Improving the relevance and suitability of cost-effectiveness analyses to inform local commissioning decisions, a worked case-study of cardiac rehabilitation in England

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Abstract

Economic evaluations of healthcare interventions are conventionally framed to inform national decision-making processes, with a focus on the expected cost-effectiveness of interventions to impact narrowly defined costs and outcomes over a long time horizon. However, a significant proportion of commissioning decisions are made at more localised levels. Research has shown that the current means of conducting and disseminating cost-effectiveness analysis is not impacting decision making at this level.

This thesis explores the relevance of the conventional framework of cost-effectiveness analysis to local decision makers and how it can be adapted to increase it. This is achieved through a combination of methodological and applied analyses using a case-study developed to inform commissioning decisions regarding the cost-effectiveness of cardiac rehabilitation (CR) for people recovering from surgery for a cardiac event.

The first element of this thesis interrogates the conventional framework of cost-effectiveness analysis, specifically whether the approach becomes inappropriate when the commissioning decision is made by a more localised decision maker. This element identifies five areas pertaining to the conventional framework which require adaptation or disaggregation to ensure their relevance to local commissioning decisions, with recommendations provided in each case.

The second element presents the development of a case study decision model to assess the cost-effectiveness of CR. As an intervention subject to national targets and with an international literature on its cost-effectiveness, but commissioned at a sub-national level, CR represents a good example on which to explore the impact of the proposed adaptations to the conventional framework of cost-effectiveness.

Finally, the five elements where the standard framework are argued to require adaptation are applied to the CR case-study, demonstrating the value of a more pragmatic approach to the conducting of cost-effective analysis rather than the normative framework typically applied.

Contents

List of Tables and Figures

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Author's declaration

I declare that this thesis is entirely my own work. The five papers that accompany this thesis are listed below and of which I am the lead author of each, with contributions by co-authors acknowledged in each publication. None of the work represented in this thesis has previously been submitted at this or any other University. All sources are acknowledged as references.

***Paper 1*: Hinde, S., Bojke, L., Horsfield, L. & Richardson, G. A. The relevant perspective of economic evaluations informing local decision makers: an exploration in weight loss services. 2019, Applied Health Economics and Health Policy. doi: 10.1007/s40258-019-00538-8.**

The candidate led the development of the idea for the study and methodology, and led the preparation of the manuscript. Contributing authors provided expert input and review of the manuscript.

Prof. Laura Bojke

***Paper 2:* Hinde, S., Howdon, D., Lomas, J., & Franklin, M. Health Inequalities: To What Extent are Decision-Makers and Economic Evaluations on the Same Page? An English Case Study. 2022, Applied Health Economics and Health Policy. doi: 10.1007/s40258-022-00739-8.**

The candidate led the development of the idea for the study and methodology, and led the preparation of the manuscript. Contributing authors provided expert input and review of the manuscript.

Dr. Daniel Howdon

***Paper 3:* Hinde, S., Bojke, L., Harrison, A. S. & Doherty, P. J. Improving Cardiac Rehabilitation Uptake: Potential health gains by socioeconomic status. 2019, European Journal of Preventative Cardiology. doi: 10.1177/2047487319848533.**

The candidate jointly developed the idea for the study, and led the preparation of the development of the mathematical model and manuscript. Contributing authors provided expert input and review of the manuscript.

Prof. Laura Bojke

Paper 4: **Hinde, S., Bojke, L., Harrison, A. S. & Doherty, P. J. Quantifying the impact of delayed delivery of cardiac rehabilitation on patients' health. 2020, European Journal of Preventative Cardiology. doi: 10.1177/2047487320912625.**

The candidate jointly developed the idea for the study and methodology, and led the preparation of the manuscript. Contributing authors provided expert input and review of the manuscript.

Prof. Laura Bojke

Paper 5: **Hinde, S., Harrison, A., Bojke, L. & Doherty, P. Achieving Cardiac Rehabilitation uptake targets: what is the value case for commissioners? A UK case-study. 2023, International Journal of Cardiology, doi: https://doi.org/10.1016/j.ijcard.2023.03.041.**

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Prof. Laura Bojke

Chapter 1: Introduction and Aims

'A man who neglects what is actually done for what should be done learns the way to destruction.'
Machiavelli

Background

Operationalised through a plethora of different evaluative frameworks and perspectives, the underlying principle of contemporary economic evaluation is the concept of seeking to maximise some outcome or set of outcomes subject to a budget constraint.

This approach has been typically conducted from the standpoint of extra-welfarism. A phrase coined by Culyer in 1989 (Culyer, 1989), extra-welfarism describes an extension of traditional welfare economics whereby the outcomes of interest in the evaluation are not considered to be overall utility to the individual, as with welfarism, but rather the direct effect on their health (Brouwer et al., 2008). While debate continues regarding the definition and distinction of the two paradigms (Sakowsky, 2021), extra-welfarism has contributed to the development of, and policy engagement with, health-based economic evaluation, by facilitating a framework of cost-effectiveness analysis relevant to decision makers commissioning health services while being grounded in economic theory (Drummond, 2015).

The impact of extra-welfarism can be evidenced through the emergence of cost-effectiveness analysis as a key component in the deliberations of national health technology assessment (HTA) agencies. Their remit is often country specific, but HTA bodies have emerged in the last few decades to provide recommendations regarding the provision of health technologies, such as pharmaceuticals and devices, and often broader health service delivery (Martelli et al., 2007).

While not the first national HTA agency to formally incorporate economic evaluation methodologies into their decision-making processes, England's National Institute for Health and Care Excellence (NICE) is widely considered to be one of the most notable adopters of economic evaluation, largely due to the clarity and openness with which it is incorporated into their guideline development and the impact of their processes and guidance on other HTA agencies (Wijnands et al., 2016).

While it has undergone several iterations and methodological developments since its initiation in 1999 (Dawoud et al., 2022), NICE have routinely produced a manual with details of their methodological approach to economic evaluation to inform HTA (NICE, 2022), often termed the 'NICE reference case', details of which are presented in ***Chapter 2*** of this thesis. The NICE reference case was arguably designed with the sole perspective of a national healthcare commissioner in mind. Specifically, one with a clear remit to seek to implement the most cost-effective interventions defined over a long time horizon and a budget that is myopic in its focus on health and social care public sector spending.

However, currently in England most healthcare budgets reside at more local levels, with Local Authorities controlling public health spending and Integrative Care Boards (ICBs) holding the majority of the NHS budget. In these instances, a national level perspective may not be appropriate. Previous studies have explored the boundary between economic evaluation and local decision-making processes, most notably through two systematic reviews (Merlo et al., 2015, Eddama and Coast, 2008). The key obstacles identified to the use of economic evaluation evidence at a local level are

presented in Box 1, with the overall finding that that while scientific rigour is important, economic evaluations cannot do anything to influence policy decisions and improve the quality of health and healthcare unless it is translated into policy decisions.

Box 1: Key obstacles against the use of economic evidence at a local level

Eddama and Coast (Eddama and Coast, 2008) defined three obstacles that may explain why economic evidence was not more widely used in local decision-making:

- *Institutional and political factors,* the inflexibility of budgets to act on the recommendations of the evidence alongside political objectives which may take precedence over the evidence.
- *Cultural reasons,* the evidence of effectiveness is considered more important in decision making than costs, the impact of a population perspective over individual patient care, the lack of time available to understand the available evidence, and poor timeliness of the production of economic evidence.
- *Methodological factors,* concerns about the quality and appropriateness of the studies available, the relevance of the studies to the decision problem at hand, and the deviating perspective taken in the studies from that faced by the decision maker.

Similarly, Merlo et al. (Merlo et al., 2015) aggregated their findings into two overarching barriers:

- *Accessibility* to policy makers, defined as 'timely access to relevant research that is understandable' *p304.*
- *Acceptability* was considered as scientific, institutional, and ethical, emphasising the need for research to be seen as unbiassed, good quality, fitting the commissioning reality, and informing issues of equality of healthcare.

More specifically, several limitations of the current approach to conducting economic evaluations to the adoption of evidence by local decision makers can be identified from the literature. Firstly, the need for economic evaluation to consider equality emerges as a consistent theme with Merlo et al. (Merlo et al., 2015), Frew and Breheny (Frew and Breheny, 2019), Frew and Breheny (Frew and Breheny, 2020), and Hill et al. (Hill et al., 2017) all noting it as a significant perceived disconnect between available economic evaluations and the needs of local decision makers.

Secondly, criticism was consistently raised that a long time horizon was the primary perspective in published analyses, with limited presentation of shorter alternatives more consistent with the financial and political cycles faced locally (Frew and Breheny, 2020, Willmott et al., 2016).

Thirdly, the theme of uncertainty recurred, referring to both the translational uncertainty, between the study setting and real-world implementation, as well as criticism of the overall presentation of the uncertainty in economic evaluations and its relevance to the local setting (Willmott et al., 2016, Frew and Breheny, 2020).

Fourthly, concerns over the relevance of the estimation of opportunity costs through the cost-effectiveness threshold were raised (Frew and Breheny, 2020, Willmott et al., 2016). This related to the potential disconnect between the threshold typically used in the literature to determine cost-effectiveness and the reality of what would be displaced locally based on commissioning realities.

Finally, the failure of economic evaluations to routinely consider the non-health related costs and outcomes in their analysis was noted as a limitation, especially with regard public health decisions (Frew and Breheny, 2019, Frew and Breheny, 2020).

Objectives of this thesis

The aim of this thesis is to explore these challenges and limitations pertaining to conducting research relevant to local decision makers, specifically how cost-effectiveness analysis can be used most effectively to address them. This is achieved through a combination of methodological and applied analyses using a case-study developed to inform commissioning decisions regarding the cost-effectiveness of cardiac rehabilitation (CR) services in England.

The first element (***Chapter 2***) consists of the interrogation of the conventional framework of cost-effectiveness analysis, exploring how it may become inaccurate when commissioning decisions are made by a more localised decision maker, leading to the issues identified in the research cited above. This element is achieved through two methodological papers. The first investigates the disconnect between the conventional evaluative framework, the 'NICE perspective', and the reality of the decision problem faced by local commissioners (***Paper 1***). The second paper explores how health inequalities are accounted for and presented in cost-effectiveness analysis compared to commissioner deliberations of health services (***Paper 2***).

To facilitate an exploration of the appropriateness of the standard 'NICE perspective' and impact of the amendments suggested in ***Chapter 2*** a case-study was developed. ***Chapter 3*** presents the development of the case-study regarding the cost-effectiveness of CR, a multi-component intervention aimed at improving the recovery and long-term health of people recovering from surgery for a cardiac event, informed by ***Papers 3 and 4***. In this chapter a conventional 'NICE perspective' of economic evaluation is applied.

Finally, in ***Chapter 4*** the findings of the methodological element are carried forwards into a focused application to the CR case-study. This final paper (***Paper 5***) seeks to increase the relevance of the cost-effectiveness analysis to the commissioning of CR services by considering each of the elements where the standard national perspective applied in economic evaluation were argued in ***Papers 1 and 2*** to differ when considering a local commissioner.

Chapter 2: Limitations Regarding the Current Application of Cost-Effectiveness Analysis

The relevant perspective of general methods of economic evaluation to inform local decision making (paper 1)

Background

To understand why economic evaluation may not be informative to local commissioning decisions, and specifically how they can be altered to improve their relevance, a case-study is used in this chapter to illustrate some of the key issues. In England, since 2002, NICE has had mandatory guidance in place for the provision of bariatric surgery for those with a body mass index (BMI) ≥ 40 or ≥ 35 with significant weight-related comorbidities and for whom all other nonsurgical interventions have failed to achieve weight loss (NICE, 2002). This guidance, and subsequent updates (NICE, 2014), has been supported by numerous economic evaluations which routinely identified bariatric surgery to be a cost-effective use of limited NHS resources (Picot et al., 2009, Avenell et al., 2018, Boyers et al., 2021).

However, despite the longstanding mandating of its provision, bariatric surgery uptake continues to be limited, with research indicating an annual penetration of surgery to those eligible of less than 0.002% (Desogus et al., 2019). In addition, studies have highlighted that local commissioning of the surgery has not been consistent with national guidance (Owen-Smith et al., 2013) and identified several barriers, including issues of affordability (Welbourn et al., 2016).

In 2018, in collaboration with my co-authors of ***Paper 1*** and the Vale of York Clinical Commissioning Group (CCG) I conducted research exploring which elements of the cost-effectiveness evidence were not consistent with the commissioning reality as part of an evaluation of their weight loss service.

To summarise this research I first provide an overview of the current framework used to inform economic evaluations relevant to the English NHS, specifically through the NICE reference case for conducting health technology assessments (NICE, 2022). I then consider the relevance of four key elements of the evaluation framework: the cost-effectiveness threshold, uncertainty, valuation of future costs and benefits, and the scope of costs included. For each element I consider how the reality faced by the commissioning decision maker may differ to that implicitly assumed by the framework, recommending alternative approaches in each case. Bariatric surgery is used as the informative case-study but with generalisability considered throughout.

Current NICE Reference Case

As discussed in ***Chapter 1***, the NICE reference case for conducting HTA (NICE, 2022) represents the most conventionally applied framework to inform cost-effectiveness analysis relevant to an English NHS perspective. A summary is provided in Table 1 below.

Table 1: Summary of the NICE reference case (NICE, 2022)

Element of health technology assessment	Reference case
Perspective on outcomes	All health effects, whether for patients or, when relevant, carers. Expressed in quality adjusted life years (QALYs), preferably using the EQ-5D-3L measure
Perspective on costs	NHS and personal social services (PSS)
Threshold	A range of £20,000 to £30,000 per QALY gained (£100,000 for highly specialised technologies)
Uncertainty	Uncertainty should be presented with discussion made regarding the spread of results and the impact of additional evidence
Time horizon	Long enough to reflect all important differences in costs or outcomes between the technologies being compared, typically lifetime
Discounting	The same annual rate for both costs and health effects (currently 3.5%)
Equity considerations	An additional QALY has the same weight regardless of socioeconomic characteristics of the individuals receiving the health benefit

While the latest NICE methodological guidance recommends additional flexibility for the NICE reference case related to the evaluation of certain interventions, such as for public health and social care (NICE, 2022), these are presented as additions to a QALY based cost-effectiveness analysis base-case. While the focus of this thesis is on the evaluation of interventions usually conceptualised under the HTA definition, as representing the vast majority of published economic evaluations (Wagstaff and Culyer, 2012) and HTA agency activity (Cyr et al., 2021), the findings are also considered to apply to other settings.

Elements where the relevance of the framework at a local level is less applicable

Building on the previous literature on the barriers faced by local decision makers, summarised in ***Chapter 1***, and direct engagement with the Vale of York CCG, I identified four areas where the NICE reference case failed to reflect the perspective faced at a local level, compromising the relevance of published cost-effectiveness analyses. These four areas are summarised below using bariatric surgery as a case-study alongside consideration of the relevance to other clinical settings.

The cost-effectiveness threshold

The NICE cost-effectiveness threshold represents the turning point or region in which gains in QALYs are no longer considered worthwhile of the additional opportunity cost that they impose elsewhere on the healthcare system. It has become synonymous with the NICE evaluation process, attracting a wide range of academic and public scrutiny for the two decades it has been part of formal policy.

Initially, NICE did not have a stated threshold, originally denying one was operated as part of their HTA process (Devlin and Parkin, 2004). However, from 2004 a threshold range was set at £20,000 to £30,000 per QALY gained which, apart from defined special cases, has remained unchanged since. The idea of a threshold range rather than a hard cut off has been argued to be a means of balancing a wider set of objectives beyond the headline incremental cost-effective threshold (ICER), such as

uncertainty or availability of other treatments (Devlin and Parkin, 2004). Importantly, the role of NICE has conventionally been identified as a 'threshold-searcher' rather than a 'threshold-setter' (Culyer et al., 2007), such that the threshold they apply should be an estimate of the marginal productivity of the NHS rather than set by policymakers or to reflect societal willingness to pay values for QALY gains.

There are two distinct reasons why the value used by NICE in their reference case may not accurately reflect the most appropriate marginal productivity of a QALY for local decision makers. Firstly, the current threshold range was never determined by quantitative estimation of the marginal productivity of the NHS, instead based on a summary of the range of ICERs deemed acceptable during NICE's early approval decisions (Devlin and Parkin, 2004, Towse et al., 2002). However, subsequent research has determined that it is a significant overestimate of the opportunity cost, initially estimated as closer to £13,000 per QALY (Claxton et al., 2015). Further research has refined this estimate to between £5,800 and £9,900 per QALY across a range of estimation methods (Martin et al., 2021). Furthermore, in 2022 Martin et al. (Martin et al., 2022) produced estimates of the marginal productivity of locally commissioned services, putting the value at £7,000 per QALY, with a 95% confidence interval of between £5,000 and £10,000 per QALY. Importantly, research has demonstrated that the use of an overestimation of the threshold has worse total health consequences than an underestimation (Claxton et al., 2015). The use of a threshold greater than these empirical estimates of the opportunity cost has been argued by NICE to allow the inclusion of other factors into the threshold, including the benefits of the NHS investing in new treatments (Dillon, 2015). The latest NICE reference case incorporates the use of severity modifiers to provide additional weight to the incremental QALYs of certain diseases, having the implicit effect of adjusting the threshold applied (Angelis et al., 2023). However, the approach has not been extended beyond disease severity, as such no formal valuation of the other factors to justify the operationalised increase in the threshold have been produced to date. Furthermore, it could be argued that the benefits of such additional factors would not be realised by local commissioners, and therefore their inclusion in a threshold estimate may not be appropriate.

The second distinct reason is that the current approach has been argued to fail to consider the budget impact of implementing the decision (Lomas et al., 2018, Pearson, 2018), violating the theoretical basis for a threshold approach (Wouterse et al., 2023). This risks both the recommendation of an intervention that is not practically affordable, but also that displaces interventions that are more cost-effective than the applied threshold implies. While NICE does routinely produce budget impact models for its recommendations these are not explicitly incorporated into the threshold applied. The role of affordability is especially evident at a local level where there is limited potential to exceed set budgets or borrow to fund services. During the engagement with the Vale of York CCG it was evident that this was a major contributing factor limiting the provision of bariatric surgery, with the upfront cost of surgery around £9000 per person and a large population meeting the NICE criteria implying an unaffordable total cost of full implementation.

To address these issues my recommendation is that economic evaluation should move away from current blunt adherence to the NICE threshold range. A more pragmatic approach should be taken, allowing consideration of the best empirical estimate of the opportunity cost and the total budget impact. Distinguishing between a policy threshold and a threshold that estimates the opportunity cost, as discussed in Lomas et al. (Lomas et al., 2022), may also add clarity as to the specific role of a threshold approach. Furthermore, I propose more consideration should be given to the ability of local commissioners to directly identify the intervention(s) that would be disinvested to integrate the new intervention. This approach would allow closer alignment to the method of cost-effectiveness league tables or 'bookshelves'; whereby the range of services provided by a funder are ranked in order of

their cost-effectiveness such that the least cost-effective can be easily identified and disinvested in by a new intervention, however these are associated with their own challenges (Drummond et al., 1993).

The impact of exceeding budgets and decision uncertainty

While discussion with members of NICE appraisal committees suggests uncertainty is reflected during deliberations[1], the NICE reference case focusses on the mean ICER value with a requirement to report uncertainty but provides no guidance on how to interpret uncertainty or its relative importance. Arguably as a result, decision uncertainty is typically considered to be symmetric, with uncertainty that would reduce the ICER equivalent in value to that would increase in it, operationalised through methods such as the cost-effectiveness acceptability curve (CEAC). Concurrently, the arm's length of NICE from service provision implies few negative implications to them should the level of uncertainty deemed acceptable result in the cost-effectiveness result being incorrect post-hoc.

This contrasts with local decision makers who face implications such as financial special measures or the forced disinvestment of services if the uncertainty in the cost-effectiveness of an intervention results in an unexpected overspend. This implies that a local decision maker may be less likely to take on an intervention where there is uncertainty regarding its cost-effectiveness, despite a favourable mean estimate. The limited evidence regarding the long-term impact of bariatric surgery on patient's weight and health, and importantly the potential need for high-cost re-surgeries were indicated to have a detrimental impact on the CCG's propensity to commission the service.

These factors suggest that the presentation of decision uncertainty in cost-effectiveness analysis should go beyond the reference case approach. Disaggregation of the uncertainty, with a focus on the risk of potential catastrophic overspends, would provide additional depth relevant to local decision makers when considering the acceptable level of uncertainty. Alternative approaches to weighting by the aversion of decision makers to extreme losses could additionally provide added value (Sendi, 2021).

The valuation of future costs and benefits

As noted in Table 1 the NICE reference case recommends the inclusion of all costs and outcomes over a long enough period to reflect all important differences, often implemented as a lifetime perspective, with future values discounted at a rate of 3.5% for both costs and outcomes. A similar approach is common across other NICE remits, e.g. for public health interventions, but with a recognition that the appropriate discount rate may vary depending on the setting (NICE, 2020).

Many healthcare services that are directly commissioned locally, including obesity services, are characterised by most of their service delivery cost being upfront but with the expected health gains and potential costs savings over the longer term, implying an important role of the discount rate and incorporating long term values.

However, as noted in ***Chapter 1*** commissioning and budgetary cycles often imply a myopic focus or prioritisation of short-term costs to the detriment of longer-term implications. This is further compounded by questions over the appropriateness of the 3.5% value to local commissioners. Previous literature has explored the suitable values to apply in economic evaluations (Claxton et al., 2011) identifying that opportunity cost and availability of alternative investment opportunities as factors influencing the appropriate rate. At a local level, the opportunity cost of investment will differ from nationally. Furthermore, investment opportunities are more limited, especially as funding made

[1] Personal communication with Professor Laura Bojke, Professor Stephen Palmer, and Ana Duarte

available by Government is often time or disease area specific, necessitating a 'spend it or lose it' mindset.

These factors, plus the closer proximity to patient and clinical decision making, are likely to impact the acceptability of the evaluative method to local decision makers when determining the analytical time-horizon and discounting levels applied. This may necessitate a more pragmatic approach to incorporating future costs and outcomes that do not take a simple linear approach to discounting over time such as hyperbolic or stepped discounting (Claxton et al., 2011).

Scope of included costs

The NICE reference case sets the scope of relevant costs to include when conducting an economic evaluation of NHS and personal social services (PSS), this implies two important assumptions. Firstly, that costs which fall outside those settings are not considered within the scope of the primary analysis. Secondly, that budgets within the NHS and PSS are fully flexible, such that money can be considered uninhibited and equivalent in its value within these settings.

From a local commissioner of healthcare services perspective, the assumption of NHS and PSS siloed budgeting is subject to the same issues as at a national level such as the challenges of reflecting that healthcare spending or disinvestment can impact private finances, charities etc. This is potentially more acute locally where relationships with specific charities or patient groups may necessitate the consideration of costs that fall outside the public health and social care budgets.

The second assumption of flexibility within the NHS and PSS budgets, may be more acute locally where financial arrangements consist of numerous individual budgets and sub-budgets, for example specialty areas within a hospital trust that in turn is separate from primary care services. This was evident in the bariatric surgery case study, and previous NHS Health Check evaluation (Hinde et al., 2017), where the lack of an aligned incentive contract between the NHS Trust, CCG, and Local Authority meant that each had minimal consideration for the budget impact on the others, especially over the longer term.

The meaning and quantification of inequality (paper 2)

Background

While emphasis has always been placed on ensuring equity of access to NHS care for equivalent need, relatively little consideration has been given, especially through the HTA process, regarding equalities in individuals' baseline health status and their ability to benefit from the care provided. To this extent, equivalent access according to need has been insufficient to alleviate inequalities in lived health experiences, with England still experiencing a 7.6-year life expectancy gap between women, and 9.4 years for men, between the least and most deprived areas (Office for National Statistics, 2021).

Since its inception, NICE has primarily adopted a 'QALY is a QALY is a QALY' approach, whereby all changes in health outcome are considered equivalent, regardless on whom they fall (Weinstein, 1988), subject to specific cases such as disease severity weighting. Criticism of this approach is longstanding (Devlin and Parkin, 2004) and its implications demonstrated by Griffin et al. in 2019 when they estimated that, of 134 interventions considered by NICE, 48% increased health inequality, with 16% implying a trade-off between increased population health and improving health inequality (Griffin et al., 2019).

In this section I summarise the research conducted for ***Paper 2*** exploring the role of inequality in the contemporary cost-effectiveness methodology contrasted with how local decision makers incorporate

inequality considerations into their commissioning processes. This analysis was conducted through a pragmatic review of publicly available commissioning guidance, decisions, and data used to inform decision making as well as input from individuals involved in local decision making through several workshops, details of which are available in the full project report (Franklin, 2021).

Inequality considerations by local decision makers

From a legal perspective, the 2010 Equalities Act informs much of the landscape in the UK and protects against direct and indirect discrimination across nine individual characteristics. The act further contains a "socioeconomic duty" for commissioning decisions to consider broader inequalities, specifying that they must "have due regard to the desirability of exercising *[their functions]* in a way that is designed to reduce the inequalities of outcome which result from socio-economic disadvantage" (Government Equalities Office, 2013). However, the limited enshrinement of this section into law has meant that public agencies can choose the extent to which they incorporate such considerations, so long as they are compliant with the Equality Act 2010.

My exploration of commissioners' approaches to incorporating inequality concerns found that while there were extensive narrative reports about its importance, there was little methodological guidance on its measurement. As a result, the focus has been on available data that could be linked to inequalities, relying on the comparative summaries of measures of healthcare utilisation and diagnoses, typically stratified into geographic groupings often based on a commissioner's jurisdiction. While there are some exceptions, such as the 2022 White Paper on 'Levelling Up the United Kingdom' (HM Government, 2022) there is limited practical analysis using estimates of lived health rather than measures of utilisation and surrogate outcomes.

This finding is consistent with an analysis by Goddard who summarised how ICBs had incorporated inequality in 23 strategic plans (Goddard, 2023). Goddard found that there was a recurring desire by ICBs to address inequalities in access to health, healthy behaviours, and the social determinants of health but with limited details of how this commitment would be quantified or evaluated.

Incorporating inequality considerations into cost-effectiveness analysis

Whilst cost-effectiveness analyses have primarily focused on the maximisation of total population health, within the last decade an increasing number of evaluations have sought to additionally consider the distribution of health across a population. In a 2021 systematic review of equity in cost-effectiveness analysis, Avanceña and Prosser (Avanceña and Prosser, 2021) identified 54 of 8,910 studies screened that incorporated equity considerations in their analysis, with 80% of these published since 2015 showing the increase in recent years but from a low baseline. Of the 54 studies the authors identified that the majority (n=46) took an 'equity impact approach', three an 'equity weighting approach', and the remaining five doing both.

Equity impact analysis takes the relatively simple approach of summarising the results of the cost effectiveness analysis stratified by the socioeconomic indicator of interest, e.g. indices of multiple deprivation (IMD), in essence conducting sub-group scenario analysis. This approach generates costs and benefits for each of the socioeconomic sub-groups alongside the full population. However, it does not readily facilitate consistent decision making about the relative value of any identified trade-off between these two outcomes.

In contrast, equity weighting analysis extends the approach by incorporating weighting of the health impact of intervention conditional on their distribution, thus facilitating explicit and consistent trading off between gains in population health and reductions in health inequality. The most common means of incorporating this weighting has been termed 'distributional cost-effectiveness analysis' (DCEA).

Details of DCEA are presented in the accompanying paper (**paper 2**) and elsewhere (Asaria et al., 2016).

Appropriateness of DCEA to local decision making

The research summarised here demonstrates that the limited consideration of the role of inequality in the NICE Reference Case contrasts with the significant weight which is placed on it by local decision makers. While there appears to be evidence available to inform commissioning decisions concerned with inequality, this was primarily utilising routine data collection on measures of resource use and surrogate outcomes rather than measures of lifelong lived health inequality of the sort applied in methods of equity impact and weighting, consistent with the findings in ***Chapter 1***.

These findings add evidence that, to be informative to the needs of local decision makers, cost-effectiveness analyses should be extended to explicitly incorporate the inequality implications of the different interventions under consideration, moving away from the prime focus on total health maximisation. While DCEA has an important part to play in ensuring a consistent approach is taken to the trade-off between total health and equality the reality of local decision making implies an equity impact approach, with a clear description of the impact on short-term and surrogate outcomes that can be observed and used as key performance indicators, may be more acceptable to a local setting.

Implications for conducting economic evaluation

The analyses presented in this chapter, summarising ***Papers 1 and 2,*** makes the case that the fundamental framework of cost-effectiveness as applied through the 'NICE perspective' has value in informing the deliberations of local decision makers. However, previous research and local realities implies the parameters required to operationalise the framework require more consideration than is routinely the case in applied cost-effectiveness analyses.

While pragmatism is the key recommendation when aiming to inform local commissioning decisions Table 2 provides recommended amendments for the five elements of the reference case considered in this chapter. These recommendations will be applied to the case study of cardiac rehabilitation, which is developed in the next chapter, in ***Chapter 4***.

Table 2: Updated summary of the appropriate cost-effectiveness reference case

Element of cost-effectiveness analysis	**NICE reference case**	**Recommended amendment to local commissioner evaluations**
Valuation of future costs and benefits	A time horizon long enough to reflect all important differences in costs or outcomes between the technologies being compared. With future costs and benefits discounted at a fixed rate of 3.5% per annum.	Consideration of shorter time horizon of interest due to commissioning and budgetary cycles with the presentation of extensive scenario analysis with different discount rates and potentially hyperbolic or stepped discounting depending on the setting.
Cost-effectiveness threshold	A range of £20,000 to £30,000 per QALY gained (£100,000 for highly specialised technologies).	Reporting of the impact of lower and evidence-based threshold values including £13,000 and £7,000/QALY. Alternatively direct comparison with interventions to be displaced or use of a health benefits package approach may be appropriate.
Budget and decision uncertainty	Uncertainty should be presented with discussion made regarding the spread of results and the impact of additional evidence.	Additional reporting of implications and likelihood of extreme negative uncertainty to avoid potential 'never events' occurring, including financial burden.
Scope of included costs and outcomes	NHS and personal social services (PSS) perspective on costs, with costs assumed portable between healthcare budgets. Focus on QALY benefits to the patient.	Reporting of costs across a wider perspective in addition to awareness of different budgets within local settings e.g. hospitals and local authorities. Consideration of wider perspective alongside QALY, e.g. carers, and other outcomes that may represent key performance indicators locally, e.g. hospital admissions.
Inequality considerations	An additional QALY has the same weight regardless of the other characteristics of the individuals receiving the health benefit, except in specific circumstances.	Stratification of key outcomes by appropriate socioeconomic status, e.g. IMD, income, ethnicity, as a minimum standard, additional exploration of DCEA where appropriate.

Chapter 3: Developing the Cost-Effectiveness of Cardiac Rehabilitation Case-Study

Background

Heart disease is the leading cause of deaths globally, killing almost 10 million people each year (WHO, accessed 04/10/2018). CR consists of a supervised programme of physical activity, education, and support, recommended for patients who have suffered from heart attacks with the aim of reducing the rate of repeat events and improving general health. However, in the UK and elsewhere uptake of CR programmes is routinely below national targets, with roughly 50% of those eligible starting a programme (British Heart Foudation, 2019) compared to a UK national target of 65-85% (NHS England, 2019). The literature has indicated that there are both supply and demand reasons for the poor uptake, with the supply factors including limited commissioning of services due to a poor level of evidence regarding the cost-effectiveness of the service to local commissioners (Shields et al., 2018, Beatty et al., 2023).

In this Chapter I describe the development of a health economic decision model to understand the potential health benefits of CR that might occur over a patient's lifetime, and cost implications to the NHS. Working collaboratively with the National Audit of Cardiac Rehabilitation (NACR) the aim was to inform robust and evidence-based commissioning of CR programmes, including those seeking to increase the uptake of CR through supply or demand levers. In addition, this analysis considers the impact of socioeconomic factors on the level of engagement with CR and the underlying natural history of the disease.

In 2018, Shields et al. (Shields et al., 2018) published a systematic review of cost-effective studies of CR identifying 19 relevant studies the majority of which concluded that CR was a cost-effective intervention. However, the reviewers noted that the quality of the studies varied significantly, with most having a short time horizon of two years or less. Furthermore, only two of the studies were directly relevant to a UK setting, both over a decade old at the time. A subsequent review published in 2023 by the same authors targeted at economic evaluations of home-based CR found similar indications of cost-effectiveness but with limited methodological robustness (Shields et al., 2023).

This chapter starts with an overview of the decision model and the statistical analyses conducted, combining the methods presented in ***papers 3 and 4.*** This includes approaches taken to modelling the impact of socioeconomic factors on the decision model and the impact of delayed commencement of CR, the respective focuses of ***papers 3 and 4***. The combined results of the papers are presented with the primary focus on applying conventional frameworks, such as the NICE perspective, with the recommendations made in the ***Chapter 2*** incorporated into the model structure in ***Chapter 4***.

The baseline model described in this Chapter takes a conventional 'NICE perspective' consistent with the current recommendations when conducting cost-effectiveness analysis in the UK, considering the costs which fall on the NHS and PSS and benefits in terms of QALYs accumulated by the patient. A lifetime time horizon was taken and discount rates of 3.5% per annum applied to both the costs and QALYs accumulated. Uncertainty was incorporated into the model through probabilistic sensitivity analysis (PSA).

Methods

Full details of the decision model structure and parameterisation are available in ***papers 3 and 4*** with this section providing a summary of the key elements relevant to this thesis.

The population

To ensure consistency with the existing definition used, including by the current NICE guidance (NICE, 2013), NACR (National Audit of Cardiac Rehabilitation, 2023), and latest Cochrane review at the time of analysis (Anderson et al., 2016) we defined the population as all adults who have had a recent ST-elevation or non-ST-elevation myocardial infarction (STEMI or non-STEMI), percutaneous coronary intervention (PCI) or coronary artery bypass grafts (CABG). This population consists of an estimated 120,000 patients in England per year (British Heart Foudation, 2019). The modelled cohort has a starting age of 67 (the age at which they are eligible for CR) and a male to female ratio of 0.70 based on the NACR observed ratio. The population does not incorporate heart failure patients who are conventionally considered a different population for CR purposes (National Audit of Cardiac Rehabilitation, 2023).

The intervention and control

A common definition of CR used is a 'comprehensive, long-term programmes involving medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counselling' (Dalal et al., 2015). The actual details of what these elements consist of and how they are delivered is known to vary significantly in response to the needs and abilities of the participants as well as the services available locally (Anderson et al., 2016).

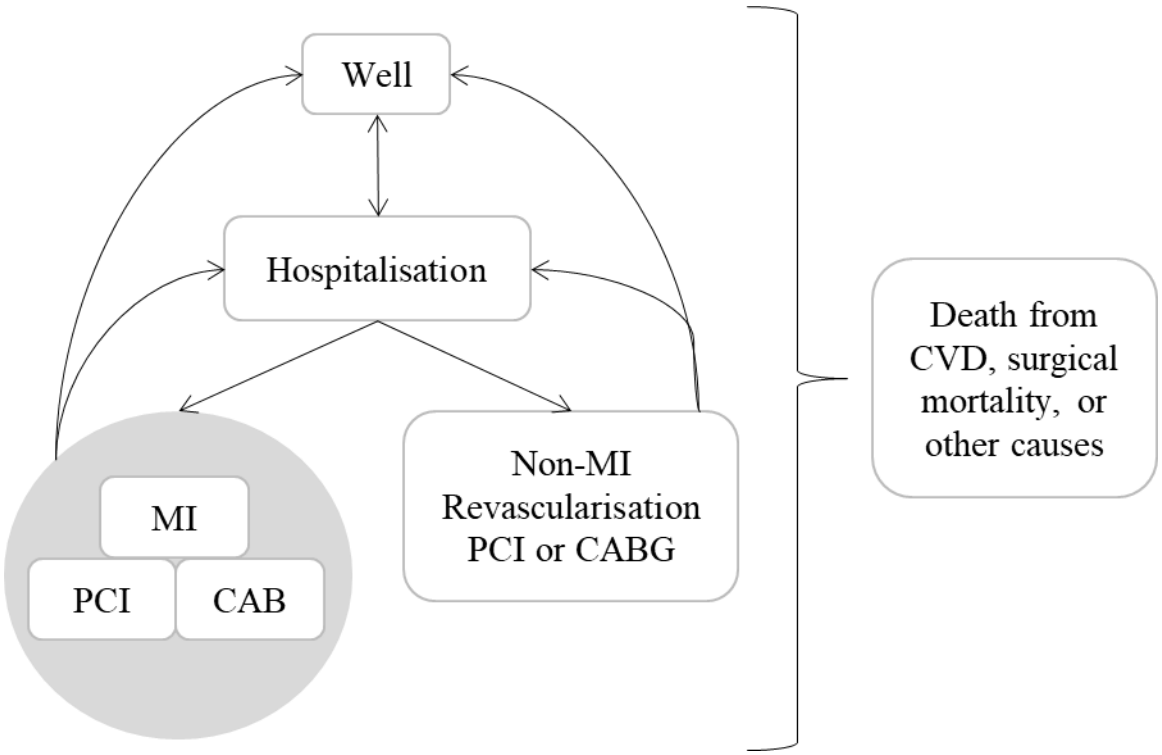
CR does, however, consist of three forms, group-based, often conducted within a hospital or community setting, home-based, where patients are provided with a range of resources and education services consistent with the group-based programme, but which they can engage with domestically, and hybrid, a combination of the two. While delivered in very different ways evidence has indicated that they are equivalent in patient outcomes with the availability of the choice between the two playing an important role in increasing the accessibility of CR (Harrison and Doherty, 2018). The decision model therefore takes the approach of combining the range of different variations and setting of CR into a single concept of CR, consistent with the approach taken in the literature, including the Cochrane review.

In the analysis, the sole comparator is assumed to be no-CR consistent with the Cochrane review (Anderson et al., 2016) and previous studies (Shields et al., 2018).

The model

The model consists of a Markov cohort model with states primarily informed by the Cochrane review (Anderson et al., 2016). Figure 1 provides a schematic of the model structure. The full cohort enters the model in the 'well' state, defined as having recovered from their initial myocardial infarction (MI) and/or revascularisation and deemed fit enough to commence CR, which they begin at this point if in the CR arm. The model, therefore, does not consider any elements of the patient pathway that occur prior to the potential commencement of CR.

Figure 1: Schematic of model for both CR and non-CR.



Parameterising the model

The majority of the transition probabilities required were drawn from the Cochrane review, with the published meta-analysis re-estimated to derive the required values. The remaining model transition probabilities were defined using other published sources and data requests made to the NACR.

The unit costs applied to the model states were derived from published literature and routine sources such as the NHS Reference Costs (now the NHS National Cost Collection) (Department of Health, 2016). The cost of CR was estimated by inflating a previous micro-costing study to contemporary values resulting in a cost of £747.67.

Health related quality of life values for each modelled state were applied as decrements to age adjusted 'normal' population values using Sullivan et al. (Sullivan et al., 2011). The applied decrements were drawn from a 2014 study of the impact of cardiovascular events on change in quality of life and utilities in patients after myocardial infarction (Lewis et al., 2014).

Modelling completion

To incorporate a differential effect for those who complete a full course of CR elements offered compared to those who may register but not complete more than a session, the analysis used the NACR's definition of a minimum required level of engagements in CR in the components offered. The model assumes that any individual who commences CR incurs the full cost of the service to the healthcare provider regardless of how much they engage. This was applied to provide a conservative assessment of the cost-effectiveness of CR. Furthermore, with group-based CR a participant who starts but drops out is unlikely to have their place filled (especially as limited engagement is often defined at the end of the full period of CR). Information from the NACR also indicated that home-based CR contracts are usually paid per person engaging in programmes rather than at completion.

For the purpose of the analysis the rate of non-completion was taken to be 24.6% of those who commence, based on data from the NACR.

Modelling the impact of socioeconomic factors

The impact of socioeconomic status, measured through the index of multiple deprivation (IMD), was incorporated into the model through the treatment effect of the programme, the background risks of CVD related events, the impact of other factors on quality of life, and other causes of mortality. The required parameters were identified through a search of the literature and analysis of NACR data, details of which are provided in ***Paper 3***. Consistent with a-priori expectations worse deprivation was associated with poorer levels of CR uptake and completion, poorer health outcomes for CVD and higher other-cause mortality.

Estimating the benefits of achieving the national target

While the primary analysis was the estimation of the cost-effectiveness of CR compared to no CR from a national perspective, the analysis additionally generated output to inform the policy aim of increasing CR uptake rate from the contemporary rate of around 50% to the target at the time of 65%, subsequently increased to 85% in the NHS Long Term Plan (NHS England, 2019).

In addition to estimating population level impacts of achieving the 65% target, including rates of cardiovascular related hospitalisation and QALY gains, I estimated the justifiable expenditure to reach the target. This estimate was calculated by using a published estimate of the marginal productivity of the NHS of £12,936/QALY (Claxton et al., 2015) to determine the increase in the cost of CR that could occur before it would no longer be a cost-effective use of limited NHS resources.

Modelling the impact of delay

Previous research has identified that not only is there significant variation in the timeliness of CR being offered to eligible patients but that a delay in starting the programme is associated with poorer engagement and reduced health gains (Pack et al., 2013). This is despite guidance on the timeframe within which CR should be offered and commenced (NICE, 2013).

Paper 4 sought to understand the impact of a delay in CR on the long-term cost and health of the patients. This was achieved through two regression analyses of the association between delayed CR and the rates of uptake and completion of the programme, using the NACR database, details of which are available in ***paper 4***. For the purposes of this analysis timely is defined as a start of CR within 28 days of referral for MI and/or PCI and 42 days for CABG patients consistent with the NACR definition (National Audit of Cardiac Rehabilitation, 2023).

Results

National perspective cost-effectiveness results

The decision model estimated that CR was a cost-effective intervention from a national perspective. Patients who did not have CR were estimated to experience an average of 4.42 QALYs from the point of CR eligibility to the end of their lives, accumulating £6863 of related costs to the NHS and PSS, discounted to present values. In contrast, CR patients experienced 0.30 more QALYs (4.72) at an additional cost of £714 (£7577), with the additional cost resulting from the upfront cost of CR. These results implied an incremental cost-effectiveness ratio of £2395/QALY, well below the conventional policy threshold of £20,000-£30,000/QALY. The PSA indicated that the ICER was highly likely to remain within the policy threshold, with a probability of cost-effectiveness of 99.8% across the simulations.

Implications of socioeconomic inequality

The differential cost and benefits accrued by patients of different IMD status are reported in Table 3. The table shows that the underlying health and corresponding cost of NHS interactions are much worse in the more deprived groups, with the most deprived being estimated to have 1.32 fewer QALYs but costing £1346 more than the least deprived when no CR is available, discounted over their lifetimes. Secondly, the use of CR is cost-effective across all the IMD groups, but the greater level of engagement with the programme means that the ICER of the programme is better for the least deprived.

Table 3: Cost-effectiveness of Cardiac rehabilitation (CR) by index of multiple deprivation (IMD)

IMD	no CR		CR		incremental		ICER /QALY	Probability CE
	disc. Cost	disc. QALY	disc. cost	disc. QALY	disc. cost	disc. QALY		
1*	£7,696	3.80	£8,420	4.03	£724	0.22	£3,240	0.996
2	£7,328	4.22	£8,046	4.49	£718	0.27	£2,630	0.997
3	£6,863	4.42	£7,577	4.72	£714	0.30	£2,395	0.998
4	£6,760	4.75	£7,443	5.07	£683	0.32	£2,133	0.996
5	£6,340	5.12	£6,983	5.44	£643	0.32	£1,991	1.000

*IMD: index of multiple deprivation; CR: cardiac rehabilitation; disc.: discounted; QALY: quality-adjusted life years; ICER: incremental cost-effectiveness ratio. *1 - most deprived.*

Benefits of improving uptake

In Table 4 I present the key evidence to inform the benefits of achieving the 65% CR uptake target from the current levels, summarised by IMD showing that current uptake is much lower in the more deprived groups. Due to this larger population who could gain, but lower individual QALY gain from CR, the total population QALY gain is similar across IMDs 1-4. The exception is IMD5 who have a similar individual QALY gain from CR as IMD3 and 4 but a higher current level of uptake. These findings translate into the similar population level justifiable expenditure by IMD.

Table 4: Annual benefits and justifiable cost of reaching 65% target, by index of multiple deprivation (IMD)

IMD	current uptake (NACR data)	Increment to 65% target	eligible population (NACR data 2015/16 data)	QALY gain per person of CR	Total QALY gain from reaching target	justifiable expenditure to reach target while cost effective	
						per person	whole pop
1*	37.61%	27.39%	22,194	0.22	1,358	£2,166	£13,167,695
2	41.97%	23.03%	22,952	0.27	1,442	£2,812	£14,863,740
3	46.21%	18.79%	23,470	0.30	1,314	£3,141	£13,849,816
4	48.14%	16.86%	27,086	0.32	1,464	£3,462	£15,812,812
5	51.75%	13.25%	22,842	0.32	978	£3,537	£10,701,547
				Total	6,556	N/A	£68,395,610

**1 = most deprived.*

Impact of delayed CR commencement

The regression analysis conducted in ***Paper 4*** estimated that a delay in CR commencement was associated with an odds ratio of 1.782 for uptake and 1.106 for completion, both statistically significant. Applying these to the population characteristics suggests that if those who currently receive a delayed CR offer were to receive a timely one, uptake would increase by 14.3% and completion by 1.9%.

The impact of a timely offer of CR to all patients compared to a delayed one are shown in Table 5. In brief, a timely offer increases costs as more patients incur the cost of CR but also experience greater number of expected life years and QALYs, at an ICER of £3286/QALY compared to a delayed CR offer.

Estimated across the annual English population currently receiving delayed CR (34,469) and the 10,753 predicted to not be taking up CR because of the delay the analysis suggests a total health loss due to the delays of 3926 life years or 2792 QALYs (undiscounted). An estimated £12.3 million per year could be justified to achieve timely CR for all patients.

Table 5: Impact of removing the delay on average health and NHS costs per patient referred for CR.

	Costs (undisc.)	Cost (disc.)	LYs (undisc.)	QALYs (undisc.)	QALYs (disc.)
Delayed CR offer	£8,763	£7,203	7.433	5.39	4.51
Timely CR offer	£8,883	£7,310	7.516	5.45	4.55
Difference (95% CI)	£120 (£14 to £267)	£107 (£23 to £219)	0.08 (0.02 to 0.18)	0.06 (0.02 to 0.13)	0.03 (0.01 to 0.09)

Chapter 4: Improving the Relevance of Economic Evaluation Evidence for Commissioners of Cardiac Rehabilitation

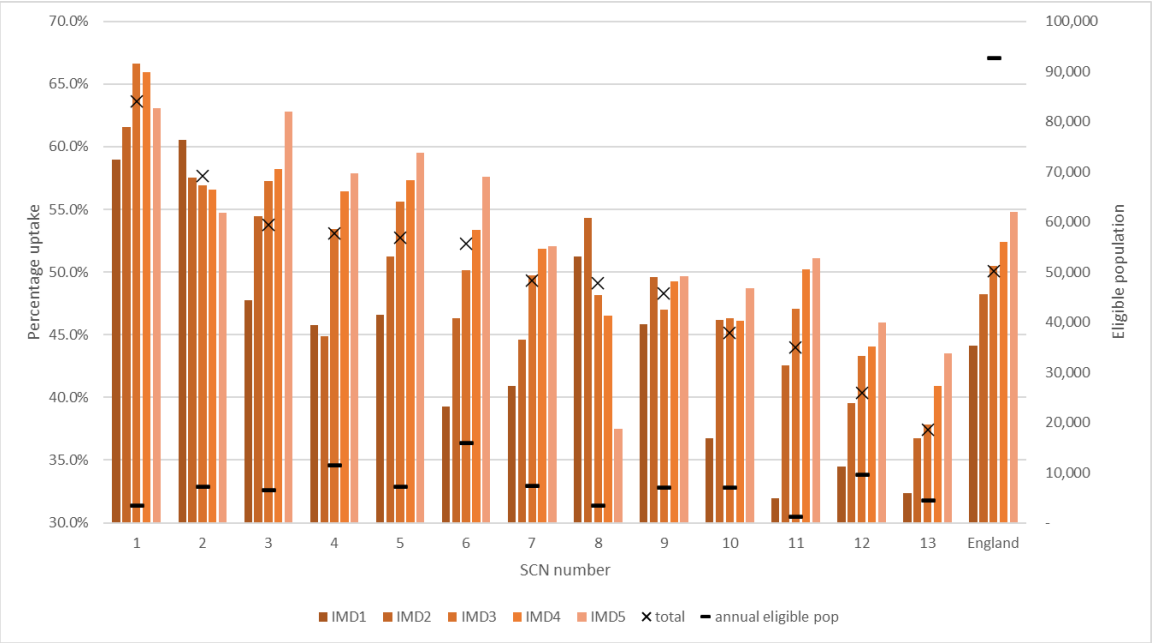
Background

The aim of this Chapter is to bring together the methodological elements developed in ***Chapter 2***, with the case study decision model described in ***Chapter 3***, as reported in ***paper 5***. To achieve this, I briefly overview the commissioning reality of CR in England and then apply the principles of the five elements identified in ***Chapter 2*** where the 'NICE perspective' does not fit with the commissioning reality.

In England, while the setting of uptake targets is done at a national level by NHS England (NHS England, 2019) the commissioning of CR services is primarily the responsibility of Strategic Clinical Networks (SCNs), of which there are 13. While each individual ICB and Trust is understood to have control over the day-to-day functioning of the service it is the individual SCNs who define most of each region's commissioning policy.

Importantly, each of the SCNs faces a unique set of challenges in achieving CR uptake targets and that can lead to differential numbers of patents completing CR. Figure 2 demonstrates that average uptake of CR varies significantly between the SCNs, from 38% to 63% against a national average of 50%. Furthermore, the distribution of uptake by IMD status differs, with the positive linear correlation between uptake and IMD at a national level breaking down for almost all SCNs, including cases such as SCN2 where the relationship is reversed. While the uniqueness and complexity of the current level of CR uptake for each SCN arguably has little impact on the appropriate framework with which to determine the cost-effectiveness of the programme it shows that each SCN starts from a very different point, highlighting the limitations of defining a meaningful national average.

Figure 2: uptake (mean and by IMD) and eligible annual population by anonymised SCN area, 2016–20 averages.



IMD – index of multiple deprivation, SCN – Strategic Clinical Network

Applying the elements

In this section I consider each of the five elements of the 'NICE perspective' of cost-effectiveness analysis identified as being of limited relevance to localised commissioning decisions in ***Chapter 2***, with respect to the CR case study.

Valuation of future costs and benefits

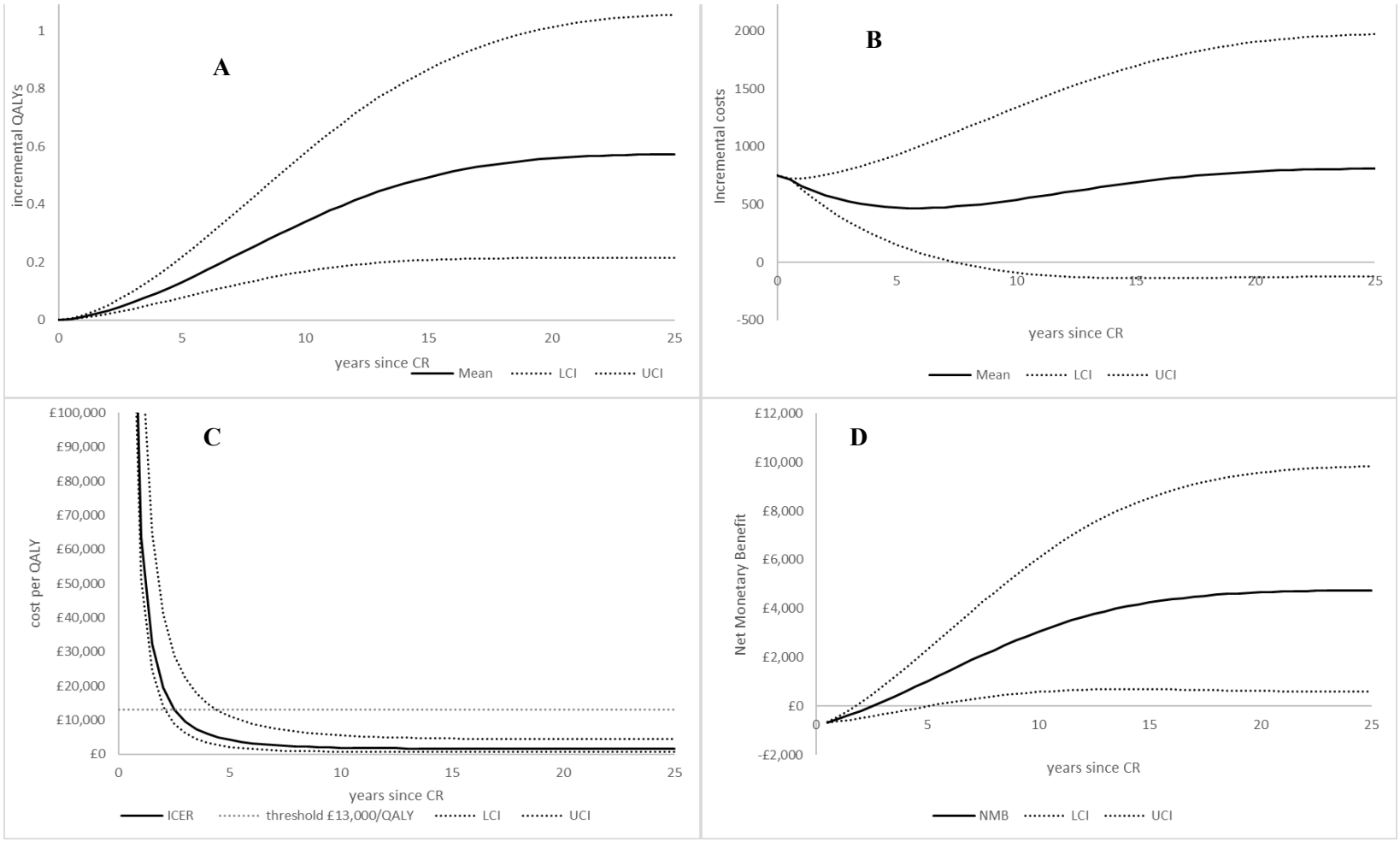
Under conventional cost-effectiveness decision frameworks all costs and benefits accrued over a sufficiently long period to reflect all important differences are considered relevant, typically operationalised as the lifetime of the patient, with a set discount rate applied to future values of 3.5% per year. In ***Chapter 2*** I identified how this long-term approach coupled with the discount rate used may not be relevant at a local level, where budgetary cycles and other factors may impact decision makers ability or willingness to consider long-term implications at all or at the rate implied but the discount rate conventionally applied.

From a CR perspective the time horizon is intrinsically important as the nature of the intervention is that the cost of provision occurs in the short-term but the benefits, both in terms of reduced care needs and patient health, are realised over the longer term. Therefore, the cost-effectiveness of CR to a decision maker with a short time horizon will automatically be lower than one with a longer time horizon.

In ***Chapter 2*** I concluded that there is insufficient evidence on either the time horizon or appropriate discount rate to provide a specific alternative to the 'NICE perspective', instead, as with many other elements, the importance is to be pragmatic to the individual setting. This is best operationalised through a clear presentation of how the costs, health outcomes, and combined effect on the ICER or net monetary benefit (NMB) change over time as each intervention will have a unique profile in these regards. Figure 3 presents these values undiscounted over a 25-year period. As expected, the figures show that the accumulation of incremental health benefit is relatively slow as the benefits of CR are in reducing long term mortality and morbidity. In contrast incremental costs are high upfront with a period of reduced cost where CR patients have fewer healthcare needs, in the longer term this is then countered by CR patients surviving longer than those who did not have CR, therefore implying healthcare costs. These trends play out in the ICER and NMB curves in Figure 3C and D, in both cases showing that CR is not cost-effective unless the time horizon is 3 years or longer (assuming a discount rate of 3.5%).

Regarding the impact of the discount rate, a lower discount rate would make CR more cost-effective, as the benefits are accrued over the long-term, but the costs accrued in the short-term.

Figure 3: graphs of the undiscounted incremental QALYs (A), incremental costs (B), cost per QALY (C), and Net Monetary Benefit (D) over time of CR versus no CR with associated uncertainty



Cost effectiveness threshold

Chapter 2 made the case that the threshold value of £20,000 to £30,000/QALY is an overestimation of the opportunity cost of additional expenditure to the NHS, with a more appropriate value indicated by previous research to be £13,000/QALY for all NHS expenditure or possibly as low as £7,000/QALY for locally commissioned services.

From a CR perspective a reduced threshold value would not affect the overall conclusion that it represents a cost-effective use of NHS resources, as the lifetime ICER from the model was £2,395/QALY, although it does necessitate a slightly longer time horizon before cost-effectiveness is achieved (see Figure 3C). However, a lower threshold reduces the justifiable expenditure that could be spent to achieve the CR uptake targets presented in ***Chapter 3***, with a threshold of £7,000/QALY (rather than £13,000/QALY) reducing the justifiable expenditure that could be spent to change a non-attender to an attender from £4,461 to £2,091 per person.

Budget and decision uncertainty

In both ***Chapters 1 and 2*** the case was made that local decision makers are more likely to be risk averse or have asymmetric risk aversion. While the original analysis from a national 'NICE perspective', reported in ***Chapter 3***, showed that CR was expected to be cost-effective in close to 100% of the PSA iterations, it is important to consider the uncertainty associated with the disentangled elements of the ICER calculation, specifically the costs and QALYs and how these accumulate over time. Doing so gives decision makers the ability to apply their own view of appropriate levels of uncertainty over different time horizons.

Figure 3 includes 95% confidence intervals applied to the costs, QALYs, discounted ICER, and NMB over time. These figures show that while the mean cost-effectiveness result become stable in the medium to long-term, shown by the flattening out of the mean ICER line, the uncertainty continues to grow. This underlines an important limitation of the 'NICE perspective', which makes no explicit trade-off between levels of uncertainty and the decision recommendation based on the ICER result. Research such as Claxton (Claxton, 1999) has been used to suggest this is appropriate, and that the decision that maximises average population health should be chosen regardless of statistical inference. However, there is inevitably a turning point where a level of uncertainty, specifically associated with negative consequences such as catastrophic health impacts or cost implications, will influence the commissioning decision made. In the case of CR, where even at the most extreme cases it is expected to be a health improving intervention at reasonable costs, this is, however, unlikely to be the case.

Scope of included costs and outcomes

There are two key elements related to the scope of included costs and outcomes in this setting, the assumed portability of funding within healthcare systems and the focus on the costs borne by the healthcare system. While the latest NICE reference case supports the inclusion of a wider perspective of costs and outcomes, there is currently no agreed method of how to achieve this (Walker et al., 2019). Therefore, the optimal current approach is to report any wider perspective implications of the competing decisions and, how the costs fall on different budgets within the health sector, for example social, secondary, or primary care.

At the time of analysis, it was not possible to identify or distinguish which local level budgets would be impacted by the decision to commission or not commission CR. For example, the initial funding of CR is not easy to characterise, with discussions with NACR and NHS England indicating that in some cases CR was funded as an individual service via the SCN but in other cases bundled within the broader funding of cardiovascular surgery. As a result, the analysis was only able to take the conventional approach of assuming equivalence of healthcare costs.

Regarding wider costs and outcomes, I identified three areas relevant to CR:

1) *Economic productivity*, the burden of cardiovascular disease on UK productivity has been shown to be significant (Liu et al., 2002) however I was unable to identify any existing literature which considered how productivity interacted with CR. As part of the analysis, I explored the application of the conventional approach to estimating productivity impact which estimates productivity to be a combination of ability to work and a measure of wage, such as the median national wage. However, as the cohort modelled was aged 67 at CR commencement, above the state retirement age in the UK, the value of such an analysis is minimal as it assumes economic value is only derived through formal employment (Drummond and McGuire, 2001).
2) *Carer impact*, as cardiovascular disease can have severe implications on individual's mobility CR has the potential to affect the dynamic between patients and any carers. As with productivity this dynamic has been researched to some extent, but the implications of CR are unclear (McHorney et al., 2021). Additionally, there are likely to be spillover effects in terms of shared learning from the CR course as patients who engage well and change their behaviour may influence those around them (Bloch et al., 2014).
3) *Out of pocket costs*, while the shift to home-based CR should reduce costs to the individual it is still typical for patients to attend CR programmes at fixed sites (e.g. hospitals). This requirement to attended locations at fixed times, typically during the working week, has implications to patients including travel and lost work or leisure time that are currently not included in the analysis.

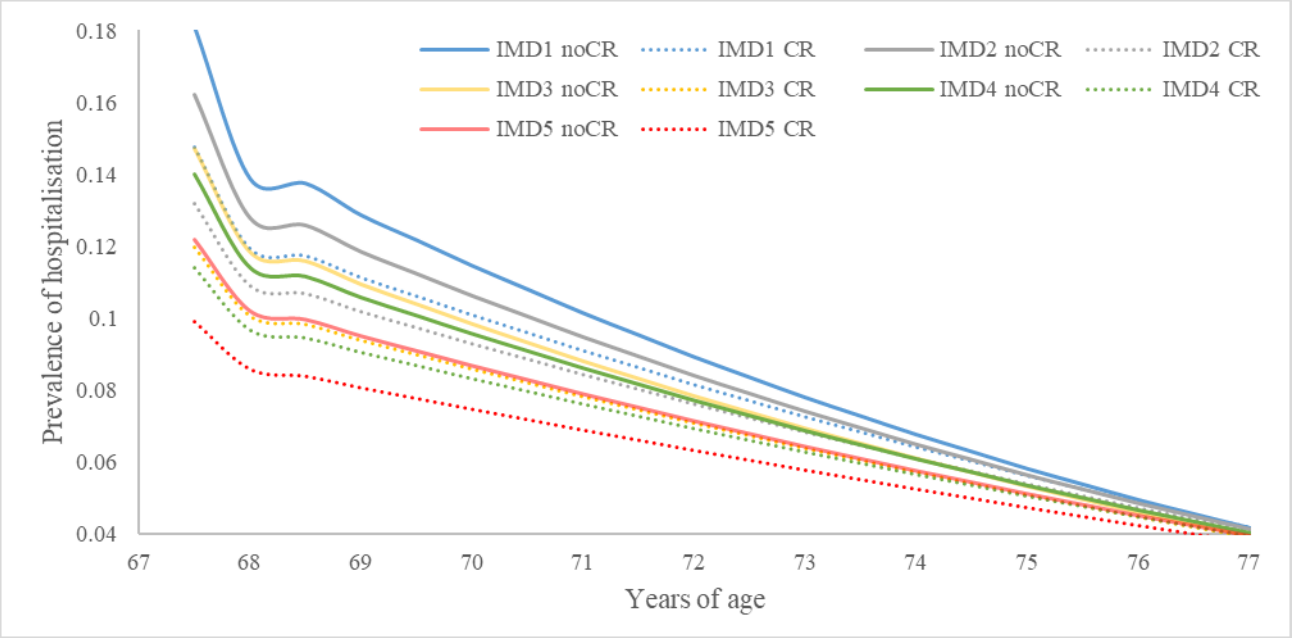
Inequality

As demonstrated in Figure 2, and throughout ***Chapter 3***, socioeconomic inequality plays a significant role in both the engagement with CR and ability to benefit from it. The most deprived IMD groups were shown in ***Chapter 3*** to not only start from a lower level of expected lifetime health without CR but also to gain 0.1 QALY less from participating with CR than the least deprived.

In ***Chapter 2*** I discussed conceptualising the role of inequality through equity impact or equity weighting approaches (e.g. DCEA). From a CR perspective DCEA is not likely to be informative as while total population health increases at the detriment of health inequality increases, representing a 'win-lose scenario', all socioeconomic groups benefit. This implies that while the social welfare of CR is greater at lower levels of inequality aversion CR would always be expected to dominate a no CR comparator at any level of inequality aversion. If, however, an intervention was evaluated that increased the health of more deprived groups but to the detriment of less deprived groups, such as the targeted screening approach in Asaria et al.'s DCEA tutorial paper (Asaria et al., 2016), DCEA would be informative in considering the trade-off necessary between a targeted approach to CR and the current universal approach.

Considering instead alternative outcome measures such as the rate of cardiac related hospitalisation, often considered a key performance indicator by commissioners, Figure 4 presents the results of additional analysis exploring the prevalence of cardiac related hospitalisation over time, stratified by IMD and CR groups. The figure shows that more deprived groups have a higher level of cardiac related hospitalisation. Additionally, even with CR the predicted level of hospitalisation is greater for the most deprived group (IMD1) than for less deprived groups without CR (IMDs 3, 4, and 5). This is indicative of the much poorer level of health and propensity to engage fully with CR in the more deprived groups.

Figure 4: Prevalence of hospitalisation by IMD and CR group over time



Chapter 5: Discussion and Conclusion

Summary

Within most health settings economic evaluation research is framed to inform national decision-making processes, with a focus on the expected cost-effectiveness of interventions to impact narrowly defined costs and outcomes over the duration of any differential effect. This is typically implemented by applying methodological guides such as the NICE reference case (NICE, 2022). However, a significant proportion of commission decisions are made at more localised levels, for example, in England roughly 60% of the NHS budget is held by local bodies (NHS England, 2023).

In ***Chapter 1*** of this thesis, I summarised how previous research has identified that the current means of conducting and disseminating economic evaluation evidence is having limited impact on local decision making, bringing into question the relevance of what is produced to those who make many of the commissioning decisions. The chapter concluded that, while many authors had previously identified and conceptualised the limited direct transfer and impact of research to a local setting, there had been few attempts made to adapt the status quo of economic evaluation methodology to address this.

As a result, in ***Chapter 2*** I explored the appropriateness of the most routinely applied framework when conducting cost-effectiveness analysis in the UK, the NICE reference case, to the commissioning decisions made at a local level using a case study of weight loss services. This chapter identified five elements of cost-effectiveness analysis where the reference case demonstrably differed from the decision problem facing local commissioners. The accumulated effect of this deviation played a role in local commissioners being reluctant to fund services which had been previously shown to be highly cost-effective under the conventional framework.

Chapter 3 detailed the development of a decision analytic model of the cost-effectiveness of CR as an intervention for patients who have recently had a heart attack. In this chapter, and the accompanying papers, the focus is on applying the conventional framework, finding that CR is a cost-effective intervention due to its relatively low upfront cost accompanied by long term health gains that result from the change in individual behaviour and risk factors that result from the intervention.

In ***Chapter 4*** I brought together the methodological developments of ***Chapter 2*** and the CR model from ***Chapter 3*** to consider how the adaptation of the framework of cost-effectiveness applied would impact the commissioning decision. The findings of the Chapter indicate that, under the adapted framework, CR is still expected to be cost-effective. However, as the aim of the adapted framework is to take a more positive approach to informing decision makers, rather than defining a normative framework, there are many elements that are best determined by the decision maker locally, for example the time horizon and appropriate opportunity cost. Additionally, the adapted framework proposes a greater level of detail regarding the components of the ICER, i.e. how costs and QALYs are generated over time, as well as elements that are known to be relevant to commissioning decisions but not included in the ICER including inequality implications and rates of hospitalisation.

Strengths

The key strengths of this thesis, and the underpinning research, lie in the squaring of the circle between the current framework of cost-effectiveness routinely applied in the UK and the realities faced by those making commissioning decisions at a local level. By not seeking to supplant the

current framework, which has been successful in facilitating the adoption of cost-effectiveness considerations into national level decision making, but adapt it the proposed approach represents a pragmatic and implementable solution. As demonstrated through the CR case-study the approach represents a valuable additional approach alongside the conventional framework in highlighting areas where the local decision problem may diverge from a national perspective, and therefore would require additional consideration regarding adoption of a policy.

Limitations

This work does, however, have several limitations. Firstly, the approach I have taken to characterise 'local decision makers' can be broadly defined as any stakeholder who has control over the commissioning of services but operates at a sub-national level. The work done in ***paper 1*** was done in collaboration with a CCG, one of 106 in England, while ***paper 2*** incorporated CCGs, local authorities, and ICSs, and the application of the case study focussed on SCNs. Each of these commissioners vary in size, scope of their commissioning responsibilities, and independence from national decision making. In turn the relevance of the conventional NICE framework to their decision-making reality is likely to vary. However, as the proposed adapted framework focusses on a shift towards a more positive approach with consideration of the relevance of each of the elements of the framework at the relevant commissioning level this does not invalidate the approach.

A broader limitation of the approach is the challenge of finding the appropriate position between commissioning reality and the necessary simplification to apply economic evaluation frameworks. The original development of the extra-welfarist approach that underpins much of what has been discussed in this thesis was done with an awareness that it represented a simplification of reality and was not meant to be a decision-making formula alone but an aide to consistent and replicable decision making.

Contribution to the academic literature

This thesis, and the accompanying publications, have contributed to research knowledge in a number of ways. Firstly, the methodological component considered in ***papers 1 and 2*** builds on existing literature that has identified the disconnect between economic evaluation and local decision-making processes. However, the literature to date has done little to determine the methodological elements of standard economic evaluation which contribute to this disconnect or to explore approaches to alleviate them.

Secondly, the economic evaluation of CR developed in ***papers 3 and 4*** represents an important research study in its own right, with the most recent systematic reviews of the area (Shields et al., 2023, Shields et al., 2018) having identified a number of limitations with the existing studies which this analysis addressed. This can further be evidenced through ***paper 3 and 4*** being the subject of an editorial in the European Journal of Preventive Cardiology (Halasz and Piepoli, 2020), a leading journal in the area with an impact factor of 8.5. The editorial, provided in appendix 1.4, commented that the papers identified the discrepancy between what best practice recommended and the reality of service delivery. The work also led to international collaboration and related publication (Driscoll et al., 2020).

Finally, the application of the methodological considerations to the CR case-study, reported in ***paper 5***, represents the first use of nationally collected audit data of CR to directly inform the health economic case for commissioning from the perspective of the local decision makers.

Impact of this work

The impact and value this research can be evidence through estimates generated from the CR model and analytical approach developed through this thesis informing the NHS Long Term Plan (NHS England, 2019), a national policy documents which sets out the 10 year ambitions for the NHS, an excerpt of which is provided in appendix 1.2. Specifically, informing the statement that 'Scaling up and improving marketing of cardiac rehabilitation to be amongst the best in Europe will prevent up to 23,000 premature deaths and 50,000 acute admissions over 10 years.'p.63. This in turn has led to the provision of additional funding and accompanying increase in service provision and uptake through the Cardiac Transformation Pathway[2].

The work was similarly referenced in the British Heart Foundation's Turning Back the Tide on Heart and Circulatory Disease report (British Heart Foudation, 2018), provided in appendix 1.3. These demonstrable impacts led to this work playing a pivotal role in a University of York Impact Case Study submitted as part of REF2021, provided in appendix 1.1.

Future developments

Criticism of the standard NICE-style approach to conducting economic evaluation is not new, and researchers have previously proposed replacements or alterations to the approach including but not limited to multi-criteria decision analysis (MCDA) (Jit, 2018), extended CEA (Verguet et al., 2016), impact inventories (Walker et al., 2019), and a local Government perspective (Candio et al., 2021). While all of these approaches have the same underlying aim of incorporating a wider or more pragmatic set of variables into the decision problem faced by decision makers; little research effort has been spent to understand the consistency of the approaches. Therefore, additional work is needed, in collaboration with service level commissioners, to identify which of the approaches that have been proposed are most informative and under what circumstances. This is vital to ensure evaluations fulfil Merlo's characterisation of accessibility and acceptability (Merlo et al., 2015) as well as ensuring consistency in the methods applied.

Conclusion

Over the last three decades the discipline of health economics has been very effective at developing evaluative frameworks to support the consistent and transparent commissioning of cost-effective healthcare interventions. This has been especially true in the UK where much of this methodological development occurred and where national policy makers were early adopters of these methods, including through the NICE process.

However, the successful adoption of the normative framework most typically applied when conducting cost-effective analysis has arguably been at the detriment of relevance to local commissioning decisions. In this thesis I have considered specific elements of the NICE framework that differ from the reality of commissioning at local levels, going on to explore the implications of different approaches for each of these elements on a de-novo model of CR for patients who have had heart attacks.

This thesis argues that cost-effectiveness analysis should step back from the strict focus on the normative framework routinely applied. Instead, more consideration should be given to the realities faced by the commissioner of the intervention or service under consideration. As Alan Williams said in 1991, years before the development of the NICE framework '*The fundamental role of analysis is clarification… clarification of objectives, constraints, problem formulation, what evidence is relevant, what is available, what has been used, what weight was given to it, how it has been interpreted…and*

[2] Personal communication with the NACR

what judgments or assumptions were made where the evidence was lacking or inconclusive.' (Williams, 1991) Without the act of clarifying the commissioning reality the risk is that we fall into Machiavelli's trap of neglecting what is actually done for what should be done.

Abbreviations

BMI	Body mass index
CABG	Coronary artery bypass graft
CCG	Clinical Commissioning Group
CEA	Cost-effective analysis
CEAC	Cost-effective acceptability curve
CR	Cardiac rehabilitation
CVD	Cardio-vascular disease
DCEA	Distributional cost-effectiveness analysis
HTA	Health technology assessment
ICB	Integrated Care Boards
ICER	Incremental cost-effectiveness ratio
IMD	Indices of multiple deprivation
MI	Myocardial infarction
NACR	National Audit of Cardiac Rehabilitation
NHS	National health service
NICE	National Institute for Health and Care Excellence
NMB	Net monetary benefit
PCI	Percutaneous coronary intervention
PSA	Probabilistic sensitivity analysis
PSS	Personal and social services
QALY	Quality adjusted life year
SCN	Strategic Clinical Network
STEMI	ST-elevation myocardial infarction
UK	United Kingdom

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Appendix 1. Impact Evidence

This appendix contains excerpts of the four demonstrations of impact of the research outlined in this thesis. They appear in the following order:

Appendix 1.1: Research Excellence Framework 2021 (REF2021) Impact Case Study submitted by the University of York incorporating the research published in paper 3 of this thesis.

Appendix 1.2: Excerpt of the NHS Long Term Plan (NHS England, 2019) containing estimates provided to the NACR as part of the research conducted for papers 3, 4, and 5.

Appendix 1.3: Excerpt of the British Heart Foundation Turning Back the Tide (British Heart Foudation, 2018) containing estimates produced as part of the research conducted for papers 3, 4, and 5.

Appendix 1.4: European Journal of Preventive Cardiology (EJPC) editorial by Halasz and Piepoli (Halasz and Piepoli, 2020) including discussion of paper 2 and paper 3 which was published in this issue of EJPC.

Impact case study (REF3)

REF2021

Institution: University of York		
Unit of Assessment: 2 - Public Health, Health Services and Primary Care		
Title of case study: Improving service quality, uptake and health outcomes for patients with heart disease attending cardiac rehabilitation.		
Period when the underpinning research was undertaken: 2014 - 2020		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	**Role(s) (e.g. job title):**	**Period(s) employed by submitting HEI:**
Patrick Doherty	Professor	Jan 2014 - present
Alex Harrison	Research Fellow	Nov 2014 - present
Laura Bojke	Reader	Oct 1999 - present
Sebastian Hinde	Research Fellow	Oct 2010 - present
Period when the claimed impact occurred: 2014 - 2020		
Is this case study continued from a case study submitted in 2014? N		

1. Summary of the impact (indicative maximum 100 words)

University of York research achieved positive impact on health policy, service quality and delivery benefitting patient health as part of cardiac rehabilitation (CR):

i. Developed key performance indicators and a new analytic approach leading to a National Certification Programme for CR demonstrating a 30% improvement in service quality;
ii. Played a key role in reducing national CR wait times by more than 50% with an associated (economically-modelled) increase in uptake of 15% and improved long-term patient health evidenced by a favourable cost per quality-adjusted life-year of GBP3,286;
iii. Improved CR provision for patients with heart failure through an award winning self-management intervention, incorporating our chair based exercise programme, leading to implementation and roll-out within the National Health Service (NHS);
iv. Strategy, policy and clinical guidance: Influenced British Heart Foundation Strategy, The NHS Long-term Plan and international clinical guidance.

2. Underpinning research (indicative maximum 500 words)

- University of York (UoY) research by **Doherty, Harrison**, **Bojke and Hinde**:
  Through a series of robust observational studies utilising national registry data Doherty and colleagues evaluated cardiac rehabilitation (CR) service quality and also determined the extent to which waiting times influenced patient outcomes. Statistical analyses accounted for confounders and used transparent reporting methods:
  Study one applied a new analytical approach utilising national registry data from routine clinical practice to evaluate the extent to which CR programmes met minimum standards and key performance indicators of service quality. This research concluded that in the period 2013 to 2014 only 27 CR programmes (12%) met all CR quality criteria and that 5% of programmes failed to meet any of the quality criteria **(3.1)**. This approach helped establish the first UK CR service performance categories and directly informed the creation of the National Certification Programme in 2016.
  Study two used logistic and multinomial regression to investigate the influence of CR timing on psychological outcomes in 39,588 post heart attack patients. This was the first study to conclude that longer wait times were associated with less than optimal mental health outcomes **(3.2)**. This complemented a previous study published in 2016 (by Doherty) confirming the benefits of timely CR on physical fitness and physical activity status.
- Doherty was co-investigator on a National Institute for Health Research (NIHR) programme grant 'Rehabilitation Enablement in Chronic Heart Failure (REACH-HF)' that developed and evaluated, through a clinical trial, a new self-managed home-based intervention for patients with heart failure. The intervention was developed with patient and carer involvement and was proven to be safe, clinically effective and cost effective. Doherty developed the chair-based exercise intervention incorporating seven exercise intensity levels quantifying the metabolic costs for each of the exercise levels. He also led the exercise prescription component of REACH-HF which created a new tailored exercise approach for patients with heart failure. Doherty was principal investigator for the York NHS Hospital trial, one of four sites across the UK that delivered REACH-HF **(3.3)**.

- Doherty was one of three co-leads on a European-wide project (Cardiac Rehabilitation Outcome Study-CROS) with the Cochrane Group, Heidelberg University. This was the first study to exclude pre-1995 CR studies as part of their systematic review and meta-analysis investigating the prognostic effects of CR in the modern era of cardiology. This research, based on a sample size of 232,295 patients, established CR effectiveness but raised serious concerns about the quality of CR interventions included in clinical trials. Through its analysis of registry (clinically based) studies, it also highlighted poor quality in CR services as part of routine clinical practice across Europe **(3.4)**.
- Doherty was co-investigator on an NIHR programme grant evaluating the effectiveness of psychological interventions through a rigorous clinical trial in patients with depression and anxiety which are conditions known to act as barriers to CR uptake. Doherty was involved in the design, implementation, analysis and dissemination of this research, which proved that CR plus behaviour activation therapy was clinically effective. The group also carried out a novel cost effectiveness systematic review of CR in the modern era of cardiology (influenced by Doherty's CROS research) which informed the first value for money case for CR **(3.5)**.
- Bojke, Hinde, Doherty and Harrison, supported by NIHR and British Heart Foundation (BHF) carried out a de novo approach to health economic modelling using and adapting systematic review evidence combined with National Audit of Cardiac Rehabilitation (NACR) data resulting in the development of a tailored health economic model evaluating increased uptake and health gains by socioeconomic status in cardiac patients attending CR. This research has directly informed the NHS England Long-term Plan targets and BHF Strategy **(3.6)**.

3. References to the research (indicative maximum of six references)
(*Quality indicator = QI*)

3.1. Doherty, PJ, Salman, A, Furze, G & Dalal, HM, **AS Harrison.** 2017, 'Does cardiac rehabilitation meet minimum standards: An observational study using UK national audit?' Open Heart, vol 4, e000519, pp. 1-5. doi.org/10.1136/openhrt-2016-000519
QI = peer reviewed funding and paper from BHF research grant (2014-17)

3.2. Sumner, J, Böhnke, JR & **Doherty, P.** 2017 'Does service timing matter for psychological outcomes in cardiac rehabilitation? Insights from the National Audit of Cardiac Rehabilitation' Eur J Prev Cardiol. 2017. doi.org/10.1177/2047487317740951
QI = peer reviewed funding and paper from BHF research grant (2017-19).

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QI = peer reviewed funding and paper from an NIHR programme grant (2014-18). Our roll-out of this research into the NHS won a BMJ Services Award in 2020

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QI = peer reviewed paper and approved project of the European Association of Preventative Cardiology (2014-17)

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QI = peer reviewed funding and paper from NIHR-CLAHRC (2014-19) and BHF grant: Transformation and innovation of cardiac rehabilitation services' (2019-22).

QI summary: all papers peer reviewed, five based on peer reviewed grants, one approved European project, three submitted in REF 2021 and one received a BMJ Service Award.

4. Details of the impact (indicative maximum 750 words)

[Impact I] Developed clinical standards and National Certification Programme

a. Research by Doherty developed key performance indicators and an analytic approach leading to the foundation of a National Certification Programme for CR (NCP_CR). This is run jointly by the British Association for Cardiovascular Prevention and Rehabilitation (BACPR) and national audit team **(3.1 & 3.2)**. The National Certification Programme monitors and reports on the quality of CR delivery against published clinical minimum standards. Longitudinal national audit data shows that CR quality has improved significantly from only 27 programmes (12%) in 2014 to 93 programmes (42%) achieving full certification status in 2020 representing a 30% improvement. British Journal of Cardiology (2016) **(5.1a)**.

b. The same research informed clinical standards and core components used by over 230 clinical programmes across the UK. (**3.1** is reference 81 in the quotation below): *"The ultimate goal is for all CR programmes to deliver services in line with the Standards and Core Components in this document, however at present most programmes are working towards the minimum standards as outlined in the NCP_CR.[81]" Page 19 BACPR Standards and Core Components (2017)* **(5.1b)**.

c. National reporting of key performance indicators as part of the NCP_CR showing that the quality of CR has increased since this research was conducted. BHF Quality and Outcomes Report 2020 page 23 (5.1c).

d. UoY research on the development and success of a national certification programme and minimum standards was viewed, by the European Association for Preventive Cardiology, as the first to implement and evaluate minimum standards which were then used to inform the development and implementation of European standardization and quality improvement of secondary prevention: *"The use of minimum standards for the evaluation of the quality of CR has been tested elsewhere [21]" Page 2* Standardization and quality improvement of secondary prevention through cardiovascular rehabilitation programmes in Europe: Eur J Prev Cardiol. 2020. Reference 21 in the quote is **3.1, (5.1d)**.

[Impact II] Improving national CR wait times and patient outcomes

a. Research presented at national and international conferences in 2015 and 2016 showed that timely CR led to improved mental health and physical health outcomes **(3.2)**. The BACPR standards writing group reviewed Doherty's research on waiting times and CR delay and used it to support timely CR as part of their standards. Using published data collected as part of NHS Digital audits the quotation below highlights more than a 50% reduction in waiting times driven by UoY research:

"In 2020, UK median CR wait times have reduced to 33 and 21 days for surgical and non-surgical patients, respectively. This represents a reduction in waiting time of 21 days for surgical patients and of 19 days for non-surgical patients compared with 2014 surpassing national targets and yielding significant improvements in service delivery and patient benefit by avoiding delay (Hinde et al 2020). This change in clinical practice owes much to sustained BHF-funded studies at the University of York on wait times. Before these studies, average wait times had only decreased by 2.5 days between 2011 and 2014." Page 20 BHF Quality and Outcomes Report 2020 **(5.2a)**.

b. UoY research on waiting times has continued to inform new versions of clinical standards evidenced by the following quotation where reference 28 in the quotation is our research on the benefits of early CR: "There is continued emphasis on the importance of early CR which is both safe and feasible, and improves patient uptake and adherence.21–28" Page 511 BACPR, Standards and Core Components. Heart 2019;105:510-515 **(5.2b)**.

c. The quotation below cites two UoY studies, on the impact of early rehabilitation on psychological outcomes and physical outcomes, as the only references used to inform the decision to include early CR as a minimum standard for CR services across Europe: *"The timing of CR has a significant impact on fitness[53] and psychological outcomes [54]" page 3 of* Standardization and quality improvement of secondary prevention through cardiovascular rehabilitation programmes in Europe: Eur J Prev Cardiol. 2020 **(5.2c)**.

d. Beyond the recognised improvement in physical and mental health outcomes for patients, evidenced through UoY research on timely CR, there is also a service level benefit achieved through enhanced uptake. Timely CR increases the likelihood of patients starting whereas delayed CR decreases the likelihood. Health economic modelling of timely CR has quantified a 15.3% benefit in CR uptake (i.e. ~ 20,786 more patients based on 2019 national audit data) and improved long-term health with a cost per quality-adjusted life-year of GBP3,286 **(5.2d)**.

[Impact III] Development and implementation of a new self-management intervention to address a known gap in CR delivery for patients with heart failure (HF).

a. The REACH-HF programme of research including Doherty's chair based exercise intervention was developed with extensive patient and carer involvement. Clinical and cost effectiveness was established **(3.3)** after which REACH-HF was rolled out through four NHS Beacon sites and four Scottish Health Boards. Roll-out was supported by NIHR, NHS England/Scotland. NHS Digital also introduced REACH-HF as a new mode of delivery option in Jan 2019 allowing clinicians to routinely record this intervention as part of an NHS provision. The REACH-HF service implementation approach, outlined above, won the BMJ Services Award for Stroke and Cardiovascular Services in 2020. The BMJ award recognised REACH-HF for its excellence in healthcare provision and for successfully implementing leading research into NHS clinical practice **(5.3a)**.

b. REACH-HF was adopted by the South West Academic Health Sciences Network **(5.3b)**.

c. The REACH-HF intervention was adopted nationally by the BHF and BACPR as part of the Covid-19 initiative to enable older patients with heart failure to exercise safely at home. In response to Covid-19 NHS service changes and an urgent need for online training of NHS staff, Doherty and REACH-HF colleagues changed their face-to-face facilitator course to online training. In doing so they successfully delivered training to 100 staff leading to an increase in home-based CR services in the UK. Doherty also adapted his chair based exercise programme making it freely available to NHS staff and patients online. National audit data pre-Covid (2019) vs Covid era (2020) confirms that the proportion of patients with heart failure taking up hospital-based CR dropped by 47% whereas home-based CR increased by 52%. Based on the success of our Covid-19 response along with development and implementation of online training for NHS staff, NICE endorsed REACH-HF as a quality assured shared learning example under the theme of Covid-19-ready-rehabilitation-for-heart-failure **(5.3c)**.

[Impact IV] Policy and practice: NHS Long-term Plan; British Heart Foundation Strategy and international clinical guidance.

a. In 2019 UoY researchers (Doherty, Harrison, Hinde, Bojke) were asked by NHS England and BHF executives to investigate, as part of NHS Long-term Plan preparations, the cost benefit of increasing CR uptake. Our findings and calculations (**3.6** also incorporating **3.5** in the cost analysis), were used to aid decision making and set targets as part of the NHS Long-term Plan and BHF Strategy:
"Scaling up and improving marketing of cardiac rehabilitation to be amongst the best in Europe will prevent up to 23,000 premature deaths and 50,000 acute admissions over 10 years" (Page 63 section 3.72 of the Long Term Plan) **(5.4a)**.

BHF strategy document (The Big Picture 2018) used our research findings and UoY based National Audit of Cardiac Rehabilitation data to set its 65% and 85% targets: *"Achieving an uptake rate of 65% would result in 8,500 fewer deaths and 21,000 fewer hospital readmissions over 10 years. And reaching 85% uptake could save a remarkable 20,000 lives and avoid nearly 50,000 admissions over the next decade, as well as saving the NHS tens of millions of pounds. Source: Hinde S, Bojke L, Harrison A, Doherty P. (2018) Modelling of potential CR uptake scenarios for the BHF vs 2015/16 NACR data"* Page 3 **(5.4a)**.

b. Our joint European collaborative research project entitled Cardiac Rehabilitation Outcome Study (CROS) was used to inform Scottish National Clinical Guidance SIGN 150:

"While CR meets the definition of a complex intervention, with studies including some or all of the elements described in the BACPR pathway, systematic reviews have concluded that the reduction in cardiovascular mortality associated with attending CR can be attributed to the exercise component.[5,6]" Page 1, Reference 6 is **3.4**, **(5.4b)**.

The CROS project systematic review and meta-analysis also informed European standards on the ability of CR to benefit patients by reducing premature death:

"Previous data, including recent meta-analysis have shown the efficacy of CR [3,5–7] *to reduce mortality"* Page 2, reference 5 is **3.4**, **(5.4b)**.

5. Sources to corroborate the impact (indicative maximum of 10 references)

The sources to corroborate impact are presented below as combination of coherent forms of evidence for each of the impact areas detailed in section 4. These have been bundled into four evidence files uploaded as part of our REF 2021 UOA 2 submission.

5.1. Clinical standards and National Certification Programme:

a) Peer reviewed paper on the *Development of the National Certification Programme* in the British Journal of Cardiology (2016)
b) BACPR *Standards and Core Components* (2017)
c) Analysis of CR quality from 2014 to 2020. BHF Quality and Outcomes Report (2020)
d) Peer reviewed paper on *Standardization and quality improvement of secondary prevention through cardiovascular rehabilitation programmes in Europe* published in the European Journal of Preventive Cardiology 2020.

5.2. Improving national CR wait times and patient outcomes:

a) BHF Quality and Outcomes Report 2020
b) Peer reviewed paper on *UK clinical standards* published in BMJ Heart 2019
c) Peer reviewed paper on *Standardization and quality improvement of secondary prevention through cardiovascular rehabilitation programmes in Europe* published in European Journal of Preventive Cardiology 2020
d) Peer reviewed paper on *Health economic modelling of timely CR uptake and quality of life outcomes* published in European Journal of Preventive Cardiology 2020.

5.3. Development and implementation of a new self-management intervention for patients with heart failure:

a) BMJ 2020 Health Services award for Stroke and Cardiovascular Services
b) South West Academic Health Science Network adoption of REACH-HF
c) NICE and NHS online resources showing how the REACH-HF intervention and Doherty's chair based exercise programme were adopted as part of the Covid-19 national initiative.

5.4. Strategy, policy and international clinical guidance:

a) BHF Strategy; NHS England Long-term Plan
b) Scottish clinical guidance and European standards.

Appendix 1.2: Excerpt of the NHS Long Term Plan (NHS England, 2019)

The NHS Long Term Plan

Cardiovascular disease

3.66. **Heart and circulatory disease, also known as cardiovascular disease (CVD), causes a quarter of all deaths in the UK[115] and is the largest cause of premature mortality in deprived areas. This is the single biggest area where the NHS can save lives over the next 10 years.** CVD is largely preventable, through lifestyle changes and a combination of public health and NHS action on smoking and tobacco addiction, obesity, tackling alcohol misuse and food reformulation. Chapter Two sets out more detail. Eating too much salt remains a leading cause of raised blood pressure, leading to thousands of heart attacks, strokes and early deaths. Reducing salt in foods by 1 gram/day, for example, could prevent 1,500 premature deaths each year and save the NHS over £140 million annually. The government has been clear that salt intake needs to reduce. Some – but insufficient – progress has been made with the voluntary salt reduction programme. The government has agreed to set out by Easter 2019 the details of how the programme's targets will be met.

3.67. **Early detection and treatment of CVD can help patients live longer, healthier lives.** Too many people are still living with undetected, high-risk conditions such as high blood pressure, raised cholesterol, and atrial fibrillation (AF). Other countries have made more progress on identification and diagnosis working towards people routinely knowing their 'ABC' (AF, Blood pressure and Cholesterol). Replicating this approach will be increasingly possible with digital technology, and major progress could be achieved working with the voluntary sector, employers, the public sector and NHS staff themselves.

3.68. **Working with local authorities and PHE, we will improve the effectiveness of approaches such as the NHS Health Check, rapidly treating those identified with high-risk conditions.** Working with voluntary sector partners, community pharmacists and GP practices will also provide opportunities for the public to check on their health, through tests for high blood pressure and other high-risk conditions. Expanding access to genetic testing for Familial Hypercholesterolaemia (FH), which causes early heart attacks and affects at least 150,000 people in England[116], will enable us to diagnose and treat those at genetic risk of sudden cardiac death. Currently only 7% of those with FH have been identified[117], but we will aim to improve that to at least 25% in the next five years through the NHS genomics programme.

3.69. **Where individuals are identified with high risk conditions, appropriate preventative treatments will be offered in a timely way.** We will support pharmacists and nurses in primary care networks (see Chapter One) to case find and treat people with high-risk conditions. Where 100 people with AF are identified and receive anticoagulation medication, an average of four strokes are averted, preventing serious disability or even death. The creation of a national CVD prevention audit for primary care will also support continuous clinical improvement.

3.70. **People with heart failure and heart valve disease will be better supported by multi-disciplinary teams as part of primary care networks.** 80% of heart failure is currently diagnosed in hospital, despite 40% of patients having symptoms that should have triggered an earlier assessment[118]. When admitted to hospital, we will improve rapid access to heart failure nurses so that more patients with heart failure, who are not on a cardiology ward, will receive specialist care and advice[119]. Better, personalised planning for patients will reduce nights spent in hospital and reduce drug spend. Greater access to echocardiography in primary care will improve the investigation of those with breathlessness, and the early detection of heart failure and valve disease.

3.71. **Fast and effective action will help save lives of people suffering a cardiac arrest.** The chance of survival from a cardiac arrest that occurs out of hospital doubles if someone receives immediate resuscitation (CPR) or a high energy electric shock to the heart (defibrillation)[120]. A national network of community first responders and defibrillators will help save up to 4,000 lives each year by 2028. This will be supported by educating the general public, including young people of school age, about how to recognise and respond to out-of-hospital cardiac arrest. We also will work with partners such as the British Heart Foundation to harness new technology and ensure the public and emergency services are able to rapidly locate this life saving equipment in an emergency. More effective mapping of data on incidence will help direct community initiatives to areas where they are most needed, with the British Heart Foundation's national Outcomes Registry allowing us to track survival rates and target unwarranted variation.

CASE STUDY:

CPR and GoodSAM

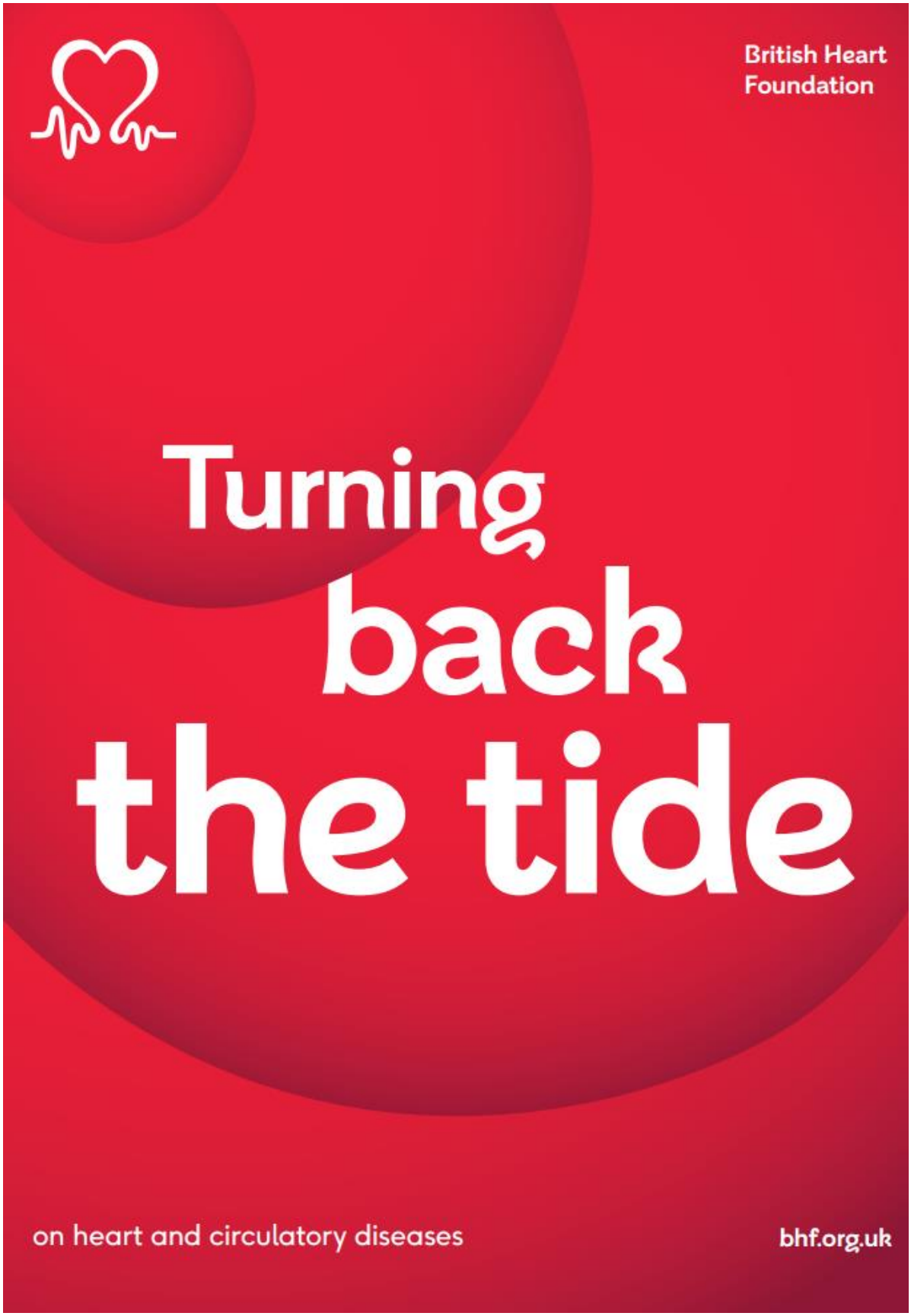
Apps and mobile technology are increasingly helping people to play a role in their own care and that of others. The GoodSAM app platform allows members of the public who can deliver basic life support (CPR) and use a defibrillator to receive alerts from anyone in their local area who needs urgent assistance. It integrates with ambulance dispatch systems and also features a crowdsourced map of defibrillators – including those in vehicles. The platform now has over 19,000 volunteers and partnerships with 80 organisations, including many NHS ambulance trusts. This is being supported to scale nationwide.

3.72. **Cardiac rehabilitation is an intervention recommended by NICE which can save lives, improve quality of life and reduce hospital readmissions[121].** Access to and uptake of cardiac rehabilitation services varies across England, and only 62,822 patients (52%) of the 121,500 eligible patients per year take up offers of cardiac rehabilitation[122]. Scaling up and improving marketing of cardiac rehabilitation to be amongst the best in Europe will prevent up to 23,000 premature deaths and 50,000 acute admissions over 10 years.

Milestones for cardiovascular disease

- **The NHS will help prevent up to 150,000 heart attacks, strokes and dementia cases over the next 10 years.**
- **We will work with our partners to improve community first response and build defibrillator networks to improve survival from out of hospital cardiac arrest.**
- **By 2028 the proportion of patients accessing cardiac rehabilitation will be amongst the best in Europe, with up to 85% of those eligible accessing care.**

Appendix 1.3: Excerpt of the British Heart Foundation Turning Back the Tide (British Heart Foudation, 2018)



4. Reimagine rehabilitation services

People recovering from a heart or circulatory event should be offered the support to help them live healthier, more active lives, protect against further harmful events and improve their quality of life.

Such services are proven to reduce hospital readmissions, and deliver better outcomes as well as value for money.[23] But only just over half of those eligible take up these services.[24] This compares poorly to some other countries in Europe where figures are as high as 90%.[25] And we know uptake is particularly low among certain groups.

Achieving an uptake rate for cardiac rehabilitation of 85% in England could lead to nearly 20,000 fewer deaths and nearly 50,000 fewer hospital admissions over the next ten years, as well as saving tens of millions of pounds in future care costs.[26]

But to do this we need a new offer, based around the person not the institution.

Personalised recovery services

Most cardiac rehabilitation is group-based and undertaken in a hospital setting. We know that certain groups (women, socially deprived communities, people from black and minority ethnic (BAME) communities, and people with heart failure) are less likely to take up services of this kind. An expansion of new models of delivery including digitally supported, home-based and more personalised 'menu-based' approaches could help tackle this problem.

What's more, rehabilitation services for cardiac, respiratory and stroke patients are separately delivered. Yet there are considerable synergies, and many patients have more than one of these conditions.

We should explore more joined up models like the 'breathlessness rehabilitation service' being trialled in Leicester.[27] Common themes such as psychological support, return to work support and lifestyle adjustments could be developed into a more accessible recovery programme across a broader set of conditions.

Innovation in digital recovery programmes

Activate Your Heart, University Hospitals of Leicester NHS Trust
Traditional cardiac rehabilitation is based on structured, group-based programmes, usually set in hospitals and leisure centres. Many patients are not accessing these services, despite evidence demonstrating their benefits.

Activate Your Heart is an interactive web-based cardiac rehabilitation service being trialled with 250 patients in Scotland. The programme offers 24/7 access to classes through patients' computers or mobile devices, cutting out the need to travel to existing sites.[28]

An evaluation of the programme in 2016 found that although recruitment could be challenging, for some patients it provides an effective option.[29] A further study observed important improvements in exercise capacity, quality of life and dietary habits in participants.[30]

23 Cardiac rehabilitation BMJ 2015; 351.
24 NACR Annual Statistical Report 2017.
25 European Society of Cardiology, various country reports.
26 Hinde, S., Bojke, L., Harrison, A., and Doherty, P. (2018) Improving Cardiac Rehabilitation Uptake: Potential health gains by socioeconomic status. Submitted for publication.
27 Chartered Society of Physiotherapy press release (2018) about University Hospitals of Leicester NHS Trust breathlessness rehabilitation service.
28 Activate Your Heart, University Hospitals of Leicester NHS Trust.
29 Evaluation of Web based Cardiac Rehabilitation (18-month trial using 'Activate Your Heart'), in Scotland, 2016.
30 Evaluating the Interactive Web-Based Program, Activate Your Heart, for Cardiac Rehabilitation Patients: A Pilot Study. Journal of Medical Internet Research, 2014.

Appendix 1.4: European Journal of Preventive Cardiology (EJPC) editorial by Halasz and Piepoli

European Journal of Preventive Cardiology

ESC European Society of Cardiology

Editor's presentation

Focus on cardiovascular rehabilitation and exercise training

European Journal of Preventive Cardiology
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SAGE

Geza Halasz[1] and Massimo F Piepoli[1,2]

The benefits gained from exercise-based cardiac rehabilitation programmes are evidence-based and widely recognized.[1,2] Furthermore, cardiac rehabilitation is a cost-effective therapy, proven to reduce premature cardiovascular and all-cause mortality and to improve health-related quality of life.[3] However, its implementation in clinical practice is still very poor.[4]

In this focus issue of the journal, some of the controversial points related to clinical implementation of cardiac rehabilitation are discussed in original research studies.

Focus on exercise training modalities

Non-linear is not superior to linear aerobic training periodization in coronary heart disease patients

The existing models of exercise prescription on cardiac rehabilitation focus mainly on aerobic exercises, with a progressive adaptation of the intensity and duration according to the patient's capacity and preference.[5] Traditional periodization, proposed in the guidelines for coronary artery disease (CAD) patients, also referred to as linear periodization, typically begins with low exercise intensity and short duration and focuses on a gradual increase in both of these parameters. However, linear periodization could potentially lead to fatigue and overreaching. To mitigate this risk, various forms of non-linear periodization (NLP), characterized by a more frequent manipulation of the training load, were used mainly in athletes.

Here, Boidin et al. compared linear periodization versus NLP, blindly randomized, in a 12-week supervised exercise programme on the cardiopulmonary exercise response in patients with CAD.[6] All patients completed cardiopulmonary exercise testing (CPET): peak oxygen uptake (peak VO_2), O_2 uptake, efficiency slope, ventilatory efficiency slope, VO_2 at the first and second ventilatory thresholds, and oxygen pulse (O_2 pulse) were measured. In short, the authors showed that after three months of aerobic exercise training both protocols similarly improved peak VO_2, peak ventilation, O_2 pulse and oxygen uptake efficiency slope. This finding confirmed that more variation (NLP), as suggested by some authors, is not necessary for greater cardiopulmonary and haemodynamic adaptations.

High-intensity interval training is superior to moderate continuous training in heart failure with preserved ejection fraction

Despite the well-known benefits of exercise-based cardiac rehabilitation, the most efficient modality and intensity are still under discussion. Traditional exercise prescription includes moderate continuous aerobic exercise training; but since the recommendation of the American Heart Association in 2007, a growing interest has emerged in high-intensity interval training (HITT). Data from meta-analyses are conflicting with randomized controlled trials regarding the benefit in peak VO_2 gain and exercise capacity. However, the majority of these studies have focused their attention on patients with heart failure with reduced ejection fraction (HFrEF) while limited data exist regarding the benefit and safety of this training in patients with heart failure with preserved ejection fraction (HFpEF).

In this issue of the journal, Donelli da Silveira et al., studying 19 patients with HFpEF, showed that HIIT induces a significantly higher increase of aerobic capacity compared with moderate continuous training while no differences were found in ventilatory efficiency and other CPET measures.[7] Although this trial was small and non-controlled, its major strength was the protocol adherence of the study population: in fact over 80% of the training sessions were performed at the prescribed intensity, which is a key factor for effective and beneficial effect of exercise training.

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Cardiac rehabilitation is effective also in patients treated according to contemporary evidence-based therapy

In 2016 The Cardiac Rehabilitation Outcome Study (CROS) was the first review and meta-analysis evaluating the prognostic effect of structured and multicomponent cardiac rehabilitation exclusively in the era of statins and early interventional revascularization for acute coronary syndrome (ACS). It confirmed the beneficial effect of cardiac rehabilitation on total mortality after ACS and after coronary artery by-pass graft (CABG) intervention also on top of the current best medical practice and interventions.[8]

Another important finding of the CROS study was that it became evident that an effective cardiac rehabilitation should be delivered according with minimal requirements (well described in a recent position paper from the Italian Association for Cardiovascular Prevention, Rehabilitation and Epidemiology),[9] the lack of which may explain in part the conflicting and negative findings of several studies and meta-analyses. The importance of quality of intervention and the need of meeting these minimal requirements has been here addressed in the CROS database by Salzwedel et al., with a focus on the volume and intensity of exercise sessions and treatment of cardiovascular risk factors during cardiac rehabilitation.[10] In brief, the authors confirmed the effectiveness of cardiac rehabilitation after ACS or CABG in reducing total mortality when delivered to agreed recognized standards, including an individually adapted and supervised exercise training and a rigorous treatment of all individual cardiovascular risk factors.

Challenging population in cardiac rehabilitation: elderly

Functional capacity following a cardiovascular event is a strong independent predictor of mortality even in elderly patients enrolled in CRP after an episode of heart failure decompensation or in cancer patients.[11,12] However, although the elderly represent an increasing proportion of cardiac patients, cardiac rehabilitation is significantly underused in this population.[13,14] To fulfil these research gaps, three studies are here presented.

EU-CaRE multi-centre observational study

The first two studies relate to the European Cardiac Rehabilitation in the Elderly (EU-CaRE) project, a European research project focusing on the effectiveness and sustainability of cardiac rehabilitation programmes in the elderly (65 years or above) enrolled in eight centres across Western Europe. Consecutive patients with CAD and heart valve replacement were included.

In the first report,[15] the authors compared the short- and long-term effects of cardiac rehabilitation programmes on exercise capacity, risk factor control and quality of life in 1633 elderly. Patients were assessed at baseline before commencing cardiac rehabilitation, after completing the cardiac rehabilitation programme and at one-year follow-up. In brief, patients undergoing surgical interventions had lower peak VO^2 at baseline and a greater increase during follow-up than CAD patients undergoing percutaneous or no revascularization. At multivariable analysis earlier cardiac rehabilitation uptake was associated with greater improvements in peak VO_2. However, despite a significant decline of patients with uncontrolled risk factors, 40.1% of CAD patients still had three or more risk factors not at target after one year.

In the second report,[16] the same group of researchers aimed to assess the predictors of pre-rehabilitation exercise capacity in the elderly patients. The most important predictors of peak VO_2 among 1282 patients were age, CABG surgery, valve surgery, HFrEF, nephropathy and peripheral artery disease. Another important finding of this study was that haemoglobin was strongly associated with peak VO_2, confirming once again the importance of the routine measurement of haemoglobin when studying exercise capacity.

Predictors of the benefit of exercise-based programme

Bierbauer et al. reported that older patients improved their exercise capacity to a lesser degree than did younger patients; however, significant improvements were shown in octogenarian patients.[17] Furthermore, clinically relevant improvements in exercise capacity were independent of patients' age and sex. These results indicated that elderly patients of both genders should be strongly encouraged to participate in cardiac rehabilitation. Furthermore, cardiac rehabilitation programmes should be tailored to these patients with a special focus on brain health and social vulnerability factors.

Quantifying the impact of delayed delivery of cardiac rehabilitation on patients' health

Despite current guidance stating that patients should be seen early, by the outpatient cardiac rehabilitation

team, and start cardiac rehabilitation within four weeks of referral, evidence showed that there is a discrepancy between recommended practice and 'real life'. To date, no studies have explored the impact of delayed start on long-term patient health and cost implication of such a delay. Here Hinde and co-authors conducted logistic regression analyses exploring the impact of a delay on uptake and completion of cardiac rehabilitation using the British Heart Foundation National Audit of Cardiac Rehabilitation database.[18] A 'timely cardiac rehabilitation' was defined as the start of cardiac rehabilitation within 28 days of referral for ACS and/or percutaneous coronary intervention and 42 days for CABG patients. The results of this study demonstrated that the failure of patients in England to start cardiac rehabilitation within the recommended timeframe resulted in a 15.3% reduction in uptake, and 7.4% in completion with an average lifetime loss of 0.08 years of life expectancy per person. To alleviate the delay an additional £12.3m could be paid by the English National Health Service.

Long-term follow-up with a smartphone application improves exercise capacity post cardiac rehabilitation

Benefits gained from cardiac rehabilitation are likely lost among individuals who discontinue their regular exercise routines and healthy habits. Adherence to healthy behaviours adopted during cardiac rehabilitation is challenging for many patients, who are often insufficiently prepared for independent exercise in their home environment. One potential approach is to use mobile health interventions, such as smartphone applications (apps), as a follow-up tool to promote adherence to lifestyle advice. The benefit of an app is that it provides real-time feedback between health staff and patients and offers an opportunity to monitor patients' health from anywhere at any time. To date several studies have demonstrated the efficacy of the use of wearable physical activity monitors (including apps) in improving exercise capacity post-cardiac rehabilitation but with a short follow-up ranging from 12 weeks to six months. To fill this gap, here Lunde et al. examined the effect of a mobile-app based follow-up for 12 months on functional capacity and exercise behaviours in patients completing cardiac rehabilitation.[19] In this study 113 patients were randomly allocated to an intervention group (IG) receiving follow-up enabled with an app and a control group (CG) receiving usual care. The major finding of the paper was a statistically significant improvement in peak VO_2 as well as in exercise performance, exercise habits and self-perceived goal achievement in the IG compared with the CG.

Declaration of conflicting interests

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Appendix 2. Published Papers

This appendix contains the five published studies which accompany this thesis and are presented in the following order:

Paper 1: Hinde, S., Bojke, L., Horsfield, L. & Richardson, G. A. The relevant perspective of economic evaluations informing local decision makers: an exploration in weight loss services. 2019, Applied Health Economics and Health Policy. doi: 10.1007/s40258-019-00538-8.

Paper 2: Hinde, S., Howdon, D., Lomas, J., & Franklin, M. Health Inequalities: To What Extent are Decision-Makers and Economic Evaluations on the Same Page? An English Case Study. 2022, Applied Health Economics and Health Policy. doi: 10.1007/s40258-022-00739-8.

Paper 3: Hinde, S., Bojke, L., Harrison, A. S. & Doherty, P. J. Improving Cardiac Rehabilitation Uptake: Potential health gains by socioeconomic status. 2019, European Journal of Preventative Cardiology. doi: 10.1177/2047487319848533.

Paper 4: Hinde, S., Bojke, L., Harrison, A. S. & Doherty, P. J. Quantifying the impact of delayed delivery of cardiac rehabilitation on patients' health. 2020, European Journal of Preventative Cardiology. doi: 10.1177/2047487320912625.

Paper 5: Hinde, S., Harrison, A., Bojke, L. & Doherty, P. Achieving Cardiac Rehabilitation uptake targets: what is the value case for commissioners? A UK case-study. 2023, International Journal of Cardiology, doi: https://doi.org/10.1016/j.ijcard.2023.03.041.

Applied Health Economics and Health Policy
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CURRENT OPINION

The Relevant Perspective of Economic Evaluations Informing Local Decision Makers: An Exploration in Weight Loss Services

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Abstract

Since 2013, obesity services in the UK National Health Service (NHS) have focused on a tiered structure, with tiers 3 (specialist weight management services) and 4 (primarily bariatric surgery) commissioned by Clinical Commissioning Groups (CCGs) and widely reported as cost effective and recommended by national guidelines. However, CCGs have been reluctant to fully conform to the guidance. We explore how the different evaluative perspective of those generating evidence from local decision makers has contributed to this failure of the CCGs to provide services considered cost effective. We explore four elements where the conventional economic evaluation framework, as applied by the National Institute for Health and Care Excellence (NICE), differ from the reality faced by local decision makers: the cost-effectiveness threshold, the implications of decision uncertainty and budgetary excess, the valuation of future costs and outcomes, and the scope of included costs. We argue that the failure of the conventional framework to reflect the reality faced by local decision makers is rendering much of the existing literature and guidance inappropriate to the key commissioners. Our analysis demonstrates that it is not reasonable to assume that the framework of economic evaluation used to inform national guidance applies to local decision makers, such as in the commissioning of weight loss services. This failure is likely to apply to the majority of cases where evidence is generated to inform national decision makers but commissioning is at a local level.

Key Points for Decision Makers

Economic evaluation methodology has been developed extensively to focus on a national decision maker's perspective, failing to reflect the different reality faced by those commissioning at a local level.

We consider the areas where the conventional National Institute for Health and Care Excellence (NICE)-style framework does not reflect the local experience, highlighting the limited relevance of published research and national guidance at the point of commissioning.

Local decision makers must be careful in their adoption of national guidance and published recommendations without consideration of the relevance of the underlying perspective of the analysis. In turn, national guidance and research should better reflect the different focus of local decision makers.

1 Introduction

The shift in policy in the UK to a tiered treatment pathway in the management of obesity in 2013/2014 was intended to move commissioning away from disjointed and inconsistent provision towards a service able to address the obesity crisis [1, 2]. In 2013/2014, a National Health Service (NHS) England (then the NHS Commissioning Board) and Public Health England Working Group defined the four-tier system of weight loss interventions that currently operates in England, outlining who should hold the commissioning responsibility for each tier [1, 2]. Prior to that, the commissioning of weight management programmes ('tier 3') was limited, and bariatric surgery ('tier 4') was primarily funded on a case-by-case basis [3]. At the Working Group's recommendation, the commission of tier 3 services was allocated to Clinical Commissioning Groups (CCGs; with tiers 1 and 2 residing with local authorities as the local government organisation responsible for a

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broader range of public service provision, including public health provision, rather than the CCGs whose primary aim is NHS provision). Tier 4 commissioning was to be transferred from the NHS Commissioning Board to CCGs in 2016 [4], with the expectation that this would occur once tier 3 services were commissioned and operating effectively, but in many cases this did not occur until 2017, with limited requirement for tier 3 provision in place.

However, the shift in policy has arguably had limited impact, with rates of morbid obesity [5] and type 2 diabetes [6] continuing to increase in the UK. Furthermore, rates of surgery have stayed stagnant or decreased in recent years [7], with CCGs being accused of unfairly restricting surgery [8–10], and have struggled with the commissioning of effective tier 3 programmes [11], despite extensive commissioning guidance [4].

In this paper, we explore the role of asymmetric perspectives between the CCG and the evidence generated to inform the clinical and cost-effective commissioning of tier 3 and 4 services from an economic evaluation viewpoint. We consider a number of factors that have contributed to the uninformative nature of much of the available economic evidence, primarily resulting from failures on the part of those generating evidence to make recommendations that reflect the realities faced by local commissioners. These issues are likely to occur throughout healthcare decision making when evidence generation and guidance is national but the commissioning and decision making is local. All challenges were identified with the support of the co-author (LH) from the Vale of York CCG who have been seeking to commission a tier 3 and 4 pathway.

2 What Does the Current Evidence Say on the Cost Effectiveness of Tiers 3 and 4?

The original NHS Commissioning Board report in 2013 provided the basis for the categorisation of weight loss services into the tiered system, defining tier 3 as "a primary/community care-based multidisciplinary team (MDT) to provide an intensive level of input to patients", and tier 4 as "specialised complex obesity services (including bariatric surgery)" [1]. The report briefly considered the evidence around the cost effectiveness of the different service options, providing reference to some studies on tier 4 services; however, at that time, nothing was published that was deemed relevant to tier 3 service provision.

Since the initiation of the tiered service in 2013/2014, there have been a number of publications regarding the effectiveness and cost effectiveness of tier 3 and 4 services, the majority of which arrive at the same conclusion, i.e. that little is known about the cost effectiveness of tier 3 services, but that tier 4 is likely to be cost effective under conventional evaluative methodology. The significant statement in the Commissioning Board report [1] that the costs of tier 4 are recouped in the short to medium term has however been discredited, as discussed below.

Both National Institute for Health and Care Excellence (NICE) clinical guidance documents produced in that time [18, 19] briefly considered the published evidence, concluding that tier 3 is an effective service for those who have failed to adequately manage their weight through tier 2 services, and tier 4 is cost effective for those with a body mass index (BMI) ≥ 40 or ≥ 35 with significant weight-related comorbidities and for whom all other non-surgical interventions have failed to achieve or maintain weight loss.

More widely, many studies of bariatric surgery have been published, of note Gulliford et al. [16] conducted a large cohort study and cost-effectiveness analysis of bariatric surgery, where all bariatric surgery patients were assumed to also receive tier 3. They found bariatric surgery to be more expensive over the life of the patients, but cost effective, with an incremental cost-effectiveness ratio (ICER) of £7129 per quality-adjusted life-year (QALY), well below conventionally applied thresholds. They further found that there was no group of patients where providing tier 4 resulted in cost savings to the NHS.

More recently, Avenell et al. [17] conducted a mixed-method analysis of bariatric surgery and lifestyle interventions for those with a BMI ≥ 35 kg/m^2. The authors found that general weight management programmes, including tier 3-type services, were cost effective compared with usual care (£1541/QALY), and that bariatric surgery was also cost effective over a 30-year time horizon (£10,126/QALY). Similar to the study by Gulliford et al., they found no evidence for long-term cost savings of bariatric surgery, however they did not conduct subgroup analysis.

Specific to tier 3, both Brown et al. [20] and Alkharaiji et al. [21] conducted systematic reviews, finding that there was reasonable evidence that tier 3-type services result in clinically meaningful weight loss. However, the follow-up period of the majority of studies was very short, with almost all being under 1 year, making any conclusions about the long-term impact and cost effectiveness highly uncertain.

3 Why has the Published Evidence Failed to Translate to Commissioning?

As the commissioners and budget holders of approximately two-thirds of the NHS budget, it is vitally important that CCGs are implementing the best available evidence, which in turn must reflect their needs and commissioning reality. While it is challenging to quantify their compliance with the evidence base, previous authors have argued that there has

been limited commissioning of tier 3 services in line with national guidance [22], and that this was due to structural barriers, including a lack of trained staff, financial barriers to new service development, and workload constraints. Others have argued that the tiering system itself is at fault [23]. While these factors are likely to play a role in the tribulations of the services, we consider the challenge to be even more fundamental, that much of the evidence generated extolling the cost effectiveness of tier 3 and 4 services is largely inappropriate for commissioning CCGs. In this section, we explore how fundamental differences in the perspective faced by the local commissioners from the national frameworks, applied to conduct cost-effectiveness analysis in the UK, have contributed to this poor level of relevance.

In any evaluation of an intervention, such as the tier 3 and 4 pathways, perspective plays a key role. If treatment strategies are to be considered and compared in terms of their associated costs and outcomes, the question of whose costs and outcomes are considered relevant, and how to measure them, must be addressed [24]. For the evaluation and commissioning of health policy to be efficient, the perspectives of the evaluators and commissioners must be aligned. Failure to do so risks inconsistent conclusions, where clinical guidance does not align with commissioning reality, and therefore inefficient outcomes for patients.

The perspective used by NICE in their considerations of cost effectiveness are well-publicised [25], and have become the default for many NHS-based economic evaluations [24], including those referenced in the previous section; broadly consisting of the estimation of lifetime costs to the NHS and Personal Social Services (PSS), and health outcomes of patients (measured as QALYs), both discounted at a rate of 3.5% per year to weigh current against future outcomes. Costs and outcomes that fall outside of this perspective are not included in the headline estimation of cost effectiveness. Any gains in health that result in an additional total cost to the NHS are considered against a cost-effectiveness decision rule 'threshold', whereby gains that cost less than £20,000 per additional QALY gained are considered cost effective.

However, the NICE perspective is based on a national decision maker deliberating on marginal changes to a large budget, who is able to offset long-term population health gains against upfront costs, and to whom the implications of failing to balance finances are very different than a local decision maker, such as CCGs. Furthermore, while the cost-effectiveness analysis is meant as an element in deliberations, it arguably plays the major role in NICE recommendations. In contrast, local decision makers are faced with short-term financial constraints, a diverse decision-making set of criteria, and very real repercussions should investment decisions prove inappropriate.

We consider there to be four areas where the NICE perspective fails to reflect the challenges faced by CCGs, and have contributed to the reduced relevance of the published literature to them as commissioners. We explore each in turn below.

3.1 The Cost-Effectiveness Threshold

The simplification of economic evaluations to a binary statement about expected cost effectiveness relative to the threshold is potentially misleading for local decision makers for two reasons. First, recent research suggests that the range used by NICE (£20,000–£30,000/QALY) is a significant overestimate of the true marginal productivity of the NHS, indicating a figure closer to £13,000/QALY [26]. Claxton et al. also argued that the true value is likely to vary significantly at a local level and that the implications of overestimating the threshold are much worse than underestimating it [26].

Furthermore, it has been argued that comparing the ICER to a fixed threshold is insufficient to determine cost effectiveness as consideration must also be made of the affordability of the intervention [27, 28]. This is especially evident for interventions with significant short-term budget impacts, such as the use of sofosbuvir to treat hepatitis C [29, 30], which was estimated to cost up to £70,000 for each of the 160,000 sufferers in England [31]. Clearly this also applies to bariatric surgery, with an estimated 1.38 million adults [5] fulfilling NICE's BMI ≥ 40 criteria, and the cost of bariatric surgery approximately £9000 per person in the first year [16]. A crude interpretation of the published research suggests that the large impact of such an intervention can be accounted for by reducing the threshold against which the ICER is compared, in certain cases below £12,000/QALY [27].

3.2 The Impact of Exceeding Budgets and Decision Uncertainty

At a national level, the implications of exceeding a budget, and of uncertainty in the impact of a new service on this budget, are undeniably different than at a local level. Taken as a simple comparison between an NICE decision and a commissioning CCG, there are few negative implications to NICE (or a publishing author) should a guidance recommendation turn out to be incorrect at a later date as they are an arm's length from commissioning decisions and funding, and subject to only minimal retrospective assessment.

In contrast, a CCG commissioning an intervention that results in an unexpected budgetary overspend face potentially serious implications such as financial special measures. Not only does a potential overspend deter the commissioning of interventions with high upfront costs, but it also discourages investment in interventions associated with

an uncertain cost impact as the implications of success and failure of the intervention are not symmetric. This implies that a CCG may be less likely to take on an investment where there is uncertainty regarding its cost effectiveness, despite a favourable point estimate.

Both of these issues are evident in tier 3 and 4 commissioning, where not only are the additional costs front heavy, with weight loss programmes and surgery implying a short-term cost but aiming to reduce long-term expenditure, but there remains a dearth of evidence on the long-term resource use implications of either, making the expected results highly uncertain.

3.3 The Valuation of Future Costs and Benefits

Under the NICE framework of evaluation, a lifetime perspective is recommended [25], with both costs and outcomes discounted at a rate of 3.5% per year. The appropriate discount rate has been argued to depend on several factors, including the opportunity cost of expenditure today, time preference, catastrophic risk, consumption growth, and the tradability of money and health [32].

Given the high upfront cost of many obesity interventions, but health gains in the long term, the discount rate applied has a significant role. While there is published literature exploring the merits of discounting and the most suitable value to apply [32, 33], there has been little consideration of the relevance of the NICE discounting approach to local decision makers. A different rate may be appropriate for local decision makers as they are likely to be faced with different decision criteria than a national decision maker, across the factors that impact the appropriate discount rate. For example, the opportunity cost of budget expenditure may differ as they may not have the same access to investment portfolios as national budget holders, budgetary and policy cycles may play a larger role, and they have more restricted budgetary independence. Furthermore, due to their proximity to patients, there may be an argument for their decisions to more closely reflect individual time preferences, known to differ from the societal time preferences that are used to inform the NICE approach [33].

Currently, it is not possible to estimate the direction of the difference in the discount rate between national and local decision makers as factors such as the availability of investment options may reduce the appropriate rate, while the short-term nature of budget cycles may increase it. Other factors, such as the reflection of individual time preferences and budgetary dependence, may imply that the assumption of exponential discounting that NICE typically applies is not appropriate, and that other approaches, such as hyperbolic or stepped discounting, are more so.

3.4 Scope of Costs Included

Finally, it is important to consider the relevance of the costs included in the analyses. Under NICE's framework, all costs to the NHS and Personal Social Services are considered relevant, with all other costs falling on public health budgets, patients, or their carers not included. However, the budgetary reality faced by CCGs as the commissioners of tier 3 and 4 services are potentially more complex. In addition to the discussion above regarding the nature of their budgetary independence, local decision makers' budgetary responsibility often differs from the NICE framework.

Two examples demonstrate this. First, it is only until recently that CCGs and NHS Trusts (the providers of services such as secondary and mental health) have started to agree on aligned incentive contracts (AICs), largely as a means of progressing towards integrated care services [34]. Without AICs, Trusts have been primarily concerned with maximising hospital income rather than system-wide budgets, implying the impact of Trust interventions on primary care budgets may not carry much weight.

Second, public health interventions such as the National Health Checks are commissioned by Local Authorities, not CCGs. As the potential future cost savings associated with such public health interventions fall on CCG budgets through healthcare resource use, and not local authority budgets, there is only limited incentive for commissions of such services to fully implement the interventions [35]. The budgetary challenges make the assumption that all NHS and PSS costs are relevant, and no others, potentially misrepresentative of the true local decision maker's perspective.

4 Discussion

The tiered approach to weight loss care in the NHS was designed to provide an effective and cost-effective framework in keeping with the shift to decentralised commissioning that resulted from the 2012 Health and Social Care Act. However, there has been limited commissioning of tier 3 and 4 services by CCGs and significant variation in what is offered [9–11, 20, 22]. This is in spite of repeated economic evaluations demonstrating that, using the NICE framework for cost effectiveness, bariatric surgery is cost effective in almost all obese patient groups [16, 17], and tier 3 services appear likely to be similarly cost effective [20, 21].

We believe that one of the key reasons for the failure of the policy to be routinely commissioned is the incompatibility of the available evidence to the commissioning CCGs; however, there are many other factors at play, including continued risks of weight stigma impacting care provision [36]. In this manuscript we have argued that the failure of the existing evidence demonstrating the cost effectiveness of the

services to reflect a local decision maker perspective has been a key barrier to its uptake. We have highlighted how failure in the national guidance and published research to appropriately consider the relevance of factors such as the cost-effectiveness threshold and the impact of uncertainty and large budgetary changes has contributed to the evidence relating to the cost effectiveness of the interventions being inapplicable to CCGs. However, if cost-effectiveness evaluations were to become completely responsive to local conditions, there would be the risk of developing a 'postcode lottery' of service provision that national decision makers such as NICE are designed to alleviate.

However, we recognise that the challenges of knowledge translation between national and local perspectives are restricted to neither economic evaluation nor weight management services. Previous research has identified the need for research, in general, to better reflect the true nature of decision making [12–14], and the health and economic value of implementing national decisions at a local level [15]; however, the relevance of the core principles underpinning the determination of cost effectiveness have been largely overlooked.

While the challenges of translating the broader national and international evidence base to local decision makers have been well explored in the literature [12–14], this debate has overlooked the impact of the asymmetries present on the core principles of economic evaluation and the question of cost effectiveness. While many of the same factors are at play as in the wider topic of knowledge transfer, it is our opinion that the additional knowledge gap present in the interpretation of economic evaluation literature has compounded the impact of this asymmetry.

5 Conclusion

As in many developed nations, the UK has spent over a decade trying to address the increasing rate of obesity in an attempt to curtail the significant long-term health implications associated with excess weight. Political desires to decentralise commissioning and clarify treatment pathways led to the recommendation of a locally commissioned tiered weight loss pathway, allowing the progression of patients through levels of increasing intensity of care, informed by the best evidence on effectiveness and cost effectiveness published at the time. However, the available guidance has failed to reflect the fundamental fact that the conventional approach to defining the most cost-effective pathway at a national level does not necessarily translate to local decision makers such as the CCGs. As a result, policies that are deemed to be cost effective have come up against repeated reluctance from local commissioners, resulting in accusations of CCGs failing their responsibility to patients. In this article, we have highlighted several reasons why this situation has occurred, and how the current divide between evidence generation and commissioning in areas such as this are to blame.

It is important that both research and national guidance considering the cost effectiveness of any intervention considers the appropriateness of the economic evaluation framework to the setting in which it is applied, not just in weight loss but all interventions. The routine use of the NICE framework risks recommendations being inappropriate to the respective commissioners, and the funding of policies that are cost effective from a national perspective, but not at a local level under the current decentralised system. However, there currently exists no equivalent framework directly structured around local decision makers' perspectives, with CCGs and local authorities primarily informed by national guidance published by NICE. Whether commissioning responsibilities and budgetary controls should be reorganised such that the perspectives of the two groups align, or economic evaluations should be conducted to reflect the realities faced by the relevant commissioner, requires further debate and research.

Author contributions SH, LB and GR conceived the idea for the manuscript, and LH provided input regarding the accuracy of the descriptions of the CCG and other local decision-maker processes. All authors read and approved the final manuscript.

Compliance with Ethical Standards

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Conflict of interest Sebastian Hinde, Louise Horsfield, Laura Bojke and Gerry Richardson have no conflicts to declare.

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CURRENT OPINION

Health Inequalities: To What Extent are Decision-Makers and Economic Evaluations on the Same Page? An English Case Study

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Abstract

Economic evaluations have increasingly sought to understand how funding decisions within care sectors impact health inequalities. However, there is a disconnect between the methods used by researchers (e.g., within universities) and analysts (e.g., within publicly funded commissioning agencies), compared to evidence needs of decision makers in regard to how health inequalities are accounted for and presented. Our objective is to explore how health inequality is defined and quantified in different contexts. We focus on how specific approaches have developed, what similarities and differences have emerged, and consider how disconnects can be bridged. We explore existing methodological research regarding the incorporation of inequality considerations into economic evaluation in order to understand current best practice. In parallel, we explore how localised decision makers incorporate inequality considerations into their commissioning processes. We use the English care setting as a case study, from which we make inference as how local commissioning has evolved internationally. We summarise the recent development of distributional cost-effectiveness analysis in the economic evaluation literature: a method that makes explicit the trade-off between efficiency and equity. In the parallel decision-making setting, while the alleviation of health inequality is regularly the focus of remits, few details have been formalised regarding its definition or quantification. While data development has facilitated the reporting and comparison of metrics of inequality to inform commissioning decisions, these tend to focus on measures of care utilisation and behaviour rather than measures of health. While both researchers and publicly funded commissioning agencies are increasingly putting the identification of health inequalities at the core of their actions, little consideration has been given to ensuring that they are approaching the problem in a consistent way. The extent to which researchers and commissioning agencies can collaborate on best practice has important implications for how successful policy is in addressing health inequalities.

Key Points for Decision Makers

Extensive methodological developments have occurred regarding the incorporation of equality considerations into cost-effectiveness analysis.

The approach has not been developed with the needs or reality (neither political or data) of the local decision makers who control the majority of health and social care funding in England.

This manuscript interrogates the differences between the two disciplines and seeks to identify a path forward.

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1 Introduction

The burden of inequalities in health are as internationally ubiquitous as they are nebulous in scope and definition. From a global perspective, inequality in health and access to care underpin the majority of the World Health Organization's (WHO) Sustainable Development Goals [1]. While the 17 targets set out in the WHO's goal to 'ensure healthy lives and promote well-being for all at all ages' would be considered a minimum standard of care in most high-income countries, they grapple with health inequality nonetheless, with the achievement of this minimum standard not a guarantee of health equity within a nation. While every nation has a unique history of how their healthcare provision has emerged over time, and the scale and type of health inequality within that country varying, pertinent health inequality challenges exist in all settings.

Central to the attempts by decision makers around the world to reduce health inequalities has been the question of where the level of action should lie between national and local agencies, how associated agencies should function, and how to maximise total health while minimising inequality [2]. The underlying trade-off being characterised as one where centralised agencies may be able to achieve greater efficiency by reducing replication of roles, but a decentralised one may be able to be more attuned and responsive to local needs [3].

In parallel to its public policy relevance, there has been a recent expansion in health and care research attempts to incorporate the impact of commissioning decisions on health inequality alongside the traditional focus of total population health [4]. This development has been motivated by two complementary factors: firstly, the recognition that existing, internationally applied, methods of cost-effectiveness analysis fail to facilitate the consistent consideration of health maximisation relative to inequality minimisation [5]. Second, the observation that assessment approaches taken by national health technology assessment agencies, such as the National Institute for Health and Care Excellence (NICE) in England, resulted in recommendations which implied overall population health improvement, but at the detriment of worsening health inequality [6].

Our aim is to understand the methodological research that has been conducted for incorporating health inequality considerations into economic evaluations (i.e., the 'researcher-led approach'), and to explore how this compares to existing approaches that have evolved within publicly funded commissioning agencies (i.e., the 'commissioner-led approach', where 'commissioner' is used in a broad sense to encompass the associated analysts and decision makers).

First, we explore the current state of play on how researcher-led approaches have sought to account for inequality alongside the traditional aim to maximise population health [7]. Second, we consider the commissioner-led approach: specifically, how local commissioners have interpreted and acted on inequalities. To facilitate a clear understanding of how these approaches compare we conducted a detailed exploration of the English setting, later reflecting on the generalisability to other national settings. Finally, we deliberate on how well the two approaches integrate, data available or required to facilitate the approaches, and potential steps to minimise any disconnect when it comes to quantifying and tackling health inequalities. This research was stimulated and informed by workshop discussions between researchers and commissioners as part of a project exploring the potential for "Unlocking data to inform public health policy and practice" [8].

2 Defining Inequality and the Context of Inequality in Health

For descriptive purposes, we define 'health inequality' as any difference in individual or group health profiles that can be quantified in a meaningful way, e.g., variation in care service use or access, healthcare needs, or their lived health experience. We consider inequality to have relevance both in terms of geographic variations (e.g., regional commissioning jurisdictions) and population sub-groups (e.g., ethnicities). For the purposes of this paper, we additionally consider health inequality to be relevant to both differences in the stock of health (outcomes such as life expectancy) and access to health care resulting from variations in supply (e.g., the number of GPs in an area), as discussed below this is consistent with the approach often taken in commissioning settings. While an interest in health inequalities is motivated by judgements that are inherently normative, we do not explore the issues regarding the normative or objective nature of inequality, which are explored elsewhere [9–11].

3 Setting the Scene: The English Context

In England, equal access to tax-funded healthcare was one of the founding principles of the National Health Service (NHS) during the 1940s [12, 13]. However, whilst this principle has been largely preserved for over 70 years [14], eliminating differences in population subgroups' health remains elusive. For example, there is a 7.6-year life expectancy gap between women, and 9.4 years for men, in the least and most deprived areas of England [15]. As is true to a varying extent internationally, health inequality in England persists despite a long-running objective of successive governments being its reduction, with a succession of national reports and strategies—the 1980 Black Report [16], the 1998 Acheson

Report [17], New Labour's Health Inequalities Strategy [18], the 2010 Marmot Review [19] and its 10-year reassessment [20]—on the topic.

In England, a plethora of commissioning and administrative structures have been created and re-created with inequality reduction routinely at the heart of their policy mandates in response to these national reports and other stimuli [21]. Related to the NHS, the current shift is towards Integrated Care Systems (ICS), with ICSs having 'improving outcomes and addressing inequalities' as a key tenet of their formation [22]. In comparison, Local Authorities (LAs) are responsible for commissioning publicly-funded social care and, since 2013, some public health services. We focus on local commissioners given that the majority of current and planned commissioning responsibility related to health in England can be attributed to LAs (e.g., City Councils), Clinical Commissioning Groups (CCGs), and (from 2022) ICSs. We provide brief details of the role of each in the English healthcare system in Sect. 5, but additional details are available elsewhere [23, 24].

4 The Researcher-Led Approach to Health Inequalities

One innovation developed and refined by health economists in recent decades has been the creation and application of a methodological framework with which to assess care interventions covering a diverse range of health-related factors (e.g., illness, acute and chronic conditions, adverse health events) using an incremental cost-effectiveness analysis (CEA) approach. In brief, this approach assesses competing interventions by their incremental impact on some measure of health-related outcome, most commonly quality-adjusted life-years (QALYs, a metric capturing both quality and quantity of life), relative to the incremental costs (usually only those borne by the care system), with the ratio of incremental costs and incremental QALYs being termed the incremental cost-effectiveness ratio (ICER). In a budget-constrained care system, this ICER is conventionally compared to some threshold value—representing the maximum ICER at which decision-makers will fund a new intervention—in order to assess cost-effectiveness. Where the aim is to ensure each individual decision increases population health, this threshold should represent the cost-effectiveness of existing interventions that are candidates for defunding in the case of acceptance of this new intervention [25]. However, in practice the threshold value often reflects a wider set of considerations than the cost-effectiveness of what may be defunded [26].

Fundamental to traditional CEA application is the notion that 'a QALY is a QALY is a QALY' [27]. This represents the idea that a QALY is equivalent, comparable, and transferable in the determination of cost-effectiveness irrespective of who gains or loses, with the primary aim being population health maximisation as measured by the QALY. However, this approach has been argued to ignore the trade-offs that are made between overall population health and health equality [28]. By overlooking such occurrences, including the opportunity cost of disinvestment falling inequitably and differential uptake of common healthcare interventions [29], CEA recommendations risk running contrary to the dual-aim of many healthcare decision makers [30]. This lack of explicit consideration of interventions' inequality impact occurs in many health technology assessment (HTA) processes internationally [31].

In the case of NICE in England, their current reference guide for conducting economic evaluations states: "An additional QALY has the same weight regardless of the other characteristics of the people receiving the health benefit" [32].[1] This is perhaps in conflict with their stated aim "to reduce health inequalities" [34], alongside an acknowledgement of the body's legal responsibilities in this regard, and a note that the institute "[takes] into account inequalities arising from socioeconomic factors and the circumstances of certain groups" [35]. While the extent to which any trade-off between equity and population health is currently considered in deliberations is at most limited, research has shown that HTA recommendations made by NICE have had quantifiable impacts on the distribution of health [36], with further research identifying that more deprived groups also bear more of the health loss burden when funding is redistributed [29]. However, in recent years there has been an increasing trend in research to explicitly reflect the trade-off between total health and inequality [4, 37].

In this section we briefly review some of the methods by which inequality has been considered in the researcher-led economic evaluation literature and explore some of the emerging methods in detail to determine their level of consistency with the commissioner-led approach.

4.1 Methods to Reflect Inequality Alongside Cost-Effectiveness

Analytical methods to account for inequality concerns alongside CEA can generally be grouped into equity impact

[1] Despite this statement, additional weight was previously given to QALYs gained subject to meeting 'end-of-life' criteria [33]. The recent methods review has seen a shift away from this approach to instead focusing on the level of severity of health burden of beneficiaries, which could, in principle, be consistent with the aim to reduce health inequalities—particularly if consideration is taken of the distribution of opportunity costs. In practice, this can be achieved by using a method that we discuss in the next section: distributional cost-effectiveness analysis (DCEA).

or equity weighting approaches [4]. Avanceña and Prosser's systematic review of CEAs incorporating equality considerations identified 54 studies, with most published since 2015. The majority were found to take an equity impact approach ($n = 46$), with five conducting both, and three equity weighting alone [4].

Equity impact analysis produces summaries of cost-effectiveness stratified by the sub-groups of interest, then reports the respective costs and health outcomes for each stratified group alongside the headline summaries of intervention cost-effectiveness for the full population. Although useful when demonstrating the potential subgroup's inequitable gains and losses, the approach does not incorporate inference of the acceptability of any health and inequality trade-off as no socially acceptable weighting is applied to the potentially competing outcomes.

In contrast, equity weighting methods explicitly incorporate differential QALY weighting, allowing for informative analysis as to any trade-off between total population health and inequality. Details of CEA methods incorporating equity weighting, often called distributional CEA (DCEA), and associated tutorials are published [38]. In brief, as with equity impact analysis, the approach involves CEA stratified by relevant subgroups, but with the additional step of allocating a set of weightings to the QALY impact by subgroup. This facilitates the estimation of incremental cost-effectiveness dependent on the weighting set applied to inequality impact versus total population gain. Inevitably the choice of weightings is a key challenge for DCEA as there is currently no routinely accepted set of weightings [28]. In practice, DCEA results are presented using a distribution of weights, so that society's aversion to inequality is directly compared against the total population QALY gains they would be willing to forgo to minimise inequality. In addition to the challenge of identifying an appropriate estimate of society's inequality aversion, there is currently no standard weighting approach; Avanceña and Prosser's review noted that eight identified equity weighting studies each took a different weighting approach [4].

Across both approaches, an additional challenge of incorporating equality concerns into CEA is determining how to categorise the groups of interest. Avanceña and Prosser found "at least 11 different equity criteria have been used" (p. 136), commonly stratified by socioeconomic status ($n = 28$) or race/ethnicity ($n = 16$) [4]. Distributional CEA tutorials recommend categorising by index of multiple deprivation (IMD) equity groups, although any grouping for which society's view of inequality aversion has been quantifiably weighted can be used. While this variation in group categorisation represents a challenge for cross-comparability, the flexibility to the decision maker's needs is an important benefit when incorporating equity. Distributional CEA does not seek to provide "an algorithmic approach to replace context-specific deliberation with a universal equity formula. Rather, it can be used as an input into context-specific deliberation by decision makers and stakeholders" (p. 119) [39].

In addition to the methods with which to implement the inclusion of inequality considerations, checklists to guide economic evaluations seeking to incorporate inequality considerations have been developed, e.g., the Equity Checklist for Health Technology Assessment [31].

5 The Meaning and Role of Inequality to Local Commissioners

Here we explore the definition and application of health inequality terminology using the setting of English local commissioning as a case study, exploring LAs', CCGs', and ICSs' mandated duty or obligation to consider or act upon inequalities in their commissioning decisions, their potential resources for quantifying their jurisdiction's inequality levels, each described alongside some examples for discussion purposes. Although we focus on English commissioners, the use of local commissioners to tackle regional health challenges, such as care access and inequality in health considerations, is common internationally, although these organisations may be named differently, with varying degrees of responsibility and geographic scope [2].

5.1 Legal Considerations: The 2010 Equalities Act

Underpinning all UK provision of public services is the 2010 Equalities Act [40], which protects against direct and indirect discrimination across nine characteristics: age, disability, gender, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation. Additionally, the Act's Sect. 1 contains a "socio-economic duty" to consider broader inequalities within a commissioner's jurisdiction: they must "have due regard to the desirability of exercising (their functions) in a way that is designed to reduce the inequalities of outcome which result from socio-economic disadvantage" [40].

However, while the 2010 Equalities Act was enshrined in law, Sect. 1 was not a legal requirement until 2018 in Scotland and 2021 in Wales; but currently (as of April 2022) it is still not a legal requirement in England. As a result, public agencies in England may choose if and how to consider inequality in their decisions. While some have acted on Sect. 1 [41], they are not legally required to beyond the nine protected characteristics: this permits significant variation in the actions taken depending on whether or not the authorities have chosen to take the socio-economic duty upon themselves [41].

5.2 Local Authorities (LAs)

Since the Health and Social Care Act 2012 [42], LAs have had a remit to deliver public health services in addition to their traditional remit, which covers social determinants of health (e.g., housing, education, social care, and transportation); thus, a LA's inequality remit goes beyond the provision of care services [43, 44]. Here we focus on LAs' public health responsibilities associated with the Health and Social Care Act 2012 and elements of the Public Health Profiles commissioning indicators provided by the Office for Health Improvement and Disparities (OHID) [45].

Despite LAs' public health remit, there is little legal requirement or good practice guidance to facilitate their attempts to alleviate health inequality. Publications such as the Local Government Organisation 2018 report 'A matter of justice: Local government's role in tackling health inequalities' [44] speaks to this, with a large emphasis of the burden of inequalities and potential solutions that fall within LA remit, but nothing on the associated legal requirements. Relatedly, and beyond Sect. 1 (whether legally enshrined or not), LAs may be seen as having a moral obligation to address inequality in their respective geographical areas and associated funding structures: council tax, business rates, and government grants. While LAs in poorer areas inevitably have lower revenues through council tax and business rates, these are supported to some extent by government grants, resulting in higher levels of total revenue than richer LAs [46]. However, since 2008 poorer LAs have lost a higher proportion of funding, associated with a corresponding reduction in relative life expectancy [47].

Local authorities' variation in actioned responsibility to reduce inequalities in their populations was demonstrated in Just Fair's 2018 report detailing quantitative interviews and analyses with seven LAs [41]. At the time of interview, they found that only one of the seven had embedded the requirements of Sect. 1 into their decision making, doing so voluntarily, with the remaining six pursuing a range of policies seeking to alleviate socio-economic disadvantage but not to the same extent.

Vital to all discussions about reducing inequality is the ability to assess the impact of any action or inaction with robust evidence, with Just Fair identifying aspects associated with data as two of their five essential features: 'meaningful data assessment' and 'using data effectively' [41]. While it is not possible to be conclusive as to how each LA uses data (e.g., social or health care data) to inform the assessment of inequality at an inter- or intra-authority level, Public Health England's Public Health Profiles, provide valuable insight [45]. This platform gives absolute and relative estimates for a wide range of health indicators and determinants of health. While these are valuable for informing inter- and intra-authority comparisons, as the majority of estimates provide a single estimate for each authority—e.g., prevalence of obesity—they are of little value when seeking to address intra-authority inequality. The exception to this within the Public Health Profiles system is the Health Inequalities Dashboard [48], which provides estimates of relative and absolute gaps within an authority for a number of inequality indicators—both health and its determinants. However, to our knowledge, informed by a review of the relevant literature on the use of data by local governments [49], it is not currently recorded how, or if, LAs use the data in their commissioning decisions.

5.3 Clinical Commissioning Groups (CCGs)

The reduction of inequalities in the access to and outcomes from healthcare interventions has been part of CCGs' remit since their formation under the Health and Social Care Act 2012. Each CCG must: "(a) reduce inequalities between patients with respect to their ability to access health services, and (b) reduce inequalities between patients with respect to the outcomes achieved for them by the provision of health services" [42].

This is reflected in CCG funding allocations from NHS England. While the allocation formula has changed over time, specifically in w met and unmet needs are reflected, inequality has always played a part in these allocations [50]. Since 2019/20, funding allocations include adjustments that reflect the relative standardised mortality ratio of those aged ≤ 75 years in the CCG's region, with the associated proportion of funding allocated on this basis being: primary care, 15%; CCG commissioned services, 10%; speciality services, 5% [51].

In addition to its role in their funding, inequality is also considered in the Oversight and Assessment process, under which NHS England conducts a statutory annual assessment of each CCG. The Oversight Framework that informs the process combines aspects of 'preventing ill health and reducing inequalities' [52], recording data on:

- Maternal smoking at delivery
- Percentage of children aged 10–11 classified as overweight or obese
- Injuries from falls in people aged 65+ years
- Antimicrobial resistance: appropriate prescribing of antibiotics in primary care
- Proportion of people on GP severe mental illness register receiving physical health checks
- Inequality in unplanned hospitalisation for chronic ambulatory and urgent care sensitive conditions

Where inequality is considered in the Oversight Framework, it is typically presented in terms of absolute inequality gradient calculated for each CCG. Importantly, these estimates

are not used as a blunt measure to assess the CCG's performance but to provide 'a focal point for joint work, support and dialogue' between the various stakeholders [53].

5.4 Integrated Care Systems (ICSs)

Integrated Care Systems will become statutory bodies in 2022, taking over the commissioning function currently held by CCGs and with their modus operandi 'improving outcomes and addressing inequalities' [22]. Underpinning this aim is the hypothesis that improved integration of services both within healthcare and between sectors represents a better approach than the more competitive process of service commissioning that underpinned CCG functioning. Local authorities and ICSs will have a duty to collaborate, replacing current collaboration processes, which may have previously existed between LAs and CCGs. Additionally, ICSs will shift to 'place-based working', focussing on individual geographic localities, the needs of their populations, and existing partnerships. As such, integration is likely to be interpreted and operationalised differently across ICSs that will inevitably vary in these elements.

At the time of writing, the details as how the modus operandi will be operationalised by the ICSs and monitored by NHS England are limited to the high-level aims outlined in the White Paper [22], with the expectation that each ICS will have significant flexibility in deciding their path forward. However, the increased focus on local needs and solutions suggests ICS decision-making is likely to shift further towards approaches that are tailored to local systems, e.g., inequality measures selected to address known local issues such as smoking cessation. Secondly, the pragmatic approach to monitoring inequality levels by NHS England for CCGs may well continue for ICSs, with the limited reporting of inequality measures (see Sect. 5.3) continuing to inform dialogue between NHS England and ICSs.

Overall, this suggests that a two-level approach to inequality might continue to emerge: one level focussing on inter-ICS comparisons to inform the funding allocation, and one level within each ICS that is specific to the needs and challenges faced locally. This risks producing potentially inconsistent pressures within each ICS as they attempt to grapple with the health and inequality considerations that are specific to their jurisdictions as well as broader inequality measures for comparisons with other ICSs [54].

6 Generalisability of the English Local Commissioning Landscape Internationally

With the diverse nature of care commissioning responsibilities internationally it is not feasible to determine whether the experience in England is directly comparable to other nations. However, it is self-evident that, due to commissioners' proximity to service provision data, such as patient care records, the most readily available approach to conceptualising and monitor health inequality will always be informed by such data. Furthermore, frameworks the UK's 2010 Equalities Act are mirrored internationally. Therefore, the experience in England, described in Sect. 5, is expected to be internationally transferable in the pertinent details.

7 Comparing the Two Approaches and Recommendations

To discuss where and how the researcher and commissioner-led approaches can begin to come together and the potential benefits of doing so, it is important to consider their relative practical and methodological strengths and limitations when the goal is to inform localised commissioning. Our suggested considerations are in Table 1.

Building on these strengths and limitations, and the English case-study, we have a number of recommendations to begin to address the disconnect:

- The time and financial costs involved with the creation of DCEA models implies that it is not feasible for each commissioner to have locally tailored models. Instead, models should be commissioned nationally, or collaboratively across LAs and ICSs, with flexibility to local context, accessibility, and co-development seen as fundamental parts of model development. Such an approach would facilitate research impact from an academic perspective, and better use the skills, knowledge, and data availability of all parties.
- A common set of agreed vocabulary around the definitions of health inequality, and agreement on how aspects of health inequality are to best quantified, e.g., through minimum data specifications and reporting standards.
- To address the overall divide in the two disciplines, closer collaboration must be prioritised with a focus on the ease with which the two settings can identify potential research partners and disseminate the latest research.
- Better reflection and documentation of where existing quantitative frameworks for determining cost-effectiveness may differ from the commissioning reality faced by the commissioners, e.g., finance and policy cycles, ring-fenced budgets, risk aversion to overspend, and diverse outcome measures.
- Development and maintenance of local and national metadata to provide a clear understanding of who holds what data relevant to healthcare inequality, and how it can be accessed. The supplementary appendix to this paper provides further details of the challenges of

Table 1 Potential benefits and limitations of researcher and commissioner-led approaches to quantitatively account for inequality considerations related to their applicability to commissioners

	Potential strengths	Potential limitations
Researcher-led approach (i.e., DCEA)	(a) Compatible with existing methods of economic evaluation (b) Flexible to the definitions of equality subgroup and the measure of health maximising (c) Explicitly demonstrates the trade-off between total population health and inequality DCEA; thus, allowing formal debate over the appropriate level of inequality aversion	(a) Requires a full CEA to be conducted; can be complex and costly to implement, and risks the ability for locally tailored analyses (b) In DCEA's current form it requires a single definition of inequality around the health outcome that is being measured, e.g., QALYs; thus, limited flexibility to fully inform cross-sectoral or broad stakeholder deliberations (c) There are outstanding questions regarding the appropriate means of estimating society's aversion to inequality (d) Risks oversimplification by overlooking structural elements that cause health inequality and inequity, with most models failing to consider the wider determinants of health
Commissioner-led approach	(a) By summarising multiple measures side-by-side, the approach does not necessitate an a priori value set of inequality aversion, allowing different stakeholders, with potentially different views on the population health inequality trade-off, to use it (b) The simplicity of reporting and positioning of the analyses makes access to real-world and timely data much easier and therefore responsive (c) Due to its development to directly inform commissioning and funding decisions, the simple reporting of health-related inequality measures is responsive to the needs of local decision makers and the budget setters in central government	(a) Summary measures of inequality and ranking of performance by area implicitly makes complete equality as the perfect solution; thus, risks placing focus on inequality rather than health burden, while ignoring the existence of inequalities that may be unavoidable (b) The focus on ranking or performance by area risks perverse incentives around performance, with stakeholders aiming to do just well enough in each measure rather than focussing on individual health. Additionally, the use of ranking risks disincentivising collaboration (c) Lack of a unifying, a priori, definition or quantification of inequality results in case-specific analyses; thus, of limited use for cross-comparability within unified budgets (d) Typically defines inequality in terms of care utilisation or individual behaviour (e.g., smoking) rather than overall health (e.g., life expectancy), which are proxies of health (e) Due to the nature of the available data much of the narrative around inequalities in this context relate to geographic groups rather than unique to patients, risking groupings that do not reflect the individual (f) The lack of a minimum or maximum set of inequality measures with the variable set often determined by data availability, risk measures of limited relevance being included in deliberations, or relevant ones excluded

CEA cost-effectiveness analysis, *DCEA* distributional cost-effectiveness analysis, *NICE* National Institute for Health and Care Excellence, *QALYs* quality adjusted life-years

identifying and accessing key data regarding pertinent inequality data in the English case study.

- Make the analysis and reporting of the distributional impact of interventions subjected to CEA as minimum standard, with the conducting of DCEA an expectation where once course of action does not strictly dominate all others.

8 Discussion

We have explored researcher- and commissioner-led approaches to define, quantify, and analyse health inequalities. Based on the English care setting example, the different perspectives and their starting points have resulted in approaches that in many ways share little beyond the use of the term 'health inequality'; this is likely to be the case

internationally. The researcher-led approach, specifically DCEA, puts overall patient health at its centre, in addition to assumptions regarding the ability to categorise patients into their demographic groups, and requires access to an underlying CEA model. In contrast, the commissioner-led approach focusses on available data, relying on the comparative summaries of measures of healthcare utilisation and diagnoses, typically stratified into geographic groupings often based on a commissioner's jurisdiction. Although, in the English setting the recent White Paper on 'Levelling Up the United Kingdom' has underlined aims to better use the Healthy Life Expectancy measure to record inequalities [55]. Availability of data and ability to quantify inequalities will be a challenge internationally, often dependent on the extent to which countries/regions are willing and able to collect the relevant and necessary data.

It would be misleading to suggest there have been no interactions to date between researchers and commissioners to inform these approaches, For example, a report commissioned by the Department of Health and Social Care has called for 'better, broader, and safer' use of health data for research and analysis [56]. However, there are a number of existing barriers to overcome in order to enable consistency across approaches. Most significantly, these include finding a common set of vocabulary around definitions of health inequality, and agreement on how aspects of health inequality are to be quantified. Research has found that while many decision makers desire a greater level of integration of economic evaluation into the decision-making process, in practice this does not occur because of issues of accessibility [57] and the perceived limited relevance of current frameworks to the reality faced by commissioners [58]. From the commissioner perspective, economic evaluations of care interventions have conventionally focussed on the national decision-making context, assuming local commissioners are able to take on a level of decision uncertainty and fund interventions based on cost-effectiveness rather than affordability [59]. Furthermore, some challenges to the alignment of the approaches are likely to be perpetual, such as commissioners' requirement to place their legal duty at the heart of any commissioning decision, and the cost of producing economic evaluations such as DCEAs to inform all budget allocation decisions.

9 Conclusion

Developments in economic evaluation methodology, specifically DCEA, have given analysts a means of presenting the cost-effectiveness of care technologies for the whole eligible population alongside the associated impact on health inequality. However, limited consideration has been given to how this approach can be applied at the point where health inequalities are most relevant and arguably best addressed, often at a local commissioner level. Additionally, lessons need to be learnt in the researcher-led world for such approaches to have greater relevance and impact, and consideration needs to be given to the data used to quantify and evaluate aspects of health inequality within different contexts. Ultimately, it is important that researchers and commissioners are consistent in their approach to defining, quantifying, and analysing health inequalities if the repeated aim of reducing health inequalities is to be achieved.

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Appendix 1: Data requirements and availability in the English setting

A necessary condition for future collaboration and bridging the disconnect between the academic and commissioner approaches is an understanding of, and access to, data that would be required to inform research frameworks, such as DCEA. While the existence and use of such data is known to be difficult to determine [42], Table A1 summarises some potential NHS and LA data sources to quantify health inequality aspects (e.g. 2010 Equalities Act's nine protected characteristics). These data sources were identified through discussions with university, LA and CCG representatives as part of the Unlocking Data project [5]. Indicative of the challenges of identifying data in these contexts, there are examples where we were unable to conclusively determine a potential data source; these are labelled 'unknown' in Table A1, which occurred mainly within a LA context.

Table A1: Potential NHS and LA data sources to quantify health inequality and associated targeted characteristics at the person or regional level (*This table should be considered representative of possible data source examples, and should not be considered a fully comprehensive list of possible data sources for where a characteristic or health inequality is quantifiably stored or not.)*

Characteristic or health inequality	NHS data source	LA data source
Health inequality examples		
Care resources consumed	Various NHS datasets covering NHS resources	Social care and care homes (LA-funded only)
Health profile measure (e.g. generic or condition-specific PROMs)	Hip and knee replacement (e.g. EQ-5D-3L); IAPT (condition-specific e.g. GAD-7 and PHQ-9)	*Unknown* [c]
Determinants of health (e.g. smoking)	Primary care	Possibly LA property tenancy data and LA-funded social care data
2010 Equalities Act - nine protected characteristics		
Age	Common across NHS data sources	LA-funded social care; many other council services
Disability	Potentially primary care, admitted patient care, others	Disabilities facilities grants; LA-funded social care
Gender ('gender reassignment' in the 2010 Act)	Not routinely available (results in new NHS number creation). Present in some MH and primary care data.	*Unknown* [c]
Marriage and civil partnership	Present in some MH-related data, Maternity services dataset, and most health records	*Unknown* [c]
Pregnancy and maternity	Maternity Services dataset and primary care records	*Unknown* [c]
Race (and ethnicity)[a]	Ethnicity is common across NHS data sources (known issues with completeness of data)	Some council services (e.g. social housing)
Religion or belief	Not routinely available.	Some council services (e.g. social housing)
Sex	Common across NHS data sources	LA-funded social care; many other council services
Sexual orientation	GUMCAD Sexually Transmitted Infection Surveillance System Data Set (not linkable)	*Unknown* [c]
Other used/recommended characteristic examples		
Socioeconomic status	Not routinely available	Stop Smoking Services Quarterly Data Set
Index of Multiple Deprivation (IMD)[b]	Derived from postcode, captured for most NHS contacts	Derived from postcode, routinely used within LAs

Acronyms. LA, local authority; MH, mental health; NHS, National Health Service; PROMs, patient-reported outcome measures.

[a] The 2010 Equalities Act specifically refers to 'race'; however, for the purpose of this table we refer and reflect on race and ethnicity.
[b] IMD is not a 'patient-level' metric as it is geographically defined based on the characteristics of the resident population of small areas i.e. Lower Layer Super Output Area (LSOA).
[c] *Unknown* implies that through discussions with university, LA, and CCG representatives as part of the Unlocking Data project, an appropriate data source could not be suggested

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Improving cardiac rehabilitation uptake: Potential health gains by socioeconomic status

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Abstract

Background: Globally, cardiac rehabilitation (CR) is recommended as soon as possible after admission from an acute myocardial infarction (MI) or revascularisation. However, uptake is consistently poor internationally, ranging from 10% to 60%. The low level of uptake is compounded by variation across different socioeconomic groups. Policy recommendations continue to focus on increasing uptake and addressing inequalities in participation; however, to date, there is a paucity of economic evidence evaluating higher CR participation rates and their relevance to socioeconomic inequality.
Methods: This study constructed a de-novo cost-effectiveness model of CR, utilising the results from the latest Cochrane review and national CR audit data. We explore the role of socioeconomic status by incorporating key deprivation parameters and determine the population health gains associated with achieving an uptake target of 65%.
Results: We find that the low cost of CR and the potential for reductions in subsequent MI and revascularisation rates combine to make it a highly cost-effective intervention. While CR is less cost-effective for more deprived groups, the lower level of uptake in these groups makes the potential health gains, from achieving the target, greater. Using England as a model, we estimate the expenditure that could be justified while maintaining the cost-effectiveness of CR at £68.4 m per year.
Conclusions: Increasing CR uptake is cost-effective and can also be implemented to reduce known socioeconomic inequalities. Using an estimation of potential population health gains and justifiable expenditure, we have produced tools with which policymakers and commissioners can encourage greater utilisation of CR services.

Keywords

Cardiac rehabilitation, myocardial infarction, economic evaluation, deprivation, inequality

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Introduction

As the leading cause of death globally, heart disease was associated with an estimated 9.43 million deaths in 2016.[1] The links between heart disease, the obesity epidemic and physical inactivity are well established,[2–5] and are the primary reason for the risk of heart-disease-related death being almost three times greater in high-income countries than low-income countries.[1] As a result, cardiac rehabilitation (CR), which is a multi-component complex intervention, has been at the forefront of attempts to reduce the impact of heart disease on population health in the developed world.[6,7] Previous Cochrane[8,9] and clinical reviews[10] have found that there are clear benefits from CR, which the National Institute for Health and Care Excellence (NICE) in England have indicated as being highly cost-effective.[11,12] As a result, in their latest guidance issued in 2013, NICE recommended that CR is offered as soon as possible after admission for acute myocardial infarction (MI),[12] a decision mirrored elsewhere in the world.[6,7,13]

Despite the guidance by NICE and similar initiatives in Europe, Canada and the US to improve the rate of

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uptake, the proportion of patients accessing CR remains stubbornly below stated national targets, such as 65% in England and 70% in the US,[6,14] with uptake ranging from 10% to 60% globally.[10,15] The problem of sub-optimal uptake is compounded by poorer uptake in more deprived groups, further compounding inequalities in health.[16]

A number of interventions have been proposed to increase CR uptake rates, including improving the education of health professionals[17] and improving the accessibility of rehabilitation centres and home provision.[18,19] However, little consideration has been given as to the level of expenditure that can be justified while maintaining the cost-effectiveness of the CR programme, or whether interventions should be stratified by deprivation group to reflect the role of deprivation in uptake and capacity to benefit.

To address these gaps in the evidence, this study explores three key aspects: (1) determine if CR can be considered cost-effective given the contemporary evidence on its effectiveness; (2) establish what economic analysis can tell us about how much can be spent on interventions to increase uptake, while maintaining cost-effectiveness; and (3) explore the role of deprivation in reducing both the potential to engage with CR and to gain from it.

Methods

In order to estimate the cost-effectiveness of CR, a scoping review of the current evidence relating to its effectiveness and cost-effectiveness was undertaken. The 2016 Cochrane review[8] was identified as the most complete contemporary systematic review of the effectiveness evidence, exploring the impact of CR on four key aspects: the rate of repeat MI; revascularisation as either percutaneous coronary intervention (PCI) or coronary artery bypass grafts (CABG); hospitalisation; and mortality (cardiovascular and all-cause). Incorporating 63 trials and 14,486 patients with heart disease, the review represents an authoritative overview of the findings of the CR literature. Details are published elsewhere,[8] but in brief the review found that CR led to a statistically significant reduction in cardiovascular mortality (but not total mortality as per the previous Cochrane review[9]) and hospitalisation, but an insignificant decrease in the rate of MI and revascularisation.

A recent systematic review of cost-effectiveness studies of CR identified a limited number of relevant studies.[20] Furthermore, while an economic evaluation was conducted to inform the NICE guidelines (CG172 and CG48) following MI,[11,12] it was not appropriate to replicate the original model as it fails to reflect current thinking around the mechanisms of CR.[8] Furthermore, up-to-date costings and evidence is now available, making the results of the NICE guidelines model inappropriate for current decision-making. As a result, a de-novo model, taking account of the modern era of cardiology, was constructed to fully incorporate the findings of the Cochrane review into an economic evaluation framework.

The population

We consider a patient population in keeping with the core studies in the CR field: the latest Cochrane review; the BHF National Audit of CR (NACR); the latest NICE guidelines on CR; and a European-led, modern era, review of CR.[8,12,21,22] This constitutes all adults who have had a recent ST-elevation or non-ST-elevation MI (STEMI or non-STEMI), PCI or CABG, consisting of an estimated 121,499 patients in England in 2015/16.[21] The modelled cohort has a starting age of 67 (the age at which they are eligible for CR) and a male-to-female ratio of 0.70.[21]

The intervention

In broad terms, CR services are defined as 'comprehensive, long term programmes involving medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counselling',[10] therefore constituting a range of potential modalities tailored to the patient's needs rather than a single fixed intervention. The 2017 NACR found the majority of patients underwent a group-based programme (between 70% and 85%) with a spread across the other modes of delivery, such as home-based. Although there is significant variation in terms of intensity, frequency and duration of CR within the mode of delivery,[20,21] recent observational studies of routine practice suggest that patient benefit is equivalent following group-based or home-based CR.[23–25]

Our approach to the mode of intervention was to be inclusive as per the Anderson review[8] and the NICE guidance,[12] incorporating the full definition of CR, as is known to occur in clinical practice.[21]

The model

Decision modelling can be used as a quantitative means of combining evidence from a variety of sources to inform a particular decision problem.[26] In this case, the Cochrane review alongside other sources of evidence, detailed in the following and in the Supplementary Appendix, are used within a Markov model structure to explore the impact of CR on the long-term health of patients and the costs to the NHS, stratified by patient deprivation.

Figure 1 provides an overview of the model. As a starting point, all patients are assumed to inhabit the 'well' state, the point at which after their first MI and/or revascularisation, they will begin CR if it is available. Due to the availability of CR at this point in the pathway only, we will not consider events prior to this point. We create two realisations of the potential patient pathway: one where CR is available and the patient undertakes it, and one where it is not available. In both realisations the patient can experience the same possible transitions, as shown in Figure 1, but the probability of them experiencing these is different in the presence of CR, as informed by the Cochrane Review[8] and national audit estimates.[21]

The model allows patients to stay in a 'well' state, experiencing no further cardiac events, or to require admission to hospital. During a hospitalisation, a patient can require no further care and return to the well state, or they can be identified as having had a MI, and can then go on to have a PCI or CABG for the MI; alternatively, they can require revascularisation (PCI or CABG) for a non-MI event. From all states, patients can die from cardiovascular disease (CVD)-related events, other causes or, in the case of revascularisations, surgical adverse events. The structure of the model is driven by the Cochrane analysis, designed around the meta-analyses conducted.

Parameter estimation

The full list of parameters, which inform the base-case analysis, is supplied in the Supplementary Appendix. The Cochrane review[8] provided the informative evidence for many of the parameter estimates required for the model. We re-estimated the meta-analyses conducted in the Cochrane review in order to provide the most flexibility to inform the decision model, which requires transition probabilities rather than the risk ratios estimated in the review. Other model parameters were estimated from other published sources and data requests made to the NACR.

The NHS reference costs were used as the main source of unit cost evidence, supplemented with estimates from published literature. Patient quality of life was modelled using the utilities generated in the Lewis et al.[27] analysis, applied as decrements to an age-adjusted profile of 'normal' population quality-of-life scores.[28]

The model is constructed in keeping with best practice as reported in the NICE Methods Guide,[29] including the use of a discount rate of 3.5% for both costs and outcomes, a lifetime analytical horizon and the use of an NHS and personal social services perspective combined with patient health outcomes measured in terms of quality-adjusted life years (QALYs).

To estimate the additional expenditure justifiable to increase the rate of uptake while remaining cost-effective, we use an estimate of the marginal productivity of the NHS of £12,936/QALY as reported by Claxton et al.[30] This was used to estimate the point at which increases in population health from an increase in CR uptake would no longer be worth the opportunity cost to the NHS of funding them in place of other activities.

The role of completion

In addition to issues of low level of uptake of CR, a number of patients who commence the programme

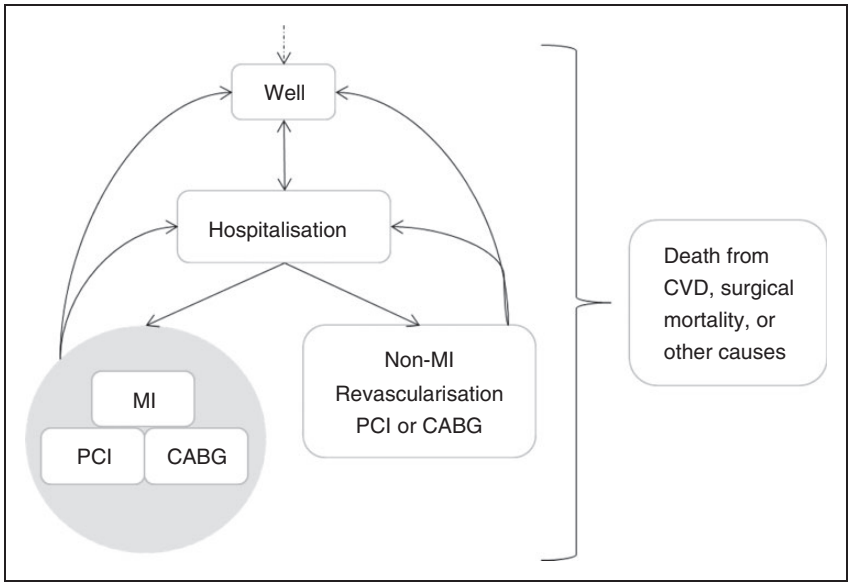

Figure 1. Schematic of model for both CR and non-CR.

do not finish it, estimated as 24.6% using the latest NACR data request. The variation in CR programmes means that the impact of a patient failing to complete can have different impacts. For example, under a cohort programme, where a group conducts the programme as a single class, it is not possible to replace someone who drops out during the course and, thus, the place is lost. In contrast, under a rolling programme where patients join and complete the programme on a continuous basis, the drop-out can be replaced by another patient with only the loss of a few sessions.

To ensure a conservative approach to estimating the cost-effectiveness of CR, our base-case analysis assumes that all patients who fail to complete a CR programme entail the full cost of the programme to the NHS but receive none of the health benefits.

Incorporating uncertainty

To explore the role of uncertainty in our model, we conducted probabilistic sensitivity analysis (PSA),[26] whereby distributions are fitted to all relevant model parameters to reflect the range of possible mean values for the cohort. The informative distributions used are detailed in the Supplementary Appendix. Such an approach explicitly incorporates the uncertainty reported in the Cochrane review regarding the effectiveness of CR. By repeatedly sampling from the informative distributions, the accumulated impact of the combined uncertainty can be reported. The results of this resampling is reported in terms of both the probability of CR being cost-effective as well as the impact of the uncertainty on the justifiable expenditure to increase CR uptake.

Incorporating the impact of deprivation

The role of social inequality and deprivation on cardiovascular health[31–33] and CR engagement[34–36] is well documented. To consider the role of deprivation both on the cardiovascular health of patients as well as their propensity to engage with CR, we modelled the correlation between a number of key parameters and an index of multiple deprivation (IMD). The parameters included were selected through a pragmatic search of the literature based on the identification of areas where deprivation was expected to have an impact a priori. The values incorporated in the model are given in Table 1, with all odds ratios indexed against IMD3 for modelling purposes. As expected, the identified a priori evidence suggests that the level of uptake and completion are worse in more deprived groups (IMD levels 1 and 2), who also experience poorer health outcomes, both for CVD and all other health concerns.

Results

Cost-effectiveness of the CR programme

The cost-effectiveness results generated by the model are presented in Table 2, reporting the following: the total discounted costs and benefits for both CR and no CR strategies, the incremental cost-effectiveness ratio (ICER) and the probability of CR being cost-effective at a threshold value of £12,936/QALY, all stratified by IMD status.

Across all IMD categories CR is associated with greater total discounted costs and QALYs than no CR, resulting in an ICER that would conventionally be considered highly cost-effective with high certainty, as the mean ICERs are below £3500/QALY for all IMD groups, and the probability of cost-effectiveness is 99.6%. The results also demonstrate the impact of socioeconomic inequality on the cost-effectiveness of CR. The poorer quality of life, life expectancy and recurrence rates of the more deprived results in the deprived cohort's baseline expected QALYs much lower, 3.80 QALYs in IMD1 compared to 5.12 in IMD5, while their poorer completion rates make their propensity to gain under the current CR system less incremental QALYs of 0.22 compared to 0.32.

Table 1. Impact of multiple deprivation on model parameters and CR engagement.

IMD	CVD mortality	Non-CVD mortality	QoL decrement	Rate of recurrence	CR uptake	CR completion (probability)
1*	1.04	1.17	0.06	1.23	0.81	0.67
2	1.00	1.06	0.02	1.10	0.91	0.72
3	1.00	1.00	0.00	1.00	1.00	0.75
4	0.93	0.96	−0.03	0.95	1.04	0.78
5	0.81	0.92	−0.05	0.83	1.12	0.80
Source	ONS[37]	ONS[38]	Love-Koh et al.[39]	Smolina et al.[40]	NACR data	NACR data

IMD: index of multiple deprivation; CVD: cardiovascular disease; QoL: quality of life; CR: cardiac rehabilitation; ONS: Office for National Statistics.
*1 = most deprived.

Table 2. Cost-effectiveness of CR by IMD.

	No CR		CR		Incremental			
IMD	Disc. cost	Disc. QALY	Disc. cost	Disc. QALY	Disc. cost	Disc. QALY	ICER/QALY	Probability CE
1*	£7696	3.80	£8420	4.03	£724	0.22	£3240	0.996
2	£7328	4.22	£8046	4.49	£718	0.27	£2630	0.997
3	£6863	4.42	£7577	4.72	£714	0.30	£2395	0.998
4	£6760	4.75	£7443	5.07	£683	0.32	£2133	0.996
5	£6340	5.12	£6983	5.44	£643	0.32	£1991	1.000

IMD: index of multiple deprivation; CR: cardiac rehabilitation; disc.: discounted; QALY: quality-adjusted life years; ICER: incremental cost-effectiveness ratio.
*1 = most deprived.

Table 3. Annual benefits and justifiable cost of reaching 65% target, by index of multiple deprivation (IMD).

IMD	Current uptake (NACR data)*	Increment to 65% target	Eligible population (NACR data 2015/2016 data)	QALY gain per person of CR	Total QALY gain for reaching target	Justifiable expenditure to reach target while cost-effective	
						Per person	Whole population
1**	37.61%	27.39%	22,194	0.22	1358	£2166	£13,167,695
2	41.97%	23.03%	22,952	0.27	1442	£2812	£14,863,740
3	46.21%	18.79%	23,470	0.30	1314	£3141	£13,849,816
4	48.14%	16.86%	27,086	0.32	1464	£3462	£15,812,812
5	51.75%	13.25%	22,842	0.32	978	£3537	£10,701,547
				Total	6556	N/A	£68,395,610

NACR: National Audit of cardiac rehabilitation; CR: cardiac rehabilitation; QALY: quality-adjusted life years.
*The numerator for this estimate of uptake is calculated using only those programmes that upload their data to NACR, averaged across 2015–2018; we assume the same rate of uptake in these programmes as those who do not upload their data to NACR. This assumption is consistent with current NACR reporting.[21]
**1 = most deprived.

Scatter plots presenting the probabilistic simulations for each of the IMD groups, and a table of results under the assumption that completion rates are 100%, are provided in the Supplementary Appendix.

The benefit and justifiable cost of reaching 65% uptake

Table 3 provides estimates of the annual total health gains (in terms of QALYs) from achieving the 65% uptake target (assuming current rates of completion), alongside the justifiable expenditure to achieve the target, stratified by IMD. The total population health gain was calculated by combining the increased uptake required to achieve the target, the estimated size of the eligible population per year and the QALY gain per person starting CR, as reported in Table 2. The total justifiable expenditure represents an estimate of the additional cost that could be spent on a CR programme while maintaining its cost-effectiveness.

Table 3 shows that while the potential health gains per person, and, therefore, the justifiable expenditure to achieve them, are less in the more deprived groups, as they have the greatest required increase in uptake to achieve a 65% target, the total justifiable expenditure to achieve them is similar in the less deprived groups. The exception is the IMD5 group who, in spite of their large potential to gain from CR, have a relatively low total justifiable expenditure (£10.7 m) due to their significantly higher current uptake greatly reducing the total gain from achieving the target. The total justifiable expenditure of £68.4 m across all groups provides an estimate of the maximum annual expenditure that could be justified if intervention was able to increase uptake to 65% in all IMD groups.

Alongside estimating the probability of CR being cost-effective, the PSA simulations can be used to show the impact of parametric uncertainty on the estimate of total justifiable annual cost to reach a 65% uptake target, as shown in Figure 2. The figure shows

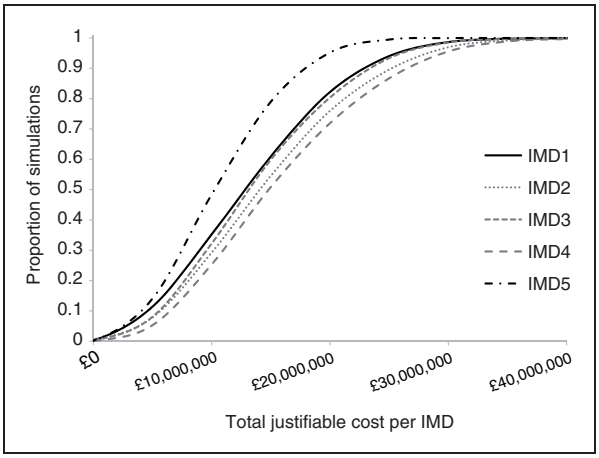

Figure 2. Cumulative distribution function for total justifiable cost, by index of multiple deprivation (IMD).

the cumulative distribution functions of total justifiable cost to achieve the target, stratified by IMD group.

For IMD1–4, roughly 90% of the simulated values occur under £26.0 m, highlighting the large variation in the estimate; for IMD5, this is under £18.0 m. The distribution of IMD5 lies apart from the others due to the lower required increase in uptake to reach a 65% target, despite the relatively greater justifiable expenditure per person.

Summing across all IMD groups gives a total justifiable expenditure of £68.4 m if all groups achieve the target, with a 95% confidence interval of £44.1 m to £94.6 m. If a 65% target was achieved, our analysis suggests this would result in a reduction of roughly 21,000 hospital admissions and 8500 deaths averted over 10 years. If a more optimistic target of 85% was set, there would be a reduction of almost 49,000 admissions over 10 years, and 19,500 fewer deaths over 10 years.

Discussion

We find that the low cost of CR and the potential for reductions in subsequent MI and revascularisation rates combine to make it a highly cost-effective intervention across all IMD groups. While the per-patient lifetime costs to the NHS of providing CR to more deprived groups is greater than those that are less deprived, and the expected QALY gains less, the lower level of current uptake in the more deprived groups makes the potential health gains from achieving a 65% target greater, and, thus, the total justifiable expenditure.

The main strength of this analysis is that this is the first economic evaluation of CR to incorporate the findings of the Cochrane review, alongside the incorporation of the role of deprivation on both cardiovascular health and engagement with CR. This framework provides estimates of justifiable expenditure which can facilitate decision makers to invest in policies to increase CR uptake.

However, the analysis also has a number of weaknesses, primarily the failure to reflect different CR programmes and the potentially restrictive structure of the model. Ideally, the economic evaluation would incorporate the range of different CR programme types to explore the relative cost-effectiveness of different approaches. However, the nature of the Cochrane review, which did not stratify by CR type, in addition to the recommendation that CR is flexible to patient preferences, made the incorporation of multiple programme types into the analysis both infeasible and potentially uninformative to decision makers. Furthermore, recent analyses suggests that outcomes and completion rates do not vary substantially between different modes of delivery.[23–25]

Similarly, the structure of the model is potentially an over-simplification of the post-event patient pathway, failing to explicitly reflect the full range of events – for example, stroke and long-term non-fatal disability. However, the use of the Cochrane review to inform the parameter estimates limited the potential to incorporate a wider set of explicit patient events.

The most valuable element of this analysis is its ability to be used as a framework to demonstrate the business case for investment in interventions which increase the uptake of CR, particularly those which address the issue of inequality of uptake.[21] Furthermore, by demonstrating the impact of uncertainty around the patient pathway, we allow decision makers to understand how the estimate of justifiable expenditure to reach a 65% target can be tailored to their aversion to risk.

Whilst the probabilistic analysis demonstrates that CR is highly likely to be cost-effective, with a probability of being cost-effective of almost 100% for all IMD categories, the uncertainty in the parameter estimates results in a wide distribution in terms of the justifiable expenditure to increase CR uptake. Therefore, while there is little value in further research in terms of demonstrating the cost-effectiveness of CR, such research would be informative to the business case of interventions seeking to increasing uptake to ensure efficient spending.

Finally, the analysis focus is on increasing CR uptake; however, there is the potential for the expenditure on CR programmes to be wasted if patients do not complete the programme. As a result, further discussion and research should be conducted to explore the role of non-completion on impacting the effectiveness and cost-effectiveness of CR, and the propensity of interventions to increase completion rates.

Conclusion

We conclude that CR, as it is currently delivered, is cost-effective across all IMD groups due to its low cost and high effectiveness in improving cardiovascular outcomes, as demonstrated by the Cochrane review. Furthermore, we show that there is a clear business case for spending money on incentives which increase CR uptake to a 65% target, stratified by IMD, with a justifiable expenditure of £68.4 m per year. Our analysis does, however, demonstrate that there is significant uncertainty around this justifiable expenditure, which originates from the uncertainty in the Cochrane review estimates of the effectiveness of CR. However, the lowest 95% confidence interval of the total justifiable expenditure is still £44.1 m, demonstrating the large potential benefit of increasing CR uptake, regardless of the significant uncertainty.

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Author contributions

PD and LB contributed to the conception and design of the work. SH conducted the mathematical modelling and analysis. AH provided data acquisition and interpretation. All authors contributed to the drafting of the submitted manuscript and gave final approval and agreement to be accountable for all aspects of work ensuring integrity and accuracy.

Declaration of conflicting interests

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Supplementary Appendix

This supplementary appendix provides details of the parameter values used to inform the mathematical model alongside additional results generated.

Table 1-A: Base-case cohort values and core model assumptions

Parameter	Value	Source
Cohort age	67	NACR report [1]
Male to female mix	0.70	NACR report [1]
Discount rate, costs	0.035	NICE Methods Guide [2]
Discount rate, outcomes	0.035	NICE Methods Guide [2]
Time horizon	lifetime	NICE Methods Guide [2]
Cycle length	6 months	Sufficient to reflect the patient pathway

Table 2-A: Transition probabilities (6 month using random effects model) and proportions

From	To	No CR		Source and notes
		Mean	**Distribution**	
Well	Hospitalisation	0.147	Gamma (SE - 0.049)	Anderson [3]
Well	CVD mortality	0.032	Gamma (0.009)	Anderson [3]
Hospitalisation	MI	0.181	Gamma (0.006)	Anderson [3]
Hospitalisation	Non-MI revasc.	0.360	Gamma (0.011)	Anderson [3]
MI	Hospitalisation	Same as well to hospitalisation		Assumption
MI	MI	0.027	Gamma (0.006)	Anderson [3]
MI	MI revasc.	0.091	Beta (alpha-1434, beta-17119)	Smolina [4], assumed the same for CR
MI	Proportion PCI to CABG	0.893	Fixed	NACR data request, assumed the same for CR
MI	CVD mortality	0.032	Gamma (0.009)	Anderson [3]
Non-MI revasc.	Hospitalisation	Same as well to hospitalisation		Assumption
Non-MI revasc.	Non-MI revasc.	0.053	Gamma (0.011)	Anderson [3]
Non-MI revasc.	Proportion PCI to CABG	0.690	Fixed	NACR data request, assumed the same for CR
PCI	Surgical mortality	0.015	Beta (7.5, 493)	Hamburger [5], assumed the same for CR
CABG	Surgical mortality	0.022	Beta (1484, 65966)	Gutacker [6], assumed the same for CR
All states	Non-CVD mortality	Age and gender adjusted life tables inflated by 1.32 to account for observed difference in Anderson from ONS, consistent with NICE approach		Anderson [3] and ONS [7], assumed the same for CR

Table 3-A: Odds Ratios and standard errors applied as treatment effect, calculated from the Anderson summaries

	OR	SE
Revasc-CABG	0.946258	0.091974
Revasc-PCI	0.889495	0.098003
Recasc-combined	0.922927	0.070797
MI	0.740435	0.076189
CV mortality	0.908784	0.047836
All mortality	0.814266	0.08611
hospitalisation	0.919239	0.067066

Table 4-A: Unit costs used in model

Parameter	Unit Cost	Distribution	Source
Cost of CR	£747.67	Fixed	Beswick [8] inflated to 2016/17 prices using PSSRU HCHS pay and prices inflation[9]
Cost of well state, per cycle	£0	Fixed	Assumption
Cost of hospitalisation, per event	£1,243.05	Random draw of categories	NHS Reference Costs 2015-16,[10] all 'unspecified check pain' categories, weighted by frequency
Cost of MI, per event	£4,023.05	Gamma (SE – 276)	Hartwell [11] inflated to 2016/17 prices, with hospitalisation cost deducted
Cost of CABG, per event	£14,326.68	Random draw of categories	NHS Reference Costs 2015-16,[10] all CABG categories, weighted by frequency
Cost of PCI, per event	£3,000.05	Random draw of categories	NHS Reference Costs 2015-16,[10] all angioplasty categories, weighted by frequency
Cost after events	£0	Fixed	Assumption that all costs are included in the event costs

Table 5-A: Quality of Life (QoL) estimates used in the model

Parameter	**QoL decrement**	**Distribution**	**Source**
All decrements are applied to age adjusted 'normal' population values from Sullivan (2011)			
Well	0	Fixed	Assumption
Hospitalisation	0.05	Gamma (SE – 0.023)	Lewis [12]
MI	0.06	Gamma (0.026)	Lewis [12]
CABG	0.06	Gamma (0.026)	Assumed same as MI
PCI	0.06	Gamma (0.026)	Assumed same as MI

Figure 1-A: Base-case Probabilistic Sensitivity Analysis (PSA) scatter plots stratified by IMD, with line showing a £20,000/QALY threshold

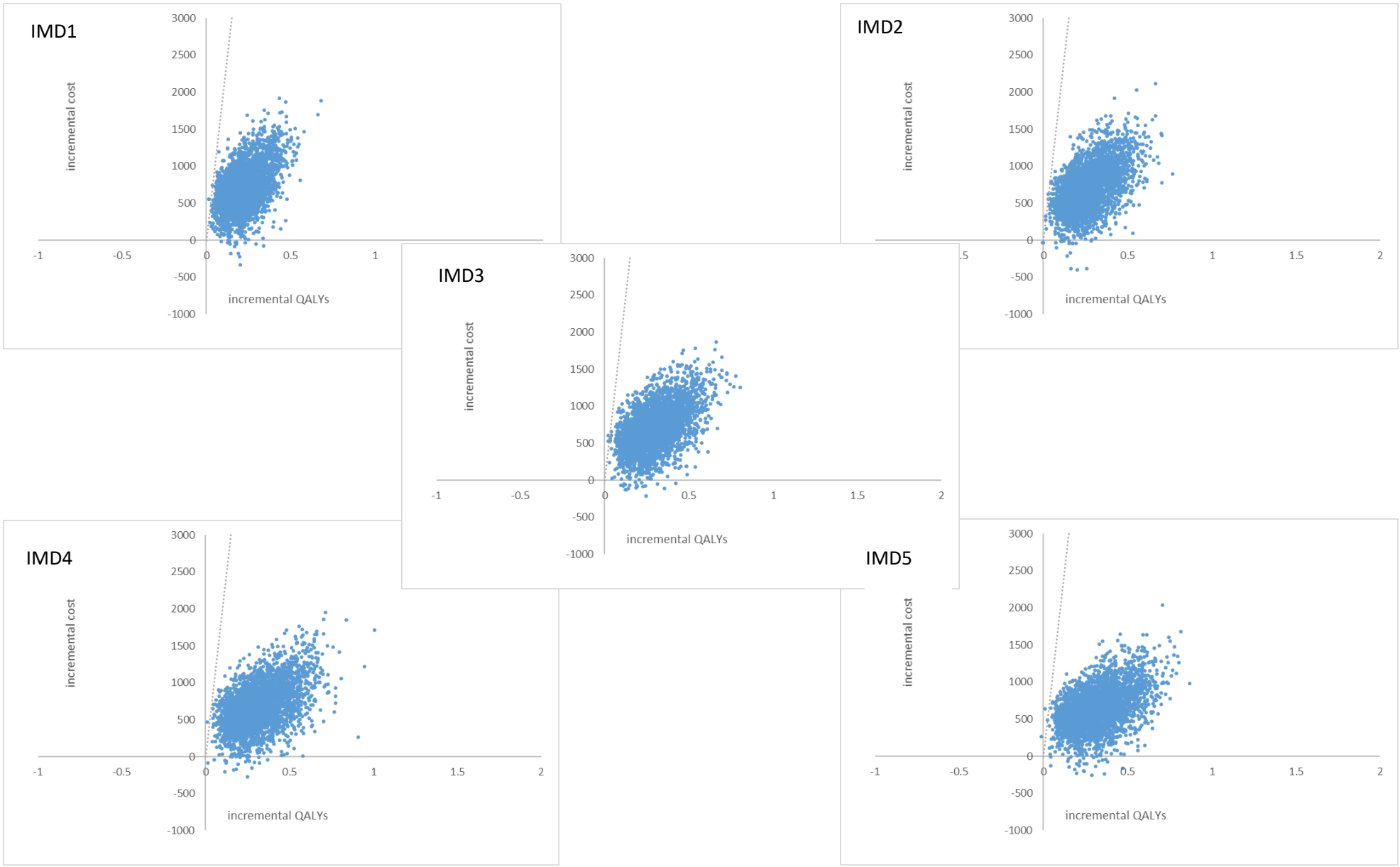

Table 5-A: Results for 100% compliance scenario

IMD	no CR		CR		incremental		ICER /QALY	Prob. CE £12,936/ QALY
	disc. cost	disc. QALY	disc. cost	disc. QALY	disc. cost	disc. QALY		
1	£7,696	3.80	£8,408	4.14	£712	0.34	£2,124	0.998
2	£7,328	4.22	£8,034	4.60	£706	0.38	£1,875	0.999
3	£6,863	4.42	£7,566	4.82	£702	0.40	£1,775	0.999
4	£6,760	4.75	£7,426	5.16	£666	0.41	£1,630	0.999
5	£6,340	5.12	£6,958	5.52	£618	0.40	£1,538	1.000

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Quantifying the impact of delayed delivery of cardiac rehabilitation on patients' health

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Abstract

Background: Despite its role as an effective intervention to improve the long-term health of patients with cardiovascular disease and existence of national guidelines on timeliness, many health services still fail to offer cardiac rehabilitation in a timely manner after referral. The impact of this failure on patient health and the additional burden on healthcare providers in an English setting is quantified in this article.

Methods: Two logistic regressions are conducted, using the British Heart Foundation National Audit of Cardiac Rehabilitation dataset, to estimate the impact of delayed cardiac rehabilitation initiation on the level of uptake and completion. The results of these regressions are applied to a decision model to estimate the long-term implications of these factors on patient health and National Health Service expenditure.

Results: We demonstrate that the failure of 43.6% of patients in England to start cardiac rehabilitation within the recommended timeframe results in a 15.3% reduction in uptake, and 7.4% in completion. These combine to cause an average lifetime loss of 0.08 years of life expectancy per person. Scaled up to an annual cohort this implies 10,753 patients not taking up cardiac rehabilitation due to the delay, equating to a loss of 3936 years of life expectancy. We estimate that an additional £12.3 million of National Health Service funding could be invested to alleviate the current delay.

Conclusions: The current delay in many patients starting cardiac rehabilitation is causing quantifiable and avoidable harm to their long-term health; policy and research must now look at both supply and demand solutions in tackling this issue.

Keywords

Cardiac rehabilitation, delay, uptake, completion, economic evaluation, cost effectiveness

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Introduction

The international burden of cardiovascular disease, both on patient health and healthcare budgets, is enormous, associated with an estimated 9.43 million deaths worldwide in 2016,[1] costing the English National Health Service (NHS) £7 billion a year to treat,[2] and the global economy an estimated $900 billion.[3] This burden is only expected to increase over time.[1,3] To attempt to alleviate its impact, policy makers have sought to increase preventative activities,[4] in addition to limiting the individual burden for patients who have cardiovascular disease.[5] A key focus of the latter has been the drive to offer cardiac rehabilitation (CR) to eligible patients who have been diagnosed with cardiovascular disease, in an attempt to reduce the risk of future cardiac events, through a comprehensive health behaviour approach including exercise training,

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education (e.g. diet and physical activity promotion) and psycho-social support.

Recent research has demonstrated that CR is both highly effective[6] and cost-effective[7] for coronary heart disease (CHD) patients. However, despite extensive guidance on the timeframe within which CR should be started after myocardial infarction (MI) or revascularisation,[5,8] there is significant variation in the timeliness of initiation.[9] International research has identified that a delay in the start of CR has contributed to the poor levels of engagement with the service, both uptake[10–12] and completion,[10,11,13] as well as impacting the propensity to benefit from the programme.[14,15] Previous authors have identified that this delay is the result of both patient and service-level factors.[16] However, to date there has been no attempt to combine these factors to determine the impact of delayed start on long-term patient health and cost burden of continued cardiovascular disease on the healthcare system.

In this paper we report de-novo regression analyses exploring the impact of a delay on uptake and completion of CR using the British Heart Foundation (BHF) National Audit of Cardiac Rehabilitation (NACR) database.[17] These regressions are used to extend an existing mathematical model of the long-term health and resource use implications of CR[7] in order to estimate the impact of the existing delay in CR initiation in an English setting. We consider: (a) the detrimental impact of the delay on the benefits of CR; (b) the population health and cost implications of the delay; and (c) the funding that can be justified to increase the offer of timely CR.

Methods

What is the scale of delayed CR initiation?

To consider the impact of a delay in CR initiation on outcomes of interest we first define what constitutes 'timely CR' from 'delayed CR'. This study uses a definition of timely being a start of CR within 28 days of referral for MI and/or percutaneous coronary intervention (PCI) and 42 days for coronary artery bypass graft (CABG) patients, this is consistent with the approach taken in the current UK audit[17] and the literature where the delay is treated categorically.[14] Figure 1 and Supplementary Table 1 provides a histogram and summary by intervention of the time between referral and initiation of CR from the available NACR data with a cut-off of 6 months.[17]

The figure shows a significant skew in waiting times, while the majority of patients achieved the target (56.4%), many had to wait much longer. Patients who started CR within the recommended period waited a median of 15 days from referral, with those who did not start CR in the recommended period waiting a median of 49 days, see Supplementary Table 1 in the Supplementary Appendix for more details. The data also demonstrate a significant variation in the demographic and socioeconomic make-up of the two groups, with women, non-white, less deprived and employed people being more likely to have a delayed start. The impact of these differences is further explored in the regression analyses reported below.

What does the evidence say on the impact of delay?

The impact of delay on uptake. When exploring the impact of a delay in CR on the rate of uptake (i.e. non-participation) it is important to note the intrinsic challenge that in order to define the impact of wait time on uptake an estimate of the wait time between referral and initiation of CR is required in both those who do and do not take up CR. However, by definition, patients who do not take up CR cannot have a CR start date, and therefore no wait time can be estimated. As a result, a proxy for the initiation date must be used, for example the initial assessment date which typically occurs just before active CR. The initial assessment is conventionally used to assess the suitability of the patient and explain the programme to them, and as such it is not part of the active intervention but intrinsically linked.

To estimate the impact of the delay on the rate of uptake, taking account of the known cofounders,[18] we conducted a logistic regression using data routinely collected through the NACR.[17] The regression estimates the impact of characteristics, including a categorical wait time variable, on the probability of uptake, therefore estimating the impact of the delay on non-participation in CR. The method of regression was backward stepwise, with an inclusion criteria of 0.1 and significance set at 0.05. This allowed the regression model to be adapted to include only statistically influential variables. As the quality of data reporting in routine datasets is relatively poor, for a robust analysis of uptake, a reduced cut of the NACR population was used to include four large programmes in which the data quality was known to be high. Data over a 4 year period (2016–2019) were used to inform the regression, resulting in a sample size of 2779 patients.

The impact of delay on completion. The second effect of a delay in CR initiation modelled in the base case analysis is the expected reduced rate of completion. Patients are most amenable to change and intervention engagement soon after a significant health shock such as CHD; therefore, their level of engagement is reduced if CR is offered with a delay. As a result, patients may

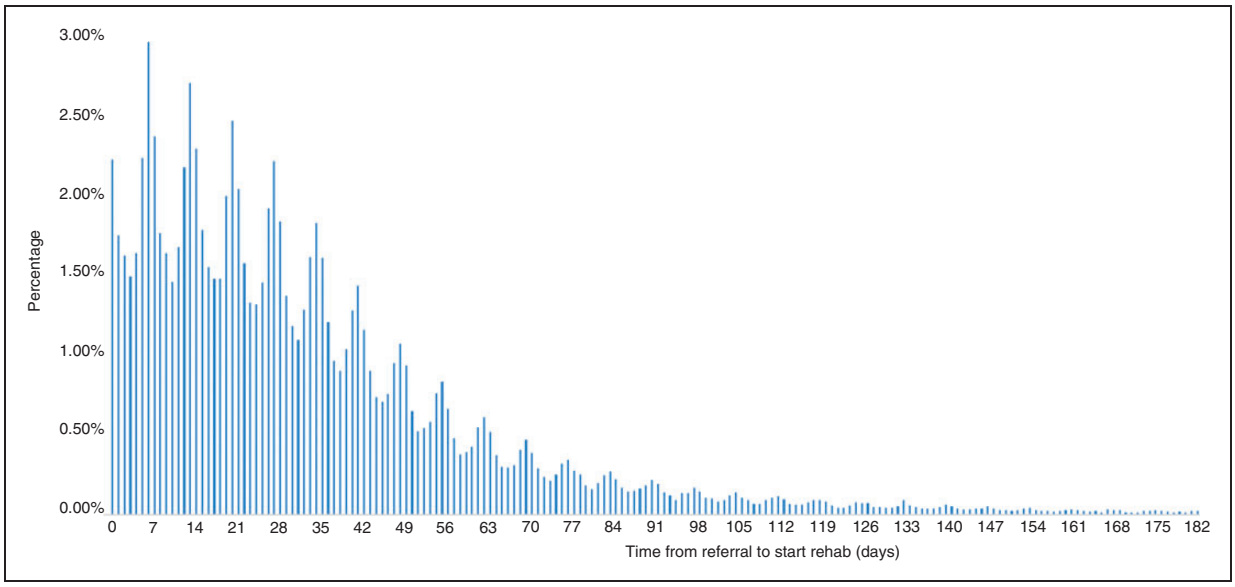

Figure 1. Histogram of waiting times from referral to initiation, 2015–2019.[17]

still start the programme but the delay impacts their likelihood of completing it.

As with the uptake analysis we conducted a logistic regression of the NACR data, seeking to estimate the impact of the delay on completion, adjusting for known confounders. However, as data completeness and quality are much higher in the dataset for completion we were able to use the full NACR population who had started the core CR programme and a wait time recorded, again over a 4 year time period, a total of 71,423 patients.

The mathematical model

The regression analyses conducted on the NACR dataset summarised above are carried forward to the mathematical model. By applying the results to the observed wait time and patient characteristics in the delayed CR initiation group, it is possible to estimate the expected increase in uptake and completion that could be achieved if all patients who are currently being delayed were to start CR within the recommended wait time. The parametric uncertainty associated with the regression analyses is incorporated into the health economic analysis using Cholesky decomposition to account for the correlation of the coefficients.[19]

To ensure consistency with existing research and UK policy recommendations, this analysis is constructed around an existing peer-reviewed mathematical model of the impact of CR, which was used to inform the NHS Long Term Plan[2] and latest British Heart Foundation (BHF) strategy.[9] Details of the model are published elsewhere,[7] but in brief the model explores the cost-effectiveness of CR for CHD patients who are eligible for CR, including all MI and revascularisation patients using the findings of the 2016 Cochrane review of CR for CHD.[6] The analysis concluded that CR was a cost-effective use of limited NHS resources, as while it entailed an additional cost over the lifetime of the patient (£714) it also entailed significant expected increases in patient health (0.30 quality-adjusted life-years; QALYs). This implied a cost per QALY incremental cost-effectiveness ratio (ICER) of £2395/QALY, far below the conventionally applied threshold for cost-effectiveness of £20,000/QALY.

Results

The results of this analysis are structured to quantify the combined impact of the delay on uptake and completion, and the implications of this on the long-term patient health and cost to the healthcare provider. All of the results are presented in terms of the expected benefits that could be achieved if those patients who did not start CR within the target time did so, with those who received timely CR assumed to receive the benefits as defined by the Cochrane review[6] and the original health economic model.[7]

What is the combined impact of delayed CR?

The results of the regression are given in Table 1, showing that for patients with a wait time that complied with the national guidance, both uptake and completion was significantly greater than for those who had a longer wait time for CR. This implies odds ratios of 1.782 for uptake and 1.106 for completion, both at P values of 0.001 or less.

Table 1. Regression analysis of factors effecting completion rates using NACR 2015 to 2019.

	Uptake			Completion		
Variable	Coefficient	S.E.	Sig.	Coefficient	S.E.	Sig.
Gender (effect of being female)	Not significant			–0.137	0.036	0.000
Age (effect of increasing by 1 year)	–0.026	0.011	0.000	0.011	0.001	0.000
Waiting time (effect of having shorter wait time <28/42 days)	0.578	0.100	0.000	0.100	0.029	0.001
Employment (effect of being employed/retired)	–0.901	–0.227	0.000	–0.227	0.040	0.000
Ethnicity (Non-white)	0.892	0.228	0.000	Not significant		
Marital status (effect of being partnered)	1.148	0.127	0.000	0.233	0.034	0.000
Patient type (base state PCI)	Not significant					0.000
Patient type (Being CABG compared with PCI)				0.256	0.039	0.000
Patient type (being other compared with PCI)				–0.037	0.057	0.510
IMD (Base state highest deprived quintile)	Not significant					0.000
IMD (effect of being 2nd quintile)				0.166	0.049	0.001
IMD (effect of being 3rd quintile)				0.345	0.049	0.000
IMD (effect of being 4th quintile)				0.467	0.049	0.000
IMD (effect of being 5th quintile)				0.571	0.048	0.000
Constant	1.144	0.394	0.004	0.128	0.098	0.190

NACR: National Audit of Cardiac Rehabilitation; PCI: percutaneous coronary intervention; IMD: Index of Multiple Deprivation.

Table 2. Estimate of the delay on uptake and completion, and a shift to timely initiation.

	Delayed CR offer	Timely CR offer	Difference (95% CI)
Uptake	45.5%	73.4%	14.3% (7.9% to 20.4%)
Completion	59.8%	75.4%	1.9% (0.8% to 3.0%)
Combined	33.4%	45.1%	11.7% (6.9% to 16.2%)

CR: cardiac rehabilitation; CI: confidence interval.

Applying the known patient characteristics to the results of the logistic regressions allows us to estimate the rate of uptake and completion for the group in which the CR is delayed and how they would change if CR started within the recommended wait time. These are reported in Table 2, showing that if the patients who currently received delayed CR were given it in a timely manner they would be expected to increase their uptake by 14.3% and their completion rate by 1.9%. Nationally, this implies 10,753 more patients would take up CR if the delay was removed, and 8757 more would complete the programme.

Also of note, the positive 95% confidence intervals indicate that the delay is never expected to result in a detrimental impact on uptake or completion. This is the result of the statistical significance of the effects identified in the previous section and has important implications regarding the overall uncertainty of the conclusions drawn below.

What is the impact of the delay on patient health and healthcare expenditure?

The impact in terms of expected patient health and healthcare costs, when these findings are applied to the baseline model, are reported in Table 3.

They show that a shift from delayed to timely CR would be expected to result in an additional 0.08 life-years on average per person referred for CR (approximately one month). This results in a gain of 0.06 QALYs, 0.03 QALYs when discounted to the present value. The result is driven by more patients achieving the health gain from completing CR (0.30 QALYs).[7] The larger proportion of the cohort receiving CR implies a greater average lifetime cost of £120, or £107 when discounted. When the cost of the higher rate of CR is excluded the difference in lifetime cost is small at £13 per person. This implies that while providing CR earlier to this group is not cost saving due to the additional CR provision, it is associated with an increase in long-term patient health at an incremental cost-effectiveness ratio of £3286/QALY.

Combining the population estimated to be currently receiving delayed CR of 34,496 (44% of the 78,997 currently receiving CR per year) and the 10,753

Table 3. Impact of removing the delay on average health and NHS costs per patient referred for CR.

	Costs (undisc.)	Cost (disc.)	LYs (undisc.)	QALYs (undisc.)	QALYs (disc.)*
Delayed CR offer	£8763	£7203	7.433	5.39	4.51
Timely CR offer	£8883	£7310	7.516	5.45	4.55
Difference	£120	£107	0.08	0.06	0.03
(95% CI)	(£14 to £267)	(£23 to £219)	(0.02 to 0.18)	(0.02 to 0.13)	(0.01 to 0.09)

CR: cardiac rehabilitation; disc.: values discounted at a rate of 3.5% per annum in line with NICE guidance (NICE 2013); undisc.: no discounting applied; Lys: life years; QALYs: quality-adjusted life-years.

estimated not to take up CR as a result of the delay, gives a total population health loss due to the delay of 3936 life-years or 2792 QALYs (undiscounted) for every year when CR is not offered in keeping with national guidance. Over a 5 year timeframe this loss of patient health can be estimated as resulting in a loss of 1587 year of life across the 450,000 patients who would have CR over that period.

What additional funding can be justified to alleviate it?

Inevitably, achieving the shift to initiation within the national guidance timeframe will require additional funding. By applying an estimate of the marginal productivity of the NHS of £12,936/QALY[20] it is possible to calculate what NHS expenditure could be justified to achieve timely CR for all patients. This implies that an additional £315 could be justified per patient in the delayed CR group while maintaining the cost-effectiveness of the service, or £137 per patient starting CR when spread across all patients, £12.3 million across the full CR population per year. Adding this to the modelled cost of CR (£748)[7] implies that a cost of up to £885 for CR could be justified as cost-effective should all patients receive it in line with national guidance on waiting times.

Discussion

There is large variation in the time at which CR is delivered in the UK and internationally,[17,21] and there is now extensive evidence that this delay is contributing to poorer uptake and completion rates, and is likely to result in decreased effectiveness of the programme. We have estimated that the delay in England is causing 3936 lost years of life across the patients' lifetime for each year the delay endures. This analysis has also demonstrated that once the additional CR enrolments are paid for the move to earlier initiation for all patients is cost neutral, and that an additional £137 could be spent per CR patient to ensure the timely start for all, increasing the recommended cost of CR to £885.

The strength of the study is that it is the first to quantify the impact of the delay in CR initiation on uptake and completion, and to estimate the additional funding that can be allocated to alleviate it. By building on an existing peer-reviewed model, which has informed policy, this analysis ensures a consistent narrative on the latest policy facing research.

There are, however, several weaknesses associated with this analysis in addition to those in the baseline model.[7] Firstly, in order to conduct a regression analysis for the impact of the delay on CR uptake we needed to use a proxy to estimate the wait time as well as relying on a reduced set of NACR data. There is the risk that such a proxy misses a proportion of patients who, due to a long wait for the assessment date, chose to not attend it, and thus cannot have a wait time estimated. Therefore, any estimate of the impact of delay on uptake is likely to underestimate the scale of patient failure to uptake; however, the use of such a proxy is both unavoidable and has precedent in the literature.[10–12,18] A further limitation is that the reduced dataset may not be representative of the wider CR population, as it contained slightly more women than the full population, but not at significant levels and the average age and ethnic mix was similar. In addition, there are potential confounders such as frailty, comorbidities and rurality, which may be important differences in the timely and delayed populations, but which are not reflected in the dataset available to us and thus not the regressions conducted.

Other authors have published estimates of the impact of the delay from referral to initiation of CR on uptake and completion of the programme. Russell et al.[12] conducted a retrospective regression analysis of 599 patients referred to a single centre CR programme in Canada, concluding an odds ratio of 0.99 (95% confidence interval of 0.98 to 0.99) for an additional wait of one day on uptake. Although the nature of the regression makes direct comparison with our analysis difficult, we consider the result to be comparable. Similarly, considering the impact of a delay on completion, Marzolini et al.[13] conducted a regression analysis which incorporated a consideration of delay on completion, in a large dataset of CABG patients in Canada

between 1995 and 2012. The authors similarly found a statistically significant correlation between log wait time and non-completion (coefficient of 2.215, $P < 0.001$). Marzolini et al. additionally explored the impact of delays in the referral to CR, an element which is not included in this analysis as it refers to a different policy question regarding the speed of referrals, and the health threshold at which patients become eligible for CR, rather than failures of the programmes to achieve timely start targets.

An additional weakness is that while we have been able to conduct an exploratory analysis to estimate the additional impact of incorporating the role of a delay in initiation on CR outcomes, reported in the Supplementary Appendix, the informative estimates are highly uncertain. Inevitably, the analysis indicates that if the impact of the delay on outcomes were incorporated the loss of patient health as a result would be even worse than in the current model, suggesting our analysis underestimates the benefits of timely CR. Further research and data collection are needed to understand the factors that influence different CR outcomes, such as long-term physical fitness.

We recommend that future studies explore the key policies and interventions that may effectively alleviate the delay, specifically further exploring whether it is a supply or demand side issue.[16] In addition, further routine data collection is require on the reasons patients do not engage with CR programmes, and the long-term impact of factors such as wait time on the effectiveness of the programme.

Author contribution

PD and LB contributed to the conception and design of the work. SH conducted the mathematical modelling and analysis. AH provided data acquisition and statistical analysis. All authors contributed to the drafting of the submitted manuscript and gave final approval and agreement to be accountable for all aspects of the work ensuring integrity and accuracy.

Declaration of conflicting interests

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Supplementary appendix

Section 1) Summary statistics of waiting time by patient type

Table A1: summary statistics of waiting time by patient type

Characteristic		Timely start		Delayed start		Total	
		Mean	SD	Mean	SD	Mean	SD
Age (years)		64	11	63	12	64	11
Treatment category (days)	MI	13.1	8.2	57.4	29.4	31.6	29.6
	MI and PCI	14.2	8.0	54.4	27.4	30.6	27.1
	PCI	14.7	7.6	56.4	29.0	31.3	28.0
	CABG	22.7	12.7	70.7	28.1	42.2	31.2
	Total	15.8	9.6	58.4	28.9	33.2	28.8
		Count	%	Count	%	Count	%
Age Grouped	<40	866	2.0%	567	2.5%	1433	2.1%
	41-50	4804	10.9%	2717	11.8%	7521	11.2%
	51-60	11540	26.3%	6063	26.3%	17603	26.3%
	61-70	13538	30.8%	6896	29.9%	20434	30.5%
	71-80	10299	23.5%	5201	22.5%	15500	23.1%
	81+	2843	6.5%	1652	7.2%	4495	6.7%
Gender	Male	34319	78.8%	17209	75.0%	51528	77.5%
	Female	9243	21.2%	5731	25.0%	14974	22.5%
Ethnicity	White	33237	75.7%	16812	72.8%	50049	74.7%
	Non-white	10653	24.3%	6284	27.2%	16937	25.3%
Employment	Employed/ Retired	23641	82.0%	13258	84.8%	36899	83.0%
	Unemployed	5199	18.0%	2368	15.2%	7567	17.0%
Marital Status	Single	6708	22.1%	3883	24.1%	10591	22.8%
	Partnered	23712	77.9%	12243	75.9%	35955	77.2%

Section 2) Additional impact of delay on outcome scenario

A number of studies have explored the impact of the delay on the effectiveness of CR. Johnson et al.[1] conducted multivariate analysis on a single centre US dataset, finding delay was significantly correlated with peak exercise capacity during the programme. Similarly, Fell et al. [2] and Sumner et al. [3], conducted regression analysis on the NACR dataset, finding the delay was correlated with a range of factors: physical activity, physical fitness, incremental shuttle walk test score, anxiety, and depressive symptoms.

While the repeated demonstration of an effect of the delay on short term physical and mental outcomes suggests an effect above and beyond the poorer level of uptake and completion, the lack of long-term analyses using outcomes directly relevant to the baseline model makes the incorporation of these studies challenging and necessitating on significant assumptions. For this reason the inclusion of the impact of delays on outcomes was not included in the primary analysis in this study, but a scenario was constructed which is presented in this appendix.

In order to incorporate the findings of these studies for a scenario analysis into the model it was first necessary to find a study which correlated any of the outcomes in these three studies to the outcomes relevant to the baseline model. Only a single outcome was identified which achieved this requirement, linking the estimated difference in self-reported physical activity from Fell et al. [2] to all cause and cardiovascular related mortality through the study by Mok et al. [4].

Fell et al. [2] report physical activity in terms of the proportion of patients achieving the recommended 150 minutes of moderate activity per week, finding an OR of 0.863 per additional day of delay. Mok et al. [4] identified, through interrogation of a population cohort in the UK, that an increase in physical activity of 1kJ/kg/day, assumed by them to be equivalent to being inactive at baseline to achieving the 150 minute target after 5 years, was associated with hazard ratios (HRs) of 0.71 for cardiovascular mortality, and 0.76 for all cause. Clearly, the combining of these studies to link the findings of Fell to our baseline model variables requires a number of significant assumptions regarding the duration of the observed effect and the comparability of the physical activity outcomes used in the two studies. If we assume that the outcome observed in Fell is life-long, the outcomes perfectly equivalent, and that the HR reported for cardiovascular mortality applied to all of the outcomes which patients are modelled as benefitting from CR it is possible to combine the outcomes to determine that the delay has a detrimental effect of 1.017 on all outcomes. This implies that the delay in CR provisions makes CR less effective in all patients by a factor of 1.017, so a relatively small impact relative to the overall benefit of CR.

The impact of this additional effect when added to the result reported in the main paper are reported in Table A2.

Table A2: model results from addition of delay impact on outcomes

	Costs (undisc.)	Cost (disc.)*	LYs (undisc.)	QALYs (undisc.)	QALYs (disc.)*
Delayed CR offer	£9,252	£7,565	7.79	5.64	4.73
Timely CR offer	£9,389	£7,629	7.91	5.70	4.80
Difference	£137	£65	0.12	0.05	0.06

While we consider the inclusion of the impact of delay on CR effectiveness to be too uncertain to include as the primary analysis it is important to note that Fell demonstrates a statistically significant impact of the delay on a number of short term outcomes and that offering CR in a timely way will, within reason, always be expected to only improve effectiveness. This implies that we would expect the benefits of timely CR to be greater than those stated in the primary analysis, and thus the justifiable expenditure to increase timeliness greater than is reported.

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Achieving cardiac rehabilitation uptake targets: What is the value case for commissioners? A UK case-study

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ABSTRACT

Cardiac Rehabilitation (CR) has become an established intervention to support patient recovery after a cardiac event, with evidence supporting its effectiveness and cost-effectiveness in improving patient health and reducing future burden on healthcare systems. However, this evidence has focussed on the national value case for CR rather than at the point at which it is commissioned. This analysis uses the UK as a case-study to explore variation in current CR engagement and disassemble the value case from a commissioner perspective.

Using data collected by the National Audit of CR (NACR), and an existing model of cost-effectiveness, we present details on the current level of CR uptake by commissioning region (Specialist Clinical Networks) in light of the current UK target of achieving 85% uptake. We then interrogate the value case for achieving the target at a commissioner level, highlighting the expected profile of health benefits and healthcare system costs over the long-term. Importantly we consider where this may differ from the national value case.

Each commissioning region has a unique level of CR uptake and sociodemographic profile. Concurrently, the value case for commissioning CR relies on the upfront cost of the service being offset by long-term healthcare savings, and health improvements.

The shift in the UK and internationally to more localised commissioning necessitates evidence of cost-effectiveness that better reflects the realities of those decision makers. This paper provides vital additional data to facilitate such commissioners to understand the value case in increasing CR uptake in line with national policy.

1. Introduction

In recent decades cardiac rehabilitation (CR) has become an established treatment component in the global struggle to reduce the rate of cardiovascular disease [1], which is responsible for 32% of all global deaths [2]. However, despite extensive evidence of its effectiveness in reducing repeat cardiac events rates of uptake have remained low [3].

In 2019 the UK's NHS Long Term Plan [4] highlighted cardiovascular disease as one of eight major health conditions to be targeted by subsequent policy intervention, primarily due to its status as the biggest cause of premature mortality [5]. Key to the proposed range of policy interventions was the extension of (CR programmes, with the target of 85% of eligible patients with acute coronary syndrome (e.g. post heart attack patients) accessing care by 2028, up from 52% in 2017 [4,6]. Concurrently, literature has identified that both patient and provider factors need to be addressed to achieve these uptake targets [7].

Within England there are currently 13 Strategic Clinical Networks (SCN), working across key NHS priority areas one of which is cardiovascular disease. SCNs are responsible for overseeing the delivery, quality, and innovation of care throughout the patient journey including CR programmes across their respect networks.

Employing internationally relevant methods of Health Technology Assessment (HTA) [8], CR has been shown to be a cost-effective use of the limited public healthcare budget, both in a UK and international setting [9]. More recently, a decision analytical model by Hinde et al. [10] supported this finding but found CR not to be cost-saving as indicated in a number of previous studies. Furthermore, this and a subsequent study [11] explored the impact of CR by socioeconomic status, finding that more deprived individuals were less likely to take up, complete, and benefit from CR programmes, suggesting some inequality

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issues to be addressed.

However, recent research has highlighted that there are a number of aspects where HTA economic evaluation methodology is not sufficient for decentralised commissioners of health, such as SCNs [12–14], bringing into question the appropriateness of applying such methods to decisions faced by such commissioners. Furthermore, commissioning of services such as CR is more complicated than the simplistic binary assessment of cost-effectiveness that HTA based analysis typically indicates, with issues such as equality of provision and poor programme uptake or completion of equal importance. [7]

In this paper we seek to produce meaningful, commissioner-level, evidence on the current provision of CR programmes and the health and cost-effectiveness case for extending the level of CR engagement to meet the ambitious targets laid out in the NHS Long Term Plan [4], with an aim of supporting local level commissioning decisions. To achieve this, we firstly summarise the existing landscape of CR provision and uptake across England using the most recent data from the National Audit of CR [6]. We apply this to an existing mathematical model of the long-term health implications of CR uptake [10] to estimate the potential health gains of achieving the NHS Long Term Plan targets. In the second part of the paper, we interrogate the aspects of the existing literature around the cost-effectiveness of CR which, while representing best practice from a national HTA economic evaluation perspective, have been shown to need additional consideration at local levels [12,13]. Through doing so we seek to provide the relevant stakeholders with additional information with which to inform commissioning decisions.

2. Methods

To achieve the aims of this paper we draw on the data for the National Audit of Cardiac Rehabilitation (NACR) covering the period 2016 to 2020 (the latest year the data was available at the time of analysis) [6] and utilise an existing decision analytical model of the cost-effectiveness of CR [10] which we have extended to provide more relevant information to the local context. An overview of the decision analytical model is provided in the Supplementary Appendix with more extensive details available from the original publications [10,11]. These resources are used to conduct three analyses.

Firstly, we explore the system and patient level impacts from a national perspective of achieving or moving towards the NHS Long Term Plan's target of achieving a CR uptake rate of 85%. This analysis re-examines the results of the original decision analytical model to estimate the impact of increases in the national uptake rate on hospital admissions, deaths (cardio-vascular related and all cause), quality adjusted life years (QALYs), and costs to the NHS. We also provide an estimate of the justifiable expenditure to achieve uptakes in CR, which uses publishes estimates of the marginal productivity of the English NHS [15] to determine the additional NHS budget that could be spent to achieve the health gains that result from increasing CR uptake, while remaining a cost-effective use of limited NHS funding.

Secondly, we use the latest NACR data to explore variations in the level of CR uptake across the thirteen SCNs contrasted against the average levels for England. In addition to reporting the level of uptake in each area we present the uptake by socio-economic group, using the index of multiple deprivation (IMD) to show the impact of deprivation on uptake but also explore the variation in this relationship across different SCNs. For the purpose of this analysis the SCNs have been anonymised.

Finally, we consider how the differences in the commissioning reality faced by SCNs compared to national decision makers impacts the value case for CR. This approach builds on previous work which has identified five areas where the conventional framework used to construct economic evaluations to inform national deliberations differs from the reality faced by those commissioning local services [12,13].

3. Results

3.1. What is the impact of increasing CR to move closer to the long term plan uptake target?

In Table 1 we explore the impact on cardiovascular and all cause deaths, quality adjusted life years (QALYs), as well as total costs both including and excluding the upfront cost of the CR. Additionally, an estimate of the justifiable expenditure to achieve the shift in CR uptake is reported, based on a marginal productivity estimate of the NHS of £12,936/QALY [15]. Table 1 additionally presents these incremental values for a range of other targets from the baseline of 50% uptake (the English CR uptake rate over the period 2016–2020). Finally, estimates are presented for any 1% change in uptake and any 1% change per individual eligible for CR in the annual cohort, these are provided to facilitate individual commissioner calculation. All of the results presented in Table 1 assume an annual eligible cohort of 118,544 [6] with a time horizon of 10 years. A 10 year time horizon was selected for these results as the time period indicated of most relevance by NHS England to inform the NHS Long Term Plan [4].

The scenario outlined in the NHS Long Term Plan [4](50% to 85%) highlights significant potential benefits of achieving the target, at both system and patient level. From a system level, hospital admissions would be expected to fall by 48,683 for the 10 year period and while total costs would increase, by £220mn, this is all the result of the additional upfront cost of CR, with costs over the 10 years falling by £90mn when the upfront cost of CR is excluded. It is important to note here that the cost of CR applied in the model, £748 per person who starts CR, may be more than applied elsewhere, for example the most recent national costing guide estimates of cost of £477 [16], for further details regarding the calculation of the higher cost see Hinde et al. [10]. The table further shows a justifiable expenditure of £549mn to achieve the 85% target for a 10 year period. This implies that if that level of NHS funding were allocated to successfully achieving the target, CR would still represent a cost-effective use of finite NHS resources. However, by extension this implies that if more were spent or the 85% target were not achieved it would not represent value for money.

3.2. What does CR uptake look like across the different local areas?

Fig. 1 shows CR uptake rates and the eligible populations for the whole of England as well as for each SCN. Each area has their average uptake reported (the 'X' on the figure) as well as the distribution of uptake by IMD (reported through the bar charts), alongside the eligible annual population (the '-'). The values presented were provided by the NACR and are averages across 2016–2020.

The figure highlights several important elements of CR uptake. Firstly, looking at the values for England the average CR uptake of 50% is accompanied by a large variation in uptake by IMD, with the more deprived having progressively lower level of uptake ranging from 44% to 55%. However, this level of CR uptake and pattern of inequality is of limited generalisability across the different SCNs.

For example, SCN13 has a similar distribution of inequality in uptake to the national level but at a much lower overall level of uptake, with an average level of 38% (32% to 44%). In contrast, SCN1 has a much higher level of uptake (64%) but a different distribution by IMD, with the third and fourth groups having the highest uptake. Finally, both SCN2 and SCN8 have inequality gradients that are the inverse of the national distribution, with increasing deprivation being consistently associated with an increase in CR uptake.

3.3. Making the economic case at a local level for achieving these targets

In Sections 3.1 and 3.2 we have highlighted that there is a substantial need and potential benefit to increasing the uptake of CR to achieve the ambitious target of 85% uptake in those who are eligible. However,

Table 1
Incremental values for national cohort (118,544 eligible people per year) over 10 years.

Scenario	new admissions	deaths - CV	deaths - all	QALYs***	Costs – all*	Costs- after CR*,**	Justifiable expenditure***
50% to 85%	−48,683	−23,769	−19,610	59,479	£220,356,718	-£89,855,917	£549,058,659
50% to 65%	−20,864	−10,187	−8404	25,491	£94,438,594	-£38,509,679	£156,873,903
50% to 60%	−13,909	−6791	−5603	16,994	£62,959,062	-£25,673,119	£235,310,854
50% to 70%	−27,819	−13,582	−11,206	33,988	£125,918,125	-£51,346,238	£313,747,805
Any 1% change	−1391	−679	−560	1699	£6,295,906	-£2,567,312	£15,687,390
any 1% increase per N in annual cohort	−0.012	−0.006	−0.005	0.014	£53	-£22	£132

* All costs and QALYs represent undiscounted values.
** This is excluding the cost of CR.
*** Justifiable expenditure is estimated as the additional cost that could be borne before the scenario no longer a cost-effective use of NHS resources.

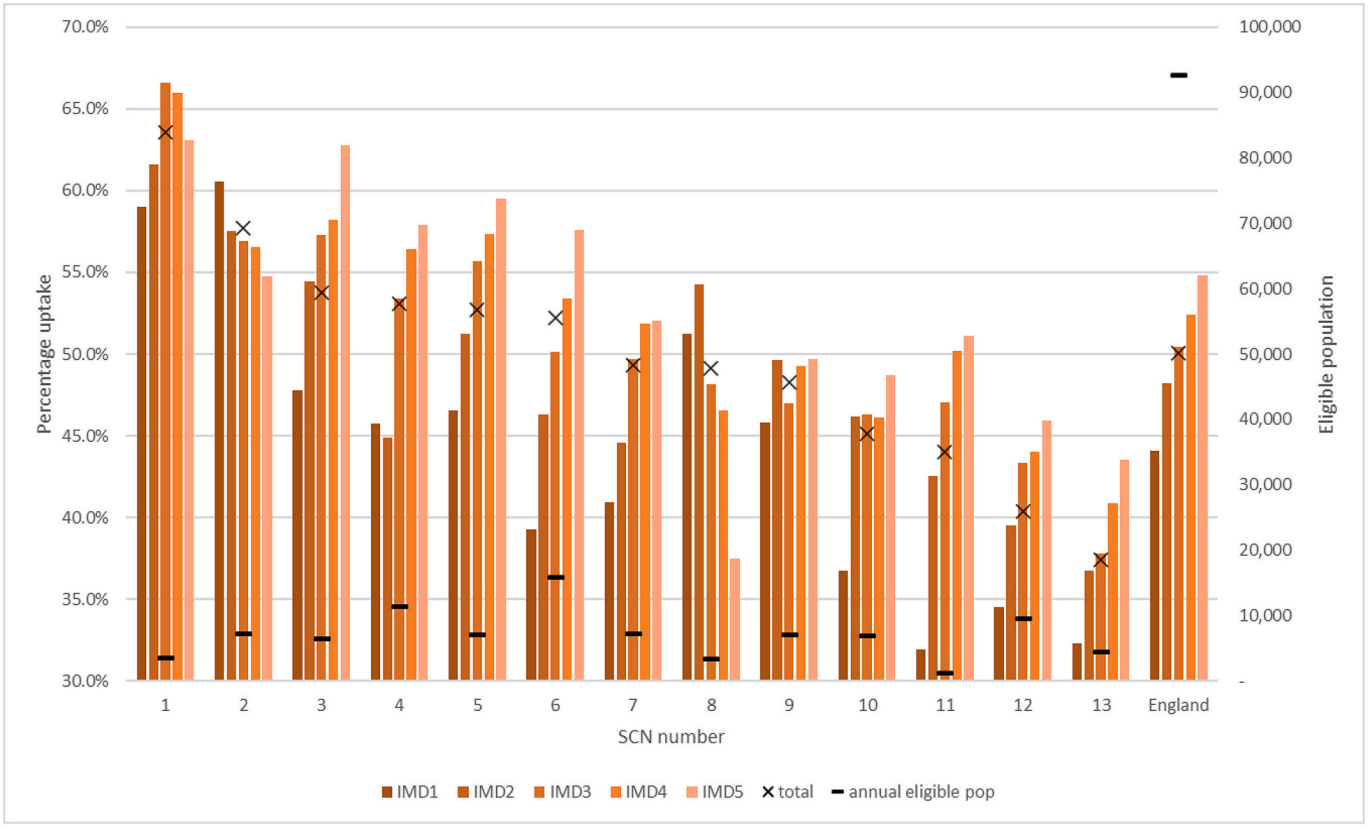

Fig. 1. uptake (mean and by IMD) and eligible annual population by anonymised SCN area, 2016–20 averages.
IMD – index of multiple deprivation, IMD1 is the most deprived, IMD5 the least

Section 3.2 further demonstrated how the current blanket ambition fails to account for the large variation in current uptake level both between geographic areas and across socio-economic deprivation. In this section we explore how the economic case can address some of the challenges faced at a local level, in making the business case for commissioning interventions to increase CR uptake.

Previous literature has made the case that, at a local level, there are elements of the framework used to inform national cost effectiveness that are not necessarily relevant or are in need of additional consideration to be most informative to the needs of local commissioning [10,13]. In this section we explore five elements in turn, reflecting on the relevance of each in a CR setting and presenting additional analyses to inform commissioning decisions.

3.3.1. *Valuation of future costs and benefits*

Under conventional HTA decision frameworks, a lifetime perspective is recommended [17], with both costs and outcomes discounted at a rate of 3.5% per year. However, the budgetary reality faced by many local commissioners makes the application of such a perspective challenging if not untenable as budgets may be required to be balanced within a financial cycle or targets set with a less than lifetime horizon. Therefore, while it might be the optimal solution for the NHS as a whole to take such a long perspective regarding the accumulation of costs and benefits, individual commissioners may by necessity deviate from such an approach.

From a health outcome perspective Fig. 2A shows that the benefits of CR, measured here in terms of incremental QALYs gained over time, are relatively slow to accumulate, reaching a maximum undiscounted value of 0.6 QALYs. This slow but constant accumulation of patient benefit over their remaining lifetime is the result of CR acting to reduce the individual's risk of future cardiac events at a modest but constant rate over the long term [3].

From a cost perspective the high upfront cost, that of the CR programme itself, is offset to some extent by medium term reductions in patient care need due to improved cardiac health. In the longer term this total cost saving is then in turn offset by patients who completed CR living longer lives and therefore being associated with additional healthcare costs later in life. This relationship is shown through the 'U-

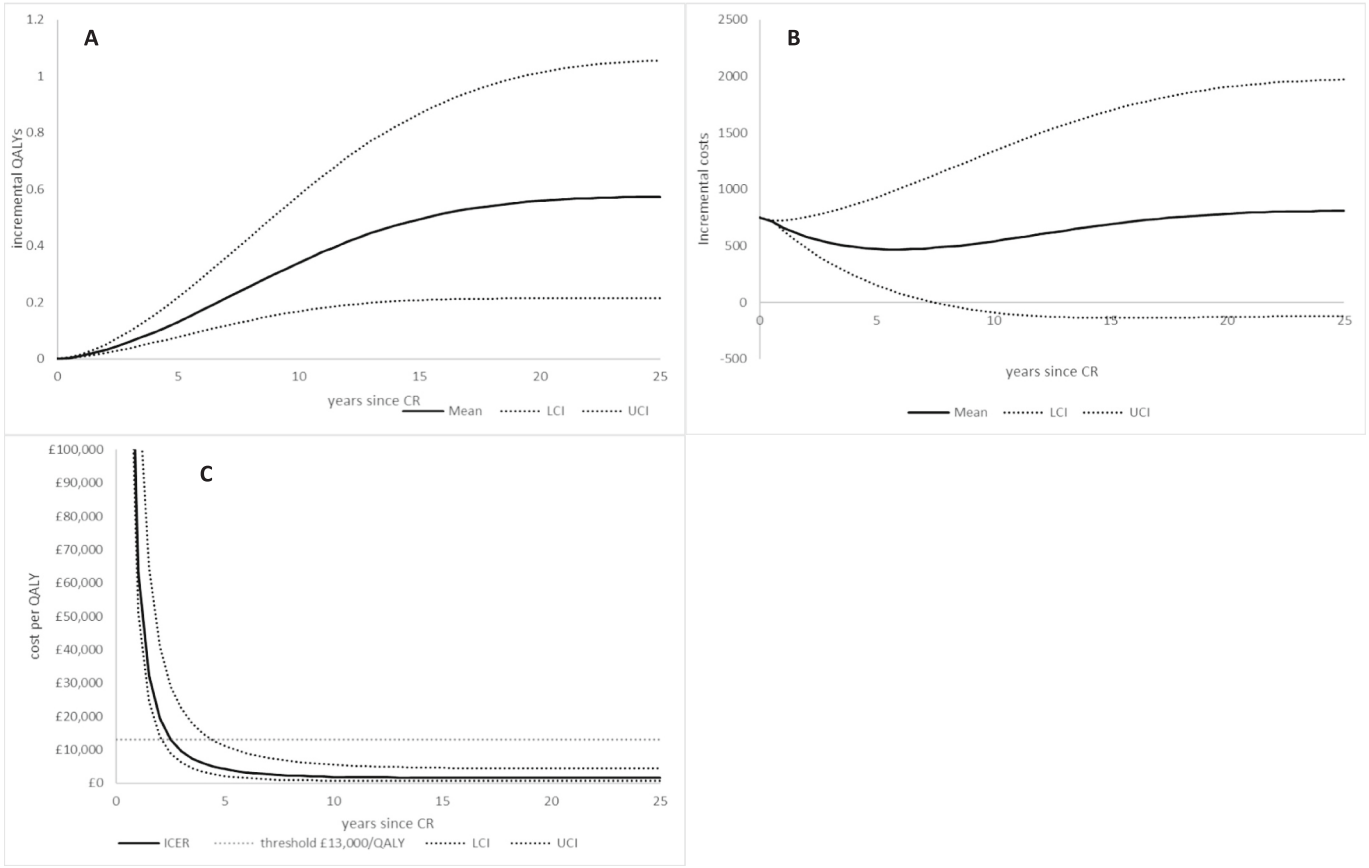

Fig. 2. graphs of the undiscounted incremental QALYs (A), incremental costs (B), cost per QALY (C), and Net Monetary Benefit (D) over time of CR versus no CR with associated uncertainty.
NB. costs (fig. A) and QALY (B) are undiscounted over time, the ICER (C) are discounted at a rate of 3.5% consistent with the NICE methods guide

shaped' trend in Fig. 2B. Importantly, in contrast to some previous studies of CR [9,18] it is not expected to be cost-saving at any point in time, therefore implying some opportunity cost of the investment in CR whatever the time horizon considered.

Combining the health benefit and cost perspectives, Fig. 2C presents the incremental cost-effectiveness ratio (ICER) of CR over time, which presents an estimate of the incremental cost per QALY gain which then requires a comparison to a cost-effectiveness threshold [19]. In the case of CR, the figures show that the upfront cost of CR implies that it is not expected to be cost-effective for the first few years after it is delivered but over the longer term it would be considered cost-effective.

3.3.2. *Cost- effectiveness threshold*

In cost-effectiveness analysis the threshold value is conventionally defined as the maximum a decision maker is willing to pay for an additional unit of health gain (e.g. a QALY) [20]. In a budget constrained system where health maximisation is the primary focus, the most appropriate cost-effectiveness threshold selected would be informed by the level of health that is displaced from any disinvestment necessary to fund the additional health improving intervention, i.e. the opportunity cost of the intervention.

In their methods guide for conducting economic evaluation NICE consider a threshold value of between £20,000 and £30,000 per QALY gain to be most appropriate [17]. NICE have further clarified that they consider this threshold value to not be a reflection of the opportunity cost of expenditure in the NHS alone, arguing that it includes a range of other unquantified factors, primarily relating to stimulating investment in the UK health sector [21]. This is supported by research which has estimated that the opportunity cost alone is significantly lower than the threshold applied by NICE, approximately to £13,000/QALY at a national level [15], or closer to £7000/QALY for locally commissioned services [22].

Therefore, while the NICE threshold is conventionally used in economic evaluations to determine cost-effectiveness of healthcare interventions in a UK setting its appropriateness to local commissioners has been brought into question both in terms of what it signifies [12] and the value applied [15].

In the CR context, exploring the ICER over time (Fig. 2C) demonstrates that the high upfront cost of the programme, but long-term health gains, results in the ICER value reducing quickly from over £100,000/QALY to within the NICE threshold range within a few years. This finding underpins the cost-effectiveness of providing CR programmes even at low thresholds and short time horizons but has implications for the estimated justifiable expenditure to increase CR uptake.

3.3.3. *Budget and decision uncertainty*

Under the NICE economic evaluation framework, the reporting of decision uncertainty, generated both through the potential cost and health benefits of completing interventions, is encouraged using a range of methodologies [17]. However, aversion to decision uncertainty is likely to be different at a local level than nationally [23].

All three graphs presented in Fig. 2 include estimates of the uncertainty associated with each element of the cost effectiveness of CR, represented through 95% confidence intervals around the expected value. 25 years was selected as the maximum time period on the x-axis for these graphs as it is the time at which the respective curves flatten, i.e. all of the cohort being modelled has died.

Importantly, the increased cost and QALY uncertainty over time has no impact on the overall profile of cost-effectiveness, with Fig. 2C indicating CR remains cost-effective at all point within the 95%

confidence interval.

While these analyses show that decision uncertainty does not impact the overall assessment of the cost-effectiveness of CR in this analysis, it is important to note that the final decision about what is considered a reasonable level of uncertainty and the implications of worse outcomes should be made at the commissioner level. For example, the approach to uncertainty taken here assumes symmetry of preference, such that the potential for better than expected outweigh the risk of worse than expected outcomes. However, a commissioner may have asymmetries of preference, for example a strong aversion to avoiding CR costs that exceed some level that are not offset by the chance that CR is cost-saving in the long term. Issues such as this are discussed elsewhere in the literature [23,24].

3.3.4. Scope of included costs and outcomes

Conventionally only the costs borne by the NHS and personal social services (PSS) and the QALY-based health impact on the individual are considered the primary focus of economic evaluation [25]. While NICE does support the inclusion of wider cost and outcomes implications [17], there is currently no agreed method on how best to incorporate these, primarily due to challenges in the accounting for different opportunity costs in different sectors [26]. However, estimates of such burden, be it positive or negative, remain an important consideration for commissioners.

In the case of CR these wider costs and outcomes can be conceptualised in three groups:

1. Economic productivity. Existing evidence has demonstrated the significant economic burden of CV disease has been reported to be significant [27]. However, in terms of CR this is difficult to quantify currently as there is limited research directly linking CR engagement and economic productivity.
2. Carer impact. Due to the mobility impact of cardiovascular disease it is associated with a significant burden on the close social network who bare much more the responsibility for providing support to the patient both in term of their own physical and mental health in addition to impacts on their own economic productivity [28]. The potential of CR to reduce future CV events implies a potential benefit to carers that is not currently incorporated into this analysis.
3. Out of pocket costs. Prior to the covid-19 pandemic the majority of CR programmes consisted of group-based activities at fixed times, entailing a cost to the patient both in terms of travel costs and the opportunity cost of attending, for example time off work. However, since then there has been a shift to home-based or hybrid programmes which are expected to entail smaller patient out of pocket burden [29]. Additionally, CR's reduction of future cardiovascular events is likely to have an impact on patient out of pocket costs.

3.3.5. Inequality

As reflected in Fig. 1, socioeconomic inequality is a significant factor in the uptake of CR across all the SCNs, but to varying extent. Furthermore, previous research has highlighted how inequality impacts individual engagement with CR completion [11] as well as the propensity to benefit from it [10] with the most deprived gaining 0.1 QALY less from engaging with CR per person while costing the NHS more over their lifetime than the least deprived. Therefore, any programme to improve uptake in CR programmes must explicitly consider the socioeconomic implications.

4. Discussion

The role of health and social care analysis, including economic evaluation, must always be to inform and hold accountable decisions made by appointed decision makers [30]. It is therefore necessary for the evidence generated by such analyses to reflect differences between national commissioning and priority setting and that at a local level [12]. To date the economic evaluation literature related to the cost-effectiveness of CR has taken the conventional HTA framework, supported by NICE among others, which focusses on the lifetime cost-effectiveness of competing alternatives with a national level commissioner in mind [9].

However, the commissioning of CR primarily occurs at a regional level through the SCNs. As our analysis has shown, each SCN faces a unique landscape relative to each other and the national setting in terms of existing provision, patient need, and available funding, and therefore each has different requirements from an economic evaluation of CR. In addition to identifying this challenge we have sought to provide a broader overview of the implications of increasing CR uptake than is currently available in the literature. To achieve this we have explored the distinct elements which make up the case for cost-effectiveness of CR and the associated increase in uptake to achieve the NHS Long Term Plan's target [4].

The strength of this paper is through increasing the accessibility and availability of evidence necessary to inform decision making at the point of commissioning. For CR this is a vital step if the NHS Long Term Plan uptake target is to be achieved, especially if it is to be achieved in a cost-effective way. By employing the decision model used to inform the NHS Long Term Plan this analysis also provides commissioners with additional understanding of how the national policy was informed by the evidence, and how it relates to their own area.

There are, however, a number of weaknesses associated with this analysis. While we have attempted to make the informing of decision making based on cost-effectiveness more relevant to local commissioners, there remain a number of area where this analysis is limited. For example, are analysis assumes that all costs relevant to the analysis are variable, and all budgets soft, with limited consideration of the issue of affordability. While these assumptions are routine in HTA economic evaluation they may play an important part when translating evidence to local commissioners, for further discussion read Howdon et al. [23].

The analysis was also forced to make a number of simplifying assumptions regarding the differences between the commissioning landscape faced by each SCN. The analysis presented only considers variation in socioeconomic characteristics (measured by IMD) and current CR uptake between the regions. When making commissioning decisions there are likely to be a number of other factors which impact the case for cost-effectiveness. These might include the cost of care such as hospitalisation, the local cost and existing supply of commissioning CR programmes, long term commissioning arrangements, as well as population characteristics such as the level of urbanisation of the population, ethnographic features, and levels of co-morbidities. These are all areas that require further research, such as the potential non-linearity between increasing CR uptake from currently levels and propensity to benefit, or analysis at a regional level prior to commissioning.

Furthermore, the analysis has assumed the effectiveness of CR at a local level matches the conclusions of an international meta-analysis [3], which informs the decision model. While this is appropriate given a lack of alternative evidence, the wide variation in current services offered by SCNs demonstrated in this paper, is likely to be associated with variation in effectiveness.

This study has also identified a number of areas where additional empirical and methodological work is required if commissioning decisions made at a local or regional level are to be well informed by economic evaluation research both in CR and more generally. Specific to CR, while this study has identified the variations in how far SCNs must go to achieve the 85% uptake target and the cost and health outcome implications of doing so, there is little research relating to the best way to achieve these increases, and to do so in an equitably way. Any interventions developed or subject to evaluation going forward would achieve greater policy impact through a clearer interrogation of the drivers of cost-effectiveness and the impact on inequality as we have reflected in this paper. Examples of such interventions include the rollout of home-based CR, such as the REACH-HF programme [29].

While such programmes may be effective in increasing total uptake by providing additional modalities of CR, carful recording is needed to ensure there are no detrimental impacts to more deprived groups.

From a more general perspective more research is required in understanding how economic evaluation methodology can best inform local commission decisions. While attempts have been made to interact with local processes [14], and to create appropriate frameworks to apply economic evaluation [12], these are in their relative infancy. Additionally methodological research is required about the most appropriate means of incorporating the additional considerations covered in Section 3.3.4 of this paper, relating to the scope of included costs and outcomes.

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CRediT authorship contribution statement

S. Hinde: Conceptualization, Methodology, Software, Writing – original draft. **A.S. Harrison:** Software, Writing – original draft, Formal analysis, Writing – review & editing, Data curation. **L. Bojke:** Conceptualization, Writing – original draft, Supervision. **P.J. Doherty:** Conceptualization, Writing – original draft, Supervision.

Declaration of Competing Interest

The authors have no conflicts of interest to declare.

Data availability

This study used data from the National Audit of Cardiac Rehabilitation (NACR) funded by the British Heart Foundation and NHS England.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2023.03.041.

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Supplementary Appendix

Methodological overview of the mathematical model

Extensive details of the model have been published previously (see Hinde et al. (2019)[1] and Hinde et al. (2020)[2]) however a summary of the model is provided below.

The model uses a Markov structure to explore the impact of CR on the long term health of patients and the costs to the NHS, stratified by patient deprivation. Figure A1 provides an overview of the model. As a starting point all patients are assumed to inhabit the 'well' state, the point at which after their first MI and/or revascularisation, they will begin CR if it is available.

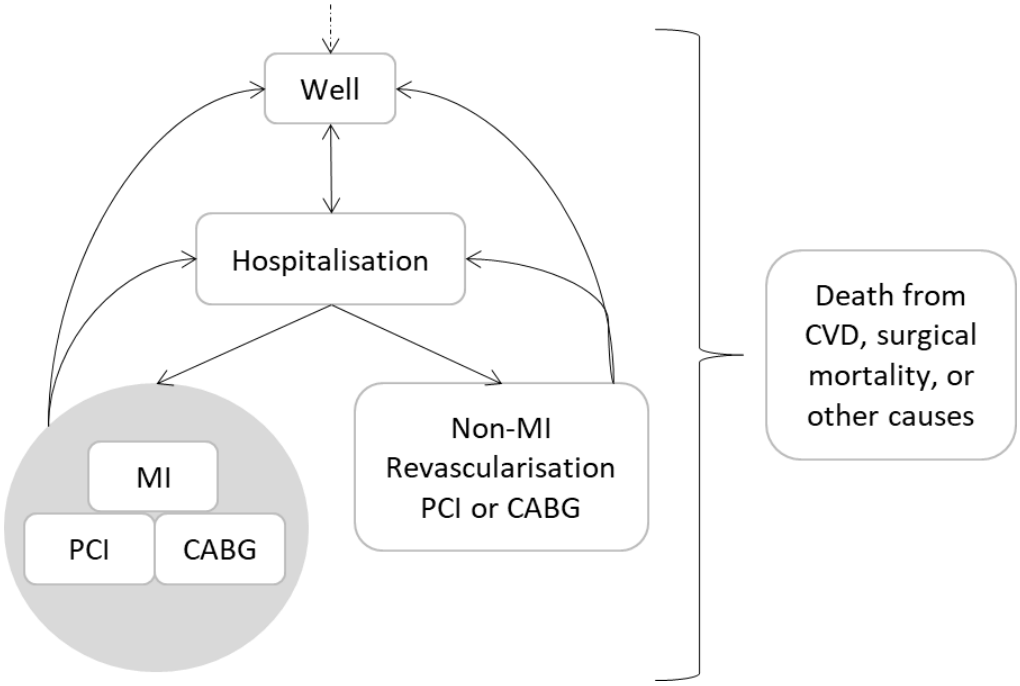

Figure A1: schematic of model for both CR and non-CR

The model allows patients to stay in a 'well' state, experiencing no further cardiac events, or to require admission to hospital. During a hospitalisation a patient can require no further care and return to the well state, or they can be identified as having had a MI and can then go on to have a PCI or CABG for the MI, alternatively they can require revascularisation (PCI or CABG) for a non-MI event. From all states patients can die from cardiovascular disease (CVD) related events, other causes, or in

the case of revascularisations, surgical adverse events. The structure of the model is driven by the Cochrane analysis[3], designed around the meta-analyses conducted.

The full list of parameters which inform the base-case analysis are given in Hinde et al. (2019)[1] the Supplementary Appendix. The Cochrane review[3] provided the informative evidence for many of the parameter estimates required for the model, with other parameters estimated from other published sources and data requests made to the NACR.

The NHS Reference Costs were used as the main source of unit cost evidence, supplemented with estimates from published literature. Patient quality of life was modelled using the utilities generated in the Lewis et al.[4] analysis applied as decrements to an age adjusted profile of 'normal' population quality of life scores.[5]

An estimated as 24.6% of patients who commence CR do not finish it, derived from data provided by NACR. To take a conservative approach to estimating the cost-effectiveness of CR, our base-case analysis assumes that all patients who fail to complete a CR programme entail the full cost of the programme to the NHS but receive none of the health benefits.

The base-case model included the following parameters which were subject to variation by deprivation status: CVD mortality, non-CVD mortality, quality of life decrement, Rate of recurrence, CR uptake, and CR completion. Details of these values are published in the original model paper[1].

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