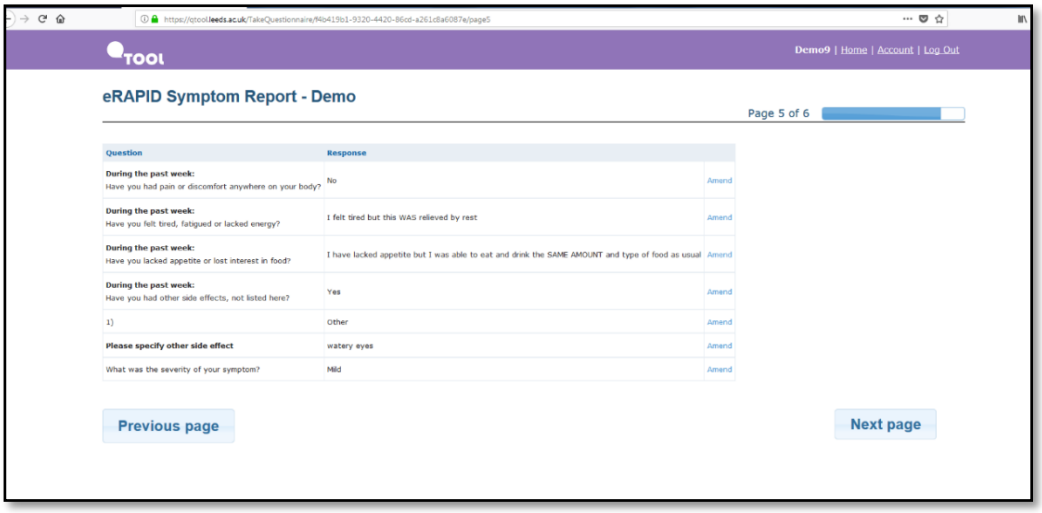
Patients can also choose to report less common symptoms from a drop down list at the end, or add free text to describe a symptom they are experiencing that they have not been asked about (see Figure 2.4).

Figure 2.4 Example 2 of eRAPID symptom report question



Patients can then review their responses to all questions and amend if necessary.

Figure 2.5 Example 3 of eRAPID symptom report



2.2.1.3 Symptom advice

Algorithms are used to provide severity dependent tailored automated advice based on patients' symptom reports. The algorithms are complex and some symptoms are considered more clinically important than others. Each question response is allocated a level of 1, 2 or 3, with 3 being the most severe, see example below. However, not all questions have a level 3 response. For example, although difficulty sleeping is a disruptive symptom for many patients, it is less clinically important in terms of safely delivering chemotherapy, and as such does not have a level 3 response (see Table 2.1).

Table 2.1 Example of eRAPID symptom question and corresponding severity level

Question	Response wording	Severity level
Diarrhoea		
Have you had diarrhoea (loose or watery stools)?	No	0
	I have had diarrhoea and opened my bowels 2-3 times more in a 24 hour period than is normal for me	1
	I have had diarrhoea and opened my bowels 4-6 times more in a 24 hour period than is normal for me	2
	I have had diarrhoea and opened my bowels over 7 times more in a 24 hour period than is normal for me or I have been incontinent (unable to control my bowels)	3
Difficulty sleeping		
Have you had difficulty	No	0
	I occasionally have difficulty falling asleep, staying asleep or I wake too early	1

sleeping?	I often have difficulty falling asleep, staying asleep or I wake too early	1
	I always have difficulty falling asleep, staying asleep or I wake too early	2

Each combination of symptoms and levels falls into one of 5 algorithm advice categories.

2.2.1.3.1 Algorithm D

Algorithm D is triggered if a patient does not report experiencing any symptoms at all. The patient is thanked for their completion, and asked to complete again next week.

2.2.1.3.2 Algorithm C

Algorithm C is slightly more complex. As a general rule, it is triggered if the severity of all symptoms patients report are at levels 1 and 2, as long as they have less than three level 2 severity symptoms. Self-management advice is provided for up to six symptoms and is listed in order of clinical importance.

2.2.1.3.3 Algorithm B

Algorithm B is triggered when a patient reports three or more symptoms with level '2' severity. Patients are shown an alert in red text at the end of the questionnaire which reads 'If your symptoms are new or have changed recently, please either contact the hospital when convenient to discuss your symptoms with the medical team or mention them at your next clinic appointment (if in the next 1-2 weeks).' Patients are provided with self-management advice for all symptoms with Level 2 severity.

2.2.1.3.4 Algorithm A2

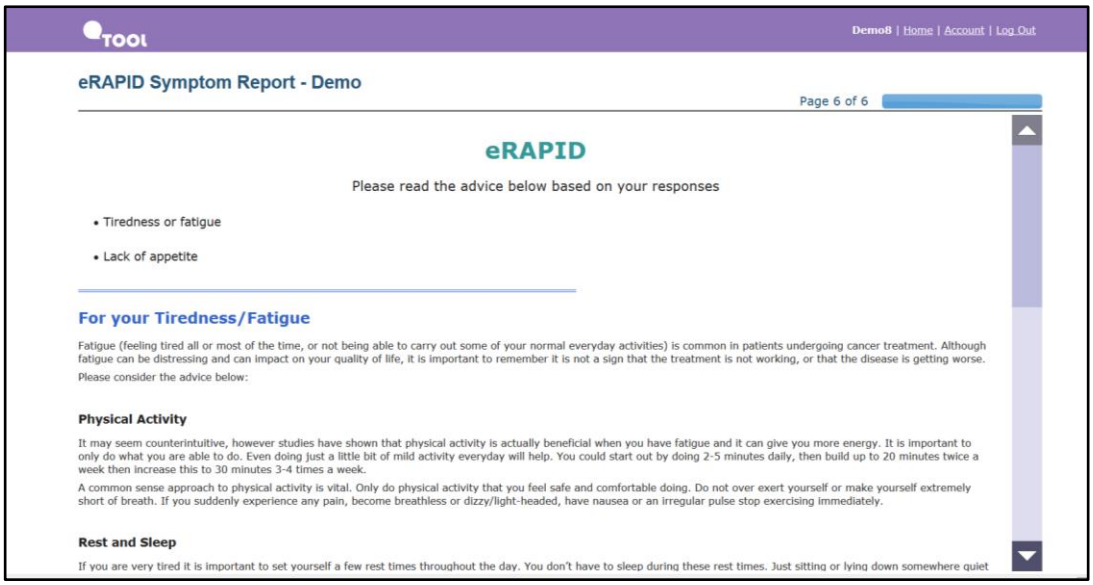
If a patient reports a Level 3 severity for any symptom, a branching question pops up to ask if this is a current problem, or a problem they have experienced previously which has now improved. If the patient reports that they are no longer experiencing the symptom, then Algorithm A2 is triggered. Patients are shown an alert in red text at the end of the

questionnaire that says ‘You have reported that you have been experiencing some serious problems which have now improved. If you have not already been in contact with your medical team, we recommend that you contact them to discuss your symptoms when convenient, or mention them at your next clinic appointment (if in the next 1-2 weeks). If you have already been in touch with your medical team regarding your symptoms, please follow the advice they have given you.’ Self-management advice is provided for Level 3 and Level 2 symptoms.

2.2.1.3.5 Algorithm A1

If a patient reports a Level 3 severity for any symptom, and subsequently indicates that the symptom is a current problem when answering the branching question, Algorithm A1 is triggered. The patient is shown an immediate alert in red text which reads ‘You have indicated a serious problem in this area. We recommend that you contact the hospital now to discuss your symptoms with the medical team (St James's University Hospital 0113 243 3144 and ask for the Oncology Patient Enquiries Bleep Holder). Before you contact the hospital and if you feel able, please complete the remaining questions.’ If the patient continues to complete the symptom report, they will again receive an alert in red text at the end which will read ‘We recommend that you contact the hospital now to discuss your symptoms with the medical team (St James's University Hospital 0113 243 3144 and ask for the Oncology Patient Enquiries Bleep Holder).’ No self-management advice is provided for any symptoms.

Figure 2.6 Example of symptom advice (Algorithm C)

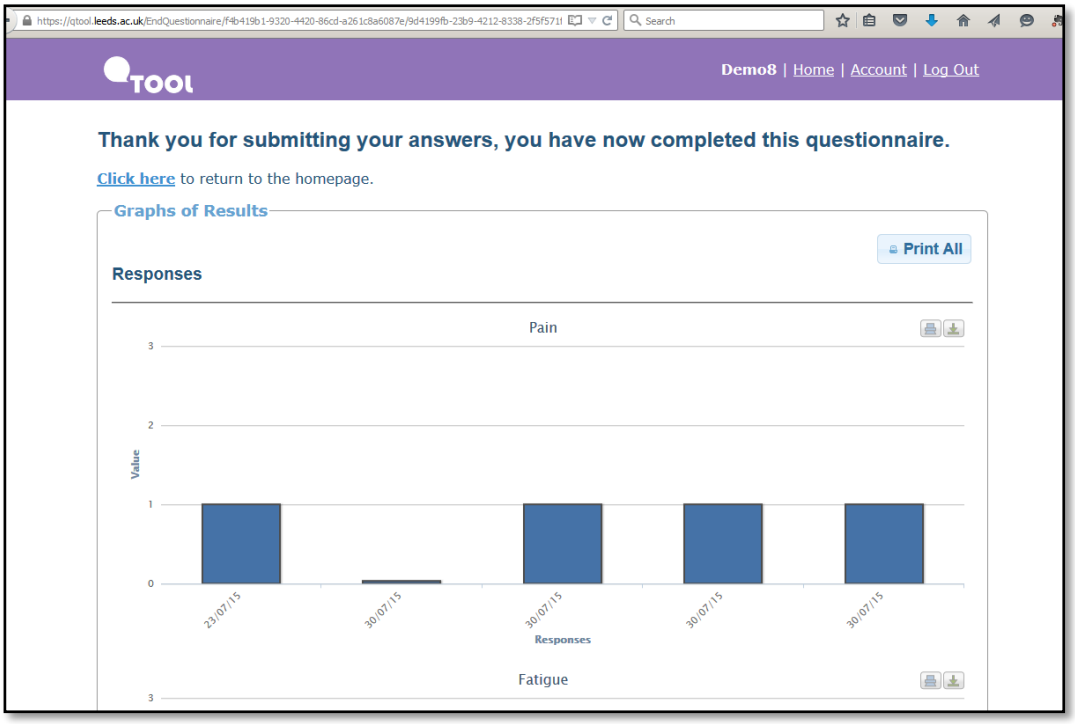


Patients then have the option to email the advice to themselves, or alternatively they can print it out.

2.2.1.4 Symptom graphs

Following completion of the symptom report and provision of the severity related symptom advice, patients are shown a graph for each symptom, representing severity changes over time. An example of the graphs is shown below in Figure 2.7.

Figure 2.7 eRAPID symptom graphs



Patients can then view the graphs of their responses at any time, or view individual completions in tabular form.

2.2.2 eRAPID from the clinician point of view

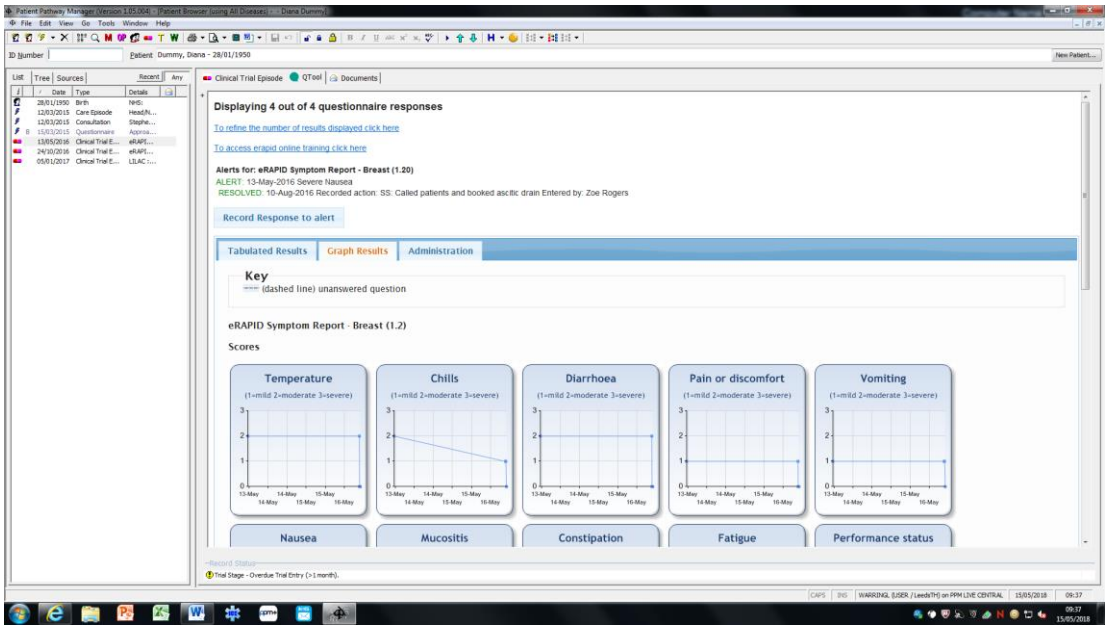
2.2.2.1 Documentation in the Electronic patient record (EPR)

Once a patient completes a symptom report, this is immediately documented in their individual EPR, on the local system Patient Pathway Manager (PPM) (within a four minute period). Clinicians use PPM to manage patient care during chemotherapy by accessing blood results and other clinical information. The eRAPID symptom report data is easily accessible on a tab within PPM, and is accessed in a similar way to blood results. Clinicians are prompted to review patient data in routine and pre-assessment consultations prior to each cycle of chemotherapy.

Clinicians have the option to view patient data in graphical form (see Figure 2.8 for example) or can view the data in a table. Both the tables and graphs automatically show the last six

completed symptom reports, but clinicians can easily configure this to view all symptom reports, or individual reports.

Figure 2.8 Example of clinician view of eRAPID symptom report data



2.2.2.2 Notifications for severe symptoms

When Algorithm A1 is triggered for any patient, an email notification is sent to key members of the patients clinical team to inform them. For data protection purposes, the email does not contain any identifiable information about the patient. The email provides the patient's unique username, and information about the severe symptom, or symptoms, that they have reported. The clinician can then log onto PPM and view a report for eRAPID which shows a list of any severe symptoms reported by patients on study in the last 2 weeks, with corresponding unique usernames. The clinicians can simply click on the relevant username, and will be brought to that patient's individual health record. They can then view more information on the patient's symptom report if they wish, or more importantly, they can check if that patient has contacted the hospital. Clinicians can also make annotations to record if they have contacted a patient or taken any action in response to the alert.

2.3 eRAPID development work overview

eRAPID is a complex intervention and the development work consisted of three separate but related work packages, described below.

2.3.1 Work stream 1: Development and evaluation of the eRAPID electronic platform.

The main aim of this work stream was to develop and evaluate a working electronic platform from which patients could securely complete the symptom assessments from home and receive automated, tailored advice, in addition to the display of symptom reports in patients' individual EPR in the hospital to be viewed by clinicians. The development and user testing of the online systems is described in a published paper [130].

To facilitate symptom reports, an existing web-based questionnaire tool (QTool) previously commissioned by the PCOR group by a private software company (X-Lab) was further developed to meet the needs of eRAPID. QTool had previously been successfully used in a large scale study to collect patient reported data from cancer survivors and link it with cancer registries [131]. The main development needed for eRAPID was the facility to provide automated, tailored advice based on scoring algorithms in response to patient symptom reports, in addition to general improvement of usability and functionality. The PCOR team worked closely with X-Lab to incorporate new functionality using scoring and dependencies to facilitate the use of scoring algorithms, which could then be used to display automated advice based on questionnaire responses.

In order to facilitate the display of patient symptom reports in individual EPRs, a link was created between QTool and the existing electronic health record system PPM used in the Leeds Teaching Hospitals Trust. This link was created via a service called QStore. The main challenge of this task was to maintain security of patient data within the EPR and work within the strict regulations of the N3 network used by the NHS (National Health Service). An

interface was developed for clinicians to view data within individual records via QStore, with a similar interface available for administrators to customise the display of patient reported data in graph and tabulated form.

Usability testing was carried out by members of a patient advisory group (n=2) and a small sample of patients receiving chemotherapy on the day unit (n=14). This usability testing was carried out in conjunction with patient review of the items and advice described in the next section.

2.3.2 Work stream 2: Selection, adaption and evaluation of patient symptom report items, self-management advice and guidelines

The main aim of work stream 2 was to develop the individual items or questions for patient report of treatment side effects, and to develop associated guidelines and self-management advice. To identify the most common symptoms and side effects experienced by patients with breast, gynaecological, colorectal, lung and renal cancer which would be suitable for self-report, an extensive literature review was undertaken, in addition to analysis of a databank of 800 cancer patients' consultations. 16 common side effects were identified and a further three item areas were added after consultation with clinical and patient representatives. Self-report items were developed by the POCR group for each side effect, using criteria which mapped directly on the Common Terminology Criteria for Adverse Events (CTCAE). The CTCAE is commonly used by clinicians to grade patients' chemotherapy toxicities. It was essential that patient self-report could map onto the CTCAE, in order for them to be clinically relevant to staff, and so that clear guidelines for necessary medical intervention could be established based on existing practice.

In order to evaluate the items for comprehensibility and relevance to patients, cognitive interviews were undertaken. 60 patients purposively sampled by age, gender and tumour group (median age 61.5, range 35–84, 12 breast, 12 gynaecological, 13 colorectal, 12 lung and 11 renal) participated. Patients were asked to complete all items on a touch screen computer

prior to taking part in an audio-recorded cognitive interview to explore understanding of each item. Following interviews, 33 amendments were made. 29% of changes related to question comprehension, 68% to response options and 3% to order effects. These amendments to phrasing and language improved patient understanding but maintained CTCAE grading and key medical information. Changes were endorsed by a patient advisory group and clinical staff [132]. The cognitive interviews are described in detail in a published paper [133]. Secondary analysis of these interviews is described in Chapter 3.

Self-management advice for each of the symptoms was collated from local and national guidelines and reputable websites. Advice was iteratively reviewed by patients (N=14) and clinical staff (N=22) during usability testing to ensure comprehensibility and clinical relevance. This advice evolved into two forms – brief, immediate advice to be displayed at the end of the self-report questionnaire for reported symptoms, and more detailed advice (lifestyle advice etc.) for each symptom to be displayed on a separate website for patients to browse at their leisure.

In addition to self-management advice where appropriate, guidelines were developed to identify thresholds for advising patients to contact the hospital. These were developed with expert clinicians from each of the relevant disease groups (breast, colorectal and gynaecological) in keeping with local and national guidelines. These were further developed into a set of algorithms to allow for automated tailored advice on the online system.

2.3.3 Work stream 3: Integration of eRAPID into clinical pathways

The main aim of this work stream was to understand existing care patient care pathways for the management of treatment side effects at St. James University Hospital and to identify how eRAPID could be most effectively integrated. In addition, methods of collecting patient information on contacts with healthcare outside of the hospital and health economics data on

additional costs patients endured as a result of their chemotherapy (e.g. non-prescription medications, travelling costs etc.) were piloted.

In order to map clinical pathways, patients (n=26), carers (n=6) and staff (n=15) at varying stages of the treatment trajectory were interviewed. An audit of the newly introduced local acute oncology service was undertaken, focusing on the telephone triage system. Patients who had unplanned admissions were asked to complete a survey about their experiences (n=40), and a subset (n=26) completed interviews to further explore their experiences. This audit is described in detail in a published paper [21], but some of the most relevant findings from the patient survey and interviews, which were integral in forming the ideas for this PhD are described in Chapter 3.

2.3.4 Field usability testing of eRAPID in a breast cancer clinic

Prior to commencement of the RCT to formally evaluate eRAPID, field usability testing of the system was carried out. The aim was to have end users (staff and patients) use eRAPID in a real life clinical setting to troubleshoot practical issues not identified by standard usability testing [134, 135], in addition to streamlining the processes of integration into clinical practice for both patients and staff. Chapter 4 describes patient experiences from this usability testing.

2.4 eRAPID RCT with internal pilot

Following the successful development of eRAPID, the PCOR team were awarded a further 5 year NIHR programme grant which commenced in July 2013 (Grant Reference Number RP-PG-0611-20,008). The programme grant aimed to evaluate eRAPID in a large scale RCT in systemic therapy, and to develop eRAPID in radiotherapy and surgery. This section focuses only on the evaluation of eRAPID in systemic therapy. The protocol for this study has been published [94]. eRAPID is currently being evaluated in a large scale RCT with patients receiving systemic cancer treatment for breast, gynaecological and colorectal cancers, which is scheduled to finish in October 2018. For the purposes of this thesis, quantitative analysis described in chapter 7 was undertaken part way through the main RCT once a sufficient sample was reached. Details of sample sizes for this thesis are given in individual chapters.

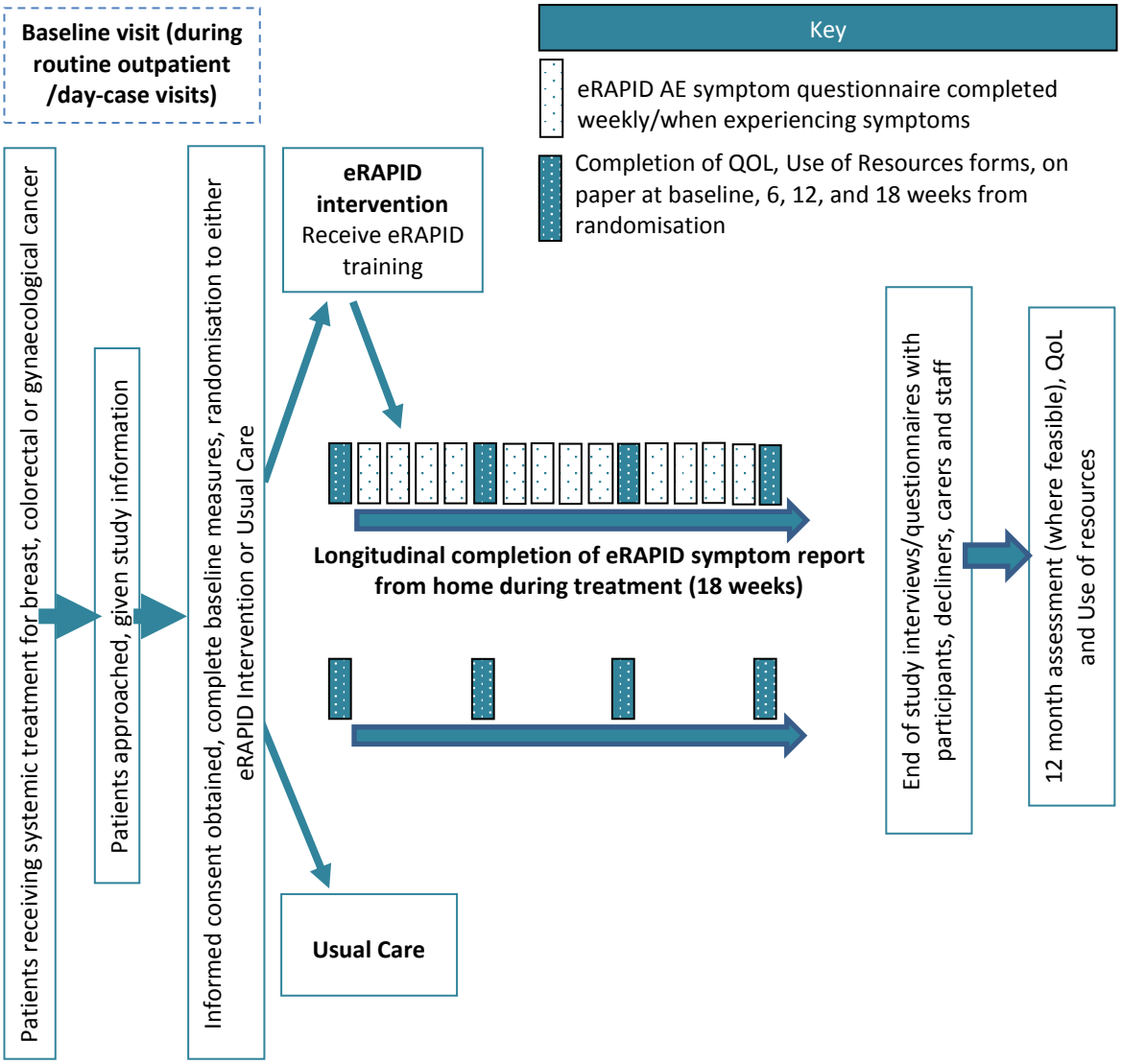
2.4.1 Study design

2.4.1.1 Overview of study design

This study was a single centre; 1:1 allocation prospective randomised two-arm parallel group design with repeated measures and mixed methods with an internal pilot phase.

The internal pilot phase (n=87) assessed the feasibility and acceptability of the intervention and allowed for minor modifications before further large scale recruitment was conducted. As only minor changes were required, the study successfully progressed to the main trial and patients recruited during this pilot phase could be included in the main analysis. The full trial aims to recruit 504 patients using methods established during the internal pilot. Figure 2.9 gives an overview of the trial design.

Figure 2.9 Overview of eRAPID RCT design



Endpoints and analysis

- Patient recruitment rates, attrition over time; proportion of missing data
- Use of resources- including hospital contacts, community health care contacts, medication and additional expenses incurred
- Patient reported outcomes- QOL: FACT-G, EORTC QLQ-C30, EQ-5D
- Clinical process measures- hospital contacts, alerts and hospital admissions, readmissions (with reasons), changes to supportive medications and chemotherapy dose changes, contacts with GP/community services will be extracted from hospital records

2.4.1.2 Usual care arm

Patients are provided with verbal and written information specific to their treatment and expected side effects, and information on what to do and who to contact if they experience problems. During their treatment (which could be weekly, 2-weekly or 3-weekly) patients have

routine consultations with either an oncologist, Clinical Nurse Specialist (CNS) or staff grade doctor to assess and manage treatment side effects and determine if they are well enough to go ahead with their next cycle of treatment. Depending on the severity of side effects being experienced by the patient, treatment doses can be reduced, and/or supportive medications changed (e.g. anti-sickness drugs, anti-diarrhoea drugs). If a patient experiences serious problems during their treatment, they are asked to contact the acute oncology ward and the nurse dealing with the patient phone call uses an Acute Triage Form to record reasons for the call and advice given.

2.4.1.3 eRAPID intervention

In addition to usual care, participants randomised to the eRAPID intervention arm receive training on using the system and are given a user manual and unique login details. Patients are asked to complete the eRAPID symptom report at least once a week and are sent a reminder by text or email. Patients are also encouraged to complete more frequently if they are experiencing problems and require support or advice. The symptom report consists of 12-15 items depending on the disease group assessing the severity of the common side effects such as: nausea, vomiting, pain, fatigue, diarrhoea, constipation, mucositis (sore mouth/tongue), temperature, chills, performance status (general activity level), fatigue, sleep, and appetite. In addition there is a free text option for participants to provide details about any additional problems they are experiencing at the end of the standard questions.

At the end of each symptom report, patients receive automated tailored advice on how to manage their symptoms and a graph is displayed for each symptom showing their responses over time. Patients also have access to the eRAPID website which consists of information on symptoms and side effects, advice about keeping healthy during cancer treatment and information on local services available.

Patient-reported information is immediately available in the EPR for clinicians to view. Clinicians are prompted to review this data at routine pre-assessment appointments. In addition, email alerts are sent to specified clinicians when a patient reports a severe issue. Patients are not informed of this, in order to ensure that patients will contact the hospital when prompted, rather than waiting for a clinician to get in touch with them.

2.4.2 Ethical considerations

The study was approved by the National Research Ethics Service (now part of the Health Research Authority) Yorkshire & The Humber Leeds East Committee in September 2014 (Reference 14/YH/1066). Local approvals from the Leeds Teaching Hospitals NHS Trust Research and Innovation Department were also obtained.

2.4.3 Patient sample and eligibility

Inclusion criteria were adult patients (aged 18 years or over) attending St James University Hospital Bexley wing with gynaecological or colorectal cancer requiring chemotherapy and breast cancer patients receiving adjuvant or neo-adjuvant chemotherapy and metastatic patients receiving their 1st-3rd line of chemotherapy. Patients needed to have been prescribed at least three months of planned chemotherapy cycles at the time of study consent and needed to be able and willing to give informed consent, to read and understand English and have access to the internet at home. Exclusion criteria were taking part in other clinical trials involving the completion of extensive patient reported outcome or QoL measures, exhibiting overt psychopathology/cognitive dysfunction or previous participation in any eRAPID studies.

2.4.3.1 Sample size

The sample size for the full trial is based on the primary outcome (FACT-G Physical Wellbeing scale, see 2.4.6.1). Allowing for 30% attrition, a minimum of 252 patients per arm (504 total) is required for a final sample size of 176 patients per arm (352 total). This is the sample

necessary to detect a 2-point change in scale with 80% power and 5% significance. This change corresponds to a small to moderate effect size (0.3) [136].

2.4.4 Recruitment processes

2.4.4.1 Identification and approach of patients

Patients were recruited from breast, gynaecological and colorectal clinics at St. James University Hospital, Leeds. Eligible patients were identified by clinical staff by screening lists prior to relevant clinics. Clinicians introduced the study to patients at their initial consultation or subsequent pre-assessment appointment prior to starting chemotherapy. Patients were given a patient information sheet (**Appendix 1)** and permission was sought for a researcher to speak to them about the study at that time, or at a subsequent appointment.

2.4.4.2 Consent and randomisation

A researcher met with the patient at a convenient time (usually after their pre-assessment appointment prior to starting chemotherapy). The researcher ensured that the patient had read the information sheet provided and had an adequate understanding of the study to provide informed consent. Patients were given the opportunity to ask questions and if they were willing to participate, they were asked to sign a consent form.

The researcher then randomised the patient to a study arm. Randomisation was performed centrally at the University of Leeds Clinical Trials Research Unit (CTRU) using the automated 24 hour telephone randomisation system. Patients were stratified by cancer site, gender and previous chemotherapy.

2.4.4.3 Patient training

Patients randomised to the eRAPID intervention arm of the study were given a brief training session prior to starting chemotherapy. Training included a short demonstration on how to

access the website and complete the symptom reports. Patients were advised to complete weekly even if they did not experience symptoms.

At their first chemotherapy treatment, patients were provided with a user manual to take home, along with a 'postcard' with relevant contact details, the eRAPID URL, and their unique username and password to access the system.

Patients were encouraged to contact the team if they experienced any problems accessing or using the system, and a phone number and/or email address was taken to send weekly reminders.

2.4.4.4 Completion of baseline outcome measures

Patients were required to complete all baseline measures before their first cycle of chemotherapy. These included a one-off socio-demographic questionnaire which included questions about patients' computer usage, in addition to the baseline completions of the outcome measures specified in section 2.4.5.1.

2.4.4.5 Study follow-up procedures

2.4.4.5.1 eRAPID intervention

Following completion of outcome measures at baseline, patients were required to complete outcome measures again at 6 weeks, 12 weeks and 18 weeks after the date of their first chemotherapy. In addition they were asked to complete health economics data on contacts with healthcare outside of the hospital, list prescription and non-prescription medications and list any additional costs incurred during the previous 6 weeks as a result of their treatment such as travel, parking, food and drink or clothes. Most of the patients in the sample were receiving chemotherapy every 3 weeks which usually coincided with when outcome measures were due. In this case, the researcher would visit the patient on the chemotherapy ward to ask them to complete the questionnaire. If the patient chemo cycle did not coincide with the due date of outcome measures, or the patient was receiving chemotherapy at a different hospital,

the questionnaire was posted out to them and a stamped addressed envelope was provided for its return.

Patients were also asked to complete the eRAPID symptom reports at least once a week and were sent a reminder by text or email. When patients were attending pre-assessment appointments, or clinic appointments, the clinician seeing the patient was prompted to check their eRAPID data and asked to complete a brief feedback form indicating whether they used the data, whether it was useful, and if so, in what way it was useful.

Clinicians were also asked to complete a symptom assessment for each patient at six weeks. This symptom assessment asked clinicians to grade patient symptoms using CTCAE criteria, and the symptoms they were asked to grade mapped directly onto the eRAPID symptom report for that clinical group.

Intervention patients were also asked to complete a system usability questionnaire at 18 weeks.

2.4.4.5.2 Usual care

Patients on the usual care arm of the study were asked to complete the same paper-based outcome measures and health economics data at 6, 12 and 18 weeks, and similarly to the intervention arm patients, these were given to patients to complete on the chemotherapy ward where possible.

Clinicians were also asked to complete a symptom assessment for usual care patients at the six week time point.

2.4.4.6 Withdrawal procedures

All patients had the right to withdraw from the study at any time without giving a reason. Patients could let the researcher know they wished to withdraw from the study via email, telephone or in person. If appropriate, patients were asked to complete a brief feedback form

on their reasons for withdrawal. The researcher completed a withdrawal form which annotated the date of withdrawal and the reasons for it.

Withdrawals were also sometimes necessary for other reasons such as cessation of chemotherapy, or occasionally if a member of the clinical team advised that it was no longer appropriate. For example, some patients' health deteriorated while they were on study and they had to be taken off chemotherapy and referred into palliative care. It was no longer appropriate for these patients to be kept on the study and so they were withdrawn by the researcher.

Initially, all patients who wished to withdraw from the eRAPID intervention were withdrawn fully from the study. However, shortly after the commencement of the main phase of the RCT the eRAPID DMEC (Data monitoring and Ethics Committee) recommended some changes to the withdrawal procedures for the study. The committee discussed the difference between patients withdrawing from the intervention and withdrawing from the trial and raised concerns that the final analysis may be biased.

Following this, some changes were made to withdrawal procedures in Oct 2016. Patient randomised to the eRAPID intervention arm of the study who wished to withdraw from the intervention were given the options to a) Withdraw from the intervention but continue to complete outcome measures and allow their medical information to be collected for the remaining 18 week study period or b) Withdraw from the intervention and completion of outcome measures but allow their medical information to be collected for the remaining 18 week study period or c) Withdraw from the intervention and completion of outcome measures and withdraw consent for collection of their medical information from that point. Similarly patients in the usual care arm had two options a) Withdraw from completion of outcome measures but allow their medical information to be collected for the remaining 18 week study period or b) Withdraw from completion of outcome measures and withdraw consent for collection of their medical information from that point.

Where patients were withdrawn for other reasons (e.g. cessation of treatment and referral to palliative care due to progression), a complete withdrawal from the study was undertaken.

2.4.5 Data collection

2.4.5.1 Outcome measures

Outcome measures were collected from all patients at baseline, six weeks, twelve weeks and eighteen weeks unless otherwise indicated.

2.4.5.1.1 Socio-demographics and computer usage (baseline only)

After consenting to participation in the study, patients were asked to complete a questionnaire to collect socio-demographic information in addition to information on current computer usage.

2.4.5.1.2 Functional Assessment in Cancer Therapy Scale (FACT-G)

The FACT-G [137] is a cancer specific measure widely used in clinical trials. It has four subscales: physical wellbeing, social or family wellbeing, emotional wellbeing, and functional wellbeing. Question responses range from 0-4. Higher scores on the questionnaire indicate better HRQL (score range, 0 to 108).

2.4.5.1.3 EORTC-QLQ-C30

The EORTC QLQ-C30 [138] is a 30-item questionnaire consisting of five functional scales (physical, emotional, cognitive, social, role), three symptom scales (fatigue, pain, nausea/vomiting), a global HRQoL scale, and six single items (anorexia, insomnia, dyspnoea, diarrhoea, constipation, financial difficulties). Questions are rated on a 4 response scale and overall scale scores are calculated from 0-100 with higher scores indicating better quality of life.

2.4.5.1.4 EQ-5D-5L

The EQ-5D [139] is a standardised instrument for use as a measure of health outcome developed by the EuroQol Group. The measure has been used with a range of health conditions and treatments and provides a simple descriptive profile and a single index value for health status that can be used as part of a health-economic evaluation. The instrument assesses five dimensions: mobility; self-care; usual activities; pain/discomfort and anxiety/depression. Each dimension has five response levels (ranging from no problems to extreme problems). The instrument also includes a scale to rate health from 0 (worst health you can imagine) to 100 (best health you can imagine).

2.4.5.1.5 Use of resources form

The use of resources form was included to assess patient use of health resources and the financial impact of cancer treatment. Patients were asked about non-hospital contacts (e.g. appointments with GPs (general practitioners)/community services, counsellors, local support services), as well as medication use and costs incurred as a consequence of cancer diagnosis/treatment. This form is based on those developed by Hulme for a recently completed trial assessing treatment for chemotherapy-related nausea/vomiting (http://www.hta.ac.uk/1723). The forms were evaluated in the eRAPID Programme Development Grant in 15 patients for clarity of concept (missing data), validity, acceptability, feasibility, and revised with user input.

2.4.5.1.6 System Usability Scale and end of study questionnaire (18 weeks only)

Patients on the intervention arm of the study were asked to complete the System Usability Scale (SUS) and an end of study questionnaire at their end of study time-point (18 weeks after baseline). The SUS is a 10 item instrument to assess subjective views of usability of different systems including hardware, software, mobile devices, websites and applications [140]. The 10 items cover the ease of using the system, its complexity and user confidence. Each item is rated from 1-5 and a composite score of overall usability can be calculated ranging from 0-100.

The end of study questionnaire **(Appendix 2)** was developed by the research team to assess patient experiences of using the eRAPID system.

2.4.5.2 Clinical process measures

Research staff collected clinical process information on all patients (intervention and usual care) from patient medical records. This was collected retrospectively at the end of the 18 week study period and included any changes to the treatment plan during the study period (e.g. dose reduction, delay, drug changed), the number of unplanned hospital admissions, number of days spent in hospital and the number of triage events. Triage events included patient phone calls to the acute oncology unit, for which the nurse would complete a triage assessment to determine the course of action, in addition to physical assessments on the unit, where patients would be assessed to determine if there was a need for admission.

2.4.5.3 Patient Interviews

2.4.5.3.1 Pilot phase

At the end of the internal pilot phase, a subset of participants per disease group in the intervention arm were purposively sampled by gender and age and invited for interview. The interview procedures and findings are detailed in full in Chapter 7.

2.4.5.3.2 Full trial

During the course of the trial, between 5-10 participants per disease group and study arm are being invited to interview. These interviews will build on those included in the pilot study by exploring in more depth with both intervention and usual care patients, their treatment experience, how they managed and monitored their symptoms and perceptions of reporting and discussing their symptoms with hospital staff.

2.4.5.4 Staff interviews

2.4.5.4.1 Pilot phase

After the pilot phase a number of health care staff (n=10) were interviewed to determine their views of eRAPID, the perceived value and use of the patient data in clinical practice (e.g. improving the detection, documentation and management of side effects, supporting treatment decision-making in routine care). Perceptions of staff training needs and recommendations for improving the system were also explored.

2.4.5.4.2 Full trial

A further 5 health professionals from each disease group will be interviewed at the end of the full trial.

2.4.6 Study Outcomes

2.4.6.1 Primary outcomes

The primary outcome for the RCT to evaluate eRAPID is the FACT-G [137]. Changes in score over time and differences between treatment arms will be explored using a multilevel repeated measures model. The model for each post-randomisation point will be adjusted for baseline score and stratification factors.

2.4.6.2 Secondary outcomes

Secondary outcomes for the trial are:

1. Cost effectiveness assessed via use of health care services (including telephone contacts and consultations from EPR), medication and personal expenses (from Use of Resources Form). In addition participant records from PPM will be linked to costs held within the local pilot database of the National Patient-Level Information and Costing System (PLICS) scheme. This provides a cost for hospital based accident and emergency department visits, outpatient attendances and inpatient stays. In addition resource use and outcome data (EQ-5D, EORTC QLQ- C30) for a subgroup of participants at 12 months post randomisation will be assessed

2. Number of alerts generated by the eRAPID severe symptom reports
3. Number of acute admissions
4. Number of weekly and additional eRAPID symptom reports completed
5. Comparison of clinician-recorded CTCAE and patient-reported symptom reports
6. Clinicians use of eRAPID symptom information during the consultation
7. Changes to supportive medication
8. Percentage of planned chemotherapy received
9. Changes to chemotherapy dose (dose reductions, delays)
10. Changes to treatment plans
11. Number of contacts with GP/community services from patients with mild/moderate side effects
12. Missing clinical data collected by researchers and the hospital database
13. Number of deaths
14. QoL and well-being (measured by FACT-G, EORTC-QLQ-C30, EQ-5D-5L)

2.5 Methodology of thesis

A detailed description of methods is provided within the individual chapters of this thesis. However, this section aims to give an overall description of the methods used, and a description of how methods were integrated into the eRAPID trial.

2.5.1 Mixed methods approach

Mixed methods is increasingly recognised as a valuable approach in health research, particularly when the area of study or research topic is multi-faceted or complex. The deductive nature of quantitative research allows researchers to control confounding variables and make some generalisations from results. However, quantitative research alone cannot explain the how and why of what is happening, which can be particularly important, not just in the early development stages of research, but throughout the whole process. Qualitative research is more inductive, and research questions may be broad, rather than having a defined hypothesis. While qualitative analysis can provide insight into complex processes, findings are not usually generalizable due to small sample sizes, and as a result, it rarely impacts on policy and practice when used alone. Mixed methods can harness the strengths and balance the weaknesses of both approaches, and is particularly useful for the complex research questions often posed in health research [141].

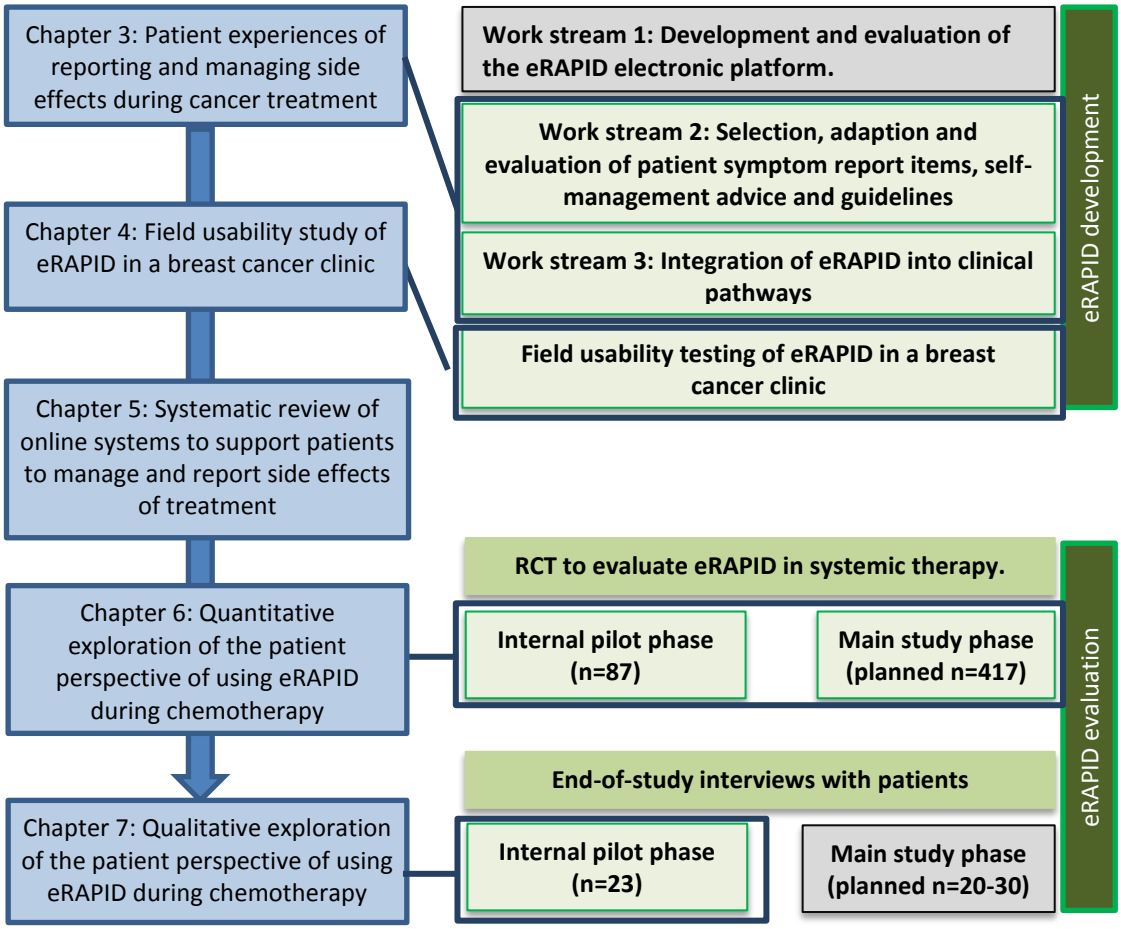
There are five common approaches used. The complementary approach uses findings from one method to illustrate results from another. The developmental approach uses results from one method to develop or inform the use of the other method. The initiation approach uses results from different methods to specifically look for areas of incongruence in order to generate new insights. The expansion approach uses different methods to examine different aspects of a research question. Finally, the triangulation approach uses data obtained by both methods to corroborate findings [142].

This thesis uses a combination of developmental and complementary approaches. The initial qualitative work described in Chapters 3 and 4, in combination with the results of the systematic review described in Chapter 5 informed the design and development of the later work. The qualitative work in Chapter 7 complements and informs the quantitative work described in Chapter 6. Data analysis for both methods of work were undertaken separately. Findings are compared, contrasted and combined in Chapter 8 using triangulation techniques [143, 144].

2.5.2 Integration with eRAPID

An overview of the source of data for each Chapter in relation to the main eRAPID development and evaluation work is outlined in Figure 2.10. Data for Chapters 3 and 4 was collected as part of the eRAPID development. Chapter 5 describes a standalone systematic review which was not integrated into the eRAPID trial. Data for Chapters 6 and 7 was collected as part of the main eRAPID evaluation.

Figure 2.10 Data from main eRAPID development and evaluation used in each chapter



The design of the thesis was closely integrated into the design of the main eRAPID studies and as such there is some overlap between work undertaken to develop and evaluate eRAPID and work undertaken for the thesis. Table 2.2 aims to summarise my specific role in each study, and subsequently where I have made original contribution.

Table 2.2 Role and contribution for each Chapter

Chapter	Design	Role in main eRAPID studies	Original contribution to thesis
Chapter 3: Patient experiences of reporting and managing side effects during cancer treatment	Cognitive interview study to explore patient understanding of self-report items for side effects of treatment (n=60)	Completed about half the interviews and half the transcribing. Completed the majority of the analysis Contributed to the main published manuscript (second author)	Planned and completed secondary analysis of interviews focusing on patient experiences of side effects of chemotherapy. Planned data check with a second researcher.

	Audit of the acute oncology ward. Surveyed patients admitted as emergency cases (n=40) and interviewed a subset of these patients to explore experiences further (n=26).	Administered the majority of surveys and interviews Completed all data analysis and arranged data check with a second researcher. Prepared the manuscript for publication (first author)	Reformatted existing analysis to focus on patient experiences prior to admission.
Chapter 4: Field usability study of eRAPID in a breast cancer clinic	Field usability study with 12 patients receiving adjuvant treatment for early breast cancer. Patients used eRAPID for 4 cycles of chemo (approx. 12 weeks). Feedback collected from staff and patients throughout and patients interviewed at the end of study period.	Assisted in the planning, development and preparation of protocol Had a lead role in implementation, organising and participating in recruitment, follow up and interviewing of patients Developed end-of-study interview schedule Analysed all of data from the study Prepared the manuscript for publication (joint first author, currently under review)	Developed the interview schedule to explore patient experiences of using eRAPID for the purpose of the thesis. Worked with PI and senior researcher to ensure the schedule also covered the necessary topics for the main usability evaluation. Reformatted existing analysis to focus on the impact of eRAPID on patients experiences of chemotherapy
Chapter 5: Systematic review of online systems to support patients to manage and report side effects of treatment	Systematic review of online systems to support patients to report and manage side effects of treatment. A taxonomy of features was developed and evidence on engagement and efficacy was reviewed.	n/a	Responsible for all elements of planning, development and implementation of the review Planned data checks with other researchers (n=3). Prepared the manuscript for publication (first author, accepted for publication 12th October).
Chapter 6: Quantitative analysis to explore the patient perspective of using eRAPID during chemotherapy	RCT with internal pilot (Total n=508). 1:1 randomisation to eRAPID intervention or usual care. Breast, gynae and colorectal patients over 18 week study period. Outcome measures collected throughout the study.	Assisted in the planning, development and preparation of protocol Contributed towards published protocol (third author) Assisted in the planning and preparation of ethics application and completed the online Integrated Research Application System (IRAS) form. Worked as part of the core eRAPID team, responsible	Developed the evaluation of patient engagement with eRAPID. Worked with technical support to set up website analytics and develop reports to assess engagement and adherence. Developed the evaluation of the impact of eRAPID on patient self-efficacy for managing side effects,

		for recruitment and follow-up of eRAPID patients, data collection and the day-to-day management of the study. Lead recruitment and follow up in the breast clinic.	self-efficacy for coping with cancer, and patient activation. Selected the appropriate measures and worked with eRAPID team to incorporate these into the trial design. Planned and implemented all data analysis
Chapter 7: Qualitative exploration of the patient perspective of using eRAPID during chemotherapy	End of study interviews with a subset of patients at the end of the internal pilot phase of the RCT (n=23) to explore motivators and barriers for patient engagement and patient engagement with the system.	Developed end-of-study interview schedule Developed framework for analysis Worked as part of the core team completing interviews Worked as part of the core team completing analysis	Developed the interview schedule to explore patient engagement and patient experiences of using eRAPID for the purpose of the thesis. Worked with PI and senior researcher to ensure the schedule also covered the necessary topics for the main trial. Reformatted existing analysis to focus on relevant topics.

Chapter 3 Patient experiences of reporting and managing side effects during cancer treatment

3.1 Background

3.1.1 Overview

Chapter 1 described some of the literature outlining the challenges associated with managing the many side effects patients experience during chemotherapy. This Chapter further explores these challenges, describing findings from two separate but complementary strands of work undertaken as part of the eRAPID development grant described in Chapter 2. This work builds on previous research by exploring patient experience of treatment with a large number of patients purposively sampled by age, gender and disease group. In addition, the experiences of patients admitted for severe side effects during treatment are explored. This work was hugely influential in developing the initial ideas for the project and highlighted the potential for eRAPID to positively impact on patient experience of chemotherapy in addition to the variation in how patients manage and engage with their health during cancer treatment.

3.1.2 Role and original contribution

As the sole research assistant on the eRAPID development grant, I had a key role on both strands of work described in this chapter. The first strand focuses on findings from cognitive interviews undertaken to evaluate newly developed self-report items for eRAPID (see section 2.3.2). The main aim of the interviews was to explore the understanding, acceptability and clinical meaningfulness of the items to ensure their accuracy and suitability for remote monitoring in routine oncology practice. I worked closely together with the research fellow on the grant to develop, conduct and analyse the cognitive interviews. I also contributed to the writing up of the main results, which were published in 2016 [133]. As part of the interviews, we also asked patients about their experiences of chemotherapy and how this compared to

their expectations. The work described in this Chapter is secondary analysis of the interviews, focusing on these themes. I was responsible for the planning and completion of this secondary analysis. This work has not previously been published as a full manuscript but has been published as a conference abstract [145].

The second strand of work focuses on an audit of the then newly established acute oncology service at St. James University Hospital (see section 2.3.3). The overall aim of the audit was to evaluate the acute oncology service in terms of patient experiences during the admission process and staff utilisation of the telephone triage system. I had a lead role in data collection, analysis and preparation of the results for publication. The main manuscript was published in 2016 [21]. The work described in this Chapter was undertaken as part of the main audit, but the results outlined here focus on patient experiences prior to their admission.

3.2 Aims

The aim of this Chapter is to summarise data from two strands of work to explore factors that influence how patients manage and report symptoms during chemotherapy, and the impact that this can have on their chemotherapy experience.

3.3 Methodology

3.3.1 Strand 1 - Secondary analysis of cognitive interviews

3.3.1.1 Eligibility and patient sample

Patients were eligible if they were over 18 years of age, had breast, gynaecological, lung, renal or colorectal cancer, were undergoing or had recently completed chemotherapy or biological treatment with curative or palliative intent, could read and understand English and did not exhibit overt psychopathology or serious cognitive dysfunction. Interviews were completed in rounds of 20 so that changes could be made to items before recommencing with the next round. We aimed to complete interviews until data saturation was reached, or until 60 interviews were completed. Patients were purposively sampled by age (overall sample 50% over 60 years, 50% under 60 years), gender (overall sample 50% male, 50% female) and tumour group (20% per disease group, Breast, Gynae, Colorectal, Lung and Renal) to ensure representation.

3.3.1.2 Recruitment and study processes

Ethical approval was granted from Leeds East Ethics Committee, on 07/06/2011: REC ref: 11/YH/0159. The cognitive interviews ran from 26th July 2011 to the 27th January 2012.
Patients were recruited from the outpatient, day case and acute oncology admissions units at the Institute of Oncology at St James University Hospital Leeds UK.
Patients were introduced to the research team by clinical staff and written informed consent was obtained. The interview could be carried out at this point, or arranged for a later date, dependent on the patient's preferences.

3.3.1.3 Patient interviews

Semi-structured cognitive interviews were conducted, the main purpose of which was to explore patient understanding of self-report items for treatment side effects, as part of the

development work for eRAPID [94]. Patients were asked to complete 2 self-report questionnaires [133] on side effects of treatment on a touch-screen computer on a single occasion in a private area in the oncology outpatient clinic at St James University Hospital, Leeds. Alternatively patients attending for treatment completed the questionnaires on the chemotherapy day unit, or in their hospital room on the acute oncology assessment unit. Immediately after completion, patients took part in cognitive interviews to explore their understanding of the items. As part of this interview, patients were also asked to elaborate on their experiences of treatment and any side effects which they had reported, and to describe how this compared to their expectations prior to commencement. Interviews were, on average, approximately 45 minutes long and were all audio-recorded.

3.3.1.4 Analysis

Interviews were transcribed verbatim and managed in NVivo version 9 software. The interviews were analysed using thematic analysis. Thematic analysis was selected as it is a flexible method which can be useful to summarise key features of large qualitative datasets, generate unanticipated insights and highlight similarities and differences [146]. An inductive approach was undertaken to identify, analyse and report patterns within the data. Interviews were analysed as they were completed throughout the data collection period and themes were coded as they emerged to create an initial framework. An iterative approach was adopted where interview extracts were reread and recoded by two researchers (LW & TH) several times to ensure all relevant extracts were included, to clarify themes and identify relationships between themes. Any disagreements were resolved by consensus after discussion.

3.3.2 Strand 2 – Patient experiences of acute admissions

3.3.2.1 Eligibility and patient sample

The Trust Research and Development department approved the audit as service evaluation and approval from the local research ethics committee was not required. However procedures were undertaken in line with the DPA (Data Protection Act) [147] and GCP (Good Clinical Practice) guidelines [148].

Eligible patients were those admitted to the acute admissions ward, 18 years or over with a diagnosis of solid tumour or haematological cancer with sufficient English to complete the questionnaire and interview.

3.3.2.2 Recruitment and study processes

During March 2011, we aimed to survey and interview consequtively admitted patients on the Acute Oncology Service (AOS). However, as the majority of admitted patients were acutely unwell and many were undergoing medical procedures, it was inappropriate to approach all patients. Instead, the researcher liaised daily with clinical staff on the ward to identify suitable patients well enough to be approached on that day.

Clinical staff approached patients and introduced them to the researcher. Patients were asked to complete a questionnaire about their experiences of the admission process and following this, those who were well enough and willing were asked to take part in the semi-structured interview to explore their experiences further.

3.3.2.3 Royal College of Physicians (RCP) survey

The questionnaire was developed by the RCP along with local and national cancer research network patient representatives, for the purpose of conducting a national audit of acute oncology services. The 29-item questionnaire asked about diagnosis, treatment regime, symptoms, experience of and satisfaction with the admission process and care within the service. It comprised of 27 closed questions with categorical responses, plus two open-ended questions, and took approximately 15 minutes to complete. We substituted ‘Macmillan Nurse’

with ‘Cancer Nurse Specialist’, and ‘ward 95 or 96’ for ‘Medical Asessment Unit’ to ensure relevance to the local services. The full questionnaire is available online in the RCP working party report [23].

3.3.2.4 Patient interviews

Patients who completed the questionnaire were also invited to take part in a semi-structured interview about their experiences of admission. The interview schedule is outlined in Table 3.1. Interviews were conducted on the admissions unit. Although it was initially planned to audio-record interviews, this proved impractical with patients receiving acute care. Therefore detailed notes were taken which allowed the flexibility to sometimes suspend interviews until a more convenient time, ensuring medical procedures and tests were prioritised.

Table 3.1 Semi-structured interview schedule for admitted patients on the acute oncology ward

Question
Please could you tell me a bit about the problem that led to your admission?
How long did the problem exist before you sought help?
Did you know who to contact for help/advice?
When did you receive information about who to contact?
Who provided the information?
How was the information about who to contact provided? (Written/verbally/both)
Did the information distinguish between what you should do if you had a problem during the night?
What happened when you contacted (insert relevant contact from q3)
What advice were you given?
Did you contact your GP (Did you consider contacting your GP at any time?
What if anything might have improved the process of admission to hospital?

3.3.2.5 Analysis

Questionnaire responses were analysed using cross tabular descriptive statistics (IBM SPSS version 19) and interview data was managed using Microsoft Excel. Thematic analysis was chosen as the most appropriate method for data analysis (see section 3.3.1.4). However, as the purpose of collecting the qualitative data was to provide more in-depth insight into the questionnaire data, a deductive approach was employed. the interview data was assigned to themes which corresponded to some of the key areas covered by the questionnaire. The broad

themes included decision to seek help, information provision, patient knowledge and understanding, routes to admission and experience of care. Two researchers (LZ and LW) assigned the qualitative data to the above themes.

3.4 Results

3.4.1 Strand 1 - Secondary analysis of cognitive interviews

3.4.1.1 Recruitment

A total of 107 patients were approached to take part in the interviews. 60 (56%) patients completed the interviews, 19 (18%) declined to take part, 20 (19%) became ineligible before they were interviewed (e.g. finished treatment) and 8 (7%) were missed (e.g. patients recruited from the acute oncology ward who were discharged before interview).

3.4.1.2 Demographic and clinical data

Table 3.2 displays the demographic and clinic data for patients. As patients were purposely sampled by age, gender and tumour group and there was fairly even distribution on these variables. The majority of patients were receiving chemotherapy (n=49, 81.7%) and only 33.3% (n=20) had chemotherapy previously. Of those 33% (n=20) who had chemotherapy previously, 21.7% (n=13) were on second line treatment, 8.3% (n=5) were on third line treatment and 3.3% (n=2) were on fourth line treatment.

Table 3.2 Demographic and clinical data for patients who took part in the cognitive interviews

	Mean	Standard deviation
Age (years)		
Age	59.6	12.2
	N	**%**
Age group		
Up to 34 years	0	0.0%
35-49 years	14	23.3%
50-59years	14	23.3%
60-69 years	18	30.0%
70+years	14	23.3%
Total	60	
Gender		
Male	27	45.%
Female	33	55.0%
Total	60	
Education		
Up to school leaving age	20	33.3%
Beyond school leaving age	17	28.3%

Degree or equivalent	23	38.3%
Total	60	
Diagnosis		
Breast	12	20.0%
Gynae	12	20.0%
Colorectal	13	21.7%
Renal	11	18.3%
Lung	12	20.0%
Total	60	
Treatment		
Chemotherapy	49	81.7%
Biological therapy	11	18.3%
Total	60	
Curative intent?		
Yes	24	40.0%
No	36	60.0%
Total	60	
Previous chemo?		
Yes	20	33.3%
No	40	66.7%
Total	60	
Treatment line		
1st line treatment (no previous chemo)	40	66.7%
2nd line treatment	13	21.7%
3rd line treatment	5	8.3%
4th line treatment	2	3.3%

3.4.1.3 Thematic analysis of interviews

Three main themes were identified from the data: 1) Perceptions of chemotherapy, 2) Managing and reporting the side effects of chemotherapy and 3) Coping with chemotherapy. An overview of the content of these themes is outlined in Table 3.3.

Table 3.3 Overview of themes identified in interviews

Theme	Description
Perceptions of chemotherapy	This theme described how patients perceived their experiences of chemotherapy, particularly in relation to their prior expectations or experiences with chemotherapy.
Managing and reporting the side effects of chemotherapy	This theme describes some of the challenges patients experienced in making decisions about when to contact the hospital and when self-management was appropriate.
Coping with chemotherapy	This theme describes some of the methods patients reported using to cope with the physical and emotional burden of chemotherapy.

3.4.1.3.1 Perceptions of chemotherapy

Most of the patients that were interviewed reported that they had generally found the experience of chemotherapy easier than they had anticipated prior to starting. Hair loss was a

recurrent theme and for many patients was synonymous with their perception of cancer and cancer treatment, and most patients had suffered it to some degree. However, in relation to other common symptoms such as pain, nausea and vomiting, patients often felt that their experiences of chemotherapy were not as severe as they had expected prior to commencing treatment.

> *"I thought it might be a bit painful, I don't know what I thought the pain would be, because you don't know actually do you, and I mean obviously people lose their hair and I don't know whether you think there's any pain associated with that"*
>
> *(Female, 64 years, Gynae)*
>
> *"I thought I'd be more sick and I thought I'd lose weight, which I didn't. I didn't know what else to expect. I knew I was gonna lose my hair, that was probably the worst thing really... I think I coped alright with it really. Some people, doctors have said oh you sailed through it. Apart from losing all my hair, I feel alright now."*
>
> *(Female, 42 years, Breast)*

The majority of patients in this sample were having chemotherapy for the first time, but many had close friends or family who had gone through chemotherapy before. Patients commonly compared their own experiences to those of their friends and family, and generally seemed to feel that they had an easier time in comparison. However, not all patients felt this way, and one patient felt that his friend's warning of the difficulty of chemotherapy was entirely accurate.

> *"He said it will knock the hell out of you. He said just beware. That was spot on… you feel tired, you just want to give in, just want to give up. Just die basically"*
>
> *(Male, 63 years, Lung)*

Some patients who were having chemotherapy for the first time didn't have any close friends or family who had been through treatment and had limited exposure to cancer and cancer

treatment prior to their diagnosis. For these patients, their perceptions of chemotherapy were heavily influenced by representations in the media, such as newspapers and television. Patients generally felt that the media portrayal of cancer and cancer treatment was much worse than their experiences had been, and caused unnecessary distress.

> *"I anticipated it being a lot worse because it's like I said to my friend, you saw Jade Goody on the TV and it was plastered over the news. I didn't even watch it to be honest, I only just saw clips of it and that was all you needed to see was how ill she was."*
>
> *(Female, 45 years, Lung)*
>
> *"What makes it worse is that you never, ever read in the paper about chemotherapy without it seeing it prefixed with the word 'gruelling' and everybody thinks that chemotherapy is gruelling and it is shit but I didn't even give up work, I have half days."*
>
> *(Female, 51 years, Breast)*

3.4.1.3.2 Managing and reporting the side effects of treatment

Patients reported that they were given information about potential side effects and that they were advised by the medical team to contact the hospital if they were concerned. However, patients were also told that side effects were part of chemotherapy and would be expected to some degree. Many patients described struggling to decide at what point their symptoms were severe enough to warrant medical attention.

> *"They send a card out saying if you get any of these headings, well I got the heading and then I was having to decide in my own mind is it really of sufficient severity to warrant following me up. Well is the patient the best person to be making that judgement?"*
>
> *(Male, 66 years, Colorectal)*
>
> *"You have absolutely no idea. And they don't really give you any guidelines, all they say usually is if there's any problems at all, give us a ring. But that's a flipping generalisation is that..."*
>
> *(Female, 45 years, Lung)*

One patient described how he had suffered from severe constipation for several days before he contacted anyone. The patient was liquidising all his food as his stomach was too painful to eat properly. However as he had been told that constipation was a common side effect of his treatment, he thought that this was normal.

> *"I got told off, 'you are not being soft you must ring us'. Then I got and read my notes properly, oh yes, I should have rung and told them but I just thought it was part of the chemo and something that happens"*
>
> *(Male, 59 years, Colorectal)*

Patients often expressed a reluctance to contact the hospital as they didn't want to 'bother' people and 'waste' staff time, particularly in the knowledge of how stretched hospital resources were.

> *"I would always think a) I'm bothering them and b) the symptoms aren't all that bad. You know, I would really need to be bedbound before I would get in touch with the hospital."*
>
> *(Female, 76 years, Breast)*
>
> *"Well you do think 'Oh they told me I could have this, I don't know if I should ring and bother them."*
>
> *(Female, 49 years, Gynae)*

Patients generally described their healthcare teams as very supportive and helpful, particularly the oncology nurses. However, one patient did describe how an unfortunate experience of a junior doctor being quite dismissive of her pain following surgery subsequently influenced her perception of contacting the hospital about any chemotherapy symptoms she might experience.

> *"The Doctor came round and he made me feel about 3 feet tall. When I couldn't sit up, this little boy, he told me that I must remember I've had a very minor procedure and that I clearly had a low pain threshold. Now, I was absolutely gutted. I felt so bad I couldn't even swear. I couldn't give him anything back at all and then I found out later, he'd done the same thing to another lady on the ward…*

But I am conscious now… I didn't think I had a low pain threshold but it has made me think, would I actually ring the ward if I had pain? I would think if I'm a wuss, do I want to take staff away from someone who is really poorly…?"

(Female, 51 years, Breast)

3.4.1.3.3 Coping with chemotherapy

Many patients wanted to be as informed as possible about their treatment and any potential side effects they might experience. Some patients reported spending a lot of time researching information about potential side effects online, and found it reassuring when they could find out that their experiences were normal and nothing to worry about.

"Sometimes you don't always know if it's relevant or you just being silly because we all have our ups and downs. So if you can just check, I think it's useful to know. Like this thing I had there, it's just a bit swollen. I looked it up online and it said it was a side effect of chemotherapy but I didn't know that. It was reassuring.. because you think well it's something that other people get as well, not just me."

(Female, 64 years, Gynae)

Many patients found that keeping a diary was a useful way to cope with symptoms and side effects, as tracking patterns of fluctuation in their side effects throughout their chemotherapy cycle allowed them to predict the times when they would feel fairly well, and the times when they would feel really poorly. Subsequently they knew what to expect each month and could even arrange social events to correspond with the times when they expected to feel better. In addition, the diarising allowed them to record strategies that had been effective in managing side effects such as nausea, so that they could try these again in the future.

"Someone would say to me 'do you fancy doing coffee next Monday?' and I'd go 'Hang on a minute, no last time Monday wasn't so good, can we leave it till Thursday?', so I didn't put myself under pressure

to arrange something for the Monday and then be thinking oh I actually don't know if I'm going to be well enough."

(Female, Breast, 48 years)

"I started keeping a journal and I found that really useful because I could look back to where I was the previous month and think 'Oh yeah, that happened, or this is to come...' I found it really helpful. I even used to write down things I had eaten that were alright and then you forget, you go back and think, 'Oh yeah, that was alright, I'll try that again'.

(Breast, 48, Female)

Conversely, other patients reported that their approach to coping with the side effects of chemotherapy was to try not to think about it too much. Some patients reported that they hadn't read any of the information given to them by the healthcare team, tried to put it out of their minds as much as possible and just tried to deal with side effects as and when they experienced them.

"I personally never read the side effects of anything I am taking until I have something. Obviously I know about tiredness, I've been on the job so long and sickness… and things like that but I don't read anything else till it happens, just to clarify it is the drug and nothing else. So I'm not one who delves into it....You have enough to worry about"

(Female, 67 years, Breast)

"Like I said, I put my head in the sand; the problems are the problems that you will face. What's the point in my knowing? It only makes you worry…and then you start looking for things."

(Female, Colorectal, 67)

3.4.2 Strand 2 – Patient experiences of acute admissions

Some key results from the audit are presented below. Demographic and clinical data are presented, followed by some key results from the RCP survey, and finally some key findings which map onto the survey results.

3.4.2.1 Demographic and clinical data.

40 patients completed the RCP questionnaire. Table 3.4 displays demographic and clinical information for the sample. The mean age of the sample was 61.1 years old with a standard deviation of 10.6 years. The majority of participants were female (n= 27, 67.5%) and a large proportion were breast patients (n=11, 32.4%). The majority of patients (n=24, 61.5%) were on chemotherapy at the time of their admission.

Of the subset of patients (n=26) who took part in the semi-structured interviews, the mean age was 59.0 years old with a standard deviation of 11.6 years. Again the majority were female (n=18, 69.2%) and on chemotherapy (n=18, 69.2%).

Table 3.4 Demographic and clinical data for patients who completed the RCP questionnaire

	Mean	SD
Age (years)		
Mean and standard deviation	61.1	10.6
	N (Total n=40)	**%**
Age group		
Up to 34 years	0	0.0%
35-49 years	6	15.0%
50-59years	10	25.0%
60-69 years	15	37.5%
70+years	9	22.5%
Total	40	
Gender		
Male	13	32.5%
Female	27	67.5%
Total	40	
Diagnosis (missing n=6)		
Breast	11	32.4%
Colorectal	7	20.6%
Upper Gastrointestinal	4	11.8%
Lung	3	8.8%
Urology	3	8.8%
Haematology	3	8.8%
Gynae	2	5.9%
Sarcoma	1	2.9%
Total	34	
Treatment (missing n=1)		
No anti-cancer treatment at present	8	20.0%
Chemotherapy	24	61.5%
Radiotherapy	4	10.3%
Biological therapy	3	7.5%
Total	39	

3.4.2.2 RCP Questionnaire responses

A summary of the responses for the questionnaire are summarised in Table 3.5. The majority of patients felt informed about potential side effects (n=32, 91.4%) and what to do if they experienced a problem (n=31, 91.2%).

94.3% (n=33) of patients reported that they had followed advice provided when they felt unwell. However, patients contacted a wide variety of health professionals before coming to hospital, with only a small proportion (n=5, 14.3%) contacting the acute oncology ward directly.

In addition, the majority of patients had felt unwell for several days before being admitted. 25.7% (n=9) felt unwell for 2-3 days and a further 31.4% (n=11) felt unwell for 4 days or more. Of the 29.7% of patients referred from a routine outpatient appointment, 60.0% (n=6/10) had felt unwell for 4 days or more, 30.0% (n=3/10) had felt unwell for 2-3 days and the remaining 10% (n=1/10) started to feel unwell the day before (missing n=1).

Table 3.5 RCP questionnaire responses

	N (Total n=40)	%
Have you been told about any problems that you could develop which are related to side effects of any cancer treatment you have had? (missing n=5)		
Yes	32	91.4%
No	3	8.6%
Total	35	
Did you feel prepared about what to do and who to contact if you had a problem? (missing n=6)		
Yes	31	91.2%
No	3	8.8%
Total	34	
Prior to this hospital admission, were you given information on what to do if you became unwell? (missing n=6)		
Yes	34	100.0%
No	0	0.0%
Total	34	
On this particular occasion, did you follow it? (missing n=5)		
Yes	33	94.3%
No	2	5.7%
Total	35	
If you contacted anyone for advice or help before attending hospital, who? (missing n=5)		
Own GP	2	5.7%
Out of hours GP	1	2.9%
Cancer Nurse Specialist	6	17.1%
Hospital consultant/secretary	6	17.1%
Wards	4	11.4%

Other	3	8.6%
Acute oncology ward	5	14.3%
Came directly from clinic/hospital app	6	17.1%
District Nurse	2	5.7%
Total	35	
How were you admitted to hospital? (missing n=3)		
Sent by the GP	2	5.4%
Referred from hospital clinic that same day	11	29.7%
I/Carer called an ambulance	4	10.8%
Drove ourselves in to ward 96/97	12	32.4%
Other	8	21.6%
Total	37	
When did you first start to feel unwell before you went to hospital? (missing n=5)		
Same day	12	34.3%
Day before	3	8.6%
2-3 days before	9	25.7%
4 or more days before	11	31.4%
Total	35	

3.4.2.3 Thematic analysis of interviews

Results described below broadly map onto the survey responses outlined in Table 3.5. Two separate themes were identified– 1) Provision of information on managing side effects (reflecting questions 1, 2 and 3) and 2) Pathway to admission (reflecting questions 4, 5, 6 and 7).

3.4.2.3.1 Provision of information on managing side effects

The interview data also supported that patients felt well-informed and were given both written and verbal information quite early on about side effects, who they should contact and what to do if they felt unwell.

> *'At the initial consultation, pre-chemo, I was given sheets of information'*
>
> *(Female, 55 years, Colorectal)*
>
> *'The oncology nurse emphasised high temperature being important'*
>
> *(Female, 52 years, Breast)*
>
> *'Right at beginning of treatment there was a card with everything highlighted - different person to ring during day and night'*
>
> *(Female, 41 years, Breast)*

3.4.2.3.2 Pathway to admission

However, the interviews also revealed that despite reporting feeling informed about what to do and who to contact if they had a problem, patients often found it difficult to apply this information to their own situation and decide whether their symptoms were enough of a 'problem' to warrant contacting the hospital, or whether they were a normal part of the chemotherapy experience. Subsequently, many patients delayed contacting the hospital.

'I was given a number to ring before I started treatment but what all the leaflets and booklets don't do is put things into perspective'

(Male, 38 years, Testicular)

'I thought it was just par for the course'

(Male, 74 years, Upper GI)

'It would help if there was a direct line for "phoning in" to ask if something is normal or ask for advice'

(Female, 59 years, Breast)

As highlighted by the questionnaire data, the majority of patients who were admitted from a routine clinic appointment had been unwell for at least several days prior to their admission. This would indicate that patients delayed contacting the hospital if they had an upcoming appointment, and this was supported by the interview data.

'I had vomiting all last week from chemo and radiotherapy. From Monday it was very bad but I had a clinic appointment so I just waited until then'

(Female, 71 years, Colorectal)

'I didn't consider ringing because I knew about my outpatient appointment'

(Female, 59 years, Breast)

For some patients, their condition had deteriorated quite a lot during this wait and they regretted not contacting someone earlier.

'Yes, coming in earlier would have been better because now I'm very dehydrated – I've just been struggling through.'

(Male, 38 years, Testicular)

Other patients made a conscious decision about when to contact the hospital in order to fit a potential admission around other priorities such as family gatherings.

'I've had constipation since last week but I had family coming to visit so I decided to wait to come in today'

(Female, 59 years, Breast)

'I'd been unwell since Saturday. I didn't ring over the weekend because I had plans and was keen to keep them. I phoned this morning because of the nose bleeds, cold, headache and rash on my head'

(Female, 40 years, Breast)

3.5 Discussion

3.5.1 Summary of findings

The aim of this Chapter was to summarise data from two strands of work to explore factors that influence how patients manage and report side effects during chemotherapy, and the impact that this can have on their chemotherapy experience.

The first strand of work described patients' perception of chemotherapy and their experiences in managing and coping with cancer and treatment. Patients often used downward social comparison and positive framing to describe their experiences. Most patients felt that they were having a relatively easier time with side effects compared to the experiences of friends and family who had been through chemotherapy, and compared to representations of chemotherapy in the media. Patients commonly describe experiences of chemotherapy in this way, and often give quite severe accounts of symptoms and side effects while maintaining that experiences are 'not that bad', particularly in comparison to other patients, which may be part due to a desire to be seen as a 'good' patient and not wanting to be seen to complain [24, 149, 150]. This downward social comparison and positive framing may be beneficial as a coping strategy, however there may be negative consequences associated. Although patients reported that they felt well informed about what to do and who to contact if they experienced problems with their cancer treatment, they often found it difficult to decide when exactly a side effect became a 'problem' and when it was just a normal part of the treatment experience. Patients were sometimes reluctant to seek medical attention for their symptoms as they didn't want to 'waste' the time of healthcare staff or take valuable resources away from other patients who might have a greater need. This is similar to previous work in this field which found that patients are not always confident making decisions about when to seek medical attention for chemotherapy side effects and often delay until symptoms escalate [12, 20].

The second strand of work also supported this. The results from the RCP survey indicated that although around a third of patients did contact the hospital on the initial day of experiencing symptoms a significant proportion had severe symptoms for up to 4 days (sometimes a week) before they were admitted to hospital and this was especially true if they had a routine clinic appointment approaching. The interview data again indicated that this delay in contacting the hospital was most often due to dismissing symptoms as 'normal' and being unsure about the need for medical attention. However, a couple of patients did report deliberately avoiding contacting the hospital about symptoms in order to fit potential hospital admissions around family life, highlighting the influence of a wider social context on how patients manage symptoms. Again, this is similar to other findings in the field [20, 25, 28].

In the first strand of work, many patients reported keeping a diary or journal throughout chemotherapy so that they could identify patterns in fluctuations of symptom severity, and subsequently identify times during the treatment cycle when they could expect to feel well, and plan social events around these times. Previous research has shown that diary keeping during chemotherapy can potentially improve patients' self-efficacy to manage their side effects and cope with their cancer treatment [151]. Conversely, other patients reported that they preferred not to read too much about potential side effects and preferred just to deal with them as and when they experienced them, potentially reflecting a more passive or avoidant coping style [152]. Patients who utilise these types of coping styles may have lower psychosocial distress but lower quality of life [153, 154].

3.5.2 Strengths and limitations

This work adds to literature on patient experience during cancer treatment and the variation in information given and action taken by patients when managing health at home.

The strengths of the first strand of work, the cognitive interview study, were a relatively large and representative sample, with sixty patients purposively sampled across age, gender and

disease group, all of whom were currently undergoing, or had recently completed cancer treatment. However, this was secondary analysis of the interviews, the main focus of which was to evaluate self-report items for the purposes of eRAPID. We asked patients retrospectively about their prior expectations and perceptions of chemotherapy, sometime after beginning treatment. Patients' recollections and perceptions are likely to have been heavily influenced by their actual experiences during chemotherapy. In addition, the analysis did not separate or take into account patients who had previous experience of chemotherapy. Again, these previous experiences are likely to have impacted on the experiences reported, and on patients' confidence in managing side effects of treatment. For example, patients who are undergoing their second or third line of treatment are likely to be more confident making decisions on when they need to contact the hospital for their symptoms. In addition, the intention of treatment (curative or disease control) may have a huge influence on how patients perceive their symptoms and what they are willing to tolerate [10, 24]. However, this data still provides valuable insight into patients' perceptions and experiences of treatment. The strengths of the second strand of research, the audit of acute oncology services were again, a relatively large sample for this patient group, with forty patients completing the survey and a further twenty six completing the interviews. However, only patients who were actually admitted to the unit and were fit and well enough to be interviewed were included in the sample. Patients who called the unit and received self-management advice or who attended the unit for assessment and were subsequently discharged were not interviewed, nor were a number severely ill patients who were admitted. Interviewing these patients may have provided a more comprehensive insight into the range of experiences patients had when contacting the hospital for symptoms and side effects. In addition, due to the nature of patients' condition, interviews needed to be kept brief, and it was not possible to audio-record interviews, which may have limited the integrity of data analysis.

3.5.3 Conclusion

Patients often experience difficulty managing the uncertainties around when and how to report and manage side effects of cancer treatment. Despite being provided with information and guidance, patients find it difficult to apply this to their own situations, and often have concerns about wasting healthcare resources. Subsequently they may delay contacting the hospital when experiencing side effects, which may result in escalation of side effects and hospital admission.

The next step in the eRAPID development work (as briefly described in Chapter 2) was to undertake field usability testing of eRAPID in a real life clinical setting. This provided an opportunity to explore how eRAPID might support patients to overcome some of these difficulties.

Chapter 4 Field usability study of eRAPID

4.1 Background

4.1.1 Overview

Chapter 2 described the eRAPID system and provided an overview of the development work undertaken, including a field usability testing study. The work described in Chapter 3 highlighted some of the challenges patients face reporting and managing side effects of cancer treatment, in particular making decisions about when to contact the hospital and when self-management of symptoms is appropriate. I was interested in how eRAPID could potentially support patients to overcome some of these issues by empowering them to make informed decisions about managing side effects. Access to tailored severity dependent symptom advice could provide patients with the practical support needed to know when self-management was appropriate without the need to 'bother' anyone and also, giving 'permission' for them to contact the hospital when they needed to do so. Similar to keeping a diary, patients could use eRAPID to record and monitor fluctuations in symptoms over each cycle of chemotherapy to identify times when they were likely to feel well and support planning social activities.

Field usability testing of eRAPID presented a good opportunity to explore how patients engaged with eRAPID and how the system supported them throughout their treatment. This chapter describes some of the findings from this testing. I was particularly interested in focusing on the patient perspective and the potential psychological benefits that eRAPID might have.

The overall purpose of the usability study was to have the end users (staff and patients) use eRAPID in a real life clinical setting. As described in Chapter 2, extensive usability testing had already been undertaken and both patient and staff representatives were involved throughout

the development process following recommended usability principles of agile development and formative evaluation [19, 155].

A considerable amount of work had also been undertaken to map existing clinical pathways and identify where eRAPID might fit in. However, field usability testing can be a useful tool to troubleshoot practical issues that may not be identified by standard usability testing [134, 135]. This was an important step to streamline some of the complex processes of integrating eRAPID into clinical practice for both patients and staff, prior to the commencement of the RCT.

Specifically the overall aims of the usability testing were to ensure that 1) training provided to both patients and staff was sufficient and feasible, 2) that procedures for patient completion and staff access of eRAPID symptom reports were feasible to both parties, 3) that symptom advice was useful and relevant to patients and 4) that the safeguards put in place for when severe symptoms were reported by patients were safe and reliable. The reliability of the eRAPID system from an IT perspective was also assessed.

For the purposes of this thesis, the usability study also provided an opportunity to explore how patients engaged with eRAPID, both in terms of adherence to weekly symptom report completions, but also in terms of how they interacted with eRAPID. End of study interviews would provide valuable insight into patients perception of how eRAPID impacted on their experience of chemotherapy, in order to inform the planning and design of the next stages of the thesis.

4.1.2 Role and original contribution

I had a key role in the planning, development and implementation of this usability testing. I contributed to the protocol and designed the evaluation tools. Specifically I developed the patient user manual with feedback questions and the interview schedule to explore patient experiences for the purpose of this thesis, while working closely with the principal investigator

and senior research fellow to ensure that requirements for the main usability testing were also met.

I led the recruitment and follow-up of patients, with support from other members of the research team. I analysed the end of study interviews, in addition to the written and verbal feedback and collated this into an end of study report, to identify issues prior to the RCT. I have written up the full results of the usability testing as a publication which was recently published in BMJ Open [156]. I have also briefly described the work in a published paper [157] discussing how the eRAPID model of care could potentially be applied to cancer survivorship and presented it as a conference poster [158].

4.2 Aims and objectives

The aims of this work were to:

1) Assess patient engagement with eRAPID over a 12 week period by adherence to weekly symptom reports
2) To explore barriers and facilitators to patient engagement by end of study interviews
3) To explore patient experiences of using eRAPID during chemotherapy by end of study interviews

4.3 Methods

4.3.1 Ethical considerations

The field usability testing took place within the Breast Oncology Service at St James University Hospital, Leeds. The Leeds Teaching Hospitals Trust Research & Innovation department approved the project as service evaluation and approval from the local research ethics committee was not required. However procedures were undertaken in line with the DPA (Data Protection Act) [147] and GCP guidelines [148].

4.3.2 Study design

4.3.2.1 Patient sample and eligibility

Patients were eligible to take part if they had a diagnosis of early breast cancer and were about to begin adjuvant or neo-adjuvant systemic treatment with at least 4 cycles planned. Patients were also required to have internet access at home and a sufficient level of English to complete the symptom assessment and understand the self-management advice provided. Patients could not be exhibiting overt psychopathology, which was assessed by clinical staff.

4.3.2.2 Recruitment processes

Eligible patients were identified by a breast oncology research nurse. Prior to starting their chemotherapy, patients were approached at clinic appointments by the oncologist or CNS, who introduced and briefly explained the eRAPID study. Interested patients were given an information sheet and introduced to an eRAPID researcher for further information. If patients were willing to speak to the researcher, information and/or training were provided in a private room in the clinic.

4.3.2.3 eRAPID demonstration and training

Researchers explained the purpose of the testing and gave patients a brief demonstration on how to access and use eRAPID. The researcher arranged to meet patients at their first chemotherapy visit, when they would be given an eRAPID unique username and password, in addition to a user manual. Patients were asked to complete the remote eRAPID symptom assessment weekly and when experiencing side effects/symptoms over their 4 cycles of chemotherapy treatment. In order to prioritise patient safety, it was strongly emphasised to patients that eRAPID was still under development and was not intended to replace any information or advice they had already received. Patients were advised to contact their clinical team if they had any concerns about symptoms or side effects.

4.3.2.4 Clinical staff use of eRAPID symptom reports

All clinical staff involved in the patients care were provided with training on how to access and interpret the eRAPID symptom reports. Prior to patients' scheduled pre-assessment or clinic appointments, the researcher prompted clinical staff to access and use available eRAPID symptom reports. Clinical nurse specialists (CNSs) tended to see patients for pre-assessment appointments before each cycle of chemotherapy. Patients also tended to have at least one clinic review appointment with an oncology consultant or registrar during the 12 weeks. Patients with more complex needs tended to be seen more often by the oncology consultants.

4.3.3 Evaluation methods

4.3.3.1 eRAPID symptom report completions

Acceptability of the system was assessed by the overall number of symptom report completions, and adherence to the weekly completion guidelines i.e. the number of weeks in which patients had at least one completion.

4.3.3.2 Written and verbal feedback

Researchers visited patients on the day ward when they were receiving chemotherapy, and at routine hospital appointments to answer queries they might have and to ask for their feedback on using eRAPID. Any queries or comments were documented. Patients were also provided with email and telephone details to contact the research team with any comments or queries, which were also documented.

The step-by-step user manual provided to patients (kept for the duration of the project) included a short assessment consisting of questions about how easy/difficult they had found tasks and patients were encouraged to add feedback or comments and return the manual at the end of the 12 week period.

4.3.3.3 Semi-structured interviews

Patients were interviewed at the end of the 12 week study period to gain more in-depth feedback on their experience of using eRAPID. The interview schedule explored patients' views of the accessibility and acceptability of eRAPID, in addition to their general views of using the system and how it impacted on the management of their symptoms and side effects during chemotherapy. The full interview schedule is outlined below in Table 4.1.

Table 4.1 Interview schedule for end of field usability study

Question	
Technical	- Did you find the eRAPID system easy to use? Were there any aspects of it you found difficult? - Did you have any difficulties finding the site, logging in etc? If so, how did you resolve them? - Do you have suggestions on how we might improve the system? - Did you use the user manual we gave you? Do you have any suggestions for how we might improve that?
Practicalities	- We asked you to complete the eRAPID questionnaire every week, and at any point you felt unwell. Did you find this manageable? Did you find it a burden to complete the questionnaire? - We approached you at your first clinic appointment, and then saw you again at your first chemotherapy appointment. Do you think this is a good time to approach patients? Are there any other times when you might come in around this time that you think would be more suitable? - How did you find the level of information given to you by the research team? - Did you have any alerts triggered for severe symptoms? Did you feel it was relevant to you? What are your views on this?

General views on using the system	- What were your expectations of using the eRAPID system (if any)? Were your expectations met? - Were there any advantages to using the system? - Were there any disadvantages to using the system? - Did you make any specific plans as to when you would complete the questionnaire? Did you set any reminders for yourself, or have a specific time which you completed it at? - Has it been difficult for you to complete the questionnaire on a weekly basis? How confident are you that you would be able to access the system on a weekly basis throughout the course of your treatment? Is there anything we could do to make this easier for you or other patients? - What factors might prevent you from using the eRAPID system? What factors might help you to access the eRAPID system? - Do you think other patients will be likely to use eRAPID? Do you think other patients would find it useful? - Was there anything you enjoyed or found pleasant about completing the questionnaire? Was there anything upsetting or unpleasant about completing the questionnaire?
Self-management	- Do you think that the system accurately assessed your symptoms? E.g. The types of questions asked, the severity level, etc. - Did you find the information on the eRAPID website useful? Did you use any of it? - Do you think that using the system had any effect on how you managed your symptoms and side effects?
Perceived role of staff/carers	- Did the doctors/nurses in charge of your care use the system in the way you thought they would? - Do you think the doctors/CNSs in charge of your care found the system useful? - Do you think that using the system influenced your consultations with the doctors/nurses in any way? If so, how? - Did anyone else (such as a relative) help you use the system? Do you think they found it useful?
Perceived influence on treatment/care	- Did you have any medications prescribed or changes in treatment because of reporting symptoms on the system? - (If had any notifications). Do you feel that this was dealt with appropriately? If not, how would you have liked it to be dealt with?
Any other	- Do you have any other comments or questions about your involvement with eRAPID?

4.3.3.4 Analysis

In the first instance a pragmatic approach to analysis was employed to identify usability or integration issues which might need to be addressed quickly and discussed with the project management team. Verbal feedback and written comments from the user manuals and written feedback forms, and issues identified from the end of study interviews were collated and subsequently categorised into themes (determined by the aspect of the system) using Microsoft Excel. At a later date, interviews were transcribed verbatim and managed in NViVO

version 9 software. Patient anonymity was maintained by allocating study numbers to participants.

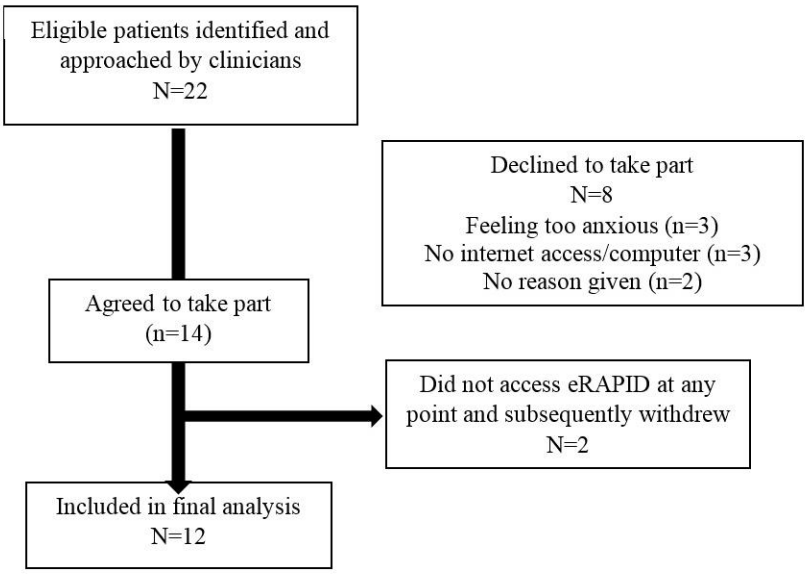
Interviews were then later coded and analysed thematically using an inductive approach (see section 3.3.1.4) [146]. The researcher (LW) created an initial framework by coding themes as they emerged. An iterative approach was adopted where interview extracts were reread and recoded several times to ensure all relevant extracts were included, to clarify themes and identify relationships between themes. A second researcher (TH) analysed 10% of the interviews separately, where differences occurred these were resolved via consensus to ensure inter-rater reliability.

4.4 Results

4.4.1 Recruitment

The testing period ran from mid-January 2014 to mid-March 2014. 22 patients were approached, 14 of which (63.6%) agreed to participate in the usability testing. However, 2 of these patients did not access the system at any point and subsequently withdrew, leaving 12/22 (54.5%) patients who actually participated. Figure 4.1 illustrates the recruitment process.

Figure 4.1 CONSORT diagram of recruitment



4.4.2 Patient sample

All 12 participating patients were starting adjuvant or neo-adjuvant chemotherapy treatment for early breast cancer. Patients had a mean age of 47.5 years (SD=10.3) with an age range of 33-73 years. Non-participants were of similar age (M=51.7, SD=12.6). Demographic information was not collected.

4.4.3 eRAPID symptom report completions

Patients were asked to complete the eRAPID symptom report at least once a week over the 12-week period. However, engagement with the system was variable between patients. 42% (5/12) of patients completed the symptom report 11-13 times, 33% (4/12) of patients completed 7-9 times and 25% (3/12) completed 4-6 times. Adherence to weekly completion (i.e. actual/expected completions per patient) ranged from 33% to 92% with an average of 63%.

4.4.4 Written and verbal feedback

All 12 patients provided some form of feedback throughout the duration of the study. A total of 25 verbal feedback comments were collected from patients at routine hospital appointments. In addition, we received one unscheduled email and one unscheduled phone call from two different patients. Only 3/12 patients (25%) returned the user manuals at the end of the study. The remaining patients reported that they had not needed to use the manuals, so had not provided feedback.

The majority of comments and feedback collected related to general usability of the system and practicalities of completion (e.g. patients forgetting to complete, or informing us they were having computer trouble). We also received feedback on specific aspects of the system such as the wording of the symptom reports, and the alerts system which resulted in changes to eRAPID prior to the RCT.

4.4.5 Thematic analysis of end of study interviews

11/12 patients who took part in the usability testing also participated in the end of study interviews. One patient was not interviewed as she was too anxious and struggling with the burden of chemotherapy at that time.

Two main themes were identified. The first theme related to patient engagement with eRAPID. Four subthemes were identified within this, which encompassed the main barriers and

motivators to patient engagement with eRAPID. The second theme related to the perceived benefits of the system described by patients. Three subthemes were identified within this which encompassed the impact of eRAPID on patients' confidence to manage symptoms and side effects, and support them in coping with cancer. The main themes and subthemes are outlined in Table 4.2.

Table 4.2 Main themes and subthemes of end of study interviews

Main theme	Subtheme
Patient engagement with eRAPID	Accessibility and acceptability of eRAPID
	Remembering to complete symptom reports
	Health status during chemotherapy
	Perception of staff use of eRAPID
Perceived benefits of eRAPID	Increasing knowledge and confidence
	Supporting decision-making on contacting the hospital
	Support for coping with cancer

4.4.5.1 Patient engagement with eRAPID

The end of study interviews explored some of the common barriers and motivations patients experienced for engaging with eRAPID and completing regular symptom reports.

4.4.5.1.1 Accessibility and acceptability of eRAPID

Patients generally found the system very easy to use, and none of the patients reported any problems with accessing the system, and all of them felt confident that this would be something they could continue to do on a weekly basis if they needed to do so.

> *"I found it really easy to use and believe me, if I can use it, anybody can."*
>
> *(P02, Female, 44 years, Breast)*
>
> *"It was quite easy to use. If I can use it anyone can because I'm not really into technology."*
>
> *(P08, Female, 40 years, Breast)*

However, one patient did comment that while she herself found it easy to complete, she thought it might be difficult for older, or less computer literate patients, particularly if they were feeling unwell throughout their treatment.

"It's how you feel on chemo. Whether it's an easy thing for you to do in terms of… not just physically but you know… sort of… if you are computer savvy and you're not scared by it. I mean I think about someone like my mum and she'd be freaked out and she couldn't do it. Yeah she would find it stressful just to be online and worrying that she'd get it wrong."

(P04, Female, 49 years, Breast)

4.4.5.1.2 Remembering to complete symptom reports

Some patients were not initially clear on how often they should be completing the symptom reports. Although all patients were asked to complete once a week, this seemed to get lost with all the other information patients were receiving at that time.

"I didn't know I had to do it every week, that's another thing. You probably told me, but because of everything else that was going on… because I think what I took from talking to you is oh just fill it in when you feel unwell. I've just cottoned on to that one part, that's not all you've said to me, you've said do it every week and if you feel unwell and I've just thought… because if you're well, you'll never fill it in will you."

(P08, Female, 40 years, Breast)

In addition, even when patients were aware that they should be completing the symptom reports weekly, some reported that they had difficulty remembering to do this, and suggested a text/email prompt to remind patients when they needed to complete.

"I don't know really…I suppose not unless you could trigger the e-mail reminder probably, we do check e-mails, yeah. And then people…it's a reminder, and if they do it they do it I suppose, and it's not a great pressure but yeah, it would be more useful, because I must admit, time flies by – or a text alert, that might be easier."

(P12, Female, 50 years, Breast)

4.4.5.1.3 Health status during chemotherapy

Some patients described how they felt less inclined to log on and complete the eRAPID symptom report when they were feeling well. One patient described how while she found it useful when she felt ill, it just wasn't a priority when she was feeling better as she was too busy catching up with other things that she had been unable to do when she was poorly.

> *"When you're poorly, it's a priority and then it goes out of the door when you're feeling better because you're doing a hundred and one things to catch up it goes kind of…it slips to the back"*
>
> *(P12, Female, 50 years, Breast)*

Conversely, other patients reported that they found it more difficult to motivate themselves to log on and complete the symptom report when they were feeling more poorly, especially if they were feeling tired and lethargic.

> *"I must admit when I was feeling worse, which is probably the times when I could do with doing it, I think it's more lack of energy and stuff, enthusiasm to do it, so it's maybe kind of a couple of days later"*
>
> *(P12, Female, 50 years, Breast)*
>
> *"Sometimes you feel so ill that you can't be bothered to log on"*
>
> *(P02, Female, 44 years, Breast)*

4.4.5.1.4 Perception of staff use of eRAPID

Some patients were aware of clinical staff using their symptom report data when they came to hospital for pre-assessment or clinic appointments and felt that having this information available to clinical staff was really useful. Patients generally had these appointments every three weeks and some commented that was sometimes difficult to remember the symptoms they had experienced in the first week. They felt that eRAPID provided clinical staff with a better overview of how they were, by prompting discussion of symptoms that they might otherwise have forgotten to mention.

> *"I think it's very good for the discussion with patients because you can immediately see what problems they've had and as I've said, it's hard when you*

come, to remember what you were like 3 weeks ago. So it's really good to have a record there. I think that's one of the biggest benefits actually."

(P04, Female, 49 years, Breast)

However, other patients were unsure of whether or not the clinicians were accessing their data. One patient thought that it would be useful for staff to be more explicit with patients about their use of the data, so that patients would be more motivated to complete regularly.

"If it's that easy for them to just bring it up and then see, they can then say to the patient 'Oh did you have some trouble with whatever, this is what advice you have…' and then the patient would think oh, they actually are bothered. So I think it would be a full circle thing."

(P10, Female, 33 years, Breast)

4.4.5.2 Perceived benefits of eRAPID

Generally, patients found eRAPID a useful and valuable tool to support them throughout their chemotherapy. Several themes emerged from patients' descriptions of their experiences of using eRAPID which are described below.

4.4.5.2.1 Increasing knowledge and confidence

Patients found the advice provided on how to manage symptoms at home useful and practical, and this was a good motivator to complete the symptom report. Patients liked that the information was accessible to them at any time so they could look back over it.

"I found it excellent and that's even me being a registered nurse. It gave really good information. I used it because I had a sore mouth and there was some very good hints there about various things. My mouth was quite dry which made it painful so things like sucking a pineapple or ice lollies."

(P05, Female, 60 years, Breast)

"Obviously your care team is at the end of the phone but that's actually in front of you and then you can go over it again, and you can go back to that information and see how you coped with it last time."

(P11, Female, 49 years, Breast)

Patients described how the self-management advice increased their confidence to self-manage their symptoms throughout treatment, and felt that eRAPID would be useful to other patients. Patients often used language like 'comforting' and 'reassuring' to describe how access to symptom advice impacted on their experience.

> *"I think especially like I say, if people feel more unwell. I think they'd find it comforting and useful because it gives you all that information at the end about how to manage different stuff. It's a really good tool."*
>
> *(P10, Female, 33 years, Breast)*

However, one patient did comment that although she did initially find the advice useful, her symptoms didn't resolve. Subsequently she felt frustrated that the information was the same each time and found that it became much less useful. Although she did continue to complete the symptom reports regularly each week, her attitude towards eRAPID, and her engagement with the self-management advice did change over time.

> *"If I'd had different responses at different treatments, then I would have found it more useful. The first time I did it I found it useful and went through the information that it gave and I made sure that I was doing the advice that it gave and then after that, it's the same every time. It wasn't as useful, I already knew it."*
>
> *(P04, Female, 49 years, Breast)*

The same patient described how her main motivation for continuing to use eRAPID was to use it as a tool for self-monitoring. Despite her symptoms remaining relatively similar on a week to week basis, she still found it useful to have a visual record of this.

> *"I thought the graphs were great. The graphs were really good. It's nice to have that visual look at where you're at. And partly that was why I did it more frequently as well. I wanted to see things coming down. But most of mine stayed the same, but you know, I wanted to see things on it. And I think if I'd had more*

severe symptoms, and I was seeing them improving as the weeks went, I would have liked it even more. But yeah, I thought the graphs were really good."

(P04, Female, 49 years, Breast)

This was a view shared by several of the other patients, many of whom also commented that their main motivation for regularly completing symptom reports was to maintain an accurate record of how their symptoms varied from week to week.

"I also love the graphs, they are probably my favourite thing. I like graphs anyway, I like that visual representation."

(P09, Female, 73 years, Breast)

4.4.5.2.2 Supporting decision-making on contacting the hospital

In addition to practical advice on how to manage their symptoms at home, patients really valued the knowledge that eRAPID would prompt them to contact the hospital if their symptoms were more severe and medical intervention was needed. A number of patients described this as a 'safety net', and said they found it 'reassuring' and 'comforting'.

"My husband was nattering because I had a temperature so then I could say to him, Look. This says I just need to keep a close eye on it. So I found that helped me and it stopped me worrying needlessly. Otherwise I would have worked myself up so it did have that safety net"

(P05, Female, 60 years, Breast)

"It was really, really useful and I think, just so you're not needing to ring up here, but I think if you're feeling a bit unwell and unsure about something, and just, do I need to say – that really does help because it will say to you whether it's mild or whatever, or you need to ring, so no I think it's really good. It's been very useful to us, especially because we've never gone through anything like this before… so rather than… either sitting there worrying or constantly ringing somebody, it's been really good"

(P12, Female, 50 years, Breast)

However, a couple of patients who did receive advice to contact the hospital for their symptoms, and subsequently were contacted by a member of the research team felt that this was unnecessary. One patient described how this really frightened her, as she really didn't want to be admitted to hospital, but felt this might happen because of what she had reported on eRAPID. This patient subsequently disengaged and did not use eRAPID again following the incident.

> *"It brought the alert up, and the hospital rang and thought I might possibly need an admission, I must admit that scared me a little bit…I said well no actually, these symptoms were a few days ago and now I'm absolutely fine… it were fantastic that they rang so quickly and I think it's a great system for that, but I just thought oh no, I don't want to go to hospital"*
>
> *(P02, Female, 44 years, Breast)*

4.4.5.2.3 Support for coping with cancer

In addition to providing practical support which they found 'reassuring', a number of patients described how they felt eRAPID had helped them to cope better throughout their cancer treatment. Quite a few patients commented on the symptom graphs which illustrated the changes in their symptoms over the 12 weeks. Some patients were able to identify patterns in symptom fluctuations throughout their chemotherapy cycles, and felt this gave them motivation to continue, in the knowledge that symptoms would resolve soon.

> *"I enjoyed looking at the graphs and comparing them, and looking back to the beginning of my treatment to see what my problems were then, and do I still have the same problems now…some of them you can see a pattern, that's always week 2 or week 3 so that's quite nice and its reassuring. For me personally, I just think I can't do this anymore, I don't like this, this is awful, and I find that I'm very disheartened and I can't see an end to it. Particularly as you get to this stage…I know I'm nearly there but not and I know I've got to come back again. So you do get quite down. But then when you look at the graphs, you can think, but I did get*

better…and my mouth has got better, and my diarrhoea has stopped and… you can see that there is a pattern and that it will get better. It makes me feel better."

(P05, Female, 60 years, Breast)

"I would recommend it to anyone. It's like a safety net for you and gives you the help to keep on going on through your treatment."

(P09, Female, 73 years, Breast)

Another patient described how she had felt like she could 'offload' by completing the questionnaire, as didn't want to offload onto her family or worry them about how she was feeling.

"I enjoyed doing it and it enlightened me… and like I say offloading and being knowledgeable about when to call the team and when not to call and how to manage it in between so I found it really helpful, yeah… I enjoyed doing it and I would probably do it again. Not that I want to come round this journey again... You're sort of chucked into a dark tunnel and it's like a little escape route"

(P11, Female, 49 years, Breast)

4.5 Discussion

4.5.1 Summary of findings

The aim of this work was to explore patient engagement with eRAPID in a field usability study, in addition to exploring patient experiences of using the system whilst undergoing chemotherapy. Patient engagement with eRAPID and adherence to the weekly symptom reports was generally good, but was variable between patients. The end of study interviews identified some barriers and facilitators for patient engagement, in addition to some key benefits perceived by patients, which are discussed below. The relationship between patient engagement with eRAPID and the benefits they reported seemed to be reciprocal, with those who were completing symptom reports weekly reporting more benefits.

Patients found the system easy to use, and weekly completions manageable and reasonable. This was encouraging as issues with technology and usability are often cited as a barrier to patient engagement with online interventions [159]. The most commonly cited reason for non-completion was forgetting. Automated prompts have been demonstrated to be effective in promoting patient engagement with online interventions and subsequently an email and text reminder service was implemented into eRAPID prior to the RCT [160].

Some patients found it difficult to complete symptom reports when they were unwell, which is to be expected with patients undergoing chemotherapy and has been identified as a barrier in previous research [159]. However, some patients also reported that they were less likely to complete symptom reports when they felt well, sometimes because they were catching up with other things in their lives which had been on hold when they felt poorly. For many patients undergoing chemotherapy, retaining a sense of normality is very important, and for some patients, this may mean trying to avoid and suppress thoughts about chemotherapy and cancer as much as possible [161-163]. However, some patients also didn't see the point of completing symptom reports when they were not experiencing symptoms. Although patients

were asked in the initial training to complete at least once a week in order to provide a more complete overview to clinicians, patients were not always aware if and when clinical staff were using their data, and subsequently some patients may have felt less inclined to complete regularly. A qualitative study by Sanders et al explored perceived barriers and facilitators for patient engagement with telehealth and telecare systems for patients with complex health needs [128] and identified patient expectations of how the system might impact on their healthcare as an influential factor in adoption. If patients view eRAPID as influential to their care, and are aware of any impact it has on consultations, they may be more likely to engage and adhere to weekly completions. As a result of this finding, staff training for eRAPID was also amended to emphasise the importance of making patients aware when accessing symptom reports.

Similarly Sanders et al found that the patient's perceptions of how the system fits with their identity, independence and self-care was another influential factor in adoption. Again, this seemed highly relevant for eRAPID patients with one patient who had been completing regular symptom reports disengaging with the system after receiving advice to contact the hospital which she did not feel was warranted. This finding enabled us to adjust the alert system prior to the RCT to avoid unnecessary patient worry and burden on clinical staff.

Patients' reports of how eRAPID impacted on their experience of chemotherapy were generally very positive. Patients reported increased confidence and knowledge in managing their symptoms and found the symptom advice useful, particularly the specific advice about when to contact the hospital. The language that patients used to describe the impact of this was often quite emotive. Some described eRAPID as a 'safety net' and said it stopped them from worrying continuously and perhaps needlessly throughout their treatment and patients often used language like 'reassuring' and 'comforting' to describe their experiences of using eRAPID. This is similar to findings from other interventions which provide tailored specific advice to patients undergoing chemotherapy [72, 164-166].

In addition, some patients really valued the graphs depicting the severity of their symptoms over time, as this supported them to self-monitor and allowed them to identify patterns of fluctuation, giving them more confidence to manage their symptoms and a greater sense of control. Some patients also said that being able to identify patterns in symptom fluctuation helped them cope and feel more motivated to carry on through their treatment, with the knowledge that symptoms were only temporary. Self-monitoring in this way may be an effective coping strategy for some patients and can support them to retain the sense of normality that many desire, by allowing them to see patterns in symptoms and plan social activities and life events around this [13]. However, other patients did not engage with the graphs at all. Individuals have different levels of graph literacy, and they may not be useful or easily interpretable for all [167, 168]. In addition, self-monitoring may not be a strategy that suits all patients, and some may actively want to avoid it, particularly when things are not going well [161].

4.5.2 Strengths and limitations

The strengths of the study were the real-life clinical setting and context, and the comprehensive methods of evaluation. The limitations of the study were a relatively modest consent rate. However, this is likely to be due to the exploratory nature of the recruitment processes used. Following feedback from patients and staff, many changes were made to these processes going forward into the RCT. However, the low consent rate coupled with the fact that the system was only evaluated in one clinic with early breast cancer patients means that the sample is likely to be biased. This patient group were relatively young compared to many other adult cancer groups [101] and subsequently more likely to be digitally agile. However, internet access and use continues to increase [101] and previous work has indicated that eRAPID is acceptable to internet users in other cancer groups [130]. In the next stages of the study, eRAPID will be evaluated with a broader range of patients [94].

4.5.3 Conclusion

eRAPID was generally well accepted by patients, but engagement was variable. End of study interviews indicated that patients found benefits from using eRAPID over and above improved symptom management, such as increased confidence to manage side effects of treatment and to cope with cancer and treatment. Furthermore the relationship between patient engagement with eRAPID and the benefits they reported seemed to be reciprocal. Those who completed symptom reports weekly seemed to experience more benefits such as improved symptom monitoring, and felt that the symptom reports were beneficial in their interactions with clinical staff. The findings from this study informed the selection of measures to assess some of the additional benefits that patients might gain from using eRAPID. The selection and justification of measures is fully described in Chapter 6. The results also informed further development of the qualitative work described in Chapter 7.

It was also interesting to note that patients' positive experiences of using eRAPID seemed to be related to specific features of the system, such as the symptom advice and the graphs. I was aware that there were other ePROM systems being developed and evaluated worldwide for patient use during chemotherapy. The next logical step was to examine available evidence on these systems in terms of patient engagement, patient experiences, and particularly whether or not this was tied in with specific features of systems

Chapter 5 Systematic review of ePROM systems to support patients to manage and report side effects of treatment

5.1 Background

5.1.1 Overview

Chapter 3 highlighted some of the challenges patients experience trying to manage side effects during chemotherapy, in particular, the lack of confidence in making decisions about when to self-manage and when to contact the hospital. The field usability study described in Chapter 4 provided a valuable opportunity to assess how eRAPID could potentially support patients to overcome some of these issues. The main findings were that although eRAPID was generally acceptable to patients, engagement with the system was variable. The emotive language that patients used to describe their experiences with eRAPID, such as 'comforting' and 'reassuring' indicated that there are other potential benefits for patients, such as increased self-efficacy and a feeling of control over symptoms, in addition to improved physical symptom management. Engagement, and some of the benefits that patients described also seemed to be related to use of specific system features such as the self-management advice and the symptom graphs. I decided that the next logical step was to conduct a systematic review to examine available evidence on other ePROM systems available to support patients to report and manage side effects of cancer treatment and investigate the engagement levels and any known associations with ePROM features and functionality.

There has been a dramatic increase in the number of these systems developed over the last decade [51, 91, 94, 169, 170] but there is considerable variation between systems in the approaches used for development, and in the features that they offer to patients. Some primarily focus on making symptom data routinely available to health professionals and

provide alerts when severe symptoms have been reported [51, 115, 116, 171-173]. Others have been developed with a greater focus on patient self-management, delivering tailored and automated self-management advice when appropriate, and advising patients to contact their healthcare team when necessary [91, 92, 174-177]. Some systems use a combination of both approaches [94] and may also include additional features such as facilitating communication with medical teams or other patients.

I was interested in exploring whether the availability or absence of certain features would impact on how patients engaged with systems [178, 179]. The terms 'engagement' and 'adherence' are often used interchangeably in this context. However, adherence suggests an optimal way to use a technology and this is not always easy to define [107]. For the purposes of this review, I refer to engagement in a broad sense of levels of patient usage of the technology. There is relatively little currently known about the underlying processes, and particularly the role that the availability of system features might play. However, there is evidence to suggest that individuals vary in the features which they value and utilise most [177], and in addition, needs may change over time, as patients become more experienced with the system, but also with their disease and treatment [180].

I was also interested in the evidence of the benefits that ePROM systems have for patients, for all aspects of QoL, but particularly in terms of psychosocial outcomes such as self-efficacy or coping. In addition, I wanted to explore whether patient outcomes were related to patient engagement with systems, and whether the presence or absence of system features had any impact on the level of patient benefit gained from using the system. Changes in behaviour or disease outcome have been more often observed with interactive interventions in comparison with those that are purely educational [181] while the use of interactive online systems is associated with greater self-efficacy (SE), better self-management and more participation in health care [81, 182-184]. However, this may only be associated with specific features such as

interactive communication and progress tracking features [185] and consultation and self-management support [127].

Systematic reviews traditionally focus on high-quality evidence for a specific research question. However, increasingly, the value of taking a broader approach to inclusion is being recognised as important to answer complex research questions, particularly in the emerging field of online health interventions [186, 187]. With this in mind the focus of this review was to take an inclusive approach to systematically review and describe the features and functions of existing systems. I also wanted to focus on understanding the level of evidence indicating whether key system features are associated with better patient system engagement and patient centred outcomes.

5.1.2 Role and original contribution

This review was undertaken for purpose of this thesis and was not part of the main eRAPID work. I was responsible for all aspects of the planning, design and implementation of the review, with support from other researchers for double coding and data extraction. I have written up the results as a manuscript, which was recently accepted in the Journal of Medical Internet Research [188]. Preliminary results have also been presented as a conference poster [189].

5.2 Aims and objectives

The aims of this systematic review are to:

1. Describe the features and functions of existing electronic symptom reporting systems developed for patients during cancer treatment.

2. Explore which features of these systems may be associated with patient engagement and outcomes. Specifically to summarise:

a. Patient engagement and whether this is related to specific system features (e.g. symptom monitoring, tailored self-management advice etc.);

b. Patient centred outcomes used to evaluate systems and whether better outcomes are associated with specific features.

5.3 Methods

5.3.1 Protocol and registration

Details of the protocol were registered on the PROSPERO (International prospective register of systematic reviews) database and can be accessed at www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016035915. There were no major deviations from the protocol. However, in order to meet the aims, study selection, data extraction and data synthesis evolved into two stages. Stage 1: Identifying and characterising available systems and Stage 2: Summarising data on patient engagement and patient centred outcomes.

5.3.2 Eligibility criteria

The review question and eligibility criteria were developed and refined using PICOS (Population, Intervention, Comparator, Outcome, Study design) criteria outlined in Table 5.1**.** For stage 1, in order to collate an overview of all systems available, all relevant publications including published abstracts, protocols and qualitative studies were included. However, discussion papers or systematic reviews were excluded. For stage 2, in order to review evidence available on patient engagement and any patient centred outcomes, feasibility studies with any evaluation data of patient use were included, rather than restricting criteria to RCTs only. Criteria was piloted by two researchers (LW and KA) on a subset of 10 randomly selected papers and subsequently refined and clarified before the next stage.

Table 5.1 PICOS criteria

PICOS	
Population	- Adults > 18, no upper age limit - Males and females - Worldwide - Any cancer diagnosis - Receiving cancer treatment OR within >3 months of completing treatment - Cancer treatment to include any treatment with significant side effects (e.g. systemic therapies, radiotherapy, biological therapies).
Intervention	- Online systems for patients to report and/or manage symptoms and side effects during cancer treatment from home.

	- Internet based or enabled systems, including mobile apps. Other forms of Interactive Health Communication Applications (IHCAs), e.g. DVDs, games were excluded. - Purely educational systems not interactive in any way were excluded. - Systems developed to assess and monitor purely psychosocial symptoms were excluded (E.g. Depression, anxiety, emotional coping or stress). Sleep and fatigue were included, however. - Systems designed to be accessed at one time-point only were excluded, access to the system had to be ongoing.
Comparator	Stage 2 only - The review included studies with any comparator including those with no comparator.
Outcomes	Stage 1 - Dependent on the nature and number of papers found, we aimed to characterise systems. For example, we identified if studies included features such as - Monitoring of symptoms by Health Care Professionals (HCPs) - Alerts for severe symptoms sent to HCPs - Monitoring of symptoms by patients (e.g. graphical or tabular) - Automated feedback/advice based on responses - Access to symptom information - Communication with other cancer patients. - Direct communication with HCPs (distinct from symptom monitoring by HCPs). Stage 2 - We aimed to collect where available, information on engagement with systems. - We also aimed to collect information on any patient centred outcomes, including but not restricted to: - Any quality of life measures - Self-efficacy measures including patient activation, patient empowerment, mastery etc. - Patient satisfaction
Study design	Stage 2 only - The review was not restricted to RCTs and feasibility studies with any evaluation data were included. Patients had to be using the system over time and there had to be at least one intended time point of use more than 3 weeks after baseline. This timeframe was selected as many standard chemotherapy treatments are administered every 3 weeks.

5.3.3 Information sources

Studies were identified from systematic searches of MEDLINE, EMBASE, PsychInfo, Web of Science, Cochrane Central Register of Controlled Trials and the Health Technology Assessment databases in March 2016. Due to the nature of the review, results were limited to those published after 2000. No restrictions were imposed on language of publication. Searches were updated on 12th September 2017.

Reference lists of relevant publications were screened to identify papers not picked up by the electronic searches. In addition, citations of selected key papers were searched.

5.3.4 Search strategy

A detailed example of the search strategy used for MEDLINE is outlined in Table 5.2. This search strategy was adapted for each of the databases.

Table 5.2: Example of search strategy used (Medline)

Database: Ovid MEDLINE
Neoplasms/
oncolog*.mp.
cancer patient*.mp.
1 or 2 or 3
Medical Informatics/
Telemedicine/
Mobile Applications/
Smartphone/
Self Report/
Self Care/
Self-Assessment/
(electronic adj2 (Patient report* or Patient-report* or Self report* or Self-report* or Self manage* or Self-manage* or Self monitor* or Self-monitor* or Symptom report* or Symptom-report* or Symptom manage* or Symptom-manage*)).mp.
(online adj2 (Patient report* or Patient-report* or Self report* or Self-report* or Self manage* or Self-manage* or Self monitor* or Self-monitor* or Symptom report* or Symptom-report* or Symptom manage* or Symptom-manage*)).mp.
(web* adj2 (Patient report* or Patient-report* or Self report* or Self-report* or Self manage* or Self-manage* or Self monitor* or Self-monitor* or Symptom report* or Symptom-report* or Symptom manage* or Symptom-manage*)).mp.
(remote* adj2 (Patient report* or Patient-report* or Self report* or Self-report* or Self manage* or Self-manage* or Self monitor* or Self-monitor* or Symptom report* or Symptom-report* or Symptom manage* or Symptom-manage*)).mp.
5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
4 and 16
limit 17 to (humans and yr="2000 -Current")

5.3.5 Study selection

For initial screening, a decision for inclusion was made based on title and where available, abstract. This was carried out by one researcher (LW) only and for this reason, a cautious approach erring on the side of over inclusion was employed. Following this, two researchers independently (LW and KA) assessed all remaining papers for relevance. Disagreements were resolved by consensus after referring to the protocol. All discussions and decision-making were documented. Where there was insufficient information to make a decision, authors were contacted for further information. If no response was received within two weeks, a final decision was made based on available information.

5.3.6 Data items

5.3.6.1 Basic information

For Stage 1, basic data was extracted on authors, title, year of publication and country of origin, in addition to the name (if any given) and type of system being described (e.g. web based or mobile app). If the system did not already have a descriptive name, an arbitrary name was assigned (e.g. System A).

5.3.6.2 Taxonomy of system features

A preliminary list of common features was created based on known key papers and systems ([51, 83, 91, 94, 169]. It was initially planned to further develop this list throughout data extraction until a comprehensive list of common and or important features was achieved. However, no additional system features other than those specified in the original list were identified.

Seven common system features were identified in the preliminary list:

1) Allowed health professionals to remotely access and monitor patient reported data
2) Allowed patients to monitor/review their symptom reports over time (e.g. graphs)
3) Included a function to send alerts to health professionals for severe symptoms
4) Provided tailored automated patient advice on symptom management
5) Provided general patient information about cancer treatment and side effects
6) Included a feature for patients to communicate with the healthcare team
7) Included a forum for patients to communicate with one another

Features could be categorised broadly as supporting patients to monitor and manage their own symptoms, supporting communication with health professionals and other patients, or supporting clinicians to monitor and manage patient symptoms.

Data was extracted from each publication on the presence of each feature. This was coded as 'Yes' only if it was explicitly described in the publication, otherwise it was coded as a 'No'. For abstracts, if it was unclear whether or not a feature was present by information available in an abstract, this was classed as 'Unable to determine'. Where information was lacking, authors

were not contacted for information. However, searches were undertaken for other publications related to the same system.

5.3.6.3 System evaluation

For Stage 2, data was extracted from studies with some form of system evaluation (patient use of system or evaluation of efficacy). This included data on the number of patient participants, baseline demographics, disease and treatment type, duration of the evaluation, methods used to assess engagement and actual usage or adherence. Where available, data was also extracted on any patient centred outcomes used and results of evaluation.

5.3.7 Data extraction

Data was extracted using the online Systematic Review Data Repository (SRDR) [190]. The form was piloted on 10 randomly selected papers and further refined. For Stage 1, three additional researchers (KA, BC, MA) each double coded a number of allocated publications, totalling 36% (n=27/77) of the overall included publications. A high level of agreement (86%) was found. Discrepancies were resolved by referring back to the protocol and additional publications where available. For stage 2, the same 3 researchers again each double coded a proportion of the included publications totalling 46% (n=13/29) and 100% agreement was found.

5.3.8 Risk of bias in individual studies

Quality was assessed using the Down and Blacks checklist for non-randomised studies [191] and was undertaken alongside data extraction. It was deemed appropriate to assess only studies which included some feasibility/evaluation data, i.e. publications included in Stage 2. Studies are given a score along a possible range of 0 to 26.

5.3.9 Synthesis of results

A narrative synthesis was undertaken using the guidelines outlined by the Economic and Social Research Council (ESRC) [192]. Microsoft excel was used to manage data. For stage 1,

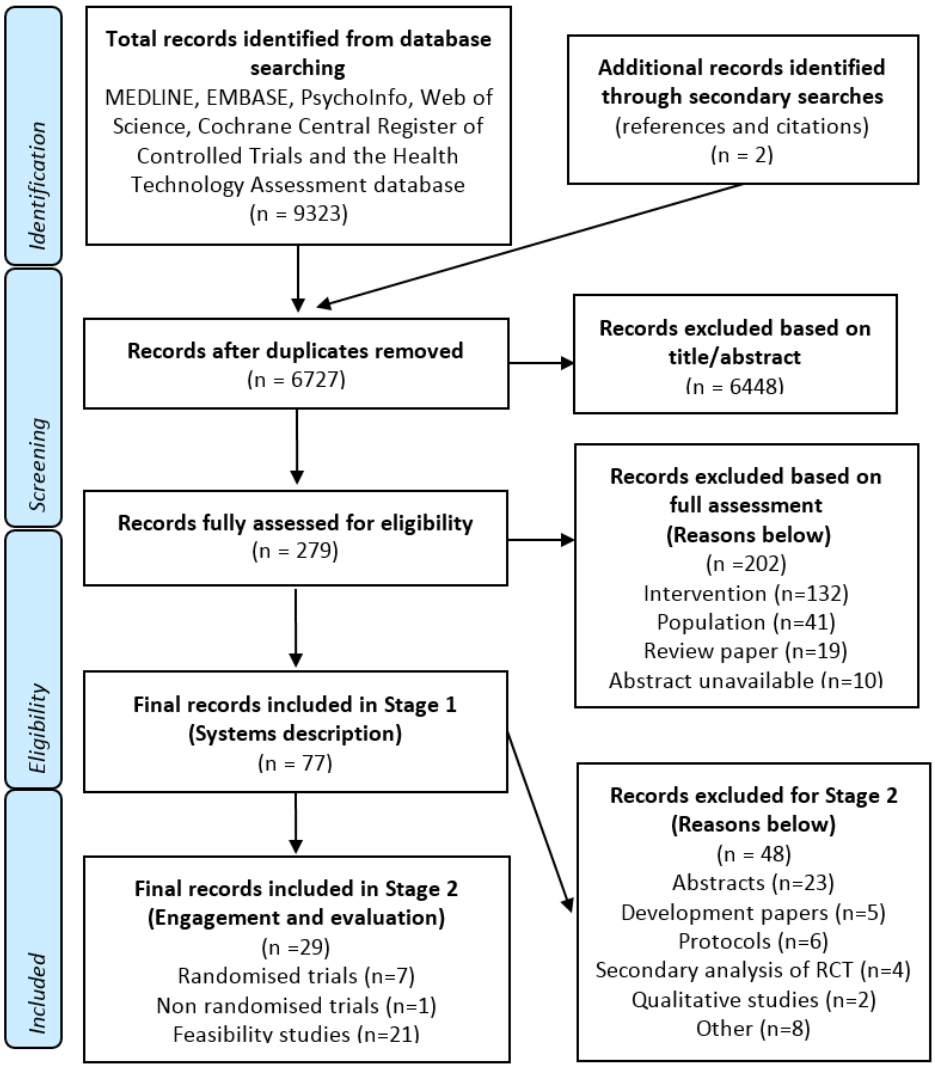
information from multiple publications relating to the same systems was pooled to form a description of features. Where information was conflicting due to earlier and later iterations of systems, the most recent description was used. For stage 2, information was collected on how patient engagement was assessed for any feasibility study or trial which included this data. For trial studies, information was collected on primary and secondary study outcomes and any results recorded. We then summarised this data to explore any relationships with system features identified in Stage 1.

5.4 Results

5.4.1 Study selection

An overview of search and selection procedures is outlined in Figure 5.1. A total of 6727 publications were identified after removal of duplicate publications, including two publications identified from secondary searches (citation and reference lists). All publications were in English. 279 publications were assessed for eligibility and a total of 202 papers were excluded at this point based on predefined eligibility criteria. (Intervention, e.g. Not home-based or web-based, n=132, Population, e.g. Patients not on active treatment, n=41, discussion paper or systematic review, n=19, or abstract unavailable, n=10). 77 publications were included in Stage 1 of the review (systems descriptions). A large proportion (30%, n=23) of these publications were abstracts. 29 publications were identified for inclusion in Stage 2 of the review (patient engagement and evaluation of systems). These were 21 feasibility studies and 8 controlled trials (7 randomised and 1 non-randomised).

Figure 5.1 Summary of papers identified and subsequently excluded/included in this review



5.4.2 Quality Assessment

Along a possible range of 0 to 26, the overall median quality assessment score of studies using the Down and Blacks checklist was 17.0 (Mean=16.2, SD=5.3, range 2-24). For the trials outlined in Table 5.5, the median score was higher at 20.0 (Mean=20.4, SD=2.6, range 17-24).

5.4.3 Stage 1: Description of systems

The 77 publications referred to 41 individual systems**.** Most originated from the USA (46%, n=19/41) or the UK (15%, n=6). Systems were commonly web-based (56%, n=24), 27% were mobile apps (5% were both) and 22% were web-enabled mobile devices purposely designed

for symptom reporting and were provided to patients for the duration of the study. Seven common system features were identified in the preliminary list (see section 5.3.6) and no additional features were identified following the review. Figure 5.2 below outlines each of the features and it's prevalence in the 41 identified systems. Features could be categorised broadly as supporting patients to monitor and manage their own symptoms, supporting communication with health professionals and other patients, or supporting clinicians to monitor and manage patient symptoms. Over half (58%) of systems had the facility for healthcare providers to monitor patient data over time, however, only 46% included the facility for patients to monitor and review their own data. Similarly, less than half the systems (41%) included a feature for delivering advice to support patients to self-manage symptoms and less than a third provided patients with access to general educational information. The two least common features were facilities to support communication between patients and healthcare providers (15%) and communication between patients themselves respectively (10%).

Figure 5.2 Overall summary of prevalence of identified system features

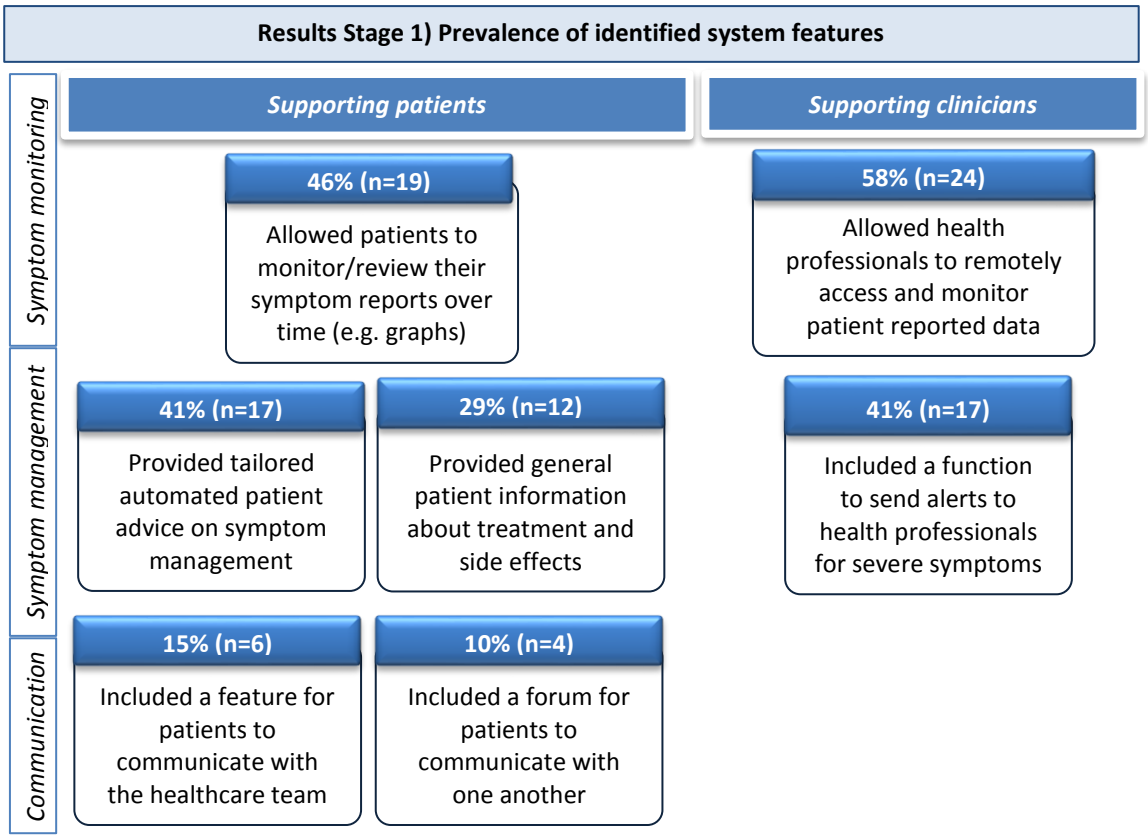


Table 5.3 provides an overview of each identified system and its associated publications, in addition to the presence or absence of each of the features identified in Figure 5.2. '✓' Denotes feature is present, 'x' denotes feature is not present and '–' denotes that it was not possible to determine whether feature was present or not.

Table 5.3: Identified systems with description of features and associated publications

System name (Country) System type	Publication (s) type (with relevant references)	Allowed health professionals to remotely access and monitor patient reported data	Allowed patients to monitor/review their symptom reports over time (e.g. graphs)	Included a function to send alerts to health professionals for severe symptoms	Provided tailored automated patient advice on symptom management	Provided general patient information about cancer treatment and side effects	Included a feature for patients to communicate with the healthcare team	Included a forum for patients to communicate with one another

ASYMs (UK) **Mobile device**	Randomised trial [169], Secondary analysis of RCT [164], Feasibility studies [193, 194], Abstracts [195-198], Other [199]	✓	x	✓	✓	x	x	x
CASSY (USA) **Web based**	Randomised trial [200]	x	✓	x	x	✓	x	✓
CHES (Austria) **Web based**	Abstract [76]	-	-	-	-	-	-	-
COPE-CIPN (USA) **Web based**	Other [201]	-	-	-	-	-	-	-
CORA (USA) **Mobile app**	Development paper [202], Protocol [203]	x	✓	x	✓	✓	x	x
eRAPID (UK) **Web based**	Protocol [94], Abstracts [204-209]	✓	✓	✓	✓	✓	x	x
eSMART (UK) **Mobile device**	Protocol [170]	✓	✓	✓	✓	✓	x	x
ESRA-C (USA) **Web based**	Randomised trial [83], Secondary analysis of RCT [210], Qualitative paper [95]	x	✓	x	✓	x	x	x
Healthweaver (USA) **Web based & Mobile app**	Feasibility study [211], Development paper [212]	x	✓	x	x	✓	x	x
HSM (UK) **Mobile device**	Feasibility study [213]	✓	x	✓	✓	✓	x	x
ICT-FP7 (France) **Mobile device**	Abstract [214]	✓	-	-	-	-	-	-
INTERAKTOR (Sweden) **Web based & Mobile app**	Protocol [215]	✓	✓	✓	✓	✓	x	x
KAIKU (Finland) **Web based**	Feasibility study [216]	✓	x	x	x	x	✓	x
MADELINE (USA) **Mobile app**	Abstract [217]	-	-	-	-	-	-	✓
MSKCC WebCore (USA) **Web based**	Abstract [218]	-	-	-	-	-	-	-
Onco-TREC (Italy) **Mobile app**	Development paper [219], Protocol [220]	✓	✓	✓	✓	x	✓	x
PatientViewpoint (USA) **Web based**	Feasibility study [221]	✓	✓	✓	x	x	x	x
PaTOS (USA) **Web based**	Feasibility study [222]	✓	x	x	x	x	x	x
Pit-a-pit (Korea) **Mobile app**	Feasibility study [74]	✓	x	x	x	x	x	x
PRISMS (Australia) **Mobile device**	Protocol [223], Abstract [224]	✓	✓	✓	✓	✓	x	x
PROCDIM (USA) **Web based**	Abstract [225]	✓	✓	-	-	-	-	-

QoC Health Inc (Canada) Mobile app	Randomised trial [82], Other [226]	✓	x	✓	x	x	x	x
RemeCoach (Belgium) Mobile device	Feasibility study [227]	x	x	✓	x	x	x	x
SCMS (Singapore) Web based	Feasibility study [166], Other [228]	✓	x	x	x	✓	✓	x
STAR (USA) Web based	Randomised trial [51], Feasibility studies [75, 115, 116, 171-173]	x	✓	✓	✓	x	x	x
The Health Buddy (R) (USA) Mobile device	Development paper [165]	✓	x	✓	✓	x	x	x
WebChoice (Norway) Web based	Randomised trial [91] Secondary analysis of RCT [92, 175], Qualitative paper[177], Other [174, 176]	x	✓	x	✓	✓	✓	✓
WRITE (USA) Web based	Abstract [229]	✓	-	-	✓	-	-	-
System A (USA) Web based	Feasibility study [230]	x	x	✓	x	x	x	x
System B (The Netherlands) Web based	Non randomised trial [87], Development paper [231], Feasibility study [232]	✓	✓	✓	x	✓	✓	✓
System C (USA) Web based	Other [233]	-	-	-	-	-	-	-
System D (Sweden) Mobile App	Feasibility study [60]	✓	✓	✓	✓	✓	x	x
System E (UK) Mobile device	Feasibility study [234]	✓	✓	✓	✓	x	x	x
System F (Canada) Web based	Abstract [235, 236]	-	✓	-	✓	-	✓	-
System G (Denmark) Web based	Abstract [237]	-	✓	-	✓	-	-	-
System H (UK) Mobile device	Other [103]	✓	x	✓	x	x	x	x
System I (USA) Web based	Abstract [238]	-	-	-	-	-	-	-
System J (USA) Web based	Abstract [239]	✓	-	-	-	-	-	-
System K (Switzerland) Mobile App	Randomised trial [240]	✓	✓	x	x	x	x	x
System L (USA) Mobile App	Feasibility study [241]	✓	x	x	x	x	x	x
System M (USA) Mobile App	Abstract [242]	-	-	-	-	-	-	-

5.4.4 Stage 2: Patient engagement and patient centred outcomes

5.4.4.1 Patient engagement

Table 5.4 summarises data on patient engagement from the 29 included studies (21 feasibility studies and 8 controlled trials). All 21 feasibility studies (100%) reported some data on patient engagement, although there was variation in how engagement was defined and measured. Three of the eight trials (38%) did not report any data on patient engagement [82, 169, 240]. Of the 29 studies, the most common method of assessing engagement was the number of symptom report completions or number of times the system was accessed (n=12, 41%) [60, 83, 87, 115, 200, 211, 213, 216, 222, 230, 232]. This was given as an overall figure for the whole sample [60, 115, 200, 216, 232], as an average per patient [115, 172, 213, 222, 232] or with a breakdown of the variance [211, 230]. Nine studies (31%) assessed adherence by number of actual completions/accesses in comparison to the number of expected completions/accesses [51, 74, 75, 172, 173, 221, 227, 234, 241]. This was reported as median or mean adherence of the overall sample for the duration of the study period [21, 74, 221, 227, 234, 241], or with a breakdown of adherence at different time points [75, 173]. Two studies (7%) categorised patients as users or non-users dependent on predefined criteria [116, 171]. Four studies (14%) combined results of patients reporting from home and in clinic [115, 116, 172, 173]. Not all studies reported on actual usage, and some used evaluation questionnaires with or without semi-structured interviews to assess acceptability to patients. [166, 193, 194, 213]

Due to the variation in the methods of reporting, it was not possible to determine if there was any overall association between engagement and specific system features.

Table 5.4: Overview of patient engagement data

System name **Patient group (No of patients (N))** **Treatment type and study duration**	**Method of evaluation/patient engagement**	**Brief summary of findings**
Feasibility studies (n=21)		
- ASyMS-R [193] - Lung (N=16) - During and a month after thoracic radiotherapy	- Evaluation questionnaire - Semi structured interviews	- Actual usage not reported - Patients perceived it to positively impact on care and promote timely reporting and management of symptoms.

- ASyMS [194] - Colorectal or Lung (N=18) - During 2 cycles of chemotherapy	- Evaluation questionnaire	- Actual usage not reported - Patients reported it helped monitor symptoms, promote self-care and improve symptom management
- HealthWeaver [211] - Breast (N=9) - Undergoing active treatment - 4 weeks	- No of completions/ accesses	- All patients used website at least 3 times weekly, 7 patients used it almost daily. - Phone component used almost daily by 5 patients,3 x weekly by 1 patient, and 1-2 x weekly by 3 patients
- HSM [213] - Lung or colorectal (N=18) - During 2 cycles of chemotherapy	- No of completions/ accesses - Evaluation questionnaires	- All patients completed 1-34 symptom reports, average 14 overall (SD = 10.2). - High variation in use of self-management advice - Patients found system easier to use and more useful than expected
- Kaiku [216] - Head & neck (N=5) - During and a month after Radiotherapy	- No of completions/ accesses	- 514 symptoms reported (including zero grades) - 23 questionnaires completed - 38 messages sent
- PatientViewpoint [221] - Breast or Prostate (N=47) - Medical oncology treatment - UTD - 3 on site visits (not specified)	- No of accesses/ expected accesses	- 190/224 symptom reports completed (85%) - Median expected questionnaires completed by individual patients was 71%. - Majority of questionnaires completed offsite (n=160; 87%)
- PaTOS [222] - Any disease site (N=30) - Chemotherapy - 10 weeks	- No of completions/ accesses	- 28/30 patients observed for 10 weeks - Total 231 accesses, 193 fully completed - Total of 1,870 symptoms observations (average: 69 per patient, 1.5 per day).
- Pit-a-pit [74] - Breast (N=30) - Neo-adjuvant chemotherapy - 90 days	- No of accesses/ expected accesses	- 1215/2700 responses (compliance=45.0 %) - Median patient-level reporting rate was 41.1% (range 6.7-95.6%)
- RemeCoach [227] - Advanced solid tumours, e.g. Colorectal, Gastric-oesophageal, and Pancreatic adenocarcinoma (N=11) - Duration of Teysuno® treatment	- No of accesses/ expected accesses	- Average daily compliance 91.2 % - Could not determine longitudinal compliance because of the low patient number using the coach for an acceptable duration of time
- SCMS [166] - Breast, Lung or Colorectal (N=4) - During 4 cycles of chemotherapy	- Evaluation questionnaire	- All patients completed at least 1 symptom report - Questionnaire revealed patients found system useful and easy to use
- STAR [75] - Gynaecologic malignancy (N=49) - Laparotomy - 6 weeks	- No of accesses/ expected accesses	- Compliance of patients gradually decreased. - 92% of patients completed preoperative session, and 74% completed week 6 session. - Majority of patients (82%) completed at least 4/7 total sessions in STAR.

- STAR [116] - Gynaecologic malignancy (N=80) - Chemotherapy - 8 weeks	- Users/non users - (logged in/did not log in)	- Patients could access from home or in clinic - 25% used only in clinic waiting area, remainder logged in from home and clinic - Most patients with home computers (83%) logged in from home without reminders.
- STAR [171] - Not specified (N=180) - Chemotherapy - 8 weeks	- Users/non users (logged in/did not log in) -	- Patients could access from home or in clinic - 2/3 voluntarily logged in from home computers without prompting.
- STAR [172] - Thoracic malignancies (N=107) - Chemotherapy - 16 months	- No of accesses/ expected accesses	- Patients could access from home or in clinic - 16 patients (15%) accessed system from home. - Home users accessed system more frequently than those using in clinic (avg =23 sessions, range, 3-144) v (avg =9, 1-36) respectively.
- STAR [115] - Lung, Gynaecologic, Breast, Genitourinary (N=286) - Duration of chemotherapy	- No of completions/ - accesses	- Patients could access from home or in clinic - Total of 8,690 logins (median, 17 logins per patient) avg 0.9 logins per patient per week. - 71% from home and 29% from clinic.
- STAR [173] - Gynaecologic malignancy (N=96) - Laparotomy - Preoperatively & weekly 6-wks post laparotomy	- No of accesses/ expected accesses	- 74% (n=71) completed at least 4/7 surveys and were considered responders. - 63% (n=69) completed preoperative session. Remaining completed subsequent surveys. - 9 (9%) patients completed only 1 survey.
- System A [230] - Hepatobiliary and GI (N=20) - Preoperatively and 2 weeks after discharge for curative resection	- No of completions/ - accesses	- 65% (13/20) completed 8 symptom assessments - 75% (15/20) completed 4 QOL assessments - Mean 7 minutes to complete MDASI and mean 4 minutes to complete EQ-5D-5L.
- System B [232] - Head and Neck cancer (N=36) - Surgery - 6 weeks	- No of completions/ - accesses	- All patients used system (total sessions = 982) - Avg no of sessions was 27.3 (S.D. 18.4, range 4-69) - Avg session 12 min. longest session 1h 38m.
- System D [60] - Prostate (N=9) - Radiation therapy - 2 weeks	- No of completions/ - accesses	- Patients reported for mean of 10 days - Estimated time for report 5 min. - Self-care advice accessed by 85%, who logged 20 views at 34 symptoms. - 59 alerts: 55 yellow and 4 red.
- System E [234] - Colon (N=6) - Complete resection	- No of accesses/ expected accesses	- Data entry compliance was excellent (98% of the twice-daily input was

- During 2 cycles of chemo		complete) from all six patients with the exception of one question
- System L [241] - Head and Neck (N=22) - Duration of Radiation therapy (approximately 5 to 7 weeks)	- No of accesses/ expected accesses	- Median compliance 71% (interquartile range [IQR], 45%-80%). - 6 patients (27%) compliance ≥80%, 2 patients (9%) 100% compliant. - Median reports submitted 34 (IQR, 21-53).
- **Controlled trials (n=8)** - ***(n refers to no of patients expected to use the system (i.e. intervention arm)**		
- ASyMS [169] - Breast, Lung or Colorectal (N=56) - 4 cycles of chemotherapy	- Not reported -	- Not reported
- CASSY [200] - Any diagnosis of cancer (N=144) - Chemotherapy, radiation or surgery - 6 months	- No of completions/ accesses	- Total number of page views=1491 - Total duration in minutes =1813.9 - Total views and duration given for individual patients
- ESRA-C [83] - Diagnosis of cancer (N=374) - Any therapeutic regimen - UTD, over 4 visits	- No of completions/ accesses -	- Median access rate of 4 (range, 2-4) at study time points - Median access rates of 1 (range, 0-8) at voluntary times.
- QoC Health Inc [82] - Breast (N=32) - Reconstructive surgery - 30 days	- Not reported	- Not reported
- STAR [51] - Metastatic Breast, Genitourinary, Gynaecologic, or Lung (N=286) - Duration of chemotherapy	- No of accesses/ expected accesses	- Computer experienced (home access) and inexperienced (clinic access) figures combined - Avg 73% completed a self-report at any given clinic visit (includes clinic completions)
- WebChoice [91] - Breast or Prostate (N=162) - Surgery plus Radiation, Chemotherapy, Hormone therapy or a combination - 1 year	- No of completions/ accesses -	- 77% logged on at least once. - 23% never logged on. - Of 103 (64%) who logged on more than once, avg logons= 60 times (range, 2-892).
- System B [87] - Head and neck cancer (N=39) - Surgery - 6 weeks	- No of completions/ accesses	- Avg no of sessions = 27, avg length of session= 12mins - Avg no of completions = 12.6 - Avg no of messages =4.5
- System K [240] - Breast cancer (N=95) - Adjuvant or neo-adjuvant chemo - 6 weeks	- Not reported	- Not reported

5.4.4.2 Patient centred outcomes

All the trials used some measure of patient centred outcome to evaluate system efficacy, most commonly validated QoL, symptom and psychosocial outcome measures. Table 5.5 below details the measures used for the individual trials and a brief summary of findings.

Table 5.5: Overview of patient-centred outcomes data

Population (N) and study design	Intervention and comparator groups	Outcomes reported	Summary of results
- ASYMs [169] - Population - Breast, Lung or Colorectal (N=112) - Study design - 2 arm randomised controlled trial - 4 cycles of chemo -	- Intervention (N=56) - Asked to complete a symptom questionnaire integrating Common Toxicity Criteria Adverse Events (CTCAE) grading system and Chemotherapy Symptom Assessment Scale - Symptom information sent in 'real time' to the study server - Patients receive severity dependent tailored self-care advice on mobile phone interface - Evidence-based risk assessment tool alerts clinicians via a dedicated 24-h pager system of any severe symptoms - Comparator (N=56) - Standard care following local guidelines and procedures related to the monitoring and reporting of chemotherapy-related toxicity including written and verbal information from the nurses administering chemotherapy.	- Primary outcomes - Paper version of online questionnaire. - Comparison between groups on Mean scores from 4 paper based completions at baseline and before each chemo cycle	- Higher reports of fatigue (p=0.04) and lower reports of hand-foot syndrome (p=0.03) in the control group compared with the intervention group - No difference on nausea, vomiting, diarrhoea, or sore mouth/throat.
- CASSY [200] - Population - Any diagnosis of cancer - Chemo, radiation or surgery - (N=261) - Study design - 2 arm randomised controlled trial - 6 months	- Intervention (N=144) - Access to psycho-educational website where patients could record and monitor symptoms via graphs and journal - Access chat room to communicate with other study patients - Audio-visual and resource library including relaxation techniques and educational videos - Telephone contact (approx. every 2 weeks) with a collaborative care coordinator with training and experience with cognitive-behavioural therapy (CBT) and psycho-oncology. - Comparator (N=117) - Usual care provided by the medical team in addition to the assessment of symptoms and blood draws at the same time as intervention patients to evaluate efficacy of the intervention.	- Primary outcomes - Depression (CES-D≥16) - Pain Brief Pain Inventory (BPI) - Anaemia (FACT-AN) - Hepatobiliary (FACT-Hep). - Secondary outcomes - Serum cytokines levels and Natural Killer Cell (NK) - Comparison at 6 months follow up	- Reductions of fatigue at 6 months (p=0.09). - Statistically and clinically significant changes in overall quality of life (p=0.05) - Reductions in pain and depression - Medium effect size for NK cell number (Phi=0.491) at 6-months [Chi-square=3.62, p=0.057].
- ESRA-C [83] - Population - Diagnosis of cancer - Any therapeutic regimen - (N=779) - Study design	- Intervention (N=374) - Participants completed cancer symptoms and quality of life (SxQoL) assessments at each study time point and ad lib between visits - Summary reports delivered to clinicians - Self-management advice given for three symptoms - Coaching to verbalize issues to healthcare team - Alert to contact healthcare team for severe symptoms	- Primary outcomes - Symptom Distress Scale (SDS) plus two items (impact on sexual activity and interest, fever/chills) to form the SDS-15.	- Intervention had lower symptom distress; mean change in SDS-15 score was 1.27 ([SD], 6.7) in control (higher distress) and −0.04 (SD, 5.8) in intervention (lower distress).

- 2 arm randomised controlled trial - UTD, over 4 visits	- Patients could monitor symptoms via graphs and journal - Self-care strategies and coaching available at any time. - Comparator (N=378) - Participants completed assessments at each study time point - Summary reports delivered to clinicians - Research staff verbally notified healthcare team of any severe symptoms reported at the time of the clinic visit. - Both groups were provided the same patient education typically available in each clinic.	- End point was change in SDS-15 total score from baseline to the end-of-study time point	- SDS-15 score reduced by estimated 1.21 (95% CI, 0.23 to 2.20; p=.02) in intervention v control group.
- QoC Health Inc [82] - Population - Breast cancer - Surgery - (N=65) - Study design - 2 arm randomised controlled trial - 30 days	- Intervention (N=32) - Follow up visits at 1 and 4 weeks replaced with examination of surgical site via photographs submitted through mobile app, in addition to completion of pain visual analog scale, and quality of recovery 9-item questionnaire. - Reporting began after discharge from the recovery room - Email reminder if submission was not received. - Surgeon used a wireless interface to access data and monitor patients' condition. - Severe scores flagged in the database for quick viewing. Red flags prompted in-person follow-up. - Physicians summarized data from mobile app using the prototypical subjective, objective, assessment, and plan note at 1 or more time points during the 30-day monitoring period. - Comparator (N=33) - Patients in conventional follow-up group had planned clinic follow-up at approximately 1 week and 4 weeks after the operation.	- Primary outcomes - Total number of follow-up visits (including specialists, family physician, and emergency department) - Total number of telephone calls and emails to the health care team - Satisfaction and convenience scores using a 5-point Likert scale. - Postoperative complications.	- Control group more likely to attend in-person follow-up care first 30 days after surgery (95% CI, 0.24-0.66; p<.001) - Intervention group sent more emails than control group (IRR, 4.13; 95% CI, 1.55-10.99; p=.005) - Intervention group reported higher convenience scores (IRR, 1.39; 95% CI, 1.09-1.77; p=.008)
- STAR [51] - Population - Metastatic Breast, Genitourinary, Gynaecologic, or Lung cancers - (N=766) - Study design - Before randomization, participants were assigned to subgroups (Computer-experienced and computer-inexperience	- Intervention (N=286) - Remote access to a web-based interface including questions adapted for patient use from CTCAE - Triggered e-mail alerts to nurses whenever patient-reported symptom worsened by 2 points or reached an absolute grade - Report tracking participant's symptoms printed at each clinic visit for both the nurse and treating oncologist. - No specific guidance provided to clinicians on actions to take in response to alerts or printed symptom profiles. - Comparators - Intervention - Computer inexperienced (N=155) - Similar to the main intervention group but accessed system in clinic only and did not have remote access - Computer experienced - Usual care. (N=253) - Computer inexperienced - Usual care (N=72) - Usual care for the computer-experienced and computer-inexperienced subgroups consisted of standard procedure for monitoring and documenting symptoms.	- Primary outcomes - EuroQol EQ-5D Index administered via paper at clinic visits every 12 ± 4 weeks throughout study participation - Secondary outcomes - Survival at 1 year - Time to first ER visit and time to first hospitalization - Time receiving active cancer treatment	- NB: Combined results for computer experienced (home system) & computer inexperienced (clinic only). intervention - Greater improvement in HRQL scores in intervention v usual care arm (34% v 18%) and worsened among fewer (38% v 53%; p<.001) - Greater survival in intervention arm (69% v 75%, p=.05) - Fewer ER visits in intervention (34% v 41%, p=.02)

d) Only computer experienced intervention used system from home - Duration of chemo	- Symptoms are discussed and documented in the medical record during clinical encounters between patients and their oncologists. - Patients encouraged to initiate telephone contact between visits for concerning symptoms.	- Number of nursing calls to patients	- Intervention received chemo for longer (8.2 v 6.3 mths, p=.002) - No difference in number of nursing calls to patients
- WebChoice [91] - Population - Breast or Prostate cancer - Surgery plus additional treatment of either Radiation, Chemo, Hormone therapy, or a combination of those) - (N=325) - Study design - 2 arm randomised controlled trial - 1 year	- Intervention (N=162) - Assessment component to monitor and report symptoms, problems, and priorities for support along physical, functional, and psychosocial dimensions - Patients receive automated tailored self-management advice based on responses - Patients receive advice to contact healthcare team when appropriate - Information can be used to create a self-care plan - Information section with access to other reliable, relevant Web resources - Communication section including (a) unrestricted support forum for group discussion, allowing patients to post messages anonymously, (b) question-and-answer area where patients, in private, can ask questions to expert nurses in cancer care. - Access to a diary to keep personal notes. - Comparator (N=163) - In addition to the letter informing them of their group assignment, participants receive information sheet with suggestions for publicly available, cancer-relevant Internet sites that could be useful to them.	- Primary outcomes - Memorial Symptom Assessment Scale Short Form(MSAS-SF) - Secondary outcomes - Center for Epidemiological Studies Depression scale - Cancer Behaviour Inventory - 15D HRQoL - Medical Outcome Study Social Support Survey	- Between-group differences significant for the Global Distress Index only (t=4.42; p=.037). - No significant differences on the other subscales or total score or any secondary outcomes. - However experimental group showed significant improvements in depression (t=−2.71; p=.007). - Control group had worsened self-efficacy (t=−2.82; p=.005) and HRQoL scores significantly (t=−2.77;p=.006),
- System B - Van den Brink (2007) [87] - Population - Head and neck cancer - Surgery - (N=163) - Study design - Non-randomised trial - 6 weeks	- Intervention (N=39) - Provided with a laptop - Patients could be monitored at home (by means of electronic questionnaires). - Could communicate (send messages) to team - Access to information, - Communicate with fellow sufferers (via a forum) - Comparator (N=128) - Routine follow-up apps at two and six weeks after discharge. - Patients could contact their care providers, both in- and outside the hospital, if considered necessary.	- Primary outcomes - QoL measure which assessed state anxiety, object anxiety, feelings of depression, uncertainty, feelings of insecurity, loss of control, self-efficacy, loneliness and complaints	- Intervention had significantly better change from baseline at 6 wks for: state anxiety (p=.01), fear related to specific head and neck problems (p=.02), physical self-efficacy (p=.03), perceived abilities in swallowing and food intake (p=.04) and general physical complaints (p=.02).
- System K - Egbring (2016) [240] - Population - Breast cancer - Adjuvant or neo-adjuvant chemo	- Intervention (N=49) - (App and physician: Patients used mobile app and reviewed reported data with treating physician at scheduled visits.) - Patients could report daily functional activity or symptoms with indication of severity. - Patients could edit a quick list of their preselected symptoms or select any of the 48 symptoms made available from the CTCAE listing.	- Primary outcomes - Daily functional activity measured by ECOG - Secondary outcomes - Symptom reporting (intervention	- Control groups showed greater decline in functional activity in contrast to intervention but not significant - At last visit, intervention & attention control patients reported

- (N=139) - Study design - 3 arm randomised controlled trial - 6 weeks	- Treating physician enabled access to review and discuss electronically reported symptoms during scheduled visits. - Comparators - Attention-control group (N=46) - (App only: Patients instructed to use the mobile app without physician review.) - Control group (N=44) - Received regular physician support	group and attention control group only) - Patient-physician communication (measure not specified) - Patient Empowerment (measure not specified)	fewer concentration issues than control group (P=.002). - At third visit, significantly more intervention & attention control patients confirmed use of the Internet for disease information compared v control

5.4.4.2.1 Self-efficacy

WebChoice [91] and System B [87] both demonstrated a positive impact on self-efficacy. WebChoice was evaluated using the Cancer Behaviour Inventory (CBI), a measure which assesses self-efficacy for coping with cancer. However, for System B, self-efficacy was only assessed as a subscale of a main measure. System K [240] reported an improvement in patient empowerment, however this was assessed using a single item regarding using the internet for information seeking, which is unlikely to be a reliable measure.

5.4.4.2.2 Other psychosocial outcomes

CASSY [200] and WebChoice [91] demonstrated significant reductions in depression in intervention compared to control groups. System B [87] demonstrated no difference on the depression subscale of a QoL measure but a significant impact on state anxiety and fear related to specific head and neck problems. WebChoice demonstrated no impact on social support [91]. QoC Health Inc [82] was primarily assessed on number of hospital contacts, but also included patient scores of convenience and satisfaction using a simple 5 point Likert scale and found an impact for convenience, but not for patient satisfaction.

5.4.4.2.3 Global QoL

CASSY [200] and STAR [51] interventions both demonstrated improvements in overall quality of life. However, in addition to the online component, CASSY included access to a collaborative

care co-ordinator with experience in cognitive behavioural therapy and psycho-oncology, which is likely to have contributed to the efficacy. In the STAR study, patients were allocated to computer experienced and inexperienced groups prior to randomisation and only the computer experienced group had access to the system from home. Results are pooled together, making it different to assess efficacy for our purposes. No significant impact on QoL was found for WebChoice [91].

5.4.4.2.4 Physical symptoms

An overall reduction of symptom distress was found in the studies assessing ESRA-C [83] and WebChoice [91]. However, in addition to the online intervention, ESRA-C also included a communication coaching component to improve symptom disclosure to physicians. System B [87] was found to have significant positive impact on the general physical complaints subscale compared to the control group.

ASyMs [169] and CASSY [200] both demonstrated positive impact on levels of fatigue while System K [240] demonstrated a lesser decline in functional activity in contrast to the control group but this was not significant. Both ASYMs and System K were evaluated using the same measure as used to assess symptoms in the intervention which may have impacted on results. Due to the considerable variation in outcomes used, and study design; it was not possible to assess any relationships with features.

5.5 Discussion

5.5.1 Summary of findings

The main aim of this review was to systematically describe and assess the features and functions of current ePROM systems available for patients to report and manage side effects of cancer treatment, in addition to understanding the level of evidence indicating whether key system features are associated with better patient engagement and outcomes.

In Stage 1 of the review, a total of 41 individual systems were identified. There was significant variation between systems, though published descriptions of systems were often limited. A taxonomy of features was developed which classified systems into those supporting clinicians to deliver patient care in an innovative way and those aimed to support patients to better self-manage their condition and identify when medical input may be needed. This was successfully applied to describe the presence or absence of common individual features in each system.

The review of features highlighted some interesting findings. It was surprising to note that while over half (58%) of systems had the facility for healthcare providers to remotely monitor patient data, fewer than half (46%) included the facility for patients to monitor and review their own data. Given the available evidence suggesting that self-monitoring is generally beneficial to support patients' self-management [18, 181, 185], this feature could be very important to improve efficacy of systems and in most cases, may be relatively easy to implement. Similarly, less than half the systems (41%) included a feature for delivering advice to support patients to self-manage symptoms and less than a third provided patients with access to general educational information. The two least common features were facilities to support communication between patients and healthcare providers (15%) and communication between patients themselves respectively (10%). Previous research has indicated that these features are highly valued and utilised by patients [81, 177, 179, 185]. It is likely that these features are less common due to complexities in their implementation and maintenance. For example, it may be difficult to engage busy clinicians to respond to patient communication in

this way, and there are ethical considerations around the need to moderate patient forums that are endorsed by a healthcare facility.

In Stage 2 of the review, little agreement was found in how patient engagement with systems was defined, measured or reported meaning it was not possible to compare levels of engagement across studies or make any conclusions on relationships with system features. In addition, reasons for engagement or lack of engagement were not routinely reported or explored. The review also indicated heterogeneity in terms of outcomes used to evaluate systems. Even of those that focused on symptoms or global quality of life, the variation in methods and measures used made meaningful comparison impossible.

Due to the heterogeneous nature of reporting engagement and outcomes, it was not possible to explore any relationships with system features. These findings are similar to other reviews undertaken in this area, which have also found that poor assessment and reporting of patient engagement with systems makes comparison between studies difficult. Brower et al made quantifiable and comparable reports of engagement part of the inclusion criteria for their review, and results indicated that facility for communication with other patients may be a very influential factor in patient engagement and needs careful consideration during system design [179]. However, other oncology specific reviews have found that methods of assessing and reporting patient engagement were too heterogeneous to make meaningful conclusions [86, 243]. Only eight trials (7 randomised and 1 non-randomised) evaluating systems were identified, none of which reported any analysis on relationships between engagement and outcomes, and three of which did not report any data on patient engagement at all. This does not seem to be unique to oncology. Donkin et al [244] set out to review the impact of patient engagement with e-therapies across a range of disease groups, and similarly found that this is not a link that is routinely explored.

Robust evidence supporting the value of systems for patient centred outcomes was limited, with a large proportion of feasibility studies identified and much fewer RCTs. While all trials

used some measure of patient centred outcome to evaluate systems, a wide range of assessment tools were used, again making comparison difficult. In addition, two of the studies used the same measure for symptom assessment as part of the intervention, as for the outcome measure. Only three trials reported any measure of self-efficacy, one of which used a study specific non-validated measure [82], and another which was assessed using a subscale of a global QoL measure [87] and finally one assessing coping self-efficacy [91]. The reviewed systems generally demonstrated positive outcomes for patients as has been found in other reviews [183].

Due to the heterogeneous nature of study designs and methods of reporting engagement and outcomes, it was not possible to explore any relationships with system features. This is a field of research that is still in its infancy, and the large number of feasibility studies and abstracts identified are likely to be indicative of this. A number of protocols for planned quality trials were identified which may contribute to understanding of associations between system features, adherence and outcomes in more depth in the future [94, 170, 203, 215, 220, 223].

5.5.2 Strengths and limitations

One of the main strengths of this review was the development of the taxonomy of system features which was successfully applied to the systems identified. This taxonomy may be useful to consider for future development and evaluation of ePROM system. Taxonomies such as the Classification of Digital Health Interventions and the Behaviour Change Technique Taxonomy have been useful in creating a common language and allowing better comparison of interventions to establish what works [245, 246]. However, these taxonomies are by design quite broad and more tailored and specific taxonomies such as the one described in this chapter are also necessary to streamline the processes of comparison for specific types of intervention. To my knowledge, this is the first systematic review in this field to identify and characterise all available ePROM systems for patients to report and manage side effects of

cancer treatment, in addition to evidence relating to patient engagement and patient centred outcomes.

In order to meet the aims of the review, many publications were included which had limited information available and some of which were of poor quality. However, this was necessary in order to meet the aims of the review and evaluate all evidence.

5.5.3 Conclusion

The systematic review indicated that even when feasibility testing was undertaken to explore patient engagement or adherence with systems, reasons for engagement, or lack of, were not routinely explored. Neither was the potential impact of patient engagement on benefits of the system, or evaluative outcomes.

There were only a small number of RCTs evaluating systems, and the outcomes chosen for evaluation varied dependent on the approach used for design with the majority focusing on symptom control. Patients using eRAPID in our usability study indicated that they found benefits from using the system over and above symptom management. The language that they used (e.g. 'reassuring', 'comforting', 'a lifeline') indicated that it improved their confidence to manage symptoms, cope with their treatment and some patients felt it improved their interactions with their healthcare teams. However it was surprising how few trials assessed psychosocial outcomes such as self-efficacy. Only three trials reported any measure of self-efficacy, and only one of these used a validated measure.

The next step of the thesis was to further explore patient engagement with eRAPID, and the psychological benefits that patients might derive from using eRAPID throughout their cancer treatment. With a planned RCT of more than 500 patients, there was an opportunity to explore this in depth both quantitatively and qualitatively. This work is described in the next two Chapters.

Chapter 6 Quantitative analysis to explore the patient perspective of using eRAPID during chemotherapy

6.1 Background

6.1.1 Overview

Chapter 3 described some of the challenges patients face managing side effects of chemotherapy. Despite guidance from their healthcare team, patients reported they were often uncertain about when self-management was appropriate, and when they needed to contact the hospital. Chapter 4 described patients' experiences of using eRAPID during chemotherapy in a field usability study. In the end of study interviews, patients often described eRAPID as 'reassuring' and reported that the advice provided increased their confidence in managing symptoms appropriately, and also provided support coping with their cancer treatment. However, adherence to weekly reporting was varied and the majority of patients reported that they did not use the eRAPID advice website.

Chapter 5 described a systematic review of systems available to support patients to report and manage side effects of cancer treatment and synthesised the available evidence on patient engagement and evaluating systems. Feasibility studies often reported on patient engagement, but there was much variation in how this was defined and measured and little exploration into potential predictive factors. Similar to findings in other chronic disease groups [244], few of the RCTs we identified reported any data on patient engagement with systems and none reported any analysis on the relationship between engagement and outcomes. While there was some evidence of potential in terms of patient outcomes, robust evidence was limited with few RCTs and very few of these assessed the impact of systems on patient centred outcomes such as self-efficacy.

Chapter 2 described the methodology of a large RCT with an internal pilot to evaluate eRAPID in systemic therapy in terms of improving the safe delivery of chemotherapy. The work described in this Chapter was integrated into the design of the RCT, and builds on previous work to further explore the potential of eRAPID to improve patient experience throughout chemotherapy. The impact of patient engagement with eRAPID is also explored, in addition to examining factors which may predict adherence to weekly symptom reports.

6.1.1 Patient engagement with eRAPID

Chapter 4 described the variability we observed in the usability study in terms of patient engagement with weekly symptom reports and use of the eRAPID website. While 42% (5/12) of patients completed the weekly symptom reports regularly throughout the study, adherence to weekly completion (i.e. actual/expected completions per patient) ranged from 33% to 92% with an average of 63%. End of study interviews also indicated that patients use of the eRAPID self-management advice was varied, with some patients reporting accessing the advice regularly, and others reporting never accessing it at all.

In this Chapter, we will further explore patient engagement with eRAPID in terms of adherence to weekly symptom report completions, and assess use of the eRAPID self-management advice website using web analytics. In addition to descriptively reporting on patient engagement, we will also be exploring the impact that engagement has on the outcomes described above of self-efficacy to self-manage throughout chemotherapy, coping self-efficacy and patient activation (PA). In other words, do patients who are more engaged with the system derive more benefit from it?

Engagement is a complex and multi-faceted issue and as outlined in Chapter 5, the evidence on adherence and engagement with systems such as eRAPID is limited. Medication adherence literature suggests that it is likely to be influenced by patients' attitudes and beliefs, clinical variables impacting patient experience of disease and treatment and a wide range of

demographic variables [247, 248]. We will explore the role of some of these variables in predicting patients' adherence to weekly symptom report completions and their use of the eRAPID website.

In addition to clinical and demographic variables and PA, we also plan to explore the role of clinicians' use of data and patient experiences of chemotherapy. Clinician use of eRAPID data in routine consultations is likely to impact on patients' attitudes and beliefs towards the system and its perceived usefulness, not just as a tool to facilitate self-management, but as a tool to provide useful information to their healthcare team and facilitate care. Patients' negative experiences during chemotherapy such as hospital admissions and treatment changes may also impact their use of eRAPID. However, this relationship is likely to be complex. Patients who have more of a symptom burden may be less likely to use eRAPID if they feel very unwell, but conversely, eRAPID is likely to be more useful to patients experiencing symptoms, than those who remain feeling well throughout their treatment.

6.1.2 The impact of eRAPID on the patient experience of chemotherapy

Three main themes were identified from the end of study interview analysis in Chapter 4, following patients' use of eRAPID in a usability study. The themes were:

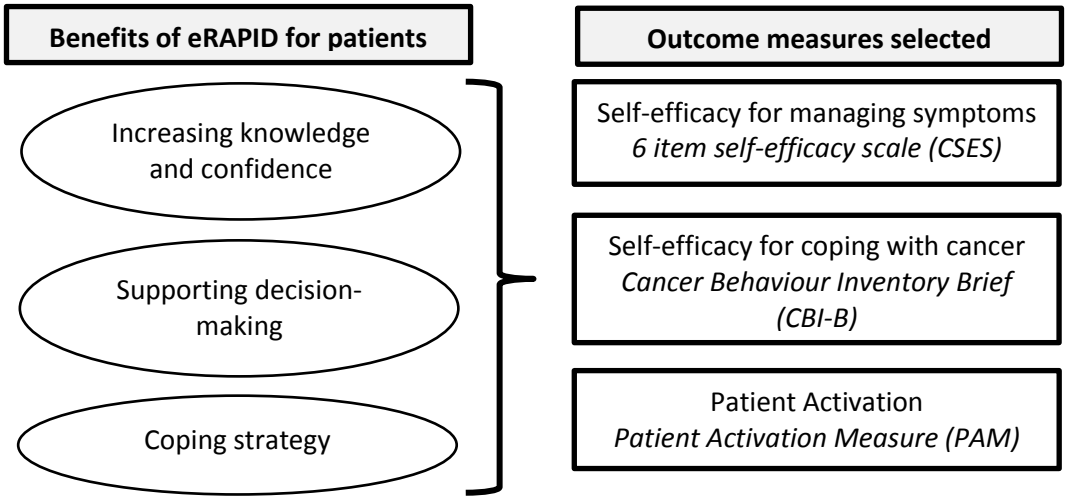
1. Increasing knowledge and confidence
   The self-management advice empowered patients by providing the information and support they needed to manage symptoms on their own terms. Patients felt confident doing this in the knowledge that the system would provide a 'safety net' if they needed to contact the hospital.

2. Supporting decision-making
   Patients felt that using the eRAPID system helped reduce their worry by aiding decision-making about when they needed to contact the hospital and when it was more appropriate to contact their health team.

3. Coping strategy
   Some patients found eRAPID useful to identify symptom patterns which helped reassure them that symptoms were temporary. This helped them to cope and gave them motivation to continue through treatment.

In order to assess the potential benefit of eRAPID to increase patients' knowledge and confidence in managing treatment side effects and support coping with their cancer treatment, three constructs and corresponding outcome measures were selected which fit the themes above. The constructs are not intended to directly map onto the themes, but rather encompass them as a whole. An overview of the outcome measures selected is illustrated in Figure 6.1. A full description of the properties of each of the selected measures is included in the methods in Section 6.3.4.

Figure 6.1 Overview of selected outcome measures



6.1.2.1 Self-efficacy for managing symptoms

Self-efficacy is defined as 'a belief of how well one can execute courses of action required to deal with prospective situations'. Self-efficacy theory posits that individuals with high levels of self-efficacy are more likely to initiate effort towards a goal and to sustain that effort in the face of obstacles and failures [249]. The increasing drive in healthcare towards self-management of chronic diseases has highlighted the important role that self-efficacy plays.

Individuals with chronic illnesses such as diabetes or chronic kidney disease are required to perform self-management behaviours daily. Higher self-efficacy in these populations has consistently been demonstrated to be associated with better diet, exercise, self-monitoring and adherence to medication [250-253].

Self-efficacy for cancer patients has been described as the belief that one can successfully execute behaviour required to produce an expected outcome in relation to cancer and its treatment [254]. As cancer is increasingly being described as a chronic illness, self-management is becoming more important, particularly with cancer survivor populations, but also within the acute treatment phase. As discussed in previous chapters, patients are required to self-manage in between routine appointments during chemotherapy and make decisions about when to contact the hospital. The impact of chemotherapy on individual patients is often unpredictable and patients can experience severe symptoms even if they are very effective at self-management. However, one would propose that patients who feel informed and confident in their ability to manage throughout treatment will be more likely to be able to effectively manage problems they may experience. There is some evidence to suggest that higher self-efficacy during chemotherapy is associated with lower symptom burden, however, due to the cross-sectional nature of studies, the nature of this relationship is unclear [255, 256]. eRAPID has the potential to increase patients' self-efficacy to manage the side effects of their cancer treatment effectively by the provision of tailored information and advice, in addition to the 'safety net' of alerts to contact the hospital if symptoms are severe.

6.1.2.2 Self-efficacy for coping with cancer

Coping self-efficacy assesses patients beliefs about maintaining a positive attitude, coping with stress and managing their emotions. Cancer patients who have higher levels of coping self-efficacy demonstrate better adjustment to their disease, better long term emotional outcomes such as less anxiety and depression and overall better QoL [257-259]. In addition, patients who

feel more confident about their ability to cope with their cancer and treatment often report better symptom management [260].

eRAPID has the potential to increase coping self-efficacy by normalising symptoms and side effects for patients, and by providing the facility for patients to monitor their symptoms, identify patterns in symptom fluctuation and consequently providing motivation to continue with treatment.

6.1.2.3 Patient Activation

Patient Activation (PA) is a concept which assesses how engaged a patient is in their own healthcare. It is comprised of the knowledge, skills, beliefs and behaviours that a patient needs to effectively manage a chronic illness [261]. While it is related to self-efficacy, it is a broader and more general concept, reflecting attitudes and approaches to self-management and engagement with health and healthcare, rather than being tied to specific behaviours.

PA is still a relatively new concept and within oncology and its role is still uncertain. Studies are scarce and those that exist are cross-sectional or poor quality [262-264]. Evidence from the use of PA in other chronic illness populations such as diabetes suggests that low levels of PA are associated with higher use of hospital resources [265] and high levels of PA are associated with an array of improved health behaviours and health outcomes [261, 266, 267]. In addition, online interventions targeted at supporting self-management can have a positive impact on activation levels [268]. eRAPID has the potential to increase patients' knowledge and skills in managing side effects of treatment and to subsequently influence engagement with self-management and health.

However, patients who are more engaged and activated may also be more likely to engage with eRAPID in the first instance. Patients high in PA are more likely to seek out information online about their illness [269] and similarly, may be more likely to engage with an

intervention such as eRAPID which offers tailored information about their treatment and management of side effects. We will explore the role of PA as a predictor of use of eRAPID.

6.1.3 Role and original contribution

As a part of the core eRAPID team, I led recruitment in the breast clinic and was responsible for recruitment and follow-up of patients, data collection and day to day management in this clinic, in addition to supporting my colleagues in other clinics when needed. I also assisted in the planning, development and preparation of the protocol and am a co-author on this publication [94]. I completed the online ethics application, with supervision from the senior researcher on the study. I developed the methods for evaluation of engagement, working with the IT manager in the group to develop reports for assessing adherence to symptom reports and web analytic reports to track usage of the eRAPID website. I selected the outcome measures for assessing the impact on patient self-efficacy for managing symptoms, self-efficacy for coping and patient activation, and worked with the senior researcher and principal investigator to integrate these into the trial design. This aspect of the trial was included in the main protocol and ethics application. I planned and executed all of the analysis described in this Chapter. I have also presented preliminary work from the internal pilot phase of the trial as a conference poster [270].

6.2 Aims and Objectives

The aims of this Chapter are:

1) To identify potential predictors of patient engagement with eRAPID.
2) To evaluate the impact of eRAPID on patient self-efficacy to manage their disease and treatment, coping self-efficacy and patient activation.
3) To explore if impact of eRAPID on these outcomes is related to patient engagement with the system

6.3 Methods

6.3.1 Design, participants, and procedure

All of the data was collected as part of the large scale RCT to evaluate eRAPID in systemic therapy. Patients were recruited from Breast, Gynae and Colorectal clinics and were randomised to receive eRAPID intervention or usual care. The study period was 18 weeks, which started at patients' first chemotherapy cycle.

The full methodology for the eRAPID RCT is outlined in Chapter 2. The outcome measures chosen specifically for this PhD are described below.

6.3.2 Evaluation of patient engagement

6.3.2.1 Adherence with weekly symptom reports

Patients in the eRAPID intervention arm of the study were asked to complete the eRAPID symptom report weekly over the 18 week study period and were sent a reminder by text or email.

A score was calculated in order to assess adherence with weekly reporting. This score was calculated from each week within which there was at least one completion report in relation to the number of weeks a completion report was expected (calculated one week from when the reminder was sent). If a patient completed more than once within a given week, additional completions were not counted. E.g. If a patient completed 4 times in week 1, but did not complete for the rest of the 18 weeks, this would be calculated as 1/18. This was then converted to a percentage of the overall expected completions. (E.g. 1/18 = 5.6%).

6.3.2.2 Use of the eRAPID website

Patients in the eRAPID intervention arm of the study could access the eRAPID website anytime and view advice on managing symptoms and side effects, keeping healthy during their cancer treatment and coping with the emotional impact of cancer. Patients were required to login to

the website using their unique username and web analytics were used to track the pages visited.

6.3.3 Clinical process measures

As part of the RCT, clinical process measures were collected for all patients (intervention and usual care) on any changes to their treatment plan during the study period (e.g. dose reduction, delay, drug changed), the number of unplanned hospital admissions, number of days spent in hospital and the number of triage events. Triage events included patient phone calls to the acute oncology unit, for which the nurse would complete a triage assessment to determine the course of action, in addition to physical assessments on the unit, where patients would be assessed to determine if there was a need for admission.

6.3.4 Outcome measures

6.3.4.1 6 item self-efficacy scale (CSES)

Self-efficacy to manage disease and treatment during chemotherapy was assessed using this 6-item scale containing items taken from several self-efficacy scales. It covers several domains that are common across many chronic diseases such as symptom control, role function, emotional functioning and communicating with physicians. Each item is rated on a scale of 1 (not at all confident) to 10 (totally confident). The summary score for the scale is the mean of the six items and can range from 1-10. The score is only calculated if there are two or less missing items. Higher number indicates higher self-efficacy.

The CSES has been demonstrated to have a reliable internal consistency (Cronbach's alpha coefficient ranging from of .91 to .93) and good convergent construct validity to other measures of self-efficacy ($r=0.578$, $P < 0.001$). The scale has a unidimensional structure [271, 272].

6.3.4.2 Cancer Behaviour Inventory Brief (CBI-B)

Coping self-efficacy was assessed using the Cancer Behaviour Inventory-Brief Version [273], a 14-item unidimensional instrument designed to assess the coping self-efficacy of cancer patients. Specifically, the CBI-B assesses areas important to coping with cancer including (a) the respondent's beliefs about maintaining independence and a positive attitude, (b) belief in their ability to participate in medical care, (c) skills important for coping and stress management, and (d) their capacity to manage their emotions/affect in difficult situations. Each of the 14 items is rated on a scale of 1 (Not at all confident) to 9 (Totally confident). The CBI-B score is calculated as the sum of all 14 answered items and can range from 28-126. Higher scores mean higher coping self-efficacy. Scores are calculated regardless of the number of missing items so long as at least one item has been answered.

The CBI-B has been demonstrated to have good internal consistency across different samples (Cronbach's alpha coefficient ranging from .84 to .88) and good external validity demonstrated by positive correlations with measures of quality of life and optimism and negative correlations with measures of depression and sickness impact. The shortened measure (CBI-B) correlates highly with the full measure (CBI-L) (r=.95) [259, 273].

6.3.4.3 Patient Activation Measure (PAM)

Patient activation was assessed using the Patient Activation Measure (PAM) [274], a tool for measuring the level of patient engagement in their healthcare. It was designed to assess an individual's knowledge, skill and confidence for self-management. The PAM 13-item scale explores beliefs, knowledge and confidence for engaging in health behaviours. Each item is rated on a four point scale from strongly disagree to strongly agree and an option for 'non applicable' is provided. To calculate the total PAM score, the summary score is divided by the number of items answered (excepting non-applicable items) and multiplied by 13. This score is then transformed to a scale with a theoretical range 0–100, based on calibration tables, with higher PAM scores indicating higher PA. These scores can be subdivided to categorise people

into one of four activation categories ranging from 1- Low activation to 4- High activation. The summary score is only calculated if there are less than 4 items missing or with an N/A response.

The PAM has been demonstrated to have a reliable internal consistency with a Cronbach's alpha coefficient ranging from 0.84 to 0.907 [266, 275, 276]. External validity has been demonstrated by positive correlations with measures of optimism, hope, self-efficacy and internal locus of control [276]. The PAM has usually been found to be unidimensional in healthy populations [274, 275], but research with patients in mental health settings revealed underlying structures of two or more factors [276, 277].

6.3.4.4 Completion of measures

Patients were asked to complete these outcome measures on paper forms both at baseline, before they commenced chemotherapy, and then again at the end of the study (18 weeks). The measures were integrated into questionnaire packs which also included other measures and information required for the main RCT. Specific information about these questionnaire packs at baseline and 18 weeks is given below.

6.3.4.4.1 Completion of measures at baseline

Patient completed measures while the researcher was completing the randomisation procedures (see section 2.4.4.2). This usually took place in a private room at the hospital following patients' pre-assessment appointment prior to starting chemotherapy. Alternatively, some patients requested to complete the randomisation procedures and the baseline measures at their first chemotherapy appointment. Where possible patients were asked to come in early before their chemotherapy appointment and this was undertaken in a private room next to the chemotherapy day unit. However, some patients were unable to come in early, or forgot on the day, and these patients completed the baseline measures on the

chemotherapy ward whilst undergoing treatment. This was generally in a room shared with other patients.

Patients were required to complete two questionnaire packs at this time point. The first was a brief socio-demographic and computer usage questionnaire (see section 2.4.5.1.1) and the second was the 'Baseline questionnaire pack'. This questionnaire included the primary outcomes and some of the secondary outcomes for the main RCT, in addition to the outcome measures described above (see section 2.4.5.1). The measures appeared in the following order: FACT-G, EQ-5D, CSES, CBI-B, PAM and the EORTC QLQC30. The order of questionnaires was not rotated.

6.3.4.4.2 Completion of measures at 18 weeks

If patients had a clinic or chemotherapy appointment at around the time their 18 week questionnaire was due, they were seen in person by a member of the research team if possible and asked to complete the questionnaire there and then. This would be in a clinic waiting room, or more often on the chemotherapy day ward. However, if the patient did not have a hospital appointment around this time, or if a member of the research team was not available, questionnaire packs were posted out to patients with a stamped addressed envelope to return it. If the questionnaire was not received back, up to two postal reminders were sent out (including the questionnaire pack and SAE) over the next two weeks.

Again, the questionnaire packs included other measures for the main RCT and appeared in the following order: FACT-G, EQ-5D, CSES, CBI-B, PAM, EORTC QLQC30 and the Use of Resources Form. Again, the order of questionnaires was not rotated.

6.3.5 Analysis

6.3.5.1 Descriptive and statistical analysis

All data was inputted into a local data management system (DMS) by the research team over the course of the study. Then data was then exported directly into IBM SPSS version 22. All analyses were completed using SPSS. Descriptive statistics were assessed using crosstabs. Due to the limited use of the selected measures in cancer populations undergoing active treatment, all 3 outcome measures were subjected to factor analysis (see section 6.4.3). A series of ANCOVAs were used to assess the impact of eRAPID on the selected outcomes, linear regression analyses were used to assess the impact of patient engagement on the outcomes and logistic regression was used to predict patient adherence to weekly symptom reporting.

6.3.5.2 Data validation

A second research assistant (ZR) validated a 10% proportion of all data by cross checking SPSS files with source data, in addition to checking a proportion of scoring for the CSES, the CBI-B and the PAM at both baseline and 18 weeks to ensure that this had been correctly calculated. Some initial issues were identified due to the different treatment of missing data of the three measures. Specifically, scores were calculated for the CSES regardless of missing data. This was addressed by recalculating all scores for this measure and following a revalidation and checking of data. No additional issues were identified and the data was deemed to be of satisfactory quality.

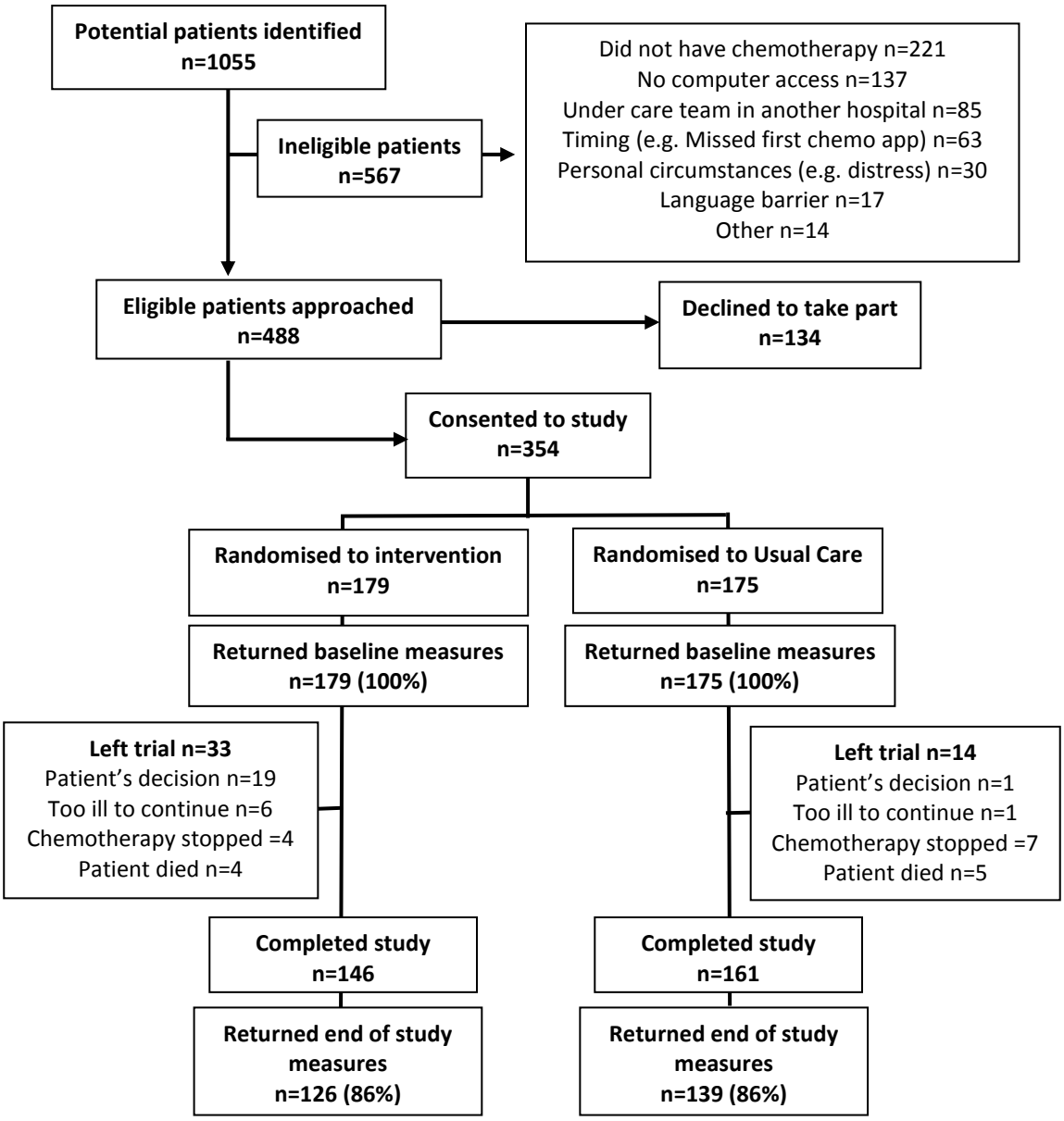
6.4 Results

6.4.1 Participants

6.4.1.1 Recruitment, withdrawals and missing data

The eRAPID RCT was not due to end until approximately October 2018. Due to the timing of this thesis, it was necessary to begin analysis before this time. Data was extracted on 5th January 2018 at which point 354 patients had completed the study. An additional 76 patients were on study at this point, but had not completed their 18 week follow up and are not included in the main analyses. The last of the 354 patients was consented to the study on 1st September 2017. Figure 6.2 illustrates the number of patients identified, ineligible and approached up until this date, in addition to information on any of the 354 patients who left the trial before their 18 week study period was completed. Only 13% (137/1055) of potential patients identified were ineligible because of a lack of internet or computer access. The consent rate for the study was 73% (354/488). The attrition rate was 13% (47/354). The return rate for 18 week questionnaires was 86% (265/307). Due to the different requirements for each stage, the number of patients included in each phase of analysis differ, and this is explicitly stated in each section.

Figure 6.2 Flow diagram of the progress through the phases of the randomised trial



Descriptive data for patients who left the trial or who did not return their 18 week questionnaires in displayed in Table 6.1 below. The majority of patients (70.2%, n=33) who left the trial were on the intervention arm of the study as intervention patients who were not actively using eRAPID were generally identified by research staff during the 18 week study period and given the option to leave the trial if they wished. There were no obvious demographic differences between patients who stayed on study and those who left trial, although there were a slightly higher proportion of patients who left in the lowest and highest

age groups and in the lowest education level group. A description of withdrawal procedures for the trial is included in section 2.4.4.6.

Table 6.1 Withdrawals and missing data

	Left trial (n=47)		Did not return 18 week Q (n=42)		Remaining sample (n=265)		Total	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Age (years)								
Mean & standard deviation	57.5	14.4	54.0	10.9	55.9	11.9	55.9	11.9
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Age group								
Up to 34 years	6	12.8%	1	2.4%	15	5.7%	22	6.2%
35-49 years	5	10.6%	12	28.6%	56	21.1%	73	20.6%
50-59years	17	36.2%	17	40.5%	96	36.2%	130	36.7%
60-69 years	8	17.0%	9	21.4%	67	25.3%	84	23.7%
70+years	11	23.4%	3	7.1%	31	11.7%	45	12.7%
Total	47		42		265		354	
Study arm								
eRAPID intervention	33	70.2%	20	47.6%	126	47.5%	179	50.6%
Usual care	14	29.8%	22	52.4%	139	52.5%	175	49.4%
Total	47		42		265		354	
Gender								
Male	8	17.0%	14	33.3%	51	19.2%	73	20.6%
Female	39	83.0%	28	66.7%	214	80.8%	281	79.4%
Total	47		42		265		354	
Education (missing n=11)								
Up to school leaving age	22	47.8%	14	35.0%	74	28.8%	110	32.1%
Beyond school leaving age	8	17.4%	10	25.0%	64	24.9%	82	23.9%
Degree/prof qualification	16	34.8%	16	40.0%	119	46.3%	151	44.0%
Total	46		40		257		343	
Cancer type								
Breast	14	29.8%	18	42.9%	118	44.5%	150	42.4%
Gynae	17	36.2%	3	7.1%	63	23.8%	83	23.4%
Colorectal	16	34.0%	21	50.0%	84	31.7%	121	34.2%
Total	47		42		265		354	
Marital status (missing n=4)								
Married/Civil Partnership	25	54.3%	25	61.0%	172	65.6%	222	63.6%
Cohabiting	6	13.0%	6	14.6%	24	9.2%	36	10.3%
Separated/Divorced	6	13.0%	3	7.3%	25	9.5%	34	9.7%
Widowed	5	10.9%	1	2.4%	12	4.6%	18	5.2%
Single	4	8.7%	6	14.6%	29	11.1%	39	11.2%
Total	46		41		262		349	

6.4.1.2 Patient demographic and clinical data

Patients who left the trial (n=47) were removed from the dataset leaving a total sample of n=307 (Intervention n=146, Usual care n=161).

Chi-square analysis were run to identify any differences between the intervention and usual care groups on baseline demographic and clinical data and computer usage. There were no significant differences at the p<.01 level between groups on gender, age, marital status, education, IMD, performance status at first chemotherapy, chemotherapy intent (curative/non-curative), whether the patient had chemo previously or any of the computer usage questions.

6.4.1.2.1 Demographic data

Data is presented in Table 6.2 for each study arm and as an overall total. The overall sample was majority female (78.8%). The mean age of the overall sample was 55.6 years (SD=11.5, range (18-82), and this was the same in both study arms.

45.5% of the overall sample had a degree or equivalent professional qualification and 24.9% had some education beyond school leaving age. Patients were grouped into quintiles from 20% least deprived to most deprived based on the national Index of Multiple Deprivation (IMD) scores [278]. There were a higher percentage of patients in the two 20% least deprived quintiles (24.5% and 26.8%) than in the two 20% most deprived groups (17.0% and 17.0%). There were no differences on any variables between study arms.

Table 6.2 Demographic data by study arm

	eRAPID intervention		**Usual care**		**Total**	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
Age (years)						
Mean and standard deviation	55.6	12.2	55.6	10.9	55.6	11.5
	N	%	N	%	N	%
Age group						
Up to 34 years	10	6.8%	6	3.7%	16	5.2%
35-49 years	32	21.9%	36	22.4%	68	22.1%
50-59years	50	34.2%	63	39.1%	113	36.8%
60-69 years	37	25.3%	39	24.2%	76	24.8%
70+years	17	11.6%	17	10.6%	34	11.1%

Total	146		161		307	
Gender						
Male	35	24.0%	30	18.6%	65	21.2%
Female	111	76.0%	131	81.4%	242	78.8%
Total	146		161		307	
Marital status (missing n=4)						
Married/Civil Partnership	102	70.8%	95	59.7%	197	65.0%
Cohabiting	9	6.3%	21	13.2%	30	9.9%
Separated/Divorced	12	8.3%	16	10.1%	28	9.2%
Widowed	6	4.2%	7	4.4%	13	4.3%
Single	15	10.4%	20	12.6%	35	11.6%
Total	144		159		303	
Education beyond school leaving age? (missing n=10)						
Up to school leaving age	43	30.1%	45	29.2%	88	29.6%
Beyond school leaving age	34	23.8%	40	26.0%	74	24.9%
Degree/professional qualification	66	46.2%	69	44.8%	135	45.5%
Total	143		154		297	
Index Multiple Deprivation (IMD) quintile (missing n=6)						
20% most deprived	28	19.2%	24	15.0%	52	17.0%
20% to 40% most deprived	18	12.3%	34	21.3%	52	17.0%
20% middle deprived	22	15.1%	23	14.4%	45	14.7%
20 to 40% least deprived	38	26.0%	44	27.5%	82	26.8%
20% least deprived	40	27.4%	35	21.9%	75	24.5%
Total	146		160		306	

6.4.1.2.2 Clinical data

Data is presented in Table 6.3 on cancer type, performance status at baseline as measured by the ECOG (Eastern Cooperative Oncology Group) measure, chemotherapy intent (curative/non-curative) and whether patients had received chemo previously (yes/no). There were a higher proportion of participants from the Breast clinic (44.3%) than in the Gynae (21.5%) and Colorectal clinics (34.2%). The majority of patients (68.9%) had a normal performance status at baseline, with only 3.7% in the two poorest status groups combined. The majority of patients were being treated with curative intent (72.2%) and had not had chemotherapy previously (75.6%). There were no differences on any variables between study arms.

Table 6.3 Clinical data by study arm

	eRAPID intervention		**Usual care**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**
Cancer type						
Breast	65	44.5%	71	44.1%	136	44.3%

Gynae	26	17.8%	40	24.8%	66	21.5%
Colorectal	55	37.7%	50	31.1%	105	34.2%
Total	146		161		307	
Performance status (at first chemo cycle), missing (n=5)						
0 - WHO - Normal	100	69.9%	108	67.9%	208	68.9%
1 - WHO - Light Work	36	25.2%	47	29.6%	83	27.5%
2 - WHO - Ambulatory >50%	6	4.2%	3	1.9%	9	3.0%
3 - WHO - Ambulatory < 50%	1	0.7%	1	0.6%	2	0.7%
Total	143		159		302	
Chemotherapy intent (missing n=1)						
Curative	104	71.2%	117	73.1%	221	72.2%
Non-curative	42	28.8%	43	26.9%	85	27.8%
Total	146		160		306	
Previous chemo received						
No	110	75.3%	122	75.8%	232	75.6%
Yes	36	24.7%	39	24.2%	75	24.4%
Total	146		161		307	

6.4.1.2.3 Computer usage

Data is presented in Table 6.4 from the baseline demographic and computer usage questionnaire on how long patients had been using a computer for, how often they used a computer and how easy they found it. High levels of computer usage were reported with the majority of patients reporting they had been using a computer for more than five years (83.7%), that they used one daily (96.1%) and found it easy to use (88.0%). There were no differences on any variables between study arms.

Table 6.4 Computer usage by study arm

	eRAPID intervention		**Usual care**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**
Level of computer usage (missing, n=1)						
Can only use a computer if I have help	9	6.2%	9	5.6%	18	5.9%
Using a computer for less than a year	0	0.0%	1	0.6%	1	0.3%
Using a computer for 1 - 2 years	6	4.1%	4	2.5%	10	3.3%
Using a computer for 2 - 5 years	9	6.2%	12	7.5%	21	6.9%
Using a computer for more than 5 years	122	83.6%	134	83.8%	256	83.7%
Total	146		160		306	
How often do you use a computer? (missing n=7)						
Daily	141	96.6%	152	95.6%	293	96.1%
Weekly	2	1.4%	3	1.9%	5	1.6%
Monthly	0	0.0%	1	0.6%	1	0.3%
Very rarely	3	2.1%	3	1.9%	6	2.0%
Total	146		159		305	
How do you find using a computer in general? (missing n=6)						
Easy	125	86.2%	140	89.7%	265	88.0%

Sometimes difficult	17	11.7%	11	7.1%	28	9.3%
Difficult	3	2.1%	4	2.6%	7	2.3%
Impossible	0	0.0%	1	0.6%	1	0.3%
Total	145		156		301	

6.4.1.3 Clinical staff

The roles of participating staff in each clinic are displayed below in Table 6.5. The majority of staff using the system were oncology consultants or specialist registrars.

Table 6.5 Clinical staff information

	Breast		Gynae		Colorectal		Total	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Oncology consultants	5	50.0%	4	40.0%	4	44.4%	13	44.8%
Specialist registrars	3	30.0%	3	30.0%	0	0.0%	6	20.7%
Staff grade doctors	0	0.0%	0	0.0%	2	22.2%	2	6.9%
Clinical Nurse Specialists	2	20.0%	3	30.0%	0	0.0%	5	17.2%
Pre-assessment nurses	0	0.0%	0	0.0%	3	33.3%	3	10.3%
Total	10		10		9		29	

6.4.2 Patient engagement with eRAPID

6.4.2.1 Descriptive data

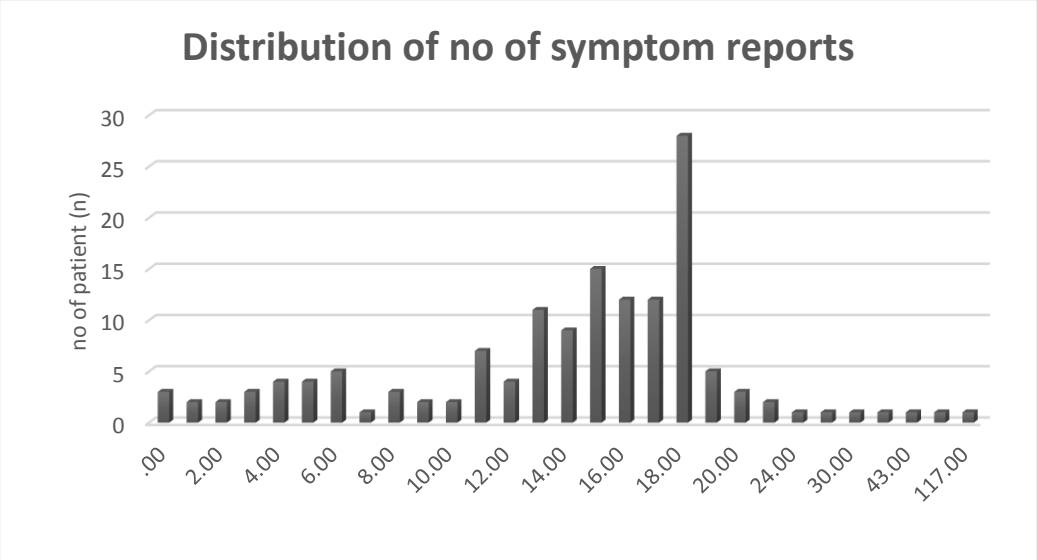
Patients who left the trial (n=47) and Usual care patients (n=161) were removed from the dataset. This left a total dataset of n=146 intervention patients. The majority of non-users were identified during the study period and given the option of leaving the trial if they no longer wished to participate. However, there were a small number of patients who did not wish to leave the trial, but did not ever use the system (n=3). These patients were considered to be passive withdrawals and were also excluded from the final dataset, leaving a total of n=143.

6.4.2.1.1 Completion of eRAPID symptom reports

The overall distribution of completion frequency is illustrated below in Figure 6.3. Patients were sent a weekly reminder by phone or email to complete a symptom report and were on study for 18 weeks, although they could complete as many times as they wished. The majority

of the distribution is from 13-19 completions. However, there are a number of outliers, both at the lower and upper ends of the distribution.

Figure 6.3 Distribution of no of symptom reports



Some of the demographic information for these outliers is displayed in Table 6.6, excluding those who never used the system at all (n=3). Outliers were identified as those approximately in the upper and lower 10% of completers. This was coded as those completed 4 or less times in the lower 10% group (n=14, 9.6%) and those with 20 or more completions in the upper 10% group (n=12, 8.2%).

There were a higher proportion of high completers in the Colorectal group (n=6, 50%) compared to the Breast (n=2, 16.7%) and Gynae groups (n=4, 33.3%). There were also a higher proportion of lower completers in the younger age groups. This may be reflective of those with young families, as there were also a higher number of patients with children (75%) in the lower completers group. There were no obvious patterns for computer usage in the groups.

Table 6.6 Demographics and computer usage of lowest 10% and highest 10% of completers

	Lower 10% (n=15)		**Higher 10% (n=17)**		**Remaining sample (n=111)**		**Total (n=143)**	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	SD
Age (years)								

Mean & standard deviation	48.4	10.6	54.4	9.6	56.6	12.3	5.7	12.2
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Age group								
Up to 34 years	2	14.3%	1	8.3%	7	5.8%	10	6.8%
35-49 years	6	42.9%	2	16.7%	24	20.0%	32	21.9%
50-59years	3	21.4%	5	41.7%	42	35.0%	50	34.2%
60-69 years	3	21.4%	4	33.3%	30	25.0%	37	25.3%
70+years	0	0.0%	0	0.0%	17	14.2%	17	11.6%
Total	14		12		120		146	
Gender								
Male	4	28.6%	2	16.7%	29	24.2%	35	24.0%
Female	10	71.4%	10	83.3%	91	75.8%	111	76.0%
Total	14				120		146	
Children under 18 in household								
Children	6	75.0%	3	42.9%	25	25.3%	34	
No children	2	25.0%	4	57.1%	74	74.7%	80	
Total								
Education beyond school leaving age? (missing n=3)								
Up to school leaving age	2	15.4%	2	16.7%	39	33.1%	43	30.1%
Beyond school leaving age	4	30.8%	3	25.0%	27	22.9%	34	23.8%
Degree/professional qualification	7	53.8%	7	58.3%	52	44.1%	66	46.2%
Total	13		12		118		143	
Index Multiple Deprivation (IMD) quintile								
20% most deprived	2	14.3%	0	0.0%	26	21.7%	28	19.2%
20% to 40% most deprived	0	0.0%	2	16.7%	16	13.3%	18	12.3%
20% middle deprived	4	28.6%	2	16.7%	16	13.3%	22	15.1%
20 to 40% least deprived	2	14.3%	5	41.7%	31	25.8%	38	26.0%
20% least deprived	6	42.9%	3	25.0%	31	25.8%	40	27.4%
Total	14		12		120		146	
Level of computer usage								
Can only use a computer if I have help	2	14.3%	0	0.0%	7	5.8%	9	6.2%
Using a computer for less than a year	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Using a computer for 1 - 2 years	0	0.0%	0	0.0%	6	5.0%	6	4.1%
Using a computer for 2 - 5 years	0	0.0%	0	0.0%	9	7.5%	9	6.2%
Using a computer for more than 5 years	12	85.7%	12	100.0 %	98	81.7%	122	83.6%
Total	14		12		120		146	
Cancer type								
Breast	4	28.6%	2	16.7%	59	49.2%	65	44.5%
Gynae	5	35.7%	4	33.3%	17	14.2%	26	17.8%
Colorectal	5	35.7%	6	50.0%	44	36.7%	55	37.7%
Total	14		12		120		146	

6.4.2.1.2 Usage of eRAPID self-management advice website

Analytics for the eRAPID self-management advice website are displayed in Table 6.7.

The eRAPID website is set out in three main sections:

1. 'Managing treatment symptoms and side effects' which offers self-management advice for common symptoms and side effects of chemotherapy.
2. 'Keeping healthy during cancer treatment' which offers more general advice on diet, exercise and self-care.
3. 'Coping with cancer and your treatment' which offers information about relaxation and local services and support that are available.

All website pages were viewed at least once. The most commonly visited pages for 'Managing treatment symptoms and side effects' were 'tiredness and fatigue' (7.0%) and 'tingling or numbness in fingers and toes' (5.1%).

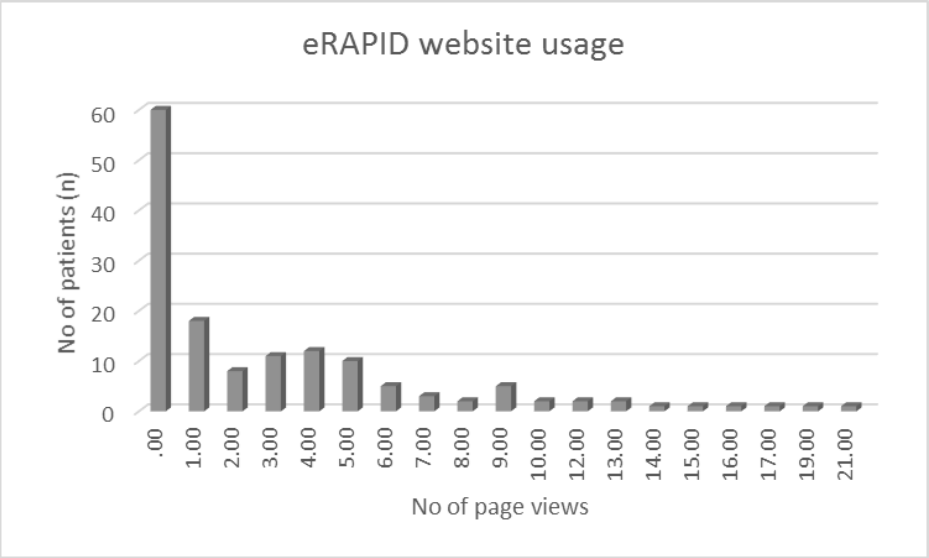
Table 6.7 Overview of website usage

	No of times page viewed	% of overall page views
Managing treatment symptoms and side effects		
tiredness-or-fatigue	44	7.0%
tingling-or-numbness-in-fingers-or-toes	32	5.1%
feeling-or-being-sick	28	4.4%
pain-aches-and-discomfort	27	4.3%
temperature-chills	26	4.1%
shortness-of-breath	23	3.6%
sore-mouth-or-tongue	23	3.6%
swelling-of-the-tummy-abdomen-ascites	21	3.3%
diarrhoea	20	3.2%
constipation	18	2.8%
difficulty-sleeping	17	2.7%
low-mood	17	2.7%
lack-of-appetite	11	1.7%
sore-hands-and-feet-hand-and-foot-syndrome	10	1.6%
anxiety	10	1.6%
pain-and-inflammation-of-the-vein-phlebitis	9	1.4%
recognising-problems-and-signs-of-central-line-infection	9	1.4%
heartburn-and-indigestion	7	1.1%
having-a-stoma	7	1.1%
Keeping healthy during cancer treatment		
physical-activity-and-exercise	39	6.2%
sleep	30	4.7%

mouth-care	27	4.3%
fluid-intake	24	3.8%
eating-well	21	3.3%
Coping with cancer and your treatment		
distracting-occupying-your-mind	29	4.6%
relaxation	26	4.1%
complementary-therapies	23	3.6%
local-services-you-can-access	22	3.5%
massage	17	2.7%
clinical-psycho-oncology-service	16	2.5%
Total		
	633	100%

59% (86/146) of patients on the intervention arm of the study accessed the website at least once during the 18 week period. Of those that did access the website, most accessed it less than 10 times over their 18 week study period. The distribution of the number of page views per patient is illustrated in Figure 6.4 below.

Figure 6.4 Frequency of eRAPID website usage



6.4.2.1.3 Clinician engagement with eRAPID

Clinicians were prompted to use patients' eRAPID data in routine consultations and complete a feedback form each time to report if and how they used the data. A total of 533 forms were completed, 230 in Breast clinics (41.6%), 215 in Colorectal clinics (38.9%) and 108 in Gynae clinics (19.5%).

Figure 6.5 illustrates the percentage of forms in each clinic (e.g. Breast, Gynae and Colorectal clinics) on which clinicians reported 'Yes' or 'No' to the question 'Did you look at the patient's eRAPID symptom information in PPM before/during consultation?'. The majority of forms completed reported 'Yes' to this question across all three clinical groups, however, a lower proportion of forms from the Breast clinic reported 'Yes' than forms completed in the Gynae and Colorectal clinics (74.0% versus 89.4% and 88.6% respectively).

Figure 6.5 Did clinicians look at eRAPID data?

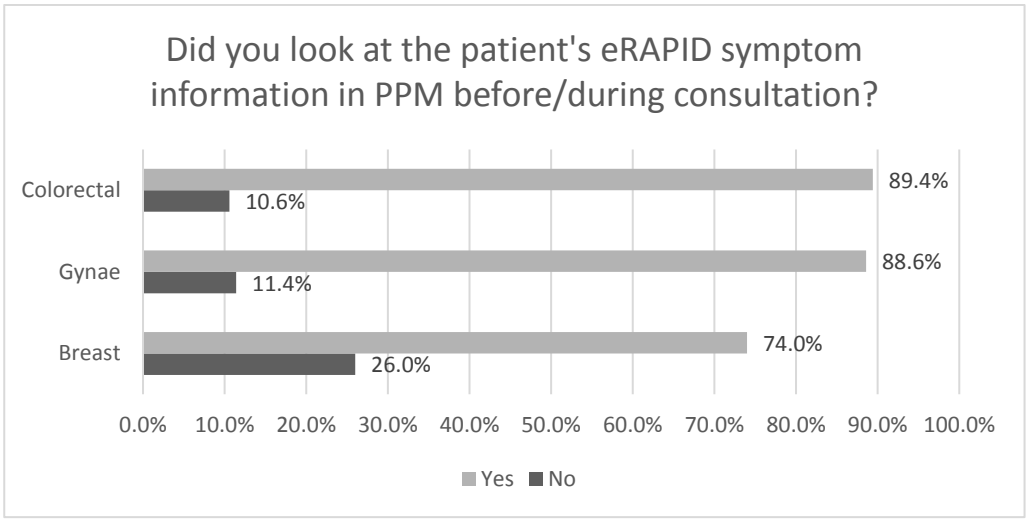


Figure 6.6 illustrates the percentage of forms in each clinic which reported 'Not at all', 'A little', 'Somewhat', 'Quite a bit' or 'Very much' to the question 'Did you use the eRAPID symptom information in the clinic discussion?'. There were a higher proportion of forms reporting 'Not at all' in the Breast and Gynae clinics than in the colorectal clinic (18.9% and 16.2% versus 7.7%). However, there was also a higher proportion of forms reporting 'Very much' in Breast and Gynae clinics compared to the Colorectal clinic (9.7% and 8.6% versus 4.8%). A large proportion of the forms completed in the colorectal clinic (52.9%) reported 'Somewhat' for this question.

Figure 6.6 Did clinicians use eRAPID data?

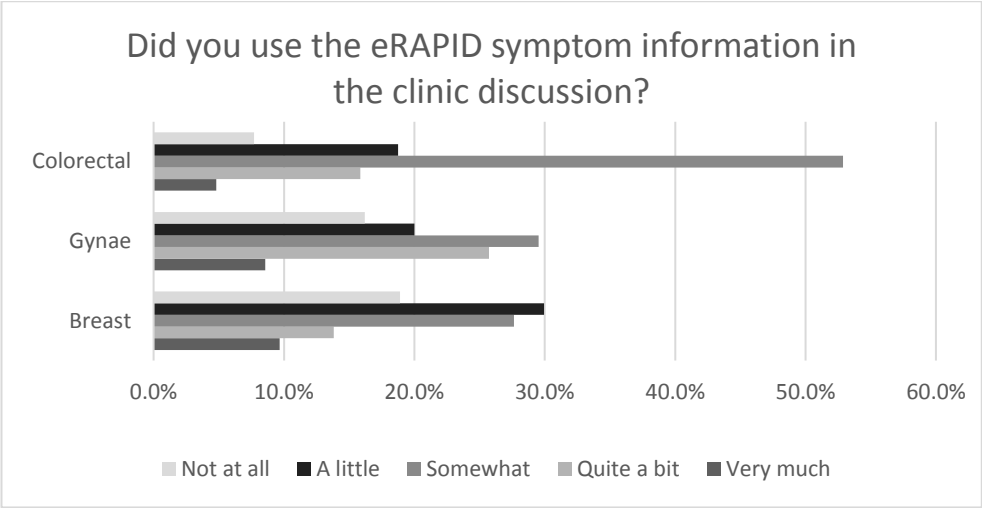


Figure 6.7 illustrates the percentage of forms in each clinic on which clinicians reported 'Not at all', 'A little', 'Somewhat', 'Quite a bit' or 'Very much' to the question 'Did you find the eRAPID symptom information useful?'. Again this followed a similar pattern to the previous question with a lower percentage of forms reporting 'Not at all' and 'Very much' in the Colorectal clinic (4.4% and 9.7%) and a high number reporting 'Somewhat' (51.9%). A higher percentage of forms completed in the Gynae clinic reported 'Very much' or 'Quite a bit' (26.2% and 21.4%).

Figure 6.7 Was the information useful?

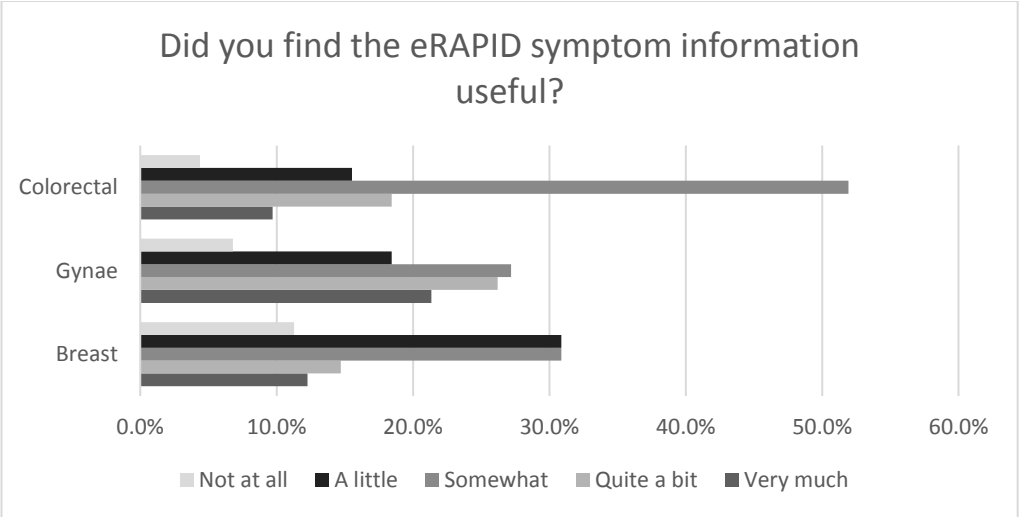
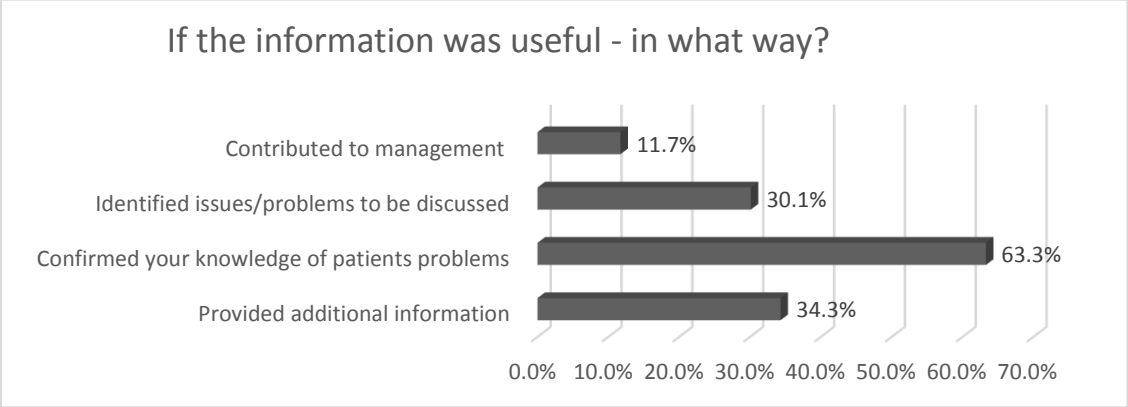


Figure 6.8 illustrates the ways in which clinicians reported that they found the data useful if they had answered yes to this question. Clinicians could select more than one way in which the information was useful, so percentages do not add up to 100%. Clinicians reported that eRAPID data confirmed their knowledge of patients problems 63.3% of the time and provided

additional information 34.3% of the time. It helped identify issues and problems for discussion 30.1% of the time but only contributed treatment management decisions 11.7% of the time.

Figure 6.8 If the information was useful, how was it useful?



6.4.2.1.4 Clinical process measures

The frequency of unplanned hospital admissions for the whole sample is shown below in Table 6.8. The majority of patients (n=220, 71.7%) did not have any unplanned hospital admissions during their 18 week study period. 15.3% (n=47) had one admission and 11.7% (n=36) had two or more admissions. 14.9% (n=45) spend between 1-4 days in hospital, and 12.5% (n=51) spend 5 or more days in hospital during the 18 week study period.

Table 6.8 Unplanned hospital admissions during 18 week study period

	N	%
No of admissions (missing n=4)		
No admissions	220	72.6%
One admission	47	15.5%
Two or more admissions	36	11.9%
Total	303	
No of days in hospital (missing n=4)		
None	220	72.6%
1-4 days in hospital	45	14.9%
5 or more days in hospital	51	12.5%
Total	303	

Table 6.9 below displays the number of triage events per patient during their 18 week study period. Again, the majority of patients did not have any triage events (n=172, 56.8%). 27.4% (n=83) had just one or two triage events and 15.8% (n=48) had 3 or more triage events.

Table 6.9 Triage events during 18 week study period

	N	%
No of triage events (missing n=4)		
None	172	56.8%
1 triage event	51	16.8%
2 triage events	32	10.6%
3 or more triage events	48	15.8%
Total	303	

Table 6.10 below shows a summary of patients who had changes to planned treatment over the 18 week study period. The majority of patients did not have any changes to planned treatment (n=180, 59.4%).

Of those that had changes to planned treatment (n=123, 40.6%), 100% had a dose reduction in chemotherapy and 93.5% had a delay in treatment. Fewer patients had their chemotherapy drug changed (n=30, 24.4%) or had their chemotherapy stopped early (n=36, 29.3%).

Table 6.10 Changes to planned treatment over the 18 week study period

	N	%
Treatment delivered as planned? (missing n=4)		
Yes	123	40.6%
No	180	59.4%
Total	303	
Details of changes to treatment (n=123)		
Chemotherapy dose reduced	123	100.0%
Treatment delayed	115	93.5%
Chemotherapy drug changed	30	24.4%
Chemotherapy stopped early	36	29.3%

6.4.2.2 Logistic regression model to predict adherence

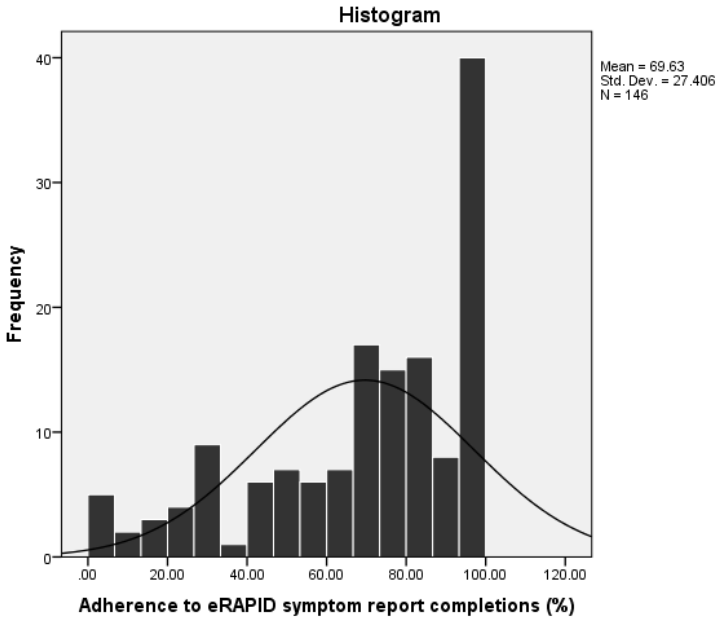
A binary logistic regression was planned to examine predictors of whether or not patients were adherent to the weekly eRAPID symptom report completions.

6.4.2.2.1 Dependent variable (Adherence)

An adherence score was calculated from each week within which there was at least one completion report in relation to the number of weeks a completion report was expected (calculated one week from when the reminder was sent). Please see section 6.3.2.1 for more details on this score.

Initially, a linear regression was planned. However, a large proportion of patients had high levels of adherence and on examination of the variable, it was highly positively skewed (skewness =-.869, SE=.201). The Kolmogorov-Smirnov test was significant at p<.001, indicating that the assumption of normality of distribution had not been met. Transforming the variable using techniques such as exp and reflective log recommended for negatively skewed variables did not improve the distribution. It was decided to dichotomise the variable into 'adherent' and 'non-adherent' users using a median split.

Figure 6.9 Frequency of distribution of Adherence to eRAPID symptom report variable



Levels of adherence were generally high, with 40% of the sample being 100% adherent. The median percentage of adherence was 78%, so all patients with 78% or more were categorised as adherent, and all those with less than 78% were categorised as non-adherent.

6.4.2.2.2 Predictor variables (Demographic data)

Cross-tabs were used to assess demographic data for adherent and non-adherent users (presented in Table 6.11). Patients in the non-adherent group were slightly younger (M=52.66, SD=12.82) than those in the adherent group (M=58.21, SD=11.10). Patients in the non-

adherent group were also more likely to have children under 18 living in the household (38.6% versus 21.1%). There were also more single people in the non-adherent group (15.2% versus 6.4%). There were no other obvious differences between groups on the other demographic variables.

Table 6.11 Demographics of Adherent and non-adherent groups

	Non-adherent (n=67)		Adherent (n=79)		Total (n=143)	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
Age (years)						
Mean and standard deviation	52.66	12.82	58.21	11.10	55.64	12.20
	N	**%**	**N**	**%**	**N**	**%**
Age group						
Up to 34 years	7	10.4%	3	3.8%	10	6.8%
35-49 years	20	29.9%	12	15.2%	32	21.9%
50-59years	19	28.4%	31	39.2%	50	34.2%
60-69 years	15	22.4%	22	27.8%	37	25.3%
70+years	6	9.0%	11	13.9%	17	11.6%
Total	67		79		146	
Gender						
Male	16	23.9%	19	24.1%	35	24.0%
Female	51	76.1%	60	75.9%	111	76.0%
Total	67		79		146	
Marital status (missing n=2)						
Married/Civil Partnership	44	66.7%	58	74.4%	102	70.8%
Cohabiting	3	4.5%	6	7.7%	9	6.3%
Separated/Divorced	6	9.1%	6	7.7%	12	8.3%
Widowed	3	4.5%	3	3.8%	6	4.2%
Single	10	15.2%	5	6.4%	15	10.4%
Total	66		78			144
How many children live in your house? (under 18) (missing n=31)						
No children	35	61.4%	45	78.9%	80	70.2%
Children	22	38.6%	12	21.1%	34	29.8%
Total	57		57		114	
Education beyond school leaving age? (missing n=10)						
Up to school leaving age	21	31.8%	22	28.6%	43	30.1%
Beyond school leaving age	16	24.2%	18	23.4%	34	23.8%
Degree/professional qualification	29	43.9%	37	48.1%	66	46.2%
Total	66		77		143	
Index Multiple Deprivation (IMD) quintile (missing n=6)						
20% most deprived	12	17.9%	16	20.3%	28	19.2%
20% to 40% most deprived	8	11.9%	10	12.7%	18	12.3%
20% middle deprived	13	19.4%	9	11.4%	22	15.1%
20 to 40% least deprived	13	19.4%	25	31.6%	38	26.0%
20% least deprived	21	31.3%	19	24.1%	40	27.4%
Total	67		79		146	

6.4.2.2.3 Predictor variables (Clinical data)

The clinical data for adherent and non-adherent users in displayed in Table 6.12 below. Although there were only a small number of patients (n=7) in the two poorer performance groups (2 and 3), the majority of these patients were in the non-adherent group (6.1% v 2.6%, 1.5% v 0.0%). There were no other obvious differences between groups on the other clinical variables.

Table 6.12 Clinical information for adherent and non-adherent users

	Non-adherent (n=64)		Adherent (n=79)		Total (n=143)	
	N	**%**	**N**	**%**	**N**	**%**
Cancer type						
Breast	31	46.3%	34	43.0%	65	44.5%
Gynae	11	16.4%	15	19.0%	26	17.8%
Colorectal	25	37.3%	30	38.0%	55	37.7%
Total	67		79		146	
ECOG performance status (missing n=3)						
0 - WHO - Normal	49	74.2%	51	66.2%	100	69.9%
1 - WHO - Light Work	12	18.2%	24	31.2%	36	25.2%
2 - WHO - Ambulatory >50%	4	6.1%	2	2.6%	6	4.2%
3 - WHO - Ambulatory < 50%	1	1.5%	0	0.0%	1	0.7%
Total	66		77		143	
Chemotherapy intent						
Curative	50	74.6%	54	68.4%	104	71.2%
Non-curative	17	25.4%	25	31.6%	42	28.8%
Total	67		79		146	
Previous chemotherapy						
No	52	77.6%	58	73.4%	110	75.3%
Yes	15	22.4%	21	26.6%	36	24.7%
Total	67		79		146	

6.4.2.2.4 Predictor variables (Computer usage)

Table 6.13 below shows the baseline levels of computer usage for patients in the adherent and non-adherent groups. There were no clear differences between either groups on baseline computer usage.

Table 6.13 Level of computer usage at baseline for adherent and non-adherent users

	Non-adherent		Adherent		Total	
	N	**%**	**N**	**%**	**N**	**%**
Level of computer usage						
Can only use a computer if I have help	5	7.5%	4	5.1%	9	6.2%
Using a computer for less than a year	0	0.0%	0	0.0%	0	0.0%
Using a computer for 1 - 2 years	6	9.0%	0	0.0%	6	4.1%
Using a computer for 2 - 5 years	2	3.0%	7	8.9%	9	6.2%

Using a computer for more than 5 years	54	80.6%	68	86.1 %	122	83.6%
Total	67		79		146	
How often do you use a computer? (missing n=2)						
Daily	62	95.4%	78	98.7 %	140	97.2%
Weekly	2	3.1%	0	0.0%	2	1.4%
Monthly	0	0.0%	0	0.0%	0	0.0%
Very rarely	1	1.5%	1	1.3%	2	1.4%
Total	65		79			144
How do you find using a computer in general? (missing n=1)						
Easy	57	85.1%	68	87.2 %	125	86.2%
Sometimes difficult	8	11.9%	9	11.5 %	17	11.7%
Difficult	2	3.0%	1	1.3%	3	2.1%
Impossible	0	0.0%	0	0.0%	0	0.0%
	67		78		145	

6.4.2.2.5 Predictor variables (Clinician use of patient data)

Each patient was expected to have 6 forms completed, as these were scheduled to coincide with 3 weekly appointments throughout the study period (3 weeks, 6 weeks, 9 weeks, 12 week, 15 weeks and 18 weeks). However, there were several reasons why forms may not always have been completed at these appointments. For example, Breast patients rarely had an appointment at 18 weeks, or occasionally the date of appointments would be changed and the researcher would not be aware to prompt the clinician to complete a form. Another common reason was that if the patient had not completed any eRAPID symptom reports, a form would not be given to the clinician to complete.

These reasons were not truly related to clinician use of patient data, and so another measure was calculated based on the question 'Did you look at the patient's eRAPID symptom information in PPM before/during consultation?'. A score was calculated for each 'Yes'/total number of forms received per patient and converted to a percentage. For example if a patient had 6 forms completed by their clinician at their consultations, but the clinician only reported using the data in 3 of the consultations, this would be calculated as 3/6=50%.

6.4.2.2.6 Selection of predictor variables

Predictor variables were selected partially based on the descriptive data, and partially based on a more simple, pragmatic approach to considering what variables might impact on patient adherence. The predictor variables chosen were age at study entry, previous computer usage, PAM baseline score, cancer type, performance status at baseline, chemotherapy intent, summary of admissions (none, one, two, three or more), summary of triage events (none, one, two, three or more), and clinician use of eRAPID data score. We initially planned to include the variable 'Children under 18 living in your household' but due to the high level of missing data, this would have made the sample size inadequate. The sample size after inclusion of all variables was n=136, which was adequate [279].

6.4.2.2.7 Binary regression

Previous computer usage, disease group, performance status at baseline, chemotherapy intent, summary of admissions and summary of triage events were categorical or ordinal variables and dummy coding was applied using the SPSS indicator option. Collinearity diagnostics were used and both tolerance and VIF values were well within range for all predictor variables, indicating that the assumption of multicollinearity was met.

When all predictor variables were held constant, the model correctly classified 55.1% of the cases (0% non-adherent, 100% adherent).

In Step 1, after all predictor variables were added to the model, the model was significantly improved (p=.001), explaining 35% of the variance (r2=.350). 75.7% of cases were correctly classified into the adherent/non-adherent groups (67.2% non-adherent and 82.7% adherent). Table 6.14 below displays the contribution of individual variables in predicting the likelihood of a patient being adherent to eRAPID completions. The only significant predictor of adherence to weekly completions was clinician use of eRAPID data in consultations (ExpB=7.57, 95% CI: 1.56-36.60, p=0.12). The overall contribution of the number of triage events was not significant (p=.095), but there were significant differences between individual parameters with patients

who had no triage events (ExpB=4.81, 95% CI: 1.09-21.25, p=0.38) or only one triage event (ExpB=6.05, 95% CI: 1.06-34.49, p=0.43) more likely to be adherent than those with three or more triage events.

Table 6.14 Exp (B) values, confidence intervals and p values for individual predictor variables

	95% CI for exp b				
	B (SE)	**Lower**	**Exp(B)**	**Upper**	**p**
Age					
Age at study entry	1.03	.99		1.08	.119
Computer usage					
I can only use a computer if I have help					.881
I have been using a computer for 1-2 years	-22.60	.00	.00	.	.999
I have been using a computer for 2-5 years	.73	.15	2.08	29.17	.587
I have been using a computer for more than 5 years	-.051	.14	.95	6.55	.958
Patient activation measure (PAM)					
PAM Baseline Summary Score	.010	.98	1.01	1.04	.576
Cancer type					
Colorectal					.261
Breast	.82	.76	2.26	6.75	.144
Gynae	-.13	.26	.88	3.03	.838
Performance status at first chemo cycle					
0-Normal					.115
1-Can do light work	1.14	.32	3.12	29.96	.325
2-Ambulatory > 50% of time	2.09	.75	8.08	87.60	.086
Chemo intent					
None curative					
Curative	-.76	.13	.47	1.64	.235
Number of Admissions during study period					
More than 3					.270
Two admissions	2.56	.23	12.88	710.43	.212
One admission	2.66	.30	14.29	687.36	.178
No admissions	1.53	.11	4.61	194.04	.423
Number of Triage events during study period					
Three or more triage events					.095
Two triage events	.45	.29	1.56	8.49	.607
One triage events	1.80	1.06	6.05	34.49	.043
No triage events	1.57	1.09	4.81	21.25	.038
Clinician use of data					
(% of consultations)	2.02	1.56	7.57	36.60	.012

6.4.2.2.8 Examination of residuals

Cooks distance, leverage and standardised residuals were examined to identify any cases which were exerting undue influence on the model. One case was identified which had a Cooks distance value of 1.21, exceeding the recommended limit of 1. This case also had a high

standardised residual of 4.94, exceeding the recommended limit of 2. Six more cases were identified which exceeded recommended limits for standardised residuals and leverage. The model was rerun with the identified cases removed.

6.4.2.2.9 Adjusted model

The adjusted model was significant at p<.001, explaining 44% of variance. Clinician use of the data remained the strongest predictor (ExpB=15.62, 95% CI: 2.52-96.74, p=.003). Age was also found to be a significant predictor in that older patients were more likely to be in the adherent group (ExpB=1.05, 95% CI: 1.00-1.09, p=.043). Performance status was also a significant predictor (p=0.028), however, due to the very small numbers in the poorer 2 (n=6) and 3 (n=0) performance status groups, this was unlikely to be meaningful. None of the other variables were significant overall.

6.4.3 Impact of eRAPID on outcome measures

The aim of this section of analysis is to assess whether the eRAPID intervention group had a greater improvement in scores at the end of the 18 week study period on the CSES, CBI-B, and PAM than the usual care group, controlling for baseline scores.

Due to the limited use of measures in cancer populations undergoing active treatment, all 3 measures were subjected to factor analysis. All available data was used for the factor analysis, including the baseline data for the 76 patients who had consented to the study but had not completed. This equated to a total sample size of 430 (n=354 patients who had completed plus n=76 patients still on study), well exceeding the recommended sample size required [279].

6.4.3.1 Self-efficacy for managing chronic disease scale (CSES)

6.4.3.1.1 Factor analysis

The 6 items of CSES were subjected to principal components analysis (PCA) using SPSS version 23. Prior to performing PCA the suitability of data for factor analysis was assessed. Inspection

of the correlation matrix revealed the presence of many coefficients of 0.3 and above. The Kaiser-Meyer-Oklin value was .897, well exceeding the recommended value of 0.6 and the Barlett's Test of Sphericity [280] reached statistical significance (p=0.000), supporting the factorability of the correlation matrix. Principal components analysis revealed the presence of only one component with a eigenvalue of 4.59 which explained 76.5% of the variance in the data. All items loaded positively onto this single factor (from .865 to .899). The six item scale had a high Cronbachs alpha (α= .939).

Table 6.15 Pattern Matrix with factor loadings for the 6 items of the CSES

		Loadings
No	**Item**	**Factor 1**
5	How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce your need to see a doctor?	.899
4	How confident are you that you can keep other symptoms or health problems you have from interfering with the things you want to do?	.880
6	How confident are you that you can do things other than just taking medication to reduce how much your illness affects your everyday life?	.871
2	How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?	.867
3	How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?	.867
1	How confident are you that you can keep the fatigue caused by your disease from interfering with your life?	.865

6.4.3.1.2 Descriptive data

The descriptive statistics of the CSES at baseline and at 18 weeks for each study arm are displayed below in Table 6.16. The possible range of scores was anywhere from 1.00 (not at all confident) to 10.00 (totally confident). The actual range of scores at baseline corresponded to this with responses ranging from 1.00 to 10.00. However, the range for 18 week scores was slightly higher at 1.33 - 10.00 for usual care patients, and 2.50 – 10.00 for eRAPID intervention patients. The mean score improved slightly from baseline to 18 weeks in both groups (M=6.83 vs M=7.28, change of 0.45), although this improvement was slightly higher in the intervention group (M=6.97 vs M=7.65, change of 0.68) than in the usual care group (M=6.70 vs M=7.28, change of 0.58).

Table 6.16 Descriptive data for the CSES at baseline and 18 weeks

	Study arm	N	Mean	SD	Actual range
CSES Baseline	**Total sample**	302	6.83	1.86	(1.00-10.00)
	eRAPID intervention	145	6.97	1.75	(1.00-10.00)
	Usual care	157	6.70	1.95	(1.00-10.00)
CSES 18 weeks	**Total sample**	252	7.28	2.00	(1.33 – 10.00)
	eRAPID intervention	123	7.65	1.81	(2.50 – 10.00
	Usual care	129	6.93	2.10	(1.33 – 10.00)

6.4.3.1.3 ANCOVA to assess impact of eRAPID on change from baseline scores

A one-way analysis of covariance (ANCOVA) was conducted to determine if there was a statistically significant difference between the eRAPID intervention group and the usual care group on CSES scores at 18 weeks, controlling for baseline CSES score.

Evaluation of the assumptions of normality of distribution, linearity, homogeneity of regression and reliability of covariates were satisfactory. Levene's test of equality of variances was non-significant (p=.663) indicating that the assumption of homogeneity of variances had been met and there were no outliers of concern. The total sample size with valid baseline and 18 week scores was n=248, well exceeding requirements [279].

The covariate, baseline CSES score, was significantly related to 18 week CSES scores (F (1, 245) =51.91, p<.001). There was also a significant effect of randomisation group after controlling for baseline scores (F (1,245) = 6.02, p=.015). However, effect sizes were modest ω^2=.20.

6.4.3.2 Cancer Behaviour Inventory (CBI-B)

6.4.3.2.1 Factor analysis

The 14 items of the CBI-B were subjected to principal components analysis (PCA) using SPSS version 23. Prior to performing PCA the suitability of data for factor analysis was assessed. Inspection of the correlation matrix revealed the presence of many coefficients of 0.3 and above. The Kaiser-Meyer-Oklin value was .92, well exceeding the recommended value of 0.6 [281]and the Barlett's Test of Sphericity [280] reached statistical significance (p=0.000), supporting the factorability of the correlation matrix. Principal component analysis revealed

the presence of two components with eigenvalues exceeding 1, which was supported by inspection of the screeplot.

To aid in the interpretation of these two components, Direct Oblimin rotation was performed. The rotated solution revealed the presence of simple structure, with both components showing a number of strong loadings above 0.5 and all variables loading on only one component. The two-component solution explained a total of 64% of the variance, with component 1 contributing 55.5% and component 2 contributing 8.5%. Components were significantly correlated to one another ($r=.673$, $p<.001$). Internal reliability was high for component 1 (9 items, $\alpha=.918$), component 2 (5 items, $\alpha=.876$) and for the full 14 item scale (14 items, $\alpha=.937$).

The items in Factor 1 encompassed a theme of the individual's belief in their own personal resources for coping. The highest loading items were 'Trying to be calm throughout treatments and not allowing scary thoughts to upset me' and 'Maintaining a positive attitude'.

The items in Factor 2 encompassed a theme of individual's belief in their own ability to access support from friends and family, and communicate with their healthcare team. The two highest loadings in this factor were for 'Seeking social support' and 'Sharing my worries or concerns with others'.

Heitzmann et al conducted psychometric analysis of the CBI-B in three large samples of American cancer patients. The samples included both patients undergoing active treatment and cancer survivors and revealed four factor structure [273]. These factors were 1) maintaining independence and a positive attitude (items 1, 2 and 3), 2) participating in medical care (items 8 and 9), 3) Coping and stress management (items 6, 7, 12 and 13), and 4) managing affect (items 4, 10 and 11). Items 5 and 14 were excluded as they did not load clearly onto any of the four factors.

Our Factor 1 broadly encompasses the items in 1) maintaining independence and a positive attitude and 3) Coping and stress management and our Factor 2 encompasses the items in 2) participating in medical care and 4) managing affect.

Proxy measures were created to represent both factors and the impact of the intervention on both factors was explored (see section 6.4.3.2.4).

Table 6.17 Pattern Matrix with factor loadings for the 14 items of the CBI-B

		Loadings	
No	**Item**	**Factor 1**	**Factor 2**
7	Trying to be calm throughout treatments and not allowing scary thoughts to upset me	.974	-.190
2	Maintaining a positive attitude	.897	-.012
6	Maintaining activities (work, home, hobbies, social)	.806	-.013
5	Putting things out of my mind at times	.798	-.006
3	Maintaining a sense of humour	.744	.106
12	Managing nausea and vomiting (whether or not I have had these problems in the past)	.700	.090
13	Coping with physical changes	.656	.156
14	Trying to be calm while waiting at least one hour for my appointment	.641	.062
1	Maintaining independence	.611	.120
10	Seeking social support	-.092	.929
11	Sharing my worries or concerns with others	-.011	.896
9	Asking physicians questions	.031	.778
4	Expressing feelings about cancer	.165	.658
8	Actively participating in treatment decisions	.218	.628

6.4.3.2.2 Descriptive data

The descriptive statistics of the CBI-B at baseline and at 18 weeks for each study arm are displayed below in Table 6.18. The CBI-B score is calculated as the sum of all 14 answered items and can range from 28-126 with 28 being the lowest possible coping self-efficacy and 126 being the highest. The actual range of scores at baseline corresponding with this for the full sample (28-126) and for the usual care group (28-126) but were slightly higher for the eRAPID intervention group (38-126). At 18 weeks, the ranges for the whole sample were slightly higher (33-126), and again were higher for the intervention group (53-126) than for the usual care group (33-126).

The mean score improved from baseline at 18 weeks for the whole sample (M=97.75 vs M=100.03, change of 2.28). Patients in the eRAPID intervention group had slightly higher scores at baseline compared to the usual care group (M=99.68 vs 95.98). Improvements in scores from baseline to 18 weeks were slightly higher in the intervention group (M=99.68 vs 102.88, change of 3.2) and the usual care group (M=95.98 vs 97.36, change of 1.38), even when baseline differences were taken into account.

Table 6.18 Descriptive data for the CBI-B at baseline and 18 weeks

	Study arm	N	Mean	SD	Actual range
CBI-B Baseline	**Total sample**	306	97.75	19.34	(28-126)
	eRAPID intervention	146	99.68	17.94	(38-126)
	Usual care	160	95.98	20.43	(28-126)
CBI-B 18 weeks	**Total sample**	254	100.03	19.34	(33-126)
	eRAPID intervention	123	102.88	17.55	(53-126)
	Usual care	131	97.36	20.59	(33-126)

6.4.3.2.3 ANCOVA to assess impact of eRAPID on change from baseline scores

A one-way analysis of covariance (ANCOVA) was conducted to determine a statistically significant difference between the eRAPID intervention group and the usual care group on CBI-B scores at 18 weeks, controlling for baseline scores.

Results of evaluation of the assumptions of normality of distribution, linearity, homogeneity of regression and reliability of covariates were satisfactory. Levene's test of equality of variances was non-significant (p=.466) indicating that the assumption of homogeneity of variances had been met and there were no outliers of concern. The total sample size with valid baseline and 18 week scores was n=253, well exceeding requirements [279].

The covariate, baseline CBI-B scores, was significantly related to 18 week CBI-B scores (F (1, 250) =135.17, p<.001). There was no significant effect of randomisation group after controlling for baseline CBI-B scores (F (1,250) = 1.32, p=.208).

6.4.3.2.4 MANCOVA to assess impact of eRAPID on change from baseline on CBI-B Factors

Based on the two factor solution found for the CBI-B in our sample, two proxy measures were calculated to represent each factor by calculating the mean score for the individual items in Factor 1 (items: 1, 2, 3, 5, 6, 7, 12, 13, 14) and Factor 2 (4, 8, 9, 10, 11).

A MANCOVA was conducted to determine a statistically significant difference between the eRAPID intervention group and the usual care group on the CBI-B factor proxy scores at 18 weeks, controlling for baseline scores. There was no significant effect of randomisation group after controlling for baseline scores on combined proxy scores ($F(2, 248)=.995$, $p=.530$)) and similarly, no impact on individual score measures for Factor 1 ($F(1, 249)=1.265$, $p=.262$)) nor Factor 2 ($F(1, 249)=.694$, $p=.406$)).

6.4.3.3 Patient Activation Measure (PAM)

6.4.3.3.1 Factor analysis

The 13 items of the PAM were subjected to principal component analysis (PCA) using SPSS version 23. Prior to performing PCA the suitability of data for factor analysis was assessed. Inspection of the correlation matrix revealed the presence of many coefficients of 0.3 and above. The Kaiser-Meyer-Oklin value was .904, well exceeding the recommended value of 0.6 [281] and the Barlett's Test of Sphericity [280] reached statistical significance ($p=0.00$), supporting the factorability of the correlation matrix. Principal components analysis revealed the presence of two components with eigenvalues exceeding 1, which was supported by inspection of the screeplot.

To aid in the interpretation of these two components, Direct Oblimin rotation was performed. The rotated solution revealed the presence of a simple structure, with both components showing a number of strong loadings above 0.5 and all variables loading on only one component. The two-component solution explained a total of 56% of the variance, with component 1 contributing 45% and component 2 contributing 11%. Components were significantly correlated to one another ($r=.560$, $p<.001$). Internal reliability was high for

component 1 (7 items, α=.847), component 2 (6 items, α=.826) and for the full 13 item scale (13 items, α=.885).

The items in Factor 1 encompassed a theme of 'Engagement and activation to change and maintain lifestyle behaviours and belief in own role in health', while the items in Factor 2 broadly encompassed a theme of 'Knowledge and self-efficacy about understanding health and treatment'.

The PAM has usually been found to be unidimensional in healthy populations [274, 275], but research with more ill patients in mental health settings also revealed a two factor structure, albeit slightly different to ours [277].

Proxy measures were created to represent both factors and the impact of the intervention on both factors was explored (see section 6.4.3.3.4).

Table 6.19 Pattern Matrix with factor loadings for the 13 items of the PAM

		Loadings	
No	**Item**	**Factor 1**	**Factor 2**
13	I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress	.809	-.074
3	I am confident I can help prevent or reduce problems associated with my health	.798	-.054
12	I am confident I can figure out solutions when new problems arise with my health	.746	.025
10	I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising	.704	.015
2	Taking an active role in my own health care is the most important thing that affects my health	.658	.057
11	I know how to prevent problems with my health	.658	.100
1	When all is said and done, I am the person who is responsible for taking care of my health	.617	.022
6	I am confident that I can tell a doctor concerns I have even when he or she does not ask	-.027	.766
4	I know what each of my prescribed medications do	-.117	.756
7	I am confident that I can follow through on medical treatments I may need to do at home	.065	.736
5	I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself	-.012	.724
9	I know what treatments are available for my health problems	.191	.630
8	I understand my health problems and what causes them	.144	.625

6.4.3.3.2 Descriptive data

The descriptive statistics of the PAM at baseline and at 18 weeks for each study arm and for the full sample are displayed below in Table 6.20. The potential range of scores is 0 to 100, with 100 being the highest level of activation and 0 being the lowest. The baseline range of scores for the whole sample corresponded with this (0.00 – 100.00) with the eRAPID intervention group having a slightly higher range (39.30 – 100.00) than the usual care group (0.00 – 100.00).

There was no discernible improvement in scores at 18 weeks, with the mean score for the overall sample actually slightly higher at baseline than at 18 weeks (M=64.27 vs 62.95, change of – 1.32). This was similar across both the eRAPID intervention group (M=64.60 vs M=63.67, change of -0.93) and the usual care group (M=63.96 vs M=62.29, change of -1.67).

Table 6.20 Descriptive data for the PAM at baseline and 18 weeks

	Study arm	N	Mean	SD	Actual range
PAM Baseline	**Total sample**	296	64.27	14.86	(0.00 - 100.00)
	eRAPID intervention	143	64.60	13.74	(39.40 – 100.00)
	Usual care	153	63.96	15.89	(0.00 - 100.00)
PAM 18 weeks	**Total sample**	254	62.95	14.23	(34.20 – 100.00)
	eRAPID intervention	121	63.67	13.17	(38.10 – 100.00)
	Usual care	133	62.29	15.15	(34.20 -100.00)

PAM levels at baseline and 18 weeks for each study arm are displayed in Table 6.21 below. Levels of activation at baseline were high for all patients, with the majority falling into the Level 3 and Level 4 categories. The distribution of levels at 18 weeks was similar to baseline, although there were slightly less patients falling into the Level 4 category overall.

Table 6.21 Levels of PAM at baseline and 18 weeks

	Study arm	Level 1		Level 2		Level 3		Level 4	
		N	%	N	%	N	%	N	%
PAM levels Baseline	**eRAPID intervention**	8	5.6%	21	14.7%	74	51.7%	40	28.0%
	Usual care	20	13.1%	16	10.5%	67	43.8%	50	32.7%
PAM levels 18 weeks	**eRAPID intervention**	11	9.1%	17	14.0%	65	53.7%	28	23.1%
	Usual care	19	14.3%	19	14.3%	64	48.1%	31	23.3%

6.4.3.3.3 ANCOVA to assess the impact of eRAPID on change from baseline scores

A one-way analysis of covariance (ANCOVA) was conducted to determine a statistically significant difference between the eRAPID intervention group and the usual care group on PAM scores at 18 weeks, controlling for baseline scores.

Results of evaluation of the assumptions of normality of distribution, linearity, homogeneity of regression and reliability of covariates were satisfactory. Levene's test of equality of variances was not significant (p=.088) indicating that the assumption of homogeneity of variances had been met and there were no outliers of concern. The total sample size with valid baseline and 18 week scores was n=245, well exceeding requirements [279].

Descriptive statistics on 18 week PAM scores, are displayed in Table 6.22 below. The intervention group had higher scores (M=63.88, SD=13.8) than the usual care group (M=62.80, SD=14.85).

Table 6.22 Descriptive statistics for 18 week PAM scores

Randomisation result	Mean	SD	N
eRAPID intervention	63.88	13.18	119
Usual care	62.80	14.85	126
Total	63.33	14.04	245

The covariate, baseline PAM scores, was significantly related to 18 week PAM scores (F (1, 242) =13066.62, p<.001). There was no significant effect of randomisation group after controlling for baseline PAM scores (F (1,242) = 12.94, p=.765).

6.4.3.3.4 MANCOVA to assess the impact of eRAPID on change from baseline on PAM factors

Based on the two factor solution found for the PAM in our sample, two proxy measures were calculated to represent each factor by calculating the mean score for the individual items in Factor 1 (items: 1, 2, 3, 10, 11, 12, 13) and Factor 2 (items: 4, 5, 6, 7, 8, 9).

A MANCOVA was conducted to determine a statistically significant difference between the eRAPID intervention group and the usual care group on the PAM factor proxy scores at 18 weeks, controlling for baseline scores. There was no significant effect of randomisation group

after controlling for baseline scores on combined proxy scores (F(2, 249)=.374, p=.688) and similarly, no impact on individual scores measures for Factor 1 (F(1, 250)=.290, p=.591)) nor Factor 2 (F(1, 250)=.750, p=.387)).

6.4.4 Relationship between patient engagement with eRAPID and outcome measures

The aim of this section of analysis is to assess whether patient engagement with eRAPID (adherence to weekly completions and use of the eRAPID website) had any impact on their outcome measure scores (CSES, CBI-B and PAM) at 18 weeks when controlling for baseline scores.

6.4.4.1 Regression analyses to assess whether patient engagement with eRAPID impacted on outcome measures

Hierarchical linear regression analyses were run to explore whether patient engagement with eRAPID had an impact on 18 week scores on the CSES, the CBI-B and the PAM.

3 separate regression analyses were run using the forced entry method, with baseline scores entered in the first block and patient adherence score and no of pages viewed on website entered in the second block.

6.4.4.1.1 CSES

Table 6.23 below shows the mean, standard deviation and n for each of the variables in the regression analyses. The mean score for CSES was slightly higher at 18 weeks than at baseline. The mean percentage of adherence to the weekly completions was almost 75%. The mean number of eRAPID website page views per patient was just over 3, but with a standard deviation of more than 4, illustrating the variation in how often patients used the website.

Table 6.23 Descriptive statistics of variables in the regression analysis to predict CSES score

	Mean	SD	N
Outcome variable			
18 week CSES Score	7.64	1.82	122
Predictor variables			

Baseline CSES Score	7.12	1.66	122
Adherence to symptom report completions (%)	74.58	24.14	122
eRAPID website page views (n)	3.13	4.19	122

Table 6.24 shows correlations between all variables. 18 week CSES score was correlated significantly with both baseline CSES score (r=.266, p=.002) and adherence to symptom report completions (r=.315, p<.001). None of the predictor variables were significantly correlated with one another, meaning the assumption of multicollinearity was met.

Table 6.24 Correlations between variables using Pearson correlation (r)

	18 week CSES	**Baseline CSES**	**Adherence to symptom report completions**	**eRAPID website page views**
18 week CSES	1.000	.266**	.315***	.004
Baseline CSES	.266**	1.000	.011	-.044
Adherence to symptom report completions	.315***	.011	1.000	.062
eRAPID website page views	.004	-.044	.062	1.000

*significant at < .05, **significant at <.010, ***significant at <.001

The Durbin-Watson statistic for the model was 1.89, indicating a lack of correlation of residual terms, meeting the requirements for the assumption of independent errors. Inspection of residual plots indicated that the normality, linearity and homoscedasticity were met.

Inspection of residual statistics indicated only 5/122 (4%) of cases with standardised residuals less than -2 or more than 2. Of these cases, none were less than -3, or more than 3 indicating than there were no cases exerting undue influence on the model. The total sample size after inclusion of the 3 variables in the model was 122, well exceeding recommendations [279].

After Step 1, with baseline CSES in the equation, a significant regression equation was found (F (1,120) = 9.110, $p < .01$), with an R^2 of .071.

After step 2, with adherence to weekly symptom reports and number of page visits to the eRAPID website added, R^2 increased to .168 (F (1,118) = 7.936, p<.001).

The beta values, standard error values and standardised betas for individual predictor variables are displayed below in Table 6.25. Adherence to the weekly symptom report completions added the most predictive value (β=.312, p<.001), followed by baseline self-

efficacy score (β=.262, p<.01). The number of visits to the eRAPID website did not add any significant predictive value (β=.004, p=.959).

Table 6.25 Beta values, standard error values and standardised betas for each step of the model

		B	SE B	β	p
Step 1	**Constant**	5.579	.703		
	Baseline CSES score	.290	.096	.266	.003
Step 2	**Constant**	3.862	.823		
	Baseline CSES score	.286	.092	.262	.002
	Adherence to symptom report completions	.023	.006	.312	.000
	eRAPID website page views	-.002	.036	-.004	.959

6.4.4.1.2 Cancer Behaviour Inventory (CBI-B)

Table 6.26 below shows the mean, standard deviation and n for each for each of the variables in the regression analyses.

Table 6.26 Descriptive statistics of variables in the regression model to predict CBI-B score

	Mean	SD	N
18 week CBI-B Score	102.9	17.55	123
Baseline CBI-B Score	101.2	16.96	123
Adherence to symptom report completions (%)	74.6	24.05	123
eRAPID website page views (n)	3.13	4.18	123

Table 6.27 shows correlations between all variables. 18 week CBI-B was correlated significantly with both baseline score (r=.560, p<.001) and adherence to symptom report completions (r=.217, p=.008). None of the predictor variables were significantly correlated with one another, meaning the assumption of multicollinearity was met.

Table 6.27 Correlations between variables using Pearson correlation (r)

	18 week CBI-B Score	Baseline CBI-B Score	Adherence to symptom report completions	eRAPID website page views
18 week CBI-B Score	1.000	.560***	.217**	.019
Baseline CBI-B Score	.560***	1.000	.017	-.034
Adherence to symptom report completions	.217**	.017	1.000	.062
eRAPID website page views	.019	-.034	.062	1.000

*significant at < .05, **significant at <.010, ***significant at <.001

The Durbin-Watson statistic for the model was 1.648, indicating a lack of correlation of residual terms, meeting the requirements for the assumption of independent errors.

Inspection of residual plots indicated that the normality, linearity and homoscedasticity were met. Inspection of residual statistics indicated only 7/123 (5.7%) of cases with standardised residuals less than -2 or more than 2. Of these cases, none were less than -3, or more than 3 indicating than there were no cases exerting undue influence on the model. The total sample size after inclusion of the 3 variables in the model was 123, well exceeding recommendations [279].

After Step 1, with baseline CBI-B score in the equation, a significant regression equation was found (F (1,122) = 55.23, $p < .001$), with an R^2 of .313.

After step 2, with adherence to weekly symptom reports and number of page visits to the eRAPID website added, R^2 increased to .357 (F (3,122) = 22.04, p<.001).

The beta values, standard error values and standardised betas for individual predictor variables are displayed below in Table 6.28. Baseline CBI-B score added the most predictive value (β=.557, p<.001), followed by adherence to the weekly symptom report completions (β=.206, p<.01). The number of visits to the eRAPID website did not add any significant predictive value (β=.026, p=.730).

Table 6.28 Beta values, standard error values and standardised betas for each step of the model

		B	SE B	β	p
Step 1	**Constant**	44.288	. 7.993		
	Baseline CBI-B score	.579	.078	.560	.000
Step 2	**Constant**	33.010	8.763		
	Baseline CBI-B score	.577	.076	.557	.000
	Adherence to symptom report completions	.150	.054	.206	.006
	eRAPID website page views	.107	.310	.026	.730

6.4.4.1.3 Patient Activation Measure (PAM)

Table 6.29 below shows the mean, standard deviation and n for each for each of the variables in the regression analyses.

Table 6.29 Descriptive statistics of the variables in the regression model to predict PAM score

	Mean	SD	N
18 week PAM Score	63.9	13.2	119
Baseline PAM Score	65.3	13.8	119
Adherence to symptom report completions (%)	74.5	24.2	119
eRAPID website page views (n)	3.2	4.2	119

Table 6.30 shows correlations between all variables. 18 week PAM score was correlated significantly with both Baseline PAM score (r=.579, p<.001) and adherence to symptom report completions (r=.206, p=.012). Baseline PAM score was significantly correlated with adherence to symptom report completions (r=.184, p=.023). However, the correlation was modest, meaning the assumption of multicollinearity was not violated.

Table 6.30 Correlations between variables using Pearson correlation (r)

	18 week PAM Score	Baseline PAM Score	Adherence to symptom report completions	eRAPID website page views
18 week PAM Score	1.000	.579***	.206*	-.052
Baseline PAM Score	.579***	1.000	.184*	-.124
Adherence to symptom report completions	.206*	.184*	1.000	.059
eRAPID website page views	-.052	-.124	.059	1.000

*significant at < .05, **significant at <.010, ***significant at <.001

The Durbin-Watson statistic for the model was 1.968, indicating a lack of correlation of residual terms, meeting the requirements for the assumption of independent errors. Inspection of residual plots indicated that the normality, linearity and homoscedasticity were met. Inspection of residual statistics indicated only 7/119 (5.8%) of cases with standardised residuals less than -2 or more than 2. This included one case greater than 3. Casewise diagnostics were examined for all 7 cases. Cook's distance, Mahalabonis distance and centred leverage values were all well within criterion, indicating that none of the cases were exerting undue influence and all cases were retained in the dataset. The total sample size after inclusion of the 3 variables in the model was 119, well exceeding recommendations [279]. After Step 1, with baseline PAM score in the equation, a significant regression equation was found (F (1,118) = 59.01, $p < .001$), with an R^2 of .335.

After step 2, with adherence to weekly symptom reports and number of page visits to the eRAPID website added, R^2 increased to .346 (F (3,118) = 20.25, p<.001).

The beta values, standard error values and standardised betas for individual predictor variables are displayed below in Table 6.31. Baseline PAM score added the most predictive value (β=.579, p<.001). Neither adherence to symptom report completions (β=.102, p=.187) or the number of visits to the eRAPID website (β=.012, p=.879) added any significant predictive value.

Table 6.31 Beta values, standard error values and standardised betas for each step of the model

		B	SE B	β	p
Step 1	**Constant**	27.782	4.802		
	Baseline PAM score	.553	.072	.579	.000
Step 2	**Constant**	24.607	5.422		
	Baseline PAM score	.536	.074	.562	.000
	Adherence to symptom report completions	.056	.042	.102	.187
	eRAPID website page views	.036	.238	.012	.879

6.5 Discussion

6.5.1 Summary of findings

The aims of this chapter were to quantitatively assess patient engagement with eRAPID and identify potential predictors, to explore the impact of eRAPID on patients' self-efficacy to manage symptoms and side effects, self-efficacy for coping with cancer and levels of activation, and to explore whether these outcomes were related to patient engagement. Patient engagement with eRAPID was generally very good, with 40% of the sample having 100% adherence to weekly completions over the 18 weeks and a median adherence level of 78%. Usage of the eRAPID website was somewhat lower than expected, with only 59% of patients accessing the website at least once.

In a logistic regression model to predict adherence to weekly symptom reports, clinician use of patient data was the only significant predictor. None of the demographic and clinical variables included in the model were associated with adherence and nor was previous computer usage. There is a common perception that older and more economically disadvantaged patients are less likely to engage in eHealth. However, this is not always found to be the case, particularly with more recent studies, and many argue that the 'digital divide' is disappearing [180, 182, 282, 283]. A feasibility study by Basch et al [116] previously identified computer experience as a predictor of engagement to their intervention. However, this study was in 2005, when computer and internet usage were much less common, and may be less of an issue going forward. In fact a more recent study by the same researchers which provided older patients with devices to complete from home, actually found that this group had the most benefit from the intervention [51]. Baseline PAM scores were correlated significantly with adherence to the intervention, suggesting it might have predictive value, however this was not found to be the case in the logistic regression model, indicating that the correlation was confounded by other variables. The only significant predictor of adherence was clinician reported use of the patient

data in consultations, highlighting the importance of this for patient engagement. However, this relationship is likely to be bi-directional.

eRAPID had a significant impact on CSES scores with patients in the intervention arm showing higher improvement in scores than those in the usual care arm at 18 weeks. As outlined in Chapter 5, self-efficacy is not often included in evaluations of online systems to support patients during chemotherapy, and those that have included it have not always used high quality measures [82, 87]. However, evaluation of online systems for cancer survivors and other chronic illnesses such as diabetes have demonstrated a similar positive impact on self-efficacy for managing symptoms [96, 183-185, 268]. Similarly research on the role of self-efficacy with patients undergoing chemotherapy is limited and generally of cross sectional nature [255, 256]. However, in other chronic illnesses such as diabetes, self-efficacy is related to better self-management behaviour and objective medical outcomes, in addition to better emotional well-being [250, 252, 253, 284-286]. Furthermore, results have been found to be consistent across different socio-demographic groups and levels of health literacy [251]. In addition, research with cancer survivors has indicated that high levels of self-efficacy can have continuing benefits for patients in their follow-up and recovery, with lower symptom burden and distress and higher HRQoL [254, 258, 287]. Higher adherence to weekly symptom reports was associated with improved CSES scores. As outlined in Chapter 5, the relationship between engagement and outcomes is rarely reported in evaluations of online systems. However, these results support the importance of sustained engagement with systems and the need for researchers to evaluate and report on engagement, in addition to the relationship between engagement and outcomes.

There was no significant impact of the eRAPID intervention on CBI-B scores, although higher adherence to weekly symptom reports was associated with improved scores. In Chapter 4, end of study interviews from field usability testing of eRAPID indicated that some patients used the symptom graphs for self-monitoring and found this beneficial to support coping. The results

may indicate that patients who were using eRAPID in this way, and were therefore more adherent to weekly reports, did find this benefit. However, it may also be that eRAPID does not fit with more passive coping strategies. Some people may prefer not to monitor symptoms, particularly when things are not going well [161]. It was initially planned to use analytics to assess patients' use of symptom graphs during eRAPID, but this was not possible due to practical limitations of the systems.

In addition, it may simply be that a more targeted intervention is necessary to positively impact on self-efficacy for coping, due to the specific stresses and anxieties that patients experience while undergoing chemotherapy. Although the eRAPID website does provide specific advice to patients on coping with cancer, levels of usage of this section of the website were low, as was usage of the website generally, suggesting that is unlikely to have had a great impact. In addition, the CBI-B had a different factor structure in our population than found in previous research, which has validated the measure in mixed samples of cancer patients at different stages of the cancer trajectory [273]. Again this difference in factor structure may be reflective of the specific concerns of patients undergoing active chemotherapy. Evaluation of the impact of eRAPID on the proxy measures for individual factors did not indicate significant results either.

There was no significant impact of the eRAPID intervention on PAM scores. Furthermore, there was no association found between changes in PA and levels of adherence to weekly symptom reports. Levels of activation were high in this sample at baseline, which may have had an impact. However, it may also be that this is not a suitable measure for use in this population. Much of previous research has focused on other chronic illnesses such as diabetes, where the measure has demonstrated potential in predicting a range of positive health outcomes and behaviours [261, 265-267]. However, the role of the measure in cancer populations, and in particular those undergoing chemotherapy is less clear and studies are cross-sectional with methodological limitations [262-264].

6.5.2 Strengths and limitations

The main strengths of this study are a large sample size and a prospective randomised controlled design. However, this study did have some limitations. In order to model predictors of adherence to weekly symptom reports, it was necessary to dichotomise the variable and conduct a logistic regression. There are criticisms of using logistic regression when the dependent variable is not truly dichotomous, as was the case in this analysis [279]. The possibility of using 'absolute adherence' (100%) was considered. In fact, a high number of patients in this sample (40%) did have 100% adherence. However, this would classify patients who missed one completion as non-adherent. Given that patients are often admitted to hospital during treatment, or experience severe side effects which may prevent them from completing, this did not seem like a true reflection of adherence. However, there were also issues with the arbitrary nature of dichotomising the variable using a median split as we are differentiating between patients, some of whom in reality had similar levels of adherence. Alternative methods such as using non-parametric analysis or using more extreme cut-offs for adherence were considered. However, these methods would have been less informative, or would have resulted in a reduced sample size for analysis, and dichotomising the variable was deemed to be the best course of action.

In addition, the requirement for patients to complete symptom assessments once a week is also somewhat arbitrary. This frequency was decided after consultation with both clinicians and patients and was deemed to be useful to clinicians and acceptable to patients in terms of burden. However, there is no evidence to demonstrate that this is the optimal frequency of completion in terms of potential benefits for patients, and other ePROM systems vary in their recommendations [51, 193]. These issues may need careful consideration in future evaluations of adherence.

Another limitation of this work is that patients who had left the trial were not included in the analysis. Intention to treat (ITT) analysis is often recommended for randomised controlled

trials. In this scenario, all patients who have been randomised are included in the final analysis, regardless of subsequent withdrawal, missing outcomes etc. The benefits of ITT analyses are that it avoids overestimation of the efficacy of interventions and prevents bias. However, there are also some criticisms of this approach. ITT analysis includes patients who may not ever have had any experience of the intervention being evaluated, and as such can dilute evidence of benefits and lead to an increased likelihood of Type II error. In addition, ITT is easier to implement when it has been integrated into the design of the trial and outcomes can be collected for patients who withdraw. It is much more difficult to implement where outcomes essential for evaluation are missing [288, 289].

The withdrawal procedures for eRAPID were changed part way through the main trial (see section 2.4.4.6) to allow for continued collection of outcomes for withdrawn patients where possible. However, outcome measures and clinical process data were not available for a large sample of the patients included in this dataset who withdrew before these procedures were introduced. In addition, there were varied and complex reasons why patients withdrew from the trial, such as deteriorating health and disease progression, or changes to treatment plan, in addition to some patients who withdrew because they did not want to use the intervention. Due to practical complexities in identifying which of these patients were suitable for inclusion, all patients who left the trial were excluded. Future analysis on the full sample will include ITT analyses in addition to PP (Per protocol) analysis.

The measure used to assess clinician use of eRAPID data in consultations had some limitations. The feedback forms were not given to clinicians to complete if patients had not completed a symptom report in a significant amount of time (approximately eight weeks or more), as there was no relevant data for them to view. In addition, forms were sometimes missed if appointments times and dates were changed. In order to try to overcome these issues, a percentage score was calculated from the number of forms completed, rather than the number of forms expected, but this will have resulted in patients with very low levels of

adherence being excluded from the analysis. A more objective measure of clinician engagement, for example, a measure to assess their use of eRAPID data in consultations more generally, may be preferable, but on the other hand, it may also fail to pick up differences in individual consultations. Alternatively previous research within the PCOR group has focused on audio-recording consultations and using qualitative methods such as consultation analysis to assess patient use of data during consultations. Data can also be quantified by assessing how symptoms are discussed, who raises discussions and assessing when PROMs data is explicitly mentioned. These methods can provide valuable insight but are costly and resource intensive [43, 44].

The impact of other variables, such as symptom burden, on patient engagement with eRAPID was not explored. As outlined in previous Chapters, data on symptom experience is not routinely collected from patients undergoing chemotherapy, and is reliant on clinician interpretation and documentation in patient records [14, 35, 36]. Extraction of this data would be complex, and likely to be unreliable and as such, the clinical process measures were deemed to be a more appropriate proxy assessment of symptom burden.

There are potential limitations on the validity of the outcome measures relating to how the measures were administered to patients. The outcome measures were included as part of a larger questionnaire pack which included the primary outcomes and some of the secondary outcomes for the main RCT (see section 6.3.4.4). This context may have influenced patients' responses. For example, it is commonly acknowledged that the order in which questions or questionnaires are presented to respondents can influence how they are answered [290, 291]. This can be as a result of response fatigue, where participants simply become tired or bored when completing questionnaires, and are less likely to answer accurately. It may also be as a result of order effects, where preceding questions which may 'prime' the participant to respond a certain way. For example, in the questionnaire pack, patients were completing QoL measures prior to completing the self-efficacy and patient activation measures. Completion of

the QoL measures may have influenced patients' perception of how they were managing with their treatment and side effects, and subsequently influenced their completion of the remaining measures.

In addition, the environment in which patients were completing the questionnaires may also have influenced their responses. For example, some patients completed the eighteen week questionnaire pack whilst undergoing chemotherapy on the day unit, whilst others were completing in their own homes, often a week or two after completing chemotherapy. The setting for completion was not recorded, and as such, it was not possible to undertake any analysis to evaluate whether this had any impact.

Future evaluations could rotate the order of questionnaires and record the environment in which patients completed the measures to allow for the possibility of later analysis to evaluate response fatigue and order effects.

The impact of symptom burden or other clinical variables on the end of study scores of the outcome measures (CSES, CBI-B and PAM) was not explored. Although it is likely that there are many factors which may predict end of study scores, the focus of this analysis was only to determine the role of engagement with eRAPID. However, future analysis is planned to explore other predictors of improvements in these outcomes.

6.5.3 Conclusions

Levels of engagement with eRAPID were high, demonstrating acceptability to patients. An exploration of predictors of engagement revealed that the only reliable predictor was clinician engagement with patient data during routine consultations. There was a positive impact of the intervention on patient self-efficacy to manage side effects of treatment, but not on self-efficacy to cope with cancer or on PA. Within the intervention group, adherence to weekly completions was a significant predictor of improvement in self-efficacy for both managing symptoms and for coping with cancer, but not for PA, highlighting the need for researchers to

evaluate and report on engagement when evaluating online systems. Barriers and motivators for engagement with eRAPID and patients' perception of clinician use of eRAPID will be explored through qualitative interviews in the next Chapter.

Chapter 7 Qualitative exploration of the patient perspective of using eRAPID during chemotherapy

7.1 Background

7.1.1 Overview

The work described in this chapter builds further on that described in Chapter 4 and in the previous chapter. Chapter 6 described quantitative analysis to explore the patient perspective of eRAPID. Patient engagement with eRAPID was explored in more depth, and validated measures were used to assess the impact of eRAPID on patient self-efficacy to manage side effects of treatment, self-efficacy to cope with cancer and their levels of PA. The main findings were that levels of engagement and adherence were generally high and eRAPID was well accepted by patients. A logistic regression model to predict engagement with eRAPID revealed that the only significant predictor was a measure of clinician use of patient data during routine consultations. There was a positive impact of the intervention on patient self-efficacy to manage side effects of treatment, but not on self-efficacy to cope with cancer or on PA.

The qualitative methods described in this chapter aim to complement the quantitative data and provide more in-depth understanding of the patient perspective of using eRAPID. Barrier and facilitators for engagement were explored, in addition to the impact eRAPID had on experience of chemotherapy. This extends upon on the previous qualitative work described in Chapter 4. The interview schedule was reviewed and refined based on the previous findings and we were able to interview a greater number of patients, across three different disease groups, using eRAPID over a longer period of time.

As highlighted in the systematic review in Chapter 5, many newly developed ePROM systems undergo feasibility testing to assess their acceptability to patients. However, few of these

studies have used qualitative methods to explore patient perspective. Research on patient engagement with ePROM systems is still in its infancy and qualitative research can provide valuable insight into how patients interact with systems to identify potential motivators and barriers for engagement, in addition to exploring patients' perceptions about how systems impact on their care [46]. Those that have used qualitative methods have reported intrinsic motivations such as 'reassurance' and support for managing symptoms and side effects as an important motivator for engagement, similar to the findings reported from the field usability testing of eRAPID described in Chapter 4 [72, 165, 166].

In other chronic illness groups such as diabetes, qualitative research has been used more frequently to inform system evaluation and development, but it still relatively uncommon. Those that have used qualitative methods have reported that technological and usability issues are commonly cited as barriers to engagement, as is poorer health status [159]. However, a qualitative study by Sanders et al [128] indicated that of equal, if not more importance is the patients' perceptions of how the system fits with their identity, independence and self-care. Some of the patients in their study reported that they felt the interventions gave them less independence and control. The majority of patients in their sample had chronic illnesses such as diabetes, which have very different processes of self-management and care than patients undergoing chemotherapy, but this may also be a relevant factor for eRAPID.

eRAPID symptom reports may highlight to clinicians if chemotherapy is not being well-tolerated, which subsequently may result in a decision to reduce the dose or delay treatment. While intuitively, this seems like a positive thing for patients, it may not be that straightforward. Patients often have anxieties around changes to planned treatment and patients differ in their willingness to tolerate side effects [292]. This is also likely to be influenced by the intention of treatment and how it is discussed with patients. For example, adjuvant treatment is sometimes described to patients an 'insurance policy', and patients may be less willing to tolerate severe side effects. Conversely, other research has suggested that

patients will be more likely to tolerate side effects if the aim of treatment is curative but value QoL over survival if the aim of the treatment is to stabilise disease [32, 293, 294].

This chapter describes qualitative work undertaken to explore these issues, in addition to informing the quantitative work described in the previous chapter.

7.1.2 Role and original contribution

I had a lead role in planning and implementing the qualitative component of the eRAPID trial. In addition to working as part of the core eRAPID team conducting and analysing interviews, I was responsible for development of the interview schedule and the analysis framework, working with the senior researcher and principal investigator to ensure that the schedule also covered the necessary topics for the main trial. This aspect of the trial was included in the main protocol and ethics application for the eRAPID RCT [94]. Preliminary results have been presented as a conference poster [295].

7.2 Aims and Objectives

The overall aim of the work described in this chapter was to qualitatively explore:

1) Barriers and facilitators for patient engagement
2) Patient experiences of using eRAPID, specifically
    a. perceptions of how eRAPID impacted on their self-management and chemotherapy experience
    b. perceptions of clinician use of eRAPID symptom reports and the impact this had on their cancer care.

7.3 Methods

7.3.1 Recruitment and patient sample

Eligible patients were those who had taken part in the internal pilot phase of the RCT(n=87) to evaluate eRAPID in systemic therapy and had been randomised to the intervention arm of the study (n=36). The full details for patient eligibility and recruitment processes for the eRAPID RCT are described in Chapter 3. A subset of patients were approached at the end of their 18 week study period and asked to take part in a semi-structured interview about their experiences of using eRAPID. Patients were approached consecutively as they completed the study, with an aim to interview 5-10 patients overall from each disease group.

7.3.2 Interview setting

Interviews took place in a private room in the oncology outpatient clinic at St James University Hospital, Leeds. Interviews were usually arranged to coincide with patients' clinic appointments to avoid the need for additional trips to the hospital, and generally took place after their clinic appointment.

7.3.3 Interview schedule

The interview schedule was based on that used for the end of study interviews in the eRAPID usability in the breast clinic (Chapter 4). However, as a result of this work, some amendments were made. Due to the variance in patient engagement observed in the usability study, questions were added on motivators and barriers for engaging with eRAPID. These questions were specifically targeted to patients' level of engagement. For example, patients who completed regularly every week were asked about their main motivations for doing so, while patients who had completed sporadically were probed on the main barriers they experienced. Specific questions were also added on patients' use of the symptom graphs, which allowed them to view their own responses over time. This feature had emerged as an important factor

in the usability study. The usability study indicated that patients did not always follow the advice to contact the hospital, so questions were added to explore this. Some general questions about patients' experiences of hospital admissions and treatment changes during chemotherapy were also added. Questions about the recruitment procedures were removed, as these were specific to the aims of the usability study. The full amended interview schedule is outlined below in Table 7.1.

Table 7.1 End of study interview schedule for pilot phase of the eRAPID RCT

Usability of eRAPID
- Did you find the eRAPID system easy to use? - Were there any technical aspects of it you found difficult? - Did you have any difficulties finding the site, logging in etc.? - If so, how did you resolve them? - Do you have suggestions on how we might improve the system? - Did you use the user manual we gave you? - Do you have any suggestions for how we might improve that?
Completion of symptom reports
If patient initially started using the system but then stopped. - You initially used the system regularly but then you stopped. - Can you remember the reasons why this was? - Did you intend on using the system again in the future? - Is there any support we could have given you to help you to complete at this time?
If patient has completed intermittently - You used the system intermittently throughout the study. - Can you remember the reasons why you didn't complete at this time? - Is there any support we could have given you to help you to complete at this time? - What made you start using the system again?
If the patient used the system regularly throughout the study. - You used the system regularly. - Can you tell us what your main motivations were for doing this? (For example, the graphs, self-management advice or for the clinicians)
General views on using the system
- What were your expectations of using the eRAPID system (if any)? - Were your expectations met? Were there any advantages to using the system? - Were there any disadvantages to using the system? - Did you complete the system when you received reminders, or did you have your own set time to complete? - Has it been difficult for you to complete the questionnaire on a weekly basis? - How confident are you that you would be able to access the system on a weekly basis throughout the course of your treatment? - Is there anything we could do to make this easier for you or other patients? - What factors might prevent you from using the eRAPID system? - What factors might help you to access the eRAPID system? - Do you think other patients will be likely to use eRAPID? - Do you think other patients would find it useful?

- Was there anything you enjoyed or found pleasant about completing the questionnaire? - Was there anything upsetting or unpleasant about completing the questionnaire?
Self-management advice
- Do you think that the system accurately assessed your symptoms? E.g. the types of questions asked, the severity level, etc. - Did you find the information on the eRAPID website useful? - Did you use any of it? - Do you think that using the system had any effect on how you managed your symptoms and side effects? - Did you receive advice to contact the hospital at any point? - Did you follow this advice? If not, what were your reasons for not following the advice?
Graphs
- Did you look at/use the graphs at the end of questionnaire? - If not, can you tell us the reason (e.g. didn't find them useful, too complicated) - If so, did you find them useful? In what way? - What did you like about them? - What did you not like about them?
Perceived role of staff
- Did the doctors/CNS use the system at your clinic appointments? - Do you think they found the system useful? - Do you think they would be likely to use this system regularly? - Do you think that using the system influenced your consultations in any way? - If so, how?
Perceived role of carers
- Did anyone else (such as a relative) help you use the system? - Do you think they found it useful? - Did you speak to any of your friends or family about your involvement in eRAPID? - What did they think of it?
Perceived influence on treatment/care
- Do you think you had any medications prescribed or changes in treatment because of reporting symptoms on the system? - Were you happy with these changes?
Alerts
- When you received the advice to contact the hospital, did you do so? - If not, what action did you take and why? - Did anybody contact you? - Did they discuss your eRAPID results with you? - What were the consequences of that contact? (E.g. Were you asked to come into hospital? Visit your GP? etc.)
Hospital admissions and triage calls
- Can you tell us a bit about your admission to hospital and what happened in the lead up to that? (Ask patient to "think aloud" about how things happened). - For example, how long did you feel unwell for before you rang the hospital? - Did you use the eRAPID system before you contacted the hospital? - If not, did you consider using the eRAPID system before you contacted the hospital? - Did the staff on the acute ward mention eRAPID to you, or did you mention it to them? - Did your admission have any effect on your treatment? (e.g. delays, dose reduction)
Outcome measures (paper questionnaire completions)
- How did you find completing the paper questionnaires every 6 weeks? - Were the questions relevant to you? - How long did they take to complete? - Do you have any other comments about these questionnaires?
Other

- Do you have any other comments or questions about your involvement with eRAPID?

7.3.4 Interview analysis

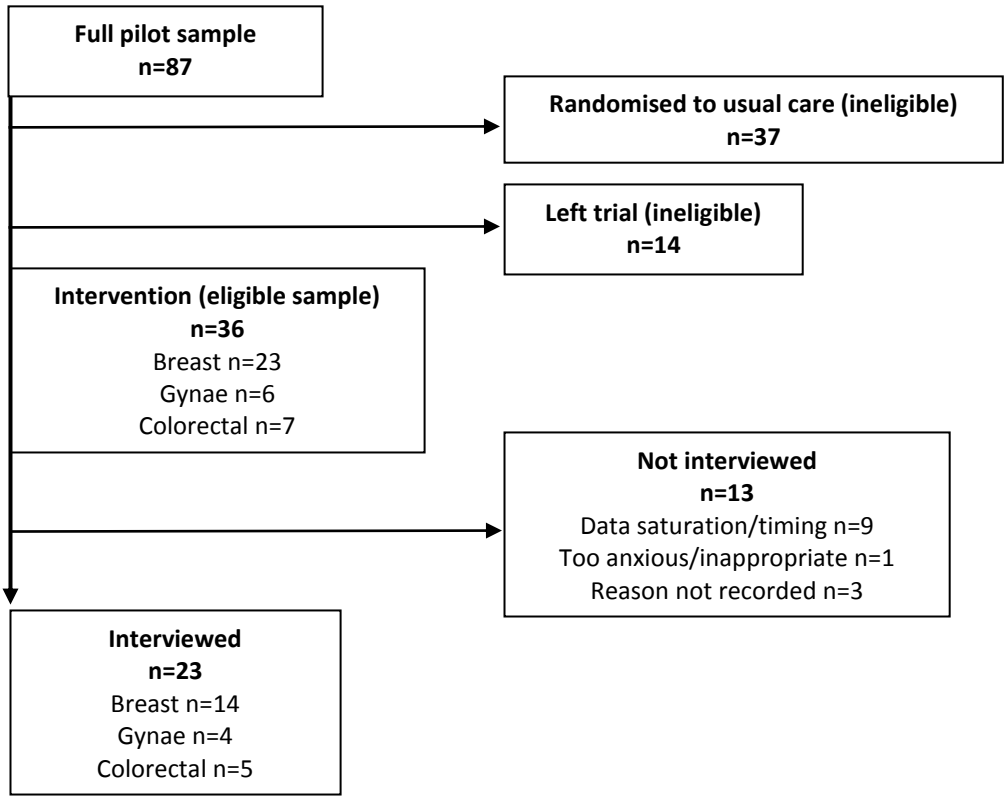
Interviews were transcribed verbatim and managed in NVivo version 10 software. The interviews were analysed using thematic analysis [146]. An initial framework of themes was developed based on the interview schedule, and the previous results from the usability interviews. After listening to initial interviews, the coding framework was amended as needed. A analysis team was assembled (LW, KA, SP, BC, MH, ZR, KK and RM). The framework was reviewed by the analysis team and some minor amendments were made. Interviews were assigned to members of the research team and each interview was coded by at least 2 researchers. An iterative approach was adopted so that changes could be made to the coding framework as new themes and relationships between themes emerged. Regular meetings were scheduled to discuss any queries or discrepancies, and these were resolved by group discussion and consensus.

7.4 Results

7.4.1 Recruitment and patient sample

Although initially, it was planned to interview 5-10 patients from each disease site, recruitment in the breast clinic was substantially higher than in colorectal and gynae clinics. As a result, a higher proportion of patients were recruited from the breast clinic to reflect the overall patient sample. Patients were recruited consecutively until data saturation was reached. The breakdown of potentially eligible patients in each group and those interviewed is outlined below in Figure 7.1 below. Interviews were 24 minutes long on average and ranged from 8 to 47 minutes.

Figure 7.1 CONSORT diagram of eligibility and recruitment of patient sample



7.4.2 Demographic and clinical info

Table 7.2 displays demographic and clinical information for patients who participated in the end of study interviews and the remaining sample (including usual care patients and those

who left the trial). Proportionally, less patients in the 50-59 years and 60-69 year age categories (30.4% versus 42.2% and 13.0% versus 26.6%) and lowest IMD deprivation group (13.0% versus 22.2%) and more patients in the two youngest age groups (8.7% versus 4.7% and 39.1% versus 20.3%) and highest level of education group (60.9% versus 40.4%) were interviewed.

Table 7.2 Demographic data for interviewed patients and remaining pilot sample

	Interviewed patients (n=23)		Remaining pilot sample N=(64)	
	Mean	**SD**	**Mean**	**SD**
Age (years)				
Mean and standard deviation	51.6	10.9	55.2	10.7
	N	**%**	**N**	**%**
Age group				
Up to 34 years	2	8.7%	3	4.7%
35-49 years	9	39.1%	13	20.3%
50-59years	7	30.4%	27	42.2%
60-69 years	3	13.0%	17	26.6%
70+years	2	8.7%	4	6.3%
Total	23		64	
Gender				
Male	4	17.4%	6	9.4%
Female	19	82.6%	58	90.6%
Total	23		64	
Cancer type				
Breast	14	60.9%	36	56.3%
Gynae	4	17.4%	17	26.6%
Colorectal	5	21.7%	11	17.2%
Total			64	
Marital status				
Married/Civil Partnership	18	78.3%	42	65.6%
Cohabiting	1	4.3%	6	9.4%
Separated/Divorced	0	0.0%	7	10.9%
Widowed	1	4.3%	3	4.7%
Single	3	13.0%	6	9.4%
Total				
Education (missing=1)				
Up to school leaving age	6	26.1%	21	32.8%
Beyond school leaving age	3	13.0%	14	22.2%
Degree/professional qualification	14	60.9%	28	44.4%
Total	20		63	
IMD Quintile (missing=1)				
20% most deprived	3	13.0%	14	22.2%
20-40% most deprived	3	13.0%	6	9.5%
20% middle deprived	6	26.1%	7	11.1%
20-40% least deprived	5	21.7%	19	30.2%
20% least deprived	6	26.1%	17	27.0%
Total	23		63	

7.4.3 Thematic analysis of interviews

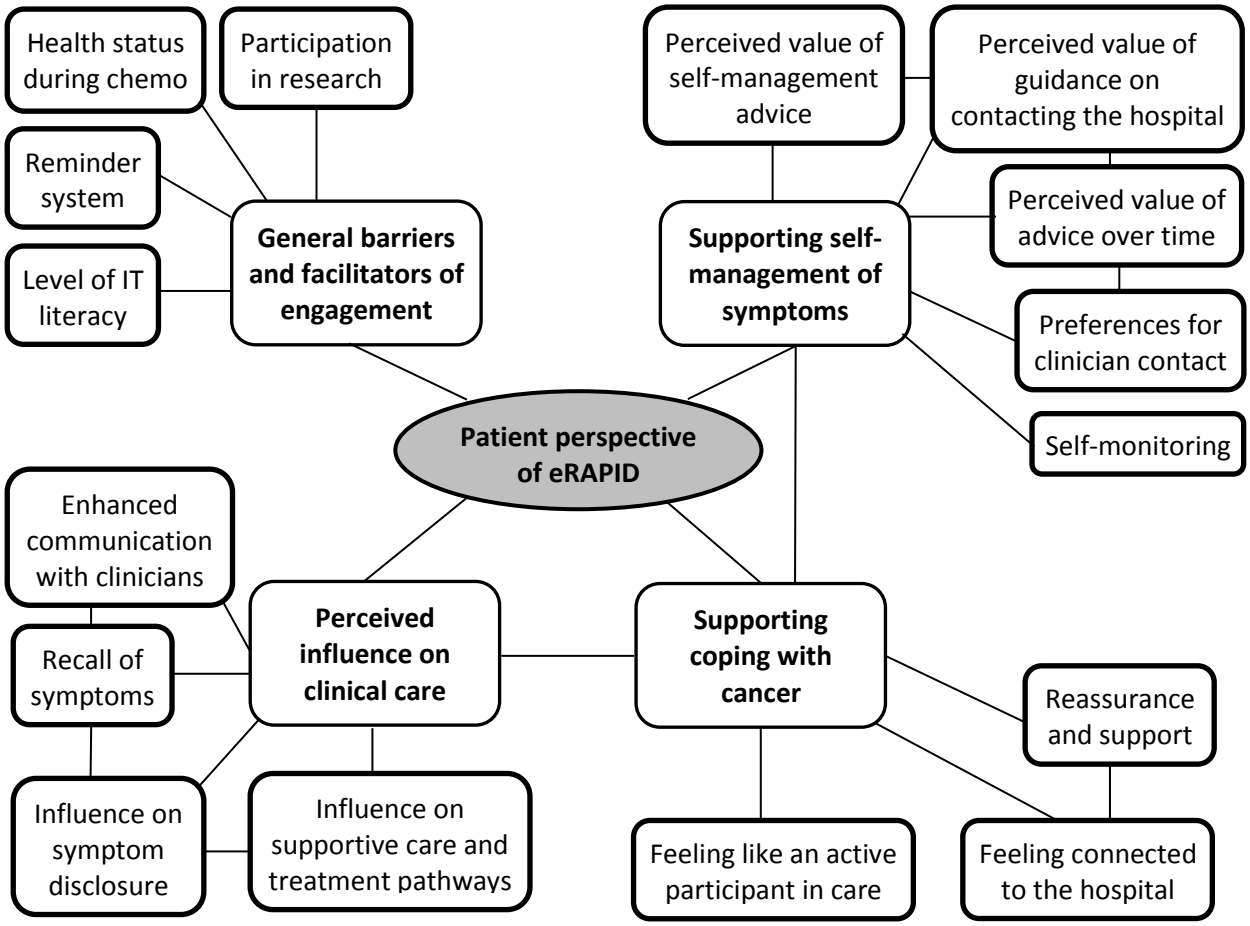
Four main themes were identified in relation to patient engagement with the system, and the main benefits of the system for patients. A thematic map of themes and subthemes and relationships between them is outlined in Figure 7.2. The themes were as follows; 1) General barriers and facilitators of engagement. This theme encompassed factors which impacted on patient engagement with eRAPID, but were not directly related to patients' perceptions of how eRAPID impacted on their chemotherapy experience.

2) Supporting self-management of symptoms. This theme describes patient experiences of how eRAPID supported self-management by the provision of tailored severity dependent advice, in addition to some situations where patients felt this support was lacking. This theme also describes how patients engaged with eRAPID as a tool for monitoring the fluctuation and pattern of symptoms throughout chemotherapy.

3) Perceived influence on clinical care. This theme describes patients' experiences of the impact of eRAPID on their consultations with clinical staff, and subsequently on their clinical care.

4) Supporting coping with cancer treatment. This theme focuses on the more psychological and emotional benefits which patients reported from using eRAPID.

Figure 7.2 Thematic map of themes and subthemes identified



7.4.3.1 General barriers and facilitators of engagement

7.4.3.1.1 Level of IT literacy

Patients generally found eRAPID easy to use, access and navigate. The majority of patients we interviewed considered themselves to have a good level of IT literacy. However, they also thought that eRAPID would be easy for patients with even basic IT skills to access and use regularly.

> *"Anybody who is reasonably IT literate wouldn't have a problem with it at all. So, yeah, I can't see why anybody wouldn't really use it."*
>
> *(00002, Female, 52 years, Breast)*
>
> *"I used to design systems and I thought it was too easy to be honest… but then you'd have some patients not very good with computers for them they'd think it's great this."*

(00082, Male, 48 years, Colorectal)

A small number of patients reported that they were not confident accessing and using IT generally. However, these patients still managed to participate in the study and complete the weekly symptom reports with some support from family members. One patient had support from her son who visited regularly and would help her to complete the symptom reports. However, she was confident in accessing the reading the advice, once the symptom report was completed.

"I read the advice but he just had to put the information on because I'm not very good on the computer really."

(00010, Female, 59 years, Breast)

Another patient described how his wife supported him to complete the symptom reports, and they went through the self-management advice together. Although neither of them were confident in using IT, they were able to manage together.

"The wife and I did it between us. She might have struggled on her own and I might have struggled on my own, but our combined effort… but I think it was good, well designed really"

(00044, Male, 70 years, Colorectal)

Some patients did express that while they themselves had found the system easy to use and navigate, they felt that other patients, in particular, older patients might struggle with it, and this would need to be taken into account for future implementation.

"Depending what age you are you might not. So for example my parents wouldn't want to do it because one false move and they'd think they'd blown it up and they wouldn't use it at all, but I think everybody else would you know, the next generation."

(00043, Female, 52 years, Breast)

7.4.3.1.2 Reminder system

In the previous usability study, the most common reason for non-completion of the weekly symptom reports identified was that patients simply forgot. Subsequently, we implemented a text and/or email reminder service. Reminders were automatically set to be sent out once a week from three days after the patient's first chemotherapy. Patients found the reminders very helpful, although most patients said that they did not tend to complete the symptom reports in line with when the reminders were received. However, patients said that receiving regular reminders helped to keep eRAPID at the forefront of their mind during treatment. This was important, as many reported that it was difficult to keep track of time and days when out of routine and trying to manage chemotherapy side effects, and many referred to suffering from 'chemo brain'.

> *"When I got the text, I didn't go and log on straightaway. It was just so that I thought, I still had it in the front of my mind, kind of all the time so it was helpful in that respect."*
>
> *(00034, Female, 24 years, Breast)*
>
> *"You'd get a bit fuzzy, I dunno like chemo brain or you'd become a bit scatty… because you're in this bubble with treatment and appointments and things, the days don't seem to mean much and then all of a sudden it's like 'I thought I'd done that' or 'I meant to do that' and then a reminder would come up. So as we went on the reminder was good cos it's like 'I completely forgot about that, yes I need to do that' and it would prompt me."*
>
> *(00017, Female, 48 years, Breast)*

7.4.3.1.3 Health status during chemotherapy

Some patients found it difficult to complete eRAPID symptom reports when they were feeling unwell, 'grotty' or tired from chemotherapy as they didn't feel up to it. The majority of patients still managed to complete regularly but found they had to work this around when they were feeling better. However, some patients did find this too difficult and subsequently disengaged with the system.

"It just wasn't a priority cos I was feeling so grotty. So a lot of things went by the by really and unfortunately that was one of them."

(00023, Female, 45 years, Colorectal)

One patient felt that eRAPID was an added pressure when she was already struggling to cope with managing family life.

"I think it was just dealing with my illness which I found really difficult. I didn't have a lot of help at home and I was just struggling to manage my symptoms, my emotions, things that I still needed to do for my children, so they, it was just a lot of pressure on me and I felt really bad about not doing it"

(00032, Female, 47 years, Gynae)

One patient commented that although it would potentially be very useful to complete a symptom report when they were feeling ill in order to receive advice on managing symptoms and provide an accurate record, they were less motivated to log and access the system during these times.

"If you're not feeling well, maybe that's the time when you really need to be filling it in, but you're less inclined to fill it in then. It's very… it is rather a vicious circle."

(00037, Female, 62 years, Breast)

Conversely, other patients reported that they were less motivated to access eRAPID and complete symptom reports when they felt well and were not experiencing very many symptoms or side effects. Some patients said that they delayed completing symptom reports, with the intention to complete in a few days if they did start experiencing side effects.

"I was thinking well I'll wait until I've had a few more symptoms 'cos I didn't have a great deal. So it was like I'll wait until I've got a few more you never know what might happen tomorrow so I'll leave it another day and another day and then I'd get like 2 weeks into the cycle, actually I really think I should fill it in, but that's what it was because I didn't have a great deal to fill in"

(00006, Female, 51 years, Breast)

One patient who had initially used the system, but used it less as she progressed through chemotherapy reported that she didn't want to access eRAPID when she felt well, as she just wanted to get on with things and not be reminded of the hospital.

> *"The more well you feel, the less likely you want to go on it and then I think 'oh I've not done it' and I'm thinking that's a good thing I've not gone on it. So to go on and tell you that I'm feeling really well to me was a bit of a waste of time and reminds me of the hospital which you kind of want to forget if you're feeling well."*
>
> *(00001, Female, 43 years, Breast)*

7.4.3.1.4 Participation in research

When asked about their main motivations for using eRAPID, some patients reported that contributing to research was an important motivator for them. Although most patients felt that they also derived some personal benefit from their participation in the trial, this motivation was independent of that. Patients spoke about wanting to 'give something back' and hoping that their contribution would help other cancer patients in the future.

> *"I think without being cushy about, it could also help somebody else in a similar situation, it is no extra effort"*
>
> *(00044, Male, 70 years, Colorectal)*
>
> *"It was a win-win and I thought well I like participating in the trial, I love what this hospital does, if I've been contributing all the better, it's a minor pay back for everything that's coming my way, but also I just hoped that it would be useful"*
>
> *(00035, Female, 47 years, Breast)*

7.4.3.2 Supporting management of symptoms

Patients reported that the advice for managing symptoms was one of the most useful features of the system, and one of the main motivators for engaging with eRAPID. There were two main aspects to the symptom advice which were valuable for patients. Firstly, the self-management

advice which they received for milder symptoms, and secondly, the advice to contact the hospital for more severe symptoms.

7.4.3.2.1 Perceived value of self-management advice

Patients found the self-management advice practical and helpful. Although patients received similar information in paper form from their oncology nurses at the beginning of treatment, they found the eRAPID information easier to access as it was specifically tailored to their symptom reports.

> *"I felt a bit nauseous but you knew it was there to go through, you know, you might try ice cubes and stuff like that. We had ice lollies. There's all this information there and you didn't have to go searching, it would just automatically come up with any problems that you had."*
>
> *(00017, Female, 48 years, Breast)*
>
> *"It reminded me actually of a couple of things, things about the eating or things about managing cos that was a big problem, eating's a big problem and so just reminding you about you know little and often or I can't remember what. The small things like getting somebody else to cook"*
>
> *(00025, Female, 65 years, Gynae)*

Some patients felt that without the availability of eRAPID advice, they would have needed to contact the hospital for routine self-management advice or reassurance. Most patients valued the fact they could manage symptoms on their own terms with reliable guidance.

> *"You can get the help without having to ring up the hospital every five minutes… Yeah because on the occasions where something different came up, I got the advice from that rather than having to call up and speak to one of the nurses."*
>
> *(00015, Male, 58 years, Colorectal)*

7.4.3.2.2 Perceived value of guidance on contacting the hospital

Patients placed high value on the knowledge that eRAPID would prompt them to take action if their symptoms were at a severe enough level, and felt reassured by this.

> *"It gave you a little, you know, a medical evaluation, which was actually quite helpful and quite useful. So rather than ring somebody up, or go to the hospital you had sensible information at your fingertips after you filled it in. It noticed immediately what was wrong with you, and gave you advice, and then suggested phoning the hospital, you know, if it was at a critical point, you know?"*
>
> *(00035, Female, 47 years, Breast)*

Patients were aware that some treatment side effects were to be expected and commonly, patients expressed that they would be reluctant to contact the hospital for fear of 'bothering' people or wasting time or resources. However, they were also trying to balance this with challenges of dealing with unfamiliar symptoms and side effects which could potentially require medical intervention and did not feel confident in making judgements about the importance or severity of the symptoms they were experiencing.

> *"You're always got that dilemma of, well, is this normal, am I wasting somebody's time, so … yeah, so to have some really clear instructions that are based on what you've just reported are really good and then you know it's the right course of action."*
>
> *(00002, Female, 52 years, Breast)*
>
> *"You don't like to just phone the hospital cos you feel like you're bothering people and you think 'This is just normal'… but when you went along the journey with eRAPID, it gave you an idea of at what point you should contact the hospital"*
>
> *(00017, Female, 48 years, Breast)*

Patients also felt that if they were advised by eRAPID to contact the hospital, this would give them 'permission' without having to feel guilty or worry that they were calling unnecessarily.

> *"I think it was terrible stomach pains and they were quite severe and because I'd put severe the little flasher came up saying, you know 'If*

this continues contact…' It didn't so that was all right. But it gives you permission and that's what I liked about it because you're thinking, am I making a fuss?. It actually gave you permission to contact."

(00007, Female, 62 years, Breast)

"There were a few times I thought am I supposed to phone the hospital? But I don't think … I'm kind of borderline but I don't feel overly bad but I think, you know, it would give you that confidence to say 'hi, my eRAPID says I should call'."

(00017, Female, 48 years, Breast)

7.4.3.2.3 Perceived value of advice over time

Some patients reported that they experienced a similar pattern of symptoms throughout all of their chemotherapy cycles. As their symptom reports were very similar on a week to week basis, they were receiving the same self-management advice from eRAPID each week, which subsequently became less useful over time. As a result, some patients who had found that the self-management advice was initially a motivator for completing symptom reports found that this became less of a motivator as they progressed through treatment.

"Yeah, I mean the only thing that was a little bit frustrating was that obviously the advice doesn't change, so mine were fairly… my responses were fairly similar all the way through, probably getting a little bit more acute if you like, but the response from the system was the same all the way through and actually that's understandable logically, but you're kind of looking for another answer, you're like, somebody tell me how I can stop it… I understand why that would be, it's just you're sort of seeking something aren't you that's probably not going to come"

(00072, Female, 33 years, Gynae)

"I only had the same things to say and then it said the same things to me. So initially that was ok because… I didn't remember everything and it was good to refresh what to do about this tingle something like that. Um but then I had a bit of a down time because the treatment wasn't working and… I wasn't well basically so then when I wasn't well I um didn't pay attention to it properly you know I didn't do it"

(00025, Female, 65 years, Gynae)

Patients also reported becoming gradually more confident in their ability to self-manage symptoms as they progressed through treatment. They also became more confident in making their own judgements on when they needed to contact the hospital. Occasionally patients even reported that they ignored advice from eRAPID to contact the hospital, if they felt it was unnecessary. As a result, patients became less reliant on the symptom advice as they progressed through treatment, and again, this seemed to reduce motivation to engage with eRAPID.

"I had previously contacted the hospital, and they had told me 'Do this, this, this'. So I kind of knew what they were going to say because it was the same old thing again. So I kind of knew what the answer was going to be, so I didn't go into emergency mode"

(00035, Female, 47 years, Breast)

"On the eRAPID it kind of sort of says it quite soon to phone the hospital and especially if it's like Saturday or Sunday you think should I? I don't really want to be calling an out of hours number. I think if I'd have had the temperature, I think that would have been more of an issue because of the infection and you are aware it's your immune system and you do need to come in but I think it's one of the things, I'll just see if it subsides."

(00017, Female, 48 years, Breast)

7.4.3.2.4 Preferences for clinician contact

A small number of patients felt that in the case of experiencing a problem, they would prefer to just contact the hospital directly. They felt that logging on to complete a symptom report would be an additional, and perhaps unnecessary step if somebody was already feeling unwell.

"You have to remember, got get that password thing or remember it and then log in which is simple to do but… it's just not as simple as sending an email or picking up the phone."

(00001, Female, 43 years, Breast)

"For example say my stoma starts bleeding, do I need to log on? But I wouldn't, the first thing I would do is ring the oncology hot line because… you don't want to be ill or in pain and think oh now I need to log on and go through all the questionnaire and see if I get a response"

(00082, Male, 48 years, Colorectal)

A couple of patients also expressed concerns that eRAPID might be intended as a replacement for clinical care. It is worth noting that the patients who expressed this concern were the first patients on the study, so it is possible that these concerns were reflective of some initial concerns by clinical staff on the purpose of eRAPID.

"Is it about trying to not have as much personal contact, sort of sending off people? I don't know it's really what's the objective because if it is about stopping people calling all the time with the same questions… but people need that don't they?"

(00001, Female, 43 years, Breast)

"I wonder if people might feel they were being fobbed off a little bit by, you know, that they might not feel they're getting the same medical care, but I don't know, I certainly didn't feel that"

(00002, Female, 52 years, Breast)

7.4.3.2.5 Self-monitoring

Patients were provided with graphs at the end of each symptom report completion which depicted the level of severity for each symptom over time. Some patients used these graphs as a tool to monitor how their symptoms fluctuated throughout their treatment. One patient described how she found this useful to self-manage symptoms, by identifying strategies that had previously been helpful.

"If I had a worse week than the previous week then I'd sit down and think to myself right what didn't I do this week that I did last week or what can I do now to make that factor the same as it was the week before so in that respect it helped. If it is better than the previous week then fair enough I am obviously doing

something right but if it was worse, then it gave me an opportunity to sit down and think right what didn't I do, and what do I need to do? That's what helped me self-manage my symptoms"

(00022, Female, 47 years, Breast)

However, for other patients the most useful aspect of the graphs was that they were able to have a visual representation of how the severity of their symptoms did fluctuate, and that this was particularly useful at the times when symptoms were at their worst, as it reassured them that symptoms were temporary.

"You'd sort of think, I'm sure this is a lot tougher than it was last time, but then when you look you'd go, actually no you felt similar, maybe for 24 hours or less but you felt similar in terms of the severity. So it kind of gave you like you say that push to say, it'll be gone again in 24 hours… 48 hours… just keep pushing through so it was useful in that sense to see those graphs."

(00072, Female, 33 years, Gynae)

"You can see actually that on that week I felt particularly bad but on the second week I didn't have those symptoms at all. So it will go… so there was some optimism"

(00006, Female, 51 years, Breast)

7.4.3.3 Perceived influence on clinical care

7.4.3.3.1 Enhanced communication with clinicians

Most patients felt that eRAPID facilitated and improved their communication with their healthcare team. Some patients felt that eRAPID positively influenced their consultations with clinicians, as clinicians could access the patient's eRAPID symptom reports before the appointment, and already have a good idea of how the patient was before the consultation started. Patients felt that this was really valuable as they felt that the clinicians were more 'prepared' going into their consultations. One patient described this as putting them 'on the same wavelength'.

"If the patient has written this down beforehand, then you can read up on the notes before they even get there, and you know, at least get how the patient's going to be, or be on the same wavelength about how their symptoms have been, how the chemo's going. So I think, yeah, I think that's a good idea, because they'd know in advance, you know 'Oh you've not had a good time this time, have you?' for example."

(00035, Female, 47 years, Breast)

"They would use that to say 'Oh you've had problems with a sore mouth this week, let's get you this prescribed' or… they'd look at that and see that there was problems with and then they'd say 'Well was there anything else?'. But it's kind of like they already had the information prepared."

(00034, Female, 24 years, Breast)

Sometimes clinicians were very explicit with patients about using the symptom reports during consultations while other times they were less so. The acknowledgement by clinicians of the value and the use of the symptoms reports patients provided was an important motivator for patient engagement.

"Our chemotherapy doctor, he would bring it up every time and show us it and talk me through any concerns that he had, so yeah I was… and again that re-incentivised me to use the system because you know it's not just a waste of time, somebody's looking at it."

(00072, Female, 33 years, Gynae)

However, some patients were not aware of clinicians using or accessing their symptom reports during consultations, and subsequently, felt much less engaged to continue using eRAPID throughout their treatment.

"Some sort of acknowledgement it's being looked at, carry on using it… I could log them all on there and maybe when I have my meeting with (doctor), he could say right let's look at all the information you've put over the last 6 months and I see this has happened this has happened etc. but if they don't say anything, you know, why are you using it?"

(00082, Male, 48 years, Colorectal)

7.4.3.3.2 Recall of symptoms

For many patients, the most important motivator for completing symptom reports each week was to provide a record for clinicians. Commonly, patients expressed that without having this record, they didn't feel that they would be able to provide an accurate picture of their symptom burden to clinicians, as it was too difficult to remember how they'd been, giving that their consultations were not always frequent. Many patients also felt that chemotherapy impacted on their memory, which made it even more important to have an accurate record.

> *"I knew that the oncologist would look at it before clinic so I thought it's good to try and do it every week so that it's as accurate as possible because when they come to ask you how your symptoms are, you can't necessarily remember how you were like four weeks ago or something or even maybe six weeks."*
>
> *(00034, Female, 24 years, Breast)*
>
> *"Even before I had the chemo I don't always remember things that I did two or three weeks ago, and what they term chemo brain, that effects it and made it even worse. So to have that information there, like I say it helps whoever is looking at it, have that information of what has gone on, but when they then reiterate it back to the patient it then jogs their memory, prompted me anyway, to say yes this was what happened"*
>
> *(00022, Female, 47 years, Breast)*

7.4.3.3.3 Influence on symptom disclosure

In addition to helping patients recall what symptoms they had experienced, some patients also felt that eRAPID impacted on what symptoms they disclosed to their clinical team. Most commonly because patients were not always sure of the relevance or importance of symptoms.

> *"I tend not to fuss over little niggles or minor pains, you know, I tend to push those to the back of my mind and try and ignore them and just get on with it. But it did make me focus on those and, in actual fact, it*

made my care better because I was mentioning them and then they could put a sort of a remedial action in place."

(00007, Female, 62 years, Breast)

"It made you think well actually if (Doctor) asks me how are things going, you're very sort of generic, you know, mine would be always, yeah, you know, the worst of it is this but generally we're doing okay. But that captured things that you probably wouldn't talk about in detail with the doctor because they were sort of lower end in comparison to others."

(00072, Female, 33 years, Gynae)

In addition, some patients also reported that they felt more comfortable disclosing potentially embarrassing symptoms as it was easier to write them down on a computer than to initiate a conversation with the clinician about it.

"I think there was something to do with a bodily function, I can't remember what it was now, and I thought, you know… I didn't feel uncomfortable writing it down."

(00002, Female, 52 years, Breast)

7.4.3.3.4 Influence on supportive care and treatment pathways

Some patients reported that they were prescribed supportive medications for symptoms and side effects that were picked up by clinicians from the eRAPID symptom reports, and that these were symptoms which they otherwise might not have mentioned to the clinician.

"I also have colitis and sometimes I get very, very bad gripey stomach pains. Now just because I get those anyway I might not have mentioned it other than somebody saying what are the symptoms you had? You know, because they are part of my existence I wouldn't have thought oh well I must mention this. But because it's asking for the symptoms I thought, yes, I can refer back to this, and in actual fact people picked up on that, the chemo nurses, and said we'll give you some Buscopan and I found that very useful and very helpful."

(00007, Female, 62 years, Breast)

"He changed the tablets, you know the sickness tablets, things like that cos he noticed I had felt sick a lot, rather than just a little bit. Whereas it should

have gone off after a time, and it hadn't been, so he changed my tablets or gave me extra ones, so that I could try different ones"

(00045, Female, 52 years, Gynae)

Patients were also asked about any changes to their chemotherapy regimens (such as dose reductions) and whether or not they perceived that eRAPID had any influence on these changes. However, few patients were aware of having had any changes to their chemotherapy regimens and of those that did, they were unsure of whether or not eRAPID had any influence.

7.4.3.4 Supporting coping with cancer treatment

7.4.3.4.1 Reassurance and support

Patients commonly used words like 'reassuring' to describe their experiences of using eRAPID. These words were not mentioned in the interview schedule, but emerged time and time again, particularly in relation to the symptom advice. As eRAPID was available to them 24 hours a day, they valued having access to information, advice and reassurance at any time, such as in the middle of the night.

"Reassurance when you're out there when you can't sleep on your steroids and it's 4 o'clock in the morning… you sometimes don't want to disturb everybody else and you're like well I'll just check this out actually I've been up for 2 hours and this is how I feel without…disturbing everybody can't you…. Almost like a chemo buddy in the night"

(00006, Female, 51 years, Breast)

Patients also found value in being able to identify that their symptoms were a common side effect of their treatment, and not necessarily anything that they needed to worry about. Patients found this reassuring and sometimes felt that the knowledge was enough, and didn't always feel that they needed to take any further action.

"It gave you options of additional, you know, ways to control those things, but just knowing that that was a genuine symptom or a

normal symptom was often enough for me, so I did use it, yeah, as much for the reassurance as anything else."

(00072, Female, 33 years, Gynae)

However, patients descriptions of the 'reassuring' and 'comforting' aspects of eRAPID went beyond the symptom advice and impact on self-management. Patients described how eRAPID became a very important part of their care, and felt it provided emotional and psychological support. Patients sometimes spoke about eRAPID being 'there for them' when they needed it.

"It just felt like part of my normality, part of my routine. As much as it was from being put out of my world into my chemo world for 18 weeks to know that it was there for me with all this information and that it would guide me."

(00017, Female, 48 years, Breast)

"It puts you back into your comfort zone, cos even if you are miles away from the hospital, it's quite a while since you had your initial treatment, it's like a comfort zone that someone is really there, listening to you."

(00044, Male, 70 years, Colorectal)

7.4.3.4.2 Feeling connected to the hospital

Patients sometimes felt that the periods in between routine hospital appointments, which could be several weeks at a time, were quite difficult as they sometimes felt isolated and alone. Some patients felt that eRAPID helped them to feel more supported and more connected to their clinical care teams during these times. One patient described it as the feeling that 'you're being looked after'.

"It's another way of having care, you know, cos I think they say, when you get to the end of your treatment it can be very hard cos you're suddenly on your own whereas I think you've got that peace of mind that in between appointments you've got some contact with the hospital even though it's not really contact so I suppose that was the enjoyment and I suppose the feeling that, you know, that you're being looked after."

(00002, Female, 52 years, Breast)

"I think it creates an empathy between patient and hospital and I think it is, in my case, it is knowing someone is there, without a form or appointment"

(00044, Male, 70 years, Colorectal)

7.4.3.4.3 Feeling like an active participant in care.

Patients reported that eRAPID enabled them to provide accurate and valuable information to their healthcare teams. In addition to the perception that this enhanced their consultations with clinicians and improved communication, this also made them feel more involved in their own care and treatment decisions. One patient recalled a conversation she had with her partner about the impact that eRAPID had on their experience of care. The following quote eloquently depicts the potential for eRAPID to empower patients to be more active participants in their own care.

"We talked about the eRAPID system being very much about your physical progression through the treatments and how they assist you with your symptoms, your side effects… but understanding your treatment and understanding your involvement in the consultation process and everything else would assist massively with your psychological process of managing cancer, you know? Because… Yeah, patient consultant involvement and the feeling involved, you know, but… it's probably a whole different study." (00072, Female, 33 years, Gynae)

7.5 Discussion

7.5.1 Summary of findings

The aim of this work was to use qualitative methods to explore barriers and motivators for patient engagement with eRAPID and the impact of eRAPID on patients' experiences of chemotherapy. Findings supported the high levels of patient engagement with eRAPID found in the quantitative assessment. eRAPID was well accepted by patients, with many facilitators for engagement described and few barriers.

Some findings were similar to those in the field usability study described in Chapter 4. Although some IT literacy was required for study eligibility, of those patients who did participate, the level of literacy was not a barrier to accessing eRAPID and even patients who described themselves as having limited IT skills reported being easily able to access and complete the symptom reports. The newly implemented reminder system was well received and seemed to keep eRAPID on the radar for patients during treatment.

Health status during chemotherapy was again identified as a potential barrier to system use, and again this was bidirectional. Some patients reported that they were less likely to complete symptom reports when they felt very unwell. This is unsurprising with patients undergoing chemotherapy and again, a commonly reported barrier for engagement [159]. Although the majority of patients still managed to engage with weekly reporting, for some the practical challenges of completion outweighed any benefits they received in terms of self-management support or input from clinical staff. However, there were also a number of patients who did not engage with completing symptom reports when they were not experiencing symptoms. Following the same finding in the usability study, patient training was adapted to emphasise the importance of regular completions, even in the absence of symptoms, in order to provide a complete picture for clinicians. However, this still remained an issue for some patients, suggesting some patients just do not want to engage with symptom reports when they feel

well, and may just want to live as normally as they can [161-163]. This may also be related to patient perception of staff engagement with symptom reports, as patients may not perceive much benefit if clinicians are not reviewing data.

Patients desire to contribute to research was also identified as a facilitator for engagement, and this was independent of any personal benefit they perceived. This was not previously identified as a motivator in the usability testing, but altruistic and extrinsic motivations have been identified as common facilitators for engagement in other similar research [164]. Although extrinsic motivations such as these are not necessarily negative, one patient did describe feeling really bad when unable to complete the symptom report due to ill health and competing responsibilities. This illustrates an ethical need for more focused research on patient engagement, as engagement may not always be indicative of patients gaining personal benefit from the system.

In terms of intrinsic motivations, and the benefits patients perceived from their interactions with eRAPID, the symptom advice was a strong motivator for engagement. Patients found it reassuring to have tailored and reliable guidance, particularly early on in their chemotherapy when they had less experience in managing problems and were most anxious. Patients reported a strong desire to self-manage where possible and appreciated clear guidance on when hospital contact was necessary. Patients reported feeling reassured and supported by symptom advice and talked about eRAPID being 'like a chemo buddy'. Again, this supports previous findings both from the field usability testing of eRAPID and from other similar research [72, 165, 166]. However, patients did not always follow advice provided by eRAPID, particularly as they progressed though treatment and became more confident in making their own judgements. It may be that this aspect of eRAPID is much more useful to patients early on in their treatment to support them through those early uncertainties.

Following findings from the usability study, patients were specifically asked about their use of the eRAPID symptom graphs, which depicted the level of severity of each reported symptom

over time. A number of patients reported that they used eRAPID as a tool for monitoring patterns in symptom fluctuation, and these patients tended to report that they remained engaged with completing regular symptom reports throughout the study period.

While the majority of patients perceived eRAPID as enhancing their care and providing valuable additional information to their clinical team, a couple of patients did express some concerns about the potential for eRAPID to replace face to face or telephone care with clinicians. This belief about supportive technologies in healthcare settings has been discussed previously and identified as a potential barrier to implementation and engagement, highlighting a need to be clear with patients about the purpose of online systems [296].

One of the main themes which emerged from this analysis was the importance of clinician use of the data in routine consultations, supporting findings from the quantitative work. eRAPID was seen to be useful for facilitating communication, acting as a useful trigger to start a dialogue with clinicians about symptoms that might otherwise not have been picked up. Many patients reported that they did not know how they would remember to tell the clinician about side effects without the eRAPID prompt, and a number of patients talked about 'chemo brain', which impacted on memory. This is an issue commonly reported by cancer patients but rarely acknowledged by oncologists [20]. In addition, patients also felt that eRAPID made them feel more connected to the hospital and their healthcare team in between routine appointments and more like active participants in their own care. Patients seemed to feel empowered by contributing towards their care and symptom management, with one patient describing the psychological benefit of using eRAPID as 'feeling involved' in their own care. However, patients' perceptions of clinician use of the data was varied. In some instances, patients reported that clinicians were very explicit about if and how they were using the symptom reports, which incentivised them to complete regularly. However, in other instances, patients were unsure of whether or not clinicians had even accessed their data, and subsequently did not see the value in completing symptom reports.

As outlined in Chapter 1, engaging clinicians to use PROMs data in consultations can be challenging [61-65]. Training clinicians has shown good promise in overcoming some of the barriers, but attitudes towards PROMs are still variable between clinicians and much more work is needed [61-64, 70].

Patients were also asked about their experiences and attitudes towards any changes to their treatment plans that had happened as a result of the symptom reports they completed for eRAPID. However, very few of the patients interviewed were aware of any changes to their treatment plan, and of those that were, they were unsure whether eRAPID data had any impact.

7.5.2 Strengths and limitations

The main strengths of this work were that it reported experiences of real patients using eRAPID over 18 weeks of treatment. This data has provided valuable insight and context to the quantitative findings discussed in the previous chapter.

However, there were some limitations. The sample was relatively young with high levels of education, and a higher number of breast patients, in comparison to gynae and colorectal patients. In addition, few of the patients interviewed had experiences of eRAPID data impacting on their treatment plans, and few patients were admitted over the course of their treatment. End of study interviews were continued going forward into the main phase of the RCT. However, a stratification plan was put into place to ensure representation across age, gender and disease group. Patients were also stratified in terms of their experiences of treatment changes and admissions to further explore the impact of eRAPID.

Although one of the aims was to inform the quantitative work described in the previous chapter, we did not explicitly ask patients about self-efficacy or activation. The interview schedule was revised for the main RCT to explore this going forward.

The general approach to the interviews was quite pragmatic in order to meet the aims of the main trial. Much of the interview schedule consisted of close ended questions specifically aimed at informing future development and implementation of eRAPID. Using a more exploratory, patient-led approach with more open-ended questions may have given a more complex insight into patients' experiences. However, an effort was made during the interviews to encourage patients to elaborate on their experiences, and to explore any unexpected themes raised. In fact, many patients did talk in detail about the more emotional impact that eRAPID had on their chemotherapy experience. This is something that will also be explored in more depth in the next round of interviews.

In addition, I have been responsible for developing the interview schedule and the framework for analysis. This development was carried out with the support of my supervisory team, but will have been heavily influenced by my own experiences of spending many years working on the development and evaluation of the eRAPID system, and of working with cancer patients at different stages of diagnosis and treatment. Most members of the research team will have had similar experiences, and this may also have impacted how the interviews were carried out. Members of the research team also saw the patients at several stages throughout their time on study and as such, built a relationship with them. Although this was in many ways beneficial for the interviews, as researchers already had a good rapport with patients, there is also a danger that this relationship may have influenced patients' responses. For example, patients may have had a greater motivation to be positive in their descriptions of eRAPID and may have over emphasised some of the benefits that eRAPID had on their chemotherapy experience.

The setting of the interviews may also have influenced the direction of what was raised. Interviews generally took place in the same clinical area that patients attended throughout their treatment and time on study. Although this influence could have been diminished by conducting the interviews in a more neutral space with less connotations and associations for

patients, this would have been practically very difficult to arrange, and would have been much less convenient for patients.

The timing of the interviews is also likely to have impacted on patients' perceptions of their experiences at that time. Interviews took place at the end of study, which for the majority of patients, also coincided with the end of chemotherapy. Patients' feelings at having finished this stage of treatment may have impacted on their interviews. In addition, not all patients would have been finished. Some patients may have been going on to have further chemotherapy, starting radiotherapy, or may have been scheduled for surgery. However, it was necessary to try and schedule interviews for this time point, in order to get a good reflection of patients' experiences of using eRAPID as soon after their study completion as possible.

7.5.3 Conclusion

eRAPID was well received by patients, with few barriers to use reported. Patients reported that the symptom advice was a motivator for engagement, and found this reassuring. However, the advice became less useful to them over time as they became more confident in managing symptoms and side effects. One of the main motivators for sustained engagement throughout the study period was to provide information to clinicians for use in consultations. However, perceptions of clinician use of the data varied. Some patients reported that clinicians were explicit with them about their use of the data, while others were unsure of whether or not their data was being used.

These findings will be discussed in the context of the quantitative findings in the final chapter

Chapter 8 Discussion

8.1 Overview of aims and findings

The overall aim of this thesis is to explore the patient perspective of using ePROM systems to report and manage symptoms and side effects during chemotherapy. The specific aims were to explore: 1) The main challenges patients face managing symptoms and side effects of chemotherapy in standard practice. 2) The potential for ePROM systems to support patients to overcome some of these challenges. 3) How patients engage with eRAPID over the course of chemotherapy treatment. 4) How eRAPID impacts on patient experience of chemotherapy. Aim 1 was addressed in Chapter 3, which highlighted some of the common challenges patients face in managing the side effects of chemotherapy, in particular, the lack of confidence patients feel in making decisions about when to self-manage and when they need to contact the hospital. Aims 2, 3 and 4 were addressed in the field usability study of eRAPID described in Chapter 4, which explored how eRAPID might support patients to overcome some of these issues. The main findings were that although eRAPID was generally acceptable to patients, patient engagement with the system was variable. End of study interviews indicated that patients found benefits from using eRAPID over and above improved symptom management, such as increased confidence to manage side effects of treatment and to cope with cancer and treatment. Aim 2 was addressed by the systematic review described in Chapter 5, which outlined available evidence on ePROM systems for patients undergoing cancer treatment. Robust evidence was scarce, with few RCTs identified. In addition, although a number of feasibility studies were identified, few explored the complex processes of engagement. Outcomes selected to evaluate systems were generally focused on improved symptom

management, and potential benefits of systems in terms of more psychosocial outcomes such as self-efficacy were not routinely assessed.

Chapter 6 addressed aims 3 and 4. Quantitative analysis was used to explore the patient perspective of eRAPID. This analysis was informed by the findings of previous chapters. Patient engagement with eRAPID was explored in more depth, and validated measures were used to assess the impact of eRAPID on patient self-efficacy to manage side effects of treatment, self-efficacy to cope with cancer and their levels of PA. In addition, the relationship between these outcomes and engagement with the system was explored. The main findings were that levels of engagement and adherence were generally high and eRAPID was well accepted by patients. A logistic regression model to predict engagement with eRAPID revealed that the only significant predictor was a measure of clinician use of patient data during routine consultations. There was a positive impact of the intervention on patient self-efficacy to manage side effects of treatment, but not on self-efficacy to cope with cancer or on PA. Within the intervention group, adherence to weekly completions was a significant predictor of improvement in self-efficacy for both managing symptoms and for coping with cancer, but not for PA.

This was supported by qualitative analysis described in Chapter 7, aiming to further explore the patient perspective of eRAPID. Barrier and facilitators for engagement were explored, in addition to the impact eRAPID had on experience of chemotherapy. The findings indicated that eRAPID was well received by patients, with few barriers to use reported. Patients reported that the symptom advice was a motivator for engagement, and found this reassuring. However, the advice became less useful to them over time as they became more confident in managing symptoms and side effects. One of the main motivators for sustained engagement throughout the study period was to provide information to clinicians for use in consultations. However, perceptions of clinician use of the data was varied. Some patients reported that clinicians were explicit with them about their use of the data, while others were unsure of whether or not

their data was being used. Patients reported psychological benefits from their use of eRAPID, and felt it improved their care.

8.2 Implications of findings

The preliminary work highlighted the need for intervention to support patients to self-manage during chemotherapy and the potential for ePROM systems such as eRAPID to provide such support. The systematic review demonstrated that although there were many ePROM systems in development, there was little focus on how patients were engaging, or why. In addition, outcomes were focused on symptom management and few were exploring psychosocial benefits. This work was integral to inform the design of the evaluation of patient engagement and experience of using eRAPID during chemotherapy.

Overall, the findings indicate that eRAPID was well received by patients. The quantitative analysis suggested levels of engagement with eRAPID were high, and this was generally supported by the qualitative data with few barriers to engagement reported.

The regression analysis did not identify any socio-demographic variables such as age or IMD deprivation scores as predictive of engagement with eRAPID. Internet access was part of the eligibility criteria for participation in the study, but only 13% of patients considered for the study were ineligible for this reason, highlighting the growing use of the internet. In addition, of those patients who did participate in the study, previous computer usage did not seem to impact on engagement. This was supported by the interviews, with even older patients who described themselves as having limited computer literacy finding the system easy to use and access. There is a common perception that older patients will be less likely to engage in eHealth, but increasingly, this is no longer found, supporting the notion that the significance and magnitude of the 'digital divide' is decreasing [282, 297, 298]. In fact, some of the descriptive data in Chapter 6 suggested that it was younger patients who were less likely to be

engaged with eRAPID. Interviews suggested this may be because differences in role and lifestyle, with patients with young families sometimes finding it difficult to manage with the burden of chemotherapy. However, the majority of patients found they were able to manage completions around other life commitments. This confirms previous findings about the importance of ensuring that systems are flexible and can adapt to patients' needs [299]. Additionally, flexibility of eRAPID symptom reports and system access was an important facilitator for engagement when patients were feeling particularly ill or unwell during chemotherapy. The interviews suggested that while poor health status could be a barrier, they were able to work it around times when they felt well, again emphasising the need for flexibility and accessibility.

Patients' levels of activation (as measured by the PAM) did not predict usage of eRAPID. As discussed in Chapter 6, there was somewhat of a ceiling effect at baseline, which may have impacted the results. In addition, the suitability of this measure in cancer populations is unclear, with previous research limited to cross sectional studies with methodological limitations [262-264]. However, interviews also indicated that some patients had extrinsic motivations for engagement such as a desire to take part in research and help others, similar to findings in other studies [164]. Patients lower in activation tend to view successful self-management as compliance, whereas those with higher levels view it as being in control [300]. In the case of eRAPID, it may be that patients lower in activation may complete the symptom report questionnaire weekly as requested, but they may not engage with other features of the system such as the self-management advice and subsequently may not perceive or experience much benefit from their participation. This highlights the value of qualitative research in this context to further understanding on the complexities of patient engagement.

A measure of clinician use of the data was identified as being associated with patient use. There were some limitations to this measure (see Chapter 6 discussion), but the important role of clinician use of data was strongly supported by the interviews. For most patients this was

their main motivation for adhering to the weekly symptom reports, and patients valued being able to provide detailed and accurate information about their symptoms, which was easily accessible to clinicians for use in their consultations. The descriptive analysis outlined in Chapter 6 suggested that clinician engagement was generally good, but variable. The challenges of engaging clinicians to use PROMs data in routine consultations are well documented. Attitudes towards the usefulness of PROMs are variable and some clinicians have concerns about making consultations longer or interference with communication [61-65]. However, many of the patients interviewed in our sample found that the PROMs data improved communication, supporting other findings [46-48, 301].

Furthermore, when clinicians were clear and explicit with patients about their use of the data, patients were more engaged to continue completing symptom reports, but also felt their role was more valued, and felt like active participants in the consultation, again supporting other findings [301]. Logically we would expect that PA, which assesses patients' engagement in their own healthcare, would assess these benefits. However, as described in Chapter 6, there was no impact of eRAPID on patients' levels of activation over time, and no relationship with engagement. Again, this may have been due to the unsuitability of the measure for use in this population and ceiling levels at baseline. Other researchers have outlined the need for a more suitable measure to assess the construct of empowerment and activation in this population [302].

There was however, an impact for eRAPID on patients' self-efficacy to manage symptoms and side effects. The qualitative data supported this, with many patients highly valuing symptom advice. Patients talked about eRAPID being 'there' for them when they needed it, and described it as 'reassuring' and 'like a chemo buddy'. Reassurance has been identified as a benefit of ePROM systems in previous qualitative work [72, 165, 166], but as highlighted in Chapter 5, psychosocial outcomes such as self-efficacy are seldom included as an outcome for ePROM system evaluation in cancer care.

Although, it would seem logical to assume that this increase in self-efficacy would be largely related to the provision of symptom advice, many patients reported that this was much more important earlier on in their chemotherapy, and less important later on as they gained confidence in their own knowledge and skills. It would then seem logical to assume that most of this benefit in terms of self-efficacy may be derived early on in the patient's chemotherapy experience, and that sustained engagement may not be necessary for patient benefit.
However, increases in self-efficacy were highly correlated with patient engagement. Similarly, although there was no difference between patients using eRAPID and usual care on self-efficacy to cope with cancer, sustained engagement was associated with improved scores. The true meaning of this relationship is unclear, as it is likely to be influenced by a number of other factors, but it does suggest that sustained engagement is important. Furthermore, the importance of sustained engagement is supported by other research [210]. As the interviews suggest that one of the main motivations for sustained engagement was clinician use of data, it may be that some of the improvements in self-efficacy scores are due to patients feeling that they are contributing towards their management and care by completing symptom reports.

8.3 Strengths and limitations

This work is contributing to an emerging field of research that is growing in importance. The nature of healthcare is changing and ePROM systems have potential to support self-management [100, 303, 304]. However, patient engagement with systems is complex, and evidence is needed to inform future development, evaluation and implementation.
As outlined in Chapter 2, much of the methodology in this thesis has been integrated into the development and evaluation of the work undertaken as part of the eRAPID development and programme grants. This has provided some unique opportunities, for example access to a large sample of patients in a real life chemotherapy setting, the opportunity to integrate into a

randomised controlled design with a large sample. In addition, the support of colleagues with data collection and analysis was invaluable. However, the integration also brought some limitations. The trial design, for example in terms of sample size, frequency of completion of outcome measures etc., were based on the primary outcomes for the trial, which needed to be prioritised. There was also a need to be conscious of patient burden for completion of outcome measures. For example, additional completion of measures, or additional patient interviews mid-way through patients' chemotherapy cycle may have provided additional insight. However, overall the minor limitations of the thesis being integrated into the main trial were far outweighed by the benefits.

The mixed methods approach used in this thesis worked well to address the research aims. The initial qualitative work, in combination with the results of the systematic review were highly informative for the design and development of the work described in Chapters 6 and 7. In addition, the combination of qualitative and quantitative methods used in these later chapters and the triangulation methods used to compare and contrast findings provided insights which would not have been possible using quantitative or qualitative methods alone.

The methodological limitations of the individual studies are discussed in the relevant chapters. However, there were some more general limitations. As highlighted in the results of this thesis, the complexities of patient engagement are inherently related to clinician engagement and it is important to understand both and to explore how they interact. Some descriptive data on clinician engagement is reported in Chapter 6, but this has not been explored further. In addition, the different clinician roles have not been differentiated in our limited assessments. As described in Chapter 2, the clinicians involved in using eRAPID include senior oncologists, specialist registrars, clinical nurse specialists and other senior nurses qualified to carry out pre-assessment consultations. In addition to differing levels of experience, these clinicians have different relationships with patients. In particular, the clinical nurse specialists seeing curative breast patients tended to see patients regularly throughout their treatment and as such, have

a very different relationship with patients than the oncologists who only tended to see them once during their treatment. Work is being undertaken as part of the main eRAPID trial to interview clinicians involved in the study to explore motivators and barriers for use and I will be involved in this analysis in the future, in addition to further analysis of the quantitative data available on clinical engagement.

During this study, researchers had relatively frequent contact with patients over the duration of the study period, seeing them approximately four to five times over the eighteen week period. This may have influenced the levels of engagement for some patients and it remains to be seen whether the same levels of engagement would be maintained in standard practice. This further highlights the key role of engagement of clinicians for future implementation.

The generalisability of the sample is somewhat limited. As described in Chapter 6, participants were predominately female, relatively young, well-educated with high performance status at baseline. Although research does support the utility of ePROMs with patient groups with more complex needs, additional support or alternative methods of PROMs reporting such as Interactive Voice Response (IVR) systems may be needed to ensure accessibility for all patient groups[77, 78, 165].

8.4 Recommendations and directions for future research

As outlined in Chapter 6, it was necessary to begin analysis for the purpose of this thesis before completion of the eRAPID RCT. Data was extracted on 5th January 2018 at which point 354 patients had completed the study. The full trial is scheduled to be completed in October 2018, following a total of 508 patients being consented. In addition, further interviews have been undertaken with patients participating in the main phase of the trial, following on from the work described in Chapter 7. I plan to rerun all the quantitative analysis described in Chapter 6 on the full dataset of patients. In addition, the second round of patient interviews

will be analysed using a similar framework to that described in Chapter 7. Following this, I plan to prepare the results for publication.

The work described in this thesis will also have a direct impact on future evaluation and implementation of eRAPID. Chapter 6 described an analysis of the relationship between patient engagement with eRAPID and the evaluative outcomes and found a positive relationship. Based on these findings, an analysis of the relationship between patient engagement with eRAPID and the primary outcome measures for the trial (QoL measures of FACT-G, EQ-5D and QLQ-C30) will be undertaken. In addition, based on the finding that use of eRAPID improved patients' self-efficacy over the 18 week study period, this assessment will also be integrated into any future evaluations of eRAPID in different clinical settings.

Finally, and potentially, most importantly, this work provides evidence of the importance of clinicians being explicit about their use of patient-reported data during consultations. Based on the findings of the field usability study described in Chapter 4, this is something we already strongly encouraged clinicians to do, and is one of the main points of our online clinician training programme. However, the quantitative and qualitative evidence from this thesis can be incorporated into the training to further illustrate to clinicians just how important this is.

There are also several recommendations and important directions for the future development, evaluation and implementation of ePROM systems that I would make based on the findings of this thesis.

There is a need for researchers to be clear and transparent when describing ePROM systems in publications. The systematic review described in Chapter 5 highlighted the lack of detail generally provided on system features, which makes it difficult for researchers developing systems to learn from one another. The taxonomy of system features described in this chapter could provide a useful tool and checklist for researchers describing their interventions.

In addition, the findings of this thesis support the benefit of providing a self-management element to ePROM systems, for example in the form of patient education and tailored advice

on how to manage side effects. As highlighted in Chapter 3, patients are already being required to take a significant amount of personal responsibility for monitoring and managing health during chemotherapy and require support. The findings in Chapters 4 and 7 illustrate that ePROM systems have the potential to provide some of this support. Yet, less than half of the systems identified in the systematic review (Chapter 5) allowed patients to view their own data, and fewer still provided any self-management element. Our findings suggest that patients may not always follow advice provided. Nevertheless, if patients are being asked to routinely complete PROMs data from home, there is an ethical responsibility provide it [78, 89].

There is also a need for researchers to report on patient engagement and to explore, and report on, the relationship between engagement and outcomes. Qualitative research should be undertaken where possible to inform quantitative assessments, and to provide insight into motivators and barriers. Theories on medication adherence (see section 1.1.5) have shown good utility in helping to understand, predict and ultimately try to improve patient adherence to medication. In a similar approach, as the evidence base on patient engagement with ePROM systems grows, researchers should aim to develop theory to help conceptualise and predict engagement.

Clinician engagement is intertwined with patient engagement and will also require ongoing qualitative and quantitative assessment to inform future development and implementation of systems. Developing training to address clinician concerns and encourage explicit use of data with patients is necessary.

This thesis also contributes to the evidence needed to support future implementation of ePROM systems by demonstrating their potential to improve patients' self-efficacy to self-manage during chemotherapy. Self-efficacy has been identified as a key indicator of improved self-management behaviours and is related to improved objective medical outcomes, in additional to better emotional well-being [250, 252, 253, 284-286]. Evidence such as this is

essential to drive the policy and investment needed to support future development, evaluation and implementation of systems. In addition to the main eRAPID trial described in this study, there are several other randomised trials currently underway which will assess the benefit of ePROM systems across a range of outcomes such as symptom burden, HRQoL, healthcare utilisation and cost effectiveness [94, 170, 215, 223]. However, this evidence will take time to be demonstrated, and one of the challenges with developing ePROM systems will be keeping up to date with current technology, and ensuring ongoing compatibility with smartphones, tablets and other home devices to ensure accessibility to all patients.

In addition, ongoing investment is needed to link ePROM systems efficiently into primary and secondary care EPRs. Significant issues remain around implementing health informatics infrastructure relating to achieving integration without compromising the security of clinical databases, and the on-going discussions on ethical challenges of sharing personal health data, particularly with recent changes to policies and guidance on data protection [305].

Recent initiatives such as the NHS QoL metric are increasing the prevalence and profile of PROMs in broader settings [306]. In addition, ePROM systems have the potential to be applied to many different healthcare settings, and potentially could provide ongoing support after cancer treatment into survivorship. Using ePROMs for remote cancer surveillance is a natural extension to this work, supporting a more efficient and tailored healthcare system and better utilisation of limited resources [52, 157, 307]. In fact, this has recently been implanted into clinical practice in St James University Hospital with a group of testicular cancer patients at low risk of recurrence [308]. However, even the best designed systems are not a quick fix for changing behaviour or providing a solution to the national health crisis. Continuing evaluation and integration of the patient perspective should be central to inform the future research and development needed before this vision becomes a reality.

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Appendix 1: Patient Information Sheet

Version 1.4 28th September 2017

eRAPID Electronic patient self-**R**eporting of **A**dverse-events: **P**atient **I**nformation and a**D**vice**:**
Randomised controlled trial in systemic cancer treatment

We would like to invite you to take part in a research study that will assess a new online system for monitoring the symptoms and side effects cancer patients can experience when receiving treatment.

Before you decide whether to take part, please read this information sheet to find out why the research is being done and what it involves. Please take time to read the information carefully. Talk to others about the study if you wish, and ask the researcher if you have any questions.

Background

eRAPID is an online system for patients to report symptoms and side effects during and after cancer treatment. Because the system is online, patients can complete questions about their symptoms from home or in clinic using the internet. This information is then immediately documented in individual patient's electronic health record in the hospital. If patients report mild symptoms the system will provide advice on how to manage them. When serious symptoms are reported patients will be encouraged to contact the hospital team and an alert will be sent to their doctor or nurse via email. The eRAPID system also involves access to a patient website with information about coping during cancer treatment and managing related symptoms.

We want to see how the system will work in practice in a large scale study – for example whether patients use the system and their experiences of using it to report their symptoms. We also want staff involved in patient care to test the system by viewing the results of the questionnaires in patient records and to tell us how useful the information is. We will be assessing how the system impacts on patient care and quality of life.

The study is part of a 5 year research programme funded by the National Institute for Health Research (NIHR). The research is led by Professor Galina Velikova who is a consultant medical oncologist with Leeds Teaching Hospitals NHS Trust.

Why have I been asked?

We are inviting patients who are receiving treatment for breast, gynaecological or colorectal cancer at St James's University Hospital. We aim to recruit a maximum of 588 patients.

Do I have to take part?

No. It is up to you to decide whether or not to take part. We are interested in understanding why people do not wish to take part in the study but you do not have to give us a reason for doing so. A decision not to take part will not affect the standard of care or treatment you receive in the future.

What will happen if I take part in the study?

You can take as much time as you need to decide if you want to take part in the study or not. If you decide to take part in the study, a member of the research team will answer any questions you have and ask you to sign a consent form.

You will be then be asked to complete some initial paper questionnaires about you and your quality of life. This study is a randomised controlled trial (RCT). This means half the participants who agree to help with the study will be asked to use the eRAPID symptom reporting system and the eRAPID website during the study (in addition to Usual Care from the hospital and cancer team) and the other half will receive Usual Care alone. This way we can compare the two groups to see if the eRAPID system has any impact on patient care. Participant allocation to one of the groups is entirely by chance.

<u>If you are assigned to the group using the eRAPID system:</u>

- The researcher will explain how to complete the online eRAPID symptom questionnaire and show you a brief demonstration of the system at a routine hospital visit.

- You will be given unique log-in details and a booklet to take home with you that explains how to use the system. You are welcome to ask a friend or family member to help you access the online system if this would be helpful though we would like you to answer the symptom questions yourself.
- Whilst you are on treatment you will receive the usual care provided by the hospital and your cancer team but in addition you will be asked to log-in to the eRAPID system from home at least once a week to complete the symptom questionnaire. We will also encourage you to complete the questionnaire at any time when you feel unwell. The questionnaire takes around 15 minutes to complete. Your responses will be immediately documented in your electronic hospital records.
- We will automatically send you a reminder each week to complete the questionnaire by your choice of email or text message.
- There may also be the opportunity to complete the questionnaire in clinic before routine appointments.
- We will also ask you at set time points (6, 12 and 18 weeks after you join the study) to complete some paper questionnaires about your quality of life and views of your health and treatment. We will also ask you to tell us about the number of contacts you have had with the hospital and GP while you are helping with the study (e.g. appointments and telephone calls). We are interested in understanding any extra financial costs you may have experienced as the result of receiving cancer treatment so the questionnaires will ask you about this too.
- At the end of the study (at 18 weeks) you may be asked to take part in an interview or to find out what you thought about the research and the eRAPID system.
- The eRAPID system is not a replacement for usual care, if you need advice on managing any symptoms or side effects you will still be advised to contact the hospital staff.

If you are assigned to the Usual Care group:

- You will receive the usual care provided by the hospital and your cancer team.
- In addition the researchers will ask you at set time points (6, 12 and 18 weeks) after you join the study) to complete paper questionnaires about your quality of life and views of your health and treatment. We will also ask you to tell us about the number of contacts you have had with the hospital and GP (appointments and telephone calls) while you are helping with the study. We are interested in understanding any extra financial costs you may have experienced as the result of receiving cancer treatment so the questionnaires will ask you about this too.
- At the end of the study (at 18 weeks) you may be asked to take part in an interview to tell us about your experience of managing any symptoms and side effects of your treatment and any contacts you had with the hospital during treatment.

Will my taking part in this study be kept confidential?

Yes. It is very important to us to respect your information (data) and keep it confidential. The answers you provide to the symptom and side effect questions, and additional questionnaires will only be seen by the research team and your clinical team. We will also ask for your permission to look at your medical records for information about the treatment you are receiving, disease condition, clinical care, hospital resource and management records

All your data (questionnaires/interviews) will be stored on secure databases within either the University of Leeds or Leeds Teaching Hospitals NHS Trust and will only be accessible by the research and clinical teams. All data stored on the University of Leeds databases will be anonymised. Any analysis or publications of results from the study will not name or identify any individual patients.

What are the disadvantages of taking part?

We do not foresee any disadvantages to your taking part in the study.

What are the possible benefits of taking part?

We hope that the completion of the online eRAPID questionnaires will help patients and staff with monitoring and managing symptoms and side effects of cancer treatment.

For participants in the Usual Care group, although there may be no personal benefits to your taking part in this study, we hope the information you provide will contribute to improving the support we can offer patients on cancer treatment in the future.

What will happen if I don't want to carry on with the study?

If you agree to take part and then later decide you want to stop being in the study that is OK. You can withdraw from the study at any time. We will ask you if we may keep the information you have provided up until that point but this will be your decision. If you withdraw from the study we may ask you to complete a brief end of study feedback form to find out what you thought about the study and using the eRAPID system for reporting side effects. Again, it will be your decision whether you wish to provide this feedback.

What if there is a problem?

If you have any concerns about any aspect of the study please speak to the researchers who will do their best to answer your questions. Their contact details are at the end of this information sheet. If you remain unhappy you may wish to contact the Leeds Teaching Hospitals NHS Trust's Patient Advice and Liaison Service (PALS)
T: 0113 2066261 or 0113 2067168
E: patient.relations@leedsth.nhs.uk

Who has reviewed the study?

The study has been reviewed by people who have experience of cancer themselves and independent experts in this area of research. All research in the NHS is also approved by a Research Ethics Committee, an independent group that works to protect your interests. This study has been reviewed and given favourable opinion by Leeds East Research Ethics Committee.

What now?

Please let the researcher know whether or not you would like to help with the study or if you have any further questions they will be happy to help answer them. If you need more time to think about taking part in the study just let the researcher know and they can speak to you at your next hospital appointment.

Thank you for taking the time to read this information sheet

If you would like to take part or have any questions please contact a member of the research team:

Kate Absolom, Senior Research Fellow
Andrea Gibson, Research Sister
Marie Holmes, Research Assistant
Beverly Clayton, Senior Research Nurse Zoe
Rogers, Research Assistant
Lorraine Warrington, Research Assistant
To contact us please:
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Appendix 2: eRAPID end of study Questionnaire

To be completed by research staff:																			
Participant Initials					DOB	Day		Month		Year				Participant ID	Centre No				Trial No			

eRAPID: Electronic patient self-Reporting of Adverse-events: Patient Information and aDvice

Systemic treatment RCT
18 WEEK SYSTEM USABILITY QUESTIONNAIRE (Intervention arm only)

We would be grateful if you could complete these questionnaires to tell us about your views of using the eRAPID system in the last few months.

Most of the questions have a choice of answers. There are no right or wrong answers; you should choose a response that best reflects you or your situation.

If after answering any of the questions you realise you have made a mistake (for example by ticking the wrong box) please cross out your answer clearly and then select the answer you meant to choose.

If you have any questions please feel free to ask the researchers. Once you have completed the questionnaires, they can be handed back to a member of the research team.

Thank you for your time and valuable contribution to the eRAPID study

Patient Report Outcomes Group (POG)

Level 6, Bexley Wing

St James's Institute of Oncology

The Leeds Teaching Hospitals NHS Trust

UNIVERSITY OF LEEDS

eRAPID- System Usability Scale

INSTRUCTIONS: Please think about how you found using the eRAPID system in the last few months to report the symptoms associated with your cancer and treatment. Rate how strongly you agree or disagree with each of the following statements by placing a check mark in the appropriate box.

	Strongly disagree				Strongly agree
1. I think that I would like to use this system frequently	1	2	3	4	5
2. I found the system unnecessarily complex	1	2	3	4	5
3. I thought the system was easy to use	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
5. I found the various functions in this system were well integrated	1	2	3	4	5
6. I thought there was too much inconsistency in this system	1	2	3	4	5
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
8. I found the system very cumbersome to use	1	2	3	4	5
9. I felt very confident using the system	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system	1	2	3	4	5

eRAPID End of study participant questionnaire

The end of study questionnaires asks about your opinion of using eRAPID to monitor the symptoms and side effects of your cancer and treatment.

Please answer all the following questions with the answer that best matches your experience. Please only provide one answer per question.						
1.	How easy or difficult was it to learn how to use the eRAPID system?	Very Easy	Easy	Neither easy nor difficult	Difficult	Very Difficult
2.	How easy or difficult did you find accessing the system? e.g. finding the website and logging in	Very Easy	Easy	Neither easy nor difficult	Difficult	Very Difficult
3.	How easy or difficult was it to answer the questions about your symptoms?	Very Easy	Easy	Neither easy nor difficult	Difficult	Very Difficult
4.	How did you feel about the amount of time it took to complete the symptom questions?	Too long		About right		Too quick
5.	How relevant were the symptom questions to you?	Not relevant at all	Very few questions were relevant	Neither relevant nor irrelevant	Quite relevant	Very relevant
6.	What did you think about completing these questionnaires every week?	Definitely too often	A little bit too often	Unsure	I was happy to complete them every week	I would have been happy to complete them more often
7.	Were there any times when you missed a week of completing the symptom questionnaire? If so, why?	Yes (please specify below)			No	
		Reason:				
8.	Did the doctors and nurses you saw during your treatment use your eRAPID symptoms information during consultations?	Yes, quite a bit		No not at all		Sometimes

9.	If yes, did you feel this improved your consultations with the staff?	Yes, quite a bit		No not at all		Sometimes
10.	To what extent do you feel that the symptom questionnaire was useful for the doctors and nurses you saw during your treatment?	Very useful	A little useful	Unsure	Not very useful	Not at all useful
11.	How useful did you find the information on the eRAPID website about the symptoms and side effects of cancer treatment?	Very useful	A little useful	Unsure	Not very useful	Not at all useful
12.	Would you recommend the eRAPID system to other cancer patients?	No		Not sure		Yes
13.	What were the good things about using the eRAPID system?					
14.	What were the bad things about using the eRAPID system?					
15.	Have you got any suggestions about how the eRAPID system could be improved?					

If you have any other comments about taking part in the eRAPID study please write them below.

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE