The potential application of cost consequence analysis to public health interventions to increase accessibility of health economic evidence to decision makers

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Abstract

This thesis explores the application of economic evaluation to public health interventions. The motivation for the thesis was experience gained through a number of applied research programmes on which the author was the lead investigator or co-lead investigator. The experience gained over the course of these programmes highlighted that cost utility analysis has significant shortcomings when applied to public health interventions. Many of these shortcomings stem from fundamental uncertainties around the attributable effect of the public health interventions which is more difficult to estimate in tightly controlled studies than other healthcare interventions, such as pharmaceuticals. In addition, where data are available they typically report easily-measured, short-term, behaviour change such as an increase in physical activity, rather than the resulting long-term health outcome, such as a reduction in cardiovascular disease. By adopting long-term (even lifetime) time horizons in economic models, health economists are often required to make heroic assumptions about the longevity and reproducibility of the short-term effects observed in studies and their relationship with health outcomes.

There are also concerns with cost utility analysis that go beyond the data inputs to the core principles of the philosophical approach that underlies this method. The foundation of cost utility analysis is extra-welfarism, which assumes that population health is the maximand in policy decisions and that presenting outcomes in a cost per quality adjusted life year (QALY) format is accessible to all relevant decision makers. In many cases, public health interventions have impacts beyond health outcomes and the decision makers for determining whether an intervention should be made available may include non-healthcare stakeholders. Environmental interventions to promote physical activity included in this thesis are a good example of this. Investment to support this intervention is unlikely to be sourced entirely from healthcare budgets, so it is important that evalutions of such programmes adopt an appropriate perspective and report outcomes in an accessible format for all decision makers.

A final concern about the application of cost utility analysis is the requirement to aggregate costs and outcomes into a composite ratio, typically the incremental cost per QALY. Whilst this provides a common denominator for decision making purposes allowing interventions to be directly compared, the use of a ratio can mask the magnitude of absolute changes in outcomes. Rather than rely on a composite ratio, decision makers would be advised to consider the absolute changes in outcomes, whether these are clinically meaningful and the degree of uncertainty around them.

The over-arching objective of this thesis is to critically assess the commonly applied methods of economic evaluation to public health interventions, with a particular focus on cost utility analysis. Rather than undertake a methodological critique, the thesis considers a series of applied economic evaluations conducted by the author, the lessons learned throughout these and the methodological preferences that resulted. These applied

studies provided the impetus to explore alternative approaches to economic evaluation, including the application of cost benefit analysis in the evaluation of environmental interventions to promote physical activity and interventions to promote breastfeeding. However, like cost utility analysis, the outcomes of cost benefit analyses aggregate costs and outcomes into a composite ratio (the cost benefit ratio) which may continue to mask uncertainty around the absolute changes in outcomes. By necessity, cost benefit analysis also excludes any outcomes which can't be quantified in monetary terms.

In light of this, cost consequence analysis was applied to subsequent economic evaluations as a means of addressing some of the shortcomings presented above. By presenting outcomes in a disaggregated format, decision makers from multiple sectors can determine how they would benefit from an intervention and the degree to which they may want to contribute to funding. Reporting outcomes in this way also eliminates the need to utilise a narrow health perspective, as in cost utility analysis, or to quantify all outcomes in monetary units as in cost benefit analysis.

On the basis of the applied research presented in this thesis, the author suggests that cost consequence analysis should be the preferred method of economic evaluation for public health interventions, particularly those that have inter-sectoral costs and effects. The thesis concludes with some reflections on alternative methods of economic evaluation and the final chapter includes a simple framework to guide the choice of economic evaluation methods. These are intended to inform future evaluatuions of public health interventions to ensure that they adopt pragmatic methods and present outcomes in an accessible format for decision makers. By doing so, researchers can increase the influence of health economics on public health service provision and contribute to more efficient use of scarce resources.

Chapter 1: Introduction

The World Health Organisation suggests that the major determinants of health care relate to the social and economic environment, the physical environment and the person's individual characteristics and behaviours (World Health Organisation 2020). These are all variables that might be influenced through public health interventions, rather than the provision of health services per se. Whilst there is a universal trend towards allocating a greater proportion of government funding to healthcare (World Health Organisation 2019) most Western governments continue to allocate the majority of their health service budget to the delivery of care and health policy is overwhelmingly focussed on the organisation of health systems and care provision. Although international comparisons of public health funding are hindered by differences in sources of funding and agencies involved, data from the United States estimates that less than 5% of total healthcare spending is allocated to public health (Mays & Smith 2009). This trend is also reflected in the United Kingdom where successive governments have made commitments relating to the importance of public health in promoting healthy behaviours and the prevention of ill-health (Wanless 2004)(Marmot 2020). In spite of this, the proportion of healthcare expenditure allocated to public health has decreased in real terms over the last decade (Kings Fund 2018).

Investment in public health programmes is often more challenging to justify than investment in the provision of treatment for ill-health (Richardson 2012). The costs and benefits of public health investments may accrue across multiple sectors, including health, social care and local authorities which can create difficulties in securing funding. Furthermore, there may be difficulties in attributing an effect to a public health intervention, particularly where these are intended to promote population level behaviours or the environment, due to confounding factors, such as changes in demographics or health behaviours over time.

From an economic perspective, the decision to prioritise investment in health care provision and limit funding for health promotion to address the determinants of health might be considered a gross inefficiency if health promotion can result in a greater return on investment than treatment. However, the extent of any inefficiency in resource allocations can only be established through more widespread application of economic evaluation to public health programmes to better understand their costs and benefits. The relative dearth of high quality and accessible economic evaluations of public health programmes relative to health interventions may partly explain these investment decisions.

This thesis will explore some of the challenges associated with conducting economic evaluations of public health programmes with the intent of recommending best practices that may increase the influence of economic evidence to decision makers. The author's experience of applying alternative approaches to the

economic evaluation of public health programmes will form the basis of the thesis and the subsequent recommendations.

1.1 Aims of the thesis

The aim of this thesis is to conduct a critical assessment of the application of commonly used methods of economic evaluation to public health interventions and develop recommendations for future evaluations. The thesis will consider the applicability of the most widely used methods of economic evaluation in healthcare, including cost-utility analysis (CUA), cost-effectiveness analysis (CEA) and cost-consequence analysis (CCA). A critical assessment of each method will be conducted considering not only the methodological strengths and weaknesses of the respective methods but also, and more importantly, their accessibility to decision makers. This thesis will comprise a critique of 9 published research studies conducted by the author which reports a series of applied economic evaluations of public health interventions. The author has an extensive publication list of applied economic evaluations. The studies selected for inclusion in this thesis were selected on the basis that they illustrate continued learning and refinement of methodologies applied to the evaluation of public health interventions over time. One additional study from 1999 is included as context (Duthie et al 1999). This study examined the use of health economics by health service decision makers and helped shape the authors attitude to economic evaluation over the course of their career. The study emphasises the need to ensure health economic methods reflect the needs of decision makers and that results are presented in an accessible fashion. Many of the insights from this study helped to inform the authors future research, including the studies herein.

In each case, the author has made a significant contribution to the design and execution of the study or has directly led the research and resulting publication. In some instances, lead authorship was granted to junior researchers who were considered to be the main contributor to a particular aspect of a study programme (e.g. the systematic review or model development) under the oversight of the author. The table below summarises the author's contribution to each study.

Table 1.1. Author's contribution to publications included in the thesis.

Chapter	Publication	Author's contribution	Citations (Google Scholar, March 2021)	Impact	Funding Source
3	Publication #1 Duthie T, Trueman P, Chancellor J, Diez L. Research into the use of health economics in decision making in the United Kingdom--Phase II. Is health economics 'for good or evil'? Health Policy 1999; 46(2):143-57.	Author's contribution: 30% Study design, interview guide, annotating responses, thematic analysis of responses and manuscript development.	121	Widely cited, including in the development of methodological guidelines from the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), early commentary on NICE methods and more recent discussion of the role of multi-criteria decision analysis.	Pharmaceutical company
4	Publication #2 Trueman P, Haynes SM, Felicity Lyons G, Louise McCombie E, McQuigg MS, Mongia S, Noble PA, Quinn MF, Ross HM, Thompson F, Broom JI, Laws RA, Reckless JP, Kumar S, Lean ME, Frost GS, Finer N, Haslam DW, Morrison D, Sloan B; Counterweight Project Team. Long-term cost-effectiveness of weight management in primary care. Int J Clin Pract. 2010; 64(6):775-83.	Author's contribution: 50% Led study design, model development, interpretation and manuscript development	68	One of the first examples of a cost effectiveness analysis of weight loss interventions based on high quality, randomised controlled trial data.	Counterweight programme
4	Publication #3 McQuigg M, Broom JI, Laws R, Reckless J, Noble P, Kumar S, McCombie L, Lean M, Lyons F, Mongia S, Frost G, Quinn M, Barth JH, Haynes S, Finer N, Haslam DW, Ross H, Hole D, Radziwonik S, Sloan B, Trueman P, O'Reilley J. Influence of	Author's contribution: 20% Led study design, interpretation and contributed to manuscript development.	13	Input to the decision to fund the Counterweight programme across Scotland by illustrating that the cost of prescribing the intervention can be partly offset by reductions in other prescribed items.	Counterweight programme

	body mass index on prescribing costs and potential cost savings of a weight management programme in primary care. J Health Serv Res Policy 2008; 13(3):158-66.				
5	Publication #4 Beale SJ, Bending MW, Trueman P, Naidoo B. Should we invest in environmental interventions to encourage physical activity in England? An economic appraisal. European Journal of Public Health 2012; 22(6): 869-873.	Author's contribution: 20% Led overall research programme, defined model structure and parameters, interpretation of results and manuscript development.	26	Direct input to NICE guideline on environmental interventions to promote physical activity. The first major deviation from the NICE reference case (cost utility analysis) in the evaluation of public health interventions which has influenced subsequent methods guidance. Cited by research conducted in multiple international studies.	National Institute for Health & Clinical Excellence
6	Publication #5 Pokhrel S, Quigley MA, Fox-Rushby J, McCormick F, Williams A, Trueman P, Dodds R, Renfrew MJ. Potential economic impacts from improving breastfeeding rates in the UK. Arch Dis Child. 2015; 100(4):334-40.	Author's contribution: 15% Co-lead investigator of research programme, input to study design, interpretation and manuscript development.	231	Input to public health policy in England and Wales and referenced in multiple international studies. Outputs reported by lay media as well as scientific press.	UNICEF UK
7	Publication #6 Pavey TG, Taylor AH, Fox KR, Hillsdon M, Anokye N, Campbell JL, Foster C, Green C, Moxham T, Mutrie N, Searle J, Trueman P, Taylor RS. Effect of exercise referral schemes in primary care on physical activity and improving health outcomes:	Author's contribution: 5% Co-lead investigator of research programme, input to search strategy, interpretation and manuscript development.	261	Input to health policy on coverage and adoption of exercise referral. Cited in guidelines developed in England, Wales and The United States.	National Institute for Health Research (NIHR) Health Technology Assessment Programme (HTAP)

	systematic review and meta-analysis. BMJ, 2011; 4;343:d6462.				
7	Publication #7 Anokye NA, Trueman P, Green C, Pavey T, Hillsdon M, Taylor RS. The cost effectiveness of exercise referral schemes. BMC Public Health 2011; 11:954.	Author's contribution: 20% Co-lead investigator of research programme, define model structure and parameters, interpretation and manuscript development.	58	Input to health policy on coverage and adoption of exercise referral. Cited in guidelines developed in England, Wales and The United States.	National Institute for Health Research (NIHR) Health Technology Assessment Programme (HTAP)
7	Publication #8 Anokye NA, Trueman P, Green C, Pavey T, Taylor RS. Physical Activity and health related quality of life. BMC Public Health 2012; 12:624	Author's contribution: 25% Study design, interpretation and manuscript development.	281	Widely cited in subsequent literature on well-being and mental health benefits of physical activity.	National Institute for Health Research (NIHR) Health Technology Assessment Programme (HTAP)
7	Publication #9 Trueman P & Anokye NA. Applying economic evaluation to public health interventions: the case of interventions to promote physical activity. J Public Health 2013; 35(1):32-9	Authors' contribution: 50% Led study design, analysis and manuscript development.	39	Cited in multiple methodological discussion papers intended to guide future evaluations of public health interventions.	National Institute for Health Research (NIHR) Health Technology Assessment Programme (HTAP)

In many cases, these studies represent a significant milestone in understanding the impact of the intervention under consideration and have resulted in directly influencing public policy decisions on investing in public health programmes. Based on the critique of these studies, recommendations will be posited for future evaluations of public health interventions.

1.2 Objectives

The thesis is intended to address the following broad objectives.

- Consider the challenges associated with the economic evaluation of public health interventions;
- Critically assess the application of economic evaluation methods to public health through a series of case studies based on the author's published outputs;
- Develop evidence-based recommendations for how future evaluations of public health interventions might build on the critique presented.

Whilst the thesis will primarily provide a critique of economic evaluations of public health interventions, it is hoped that it will illustrate how the methods applied have developed over time to improve accessibility for decision makers, based on continuous learning. It is also intended to provide some guidance for researchers on how to justify the most appropriate methods for economic evaluation of public health interventions.

1.3 Structure of the thesis

The thesis will start with an introduction to the economics of public health interventions to provide context. This will include reference to best practice guidelines for economic evaluations of public health interventions as well as critical evaluations of alternative methods of cost effectiveness analysis. Chapter 3 will provide further context by considering research into the use of health economics by decision makers. Whilst not restricted to public health interventions, this study was a critical study in the author's development, highlighting the need for economic methods to be accessible to healthcare decision makers. Chapters 4 to 7 will consider applied economic evaluations of public health interventions conducted by the author. These evaluations were conducted on behalf of the National Institute for Health and Care Excellence (NICE), the National Institute for Health Research Health Technology Assessment programme (NIHR HTA), UNICEF and the Counterweight programme. These represent a significant body of applied economic research on public health interventions and illustrate continued development in the methods to ensure that they are accessible and relevant to decision makers. Finally, Chapter 8 will provide reflections on the content as well as recommendations for future research.

A summary of the chapter headings is provided below:

Chapter 2: the economics of public health interventions.

Chapter 3: Research into the relevance of health economics to decision makers.

Chapter 4: The application of cost utility methods to weight management interventions.

Chapter 5: The application of cost effectiveness analyses to environmental interventions to promote physical activity.

Chapter 6: The application of cost-benefit analysis to interventions to promote breastfeeding.

Chapter 7: The application of economic evaluation to exercise referral schemes to promote physical activity.

Chapter 8: Summary, recommendations & conclusions.

The next chapter will provide context by describing public health interventions and outlining the challenges inherent in economic evaluations of such interventions.

Chapter 2: The economics of public health interventions

This chapter is intended to provide context for the thesis by defining public health interventions and considering how evidence can be generated on their effectiveness and cost effectiveness.

2.1. What is a public health intervention?

Public health interventions are intended to '*promote or protect health or prevent ill health in communities or populations*' (Rychetnik et al 2002). In some instances, interventions may seek to improve health across the entire population, for example through air quality regulations, whilst in others the intent might be to influence health in a sub-group of the population such as interventions to promote healthy eating in children. Such interventions may seek to directly promote health, for example through vaccination to protect against future illness, or indirectly through affecting a determinant of health, such as tobacco consumption or the changes to the physical environment.

Successive policy initiatives have spoken to the importance of health promotion and the prevention of ill-health, distinct from the treatment of ill-health (Marmot 2020). Commentators have also pointed out that healthcare provision is a less important determinant of health than individual behaviours and the environment (McGinnis et al 2002), yet the spending of health budgets seems to be in conflict with the majority of spending going to managing, rather than preventing, ill-health. Indeed, it has been previously stated the focus of the National Health Service on the treatment of ill-health means it would be better described as a National Sickness Service, rather than a National Health Service (Heath 2007).

The World Health Organisation suggests that the major determinants of health care relate to the social and economic environment, the physical environment and the person's individual characteristics and behaviours (World Health Organisation 2020). Combined these factors contribute to a significant number of global preventable deaths. For example, nine environmental and behaviour risk factors account for 45% of all global cancer deaths, eight behavioural factors account for 75% of all deaths related to coronary heart disease whilst unhealthy or unsafe environments are responsible for 1 in 4 of all childhood deaths globally (World Health Organisation 2011).

It is estimated that preventable diseases result in over 130,000 premature deaths per annum in England & Wales (Office of National Statistics 2020), equivalent to approximately 2.6 million life years lost. In many cases, the deaths attributable to diseases associated with smoking, a lack of physical activity, obesity and alcohol abuse could be avoided through lifestyle and behavioural changes. These preventable diseases create a significant economic burden to the health service; obesity alone is estimated to cost the National Health Service over £6 billion per year in treatment costs, obesity related conditions, lost productivity and premature death (Public Health England 2017).

Despite these dramatic estimates of human and economic impacts, data suggest that only around 3% of total health service expenditure is dedicated to public health interventions and that this has decreased following the transition of responsibility for public health from the health service to local authorities in 2013 (The Kings Fund 2018).

2.2 Estimating the effect of public health interventions

It has been suggested that the limited investment in public health interventions results, at least in part, from a dearth of evidence on their clinical and cost effectiveness (Wilmott et al 2016). Principles for evaluating healthcare interventions are well established and include a widely accepted hierarchy of evidence (Guyatt et al 1995). These principles are widely applied in post-hoc critical appraisals of healthcare interventions, Health Technology Assessment (HTA) and option appraisals of potential healthcare investments. However, the application of these principles to public health interventions is challenging, both from a practical perspective and a methodological perspective.

The hierarchy of evidence holds that the randomised controlled trial (RCT) is the most robust method to estimate causality between a healthcare intervention and an outcome. The principles of the RCT that lead to this conclusion are a) randomisation can eliminate selection bias; b) blinding can eliminate observational bias and c) the comparator provides a control group.

There is widely held perception that RCTs of public health interventions are difficult and infrequent but this is very much dependent on the nature of the intervention. Weatherly and colleagues undertook a review of 154 published economic studies of public health interventions conducted between 2000-2005 (Weatherly et al 2009). Of these, 58 studies (38%) were based on randomised controlled trial evidence although it should be noted that these were typically studies of individual level interventions designed to change health behaviours, such as smoking or physical activity. Where public health interventions include more complex and/or population level interventions, then there are some more significant challenges to conducting RCTs (Craig et al 2008). In some cases, it may be inappropriate or even unethical to randomise participants to an intervention where there is overwhelming evidence to suggest that the intervention will result in improved outcomes. For example, consider whether participants could be randomised between access to clean or polluted water.

Similarly, in some cases it may be impossible to ensure that the control group is not exposed to an intervention, particularly in the case of population level health promotional interventions, such as clean air initiatives. Even if these variables can be controlled, the ability to control for confounding health and lifestyle factors, such as increasing public knowledge about the harms of particular behaviours, in the control and intervention group may create further complexity. Furthermore, given the nature of many public health interventions, it would be impractical to follow-up participants for a long-enough period to fully capture any resulting health benefits.

The result is that there may be questions about the degree of attribution between the intervention and the outcome.

The combination of these issues means that many commentators have acknowledged that whilst RCT level evidence on public health interventions is desirable it is often unfeasible meaning that observational study designs are often used for their evaluation (Frieden 2017). The result is that many assessment bodies conclude that their effect may be considered unproven or uncertain at best.

2.3 Estimating the cost effectiveness of public health interventions

In addition to calls for more robust evidence on the effectiveness of public health interventions there have also been demands for better economic evidence to justify their cost (Wilmott et al 2016). From an economic perspective, the decision to invest in public health programmes should not be treated differently to investment in any other healthcare intervention. As with all investment decisions the principles of scarcity and choice should be considered. Given that healthcare budgets are finite (scarce) then choices have to be made in how to allocate the available funds to ensure that the available resources are used effectively. Allocating funds to public health interventions is associated with an opportunity cost and it is important that these investments can be objectively justified with economic evidence to illustrate that resources could not be deployed more effectively elsewhere.

There are multiple methods of economic evaluation applied to healthcare (these are sometimes collectively referred to as cost benefit analyses although there are discrete forms of economic evaluation within this definition). The main methods include:

Cost benefit analysis (CBA): a comparison of costs and benefits with both valued in monetary units;

Cost utility analysis (CUA): a comparison of costs and benefits with costs valued in monetary units and benefits typically valued in quality adjusted life years or a similar composite unit of life expectancy and quality of life;

Cost effectiveness analysis (CEA): a comparison of costs and benefits with costs valued in monetary terms and outcomes valued in natural units, such as life years;

Cost minimisation analysis (CMA): a comparison of costs in monetary units with the assumption that outcomes of competing interventions are identical;

Cost consequence analysis (CCA): a comparison of costs and benefits with costs reported in monetary units and benefits reported in disaggregated natural units.

The application of cost benefit techniques to healthcare was envisaged as a rational framework for prioritising the use of healthcare resources within a budget constraint and delivering *good value for money* (Russell 2015). The initial application of economics to healthcare was dominated by attempts to apply cost benefit analysis

techniques, as used in other sectors, or cost effectiveness analyses, reporting the costs of competing interventions in monetary units and outcomes typically quantified in natural units, for example life years or a change in blood pressure. Over time, methodologists recognised that the use of natural units to report outcomes was helpful when comparing similar interventions but was more challenging when comparing investment decisions that might result in different outcomes. In order to increase the portability of findings, methods emerged to develop a *'common currency'* for outcomes, capable of capturing impacts on both quality of life and quantity of life. These two vectors were most commonly combined into a Quality Adjusted Life Year (QALY) or disability adjusted life year (DALY) which forms the basis for cost utility analysis. A review of the published literature on health economics illustrates the increasing prevalence of cost utility studies over time, driven in part by the academic community and guidelines for the conduct of economic evaluation (Pitt et al 2016).

The increasing prevalence of cost utility analysis also reflects a wider interest in the objective function that should be applied to healthcare. The early application of cost effectiveness was founded in the principles of Pareto welfare, which assumes that *individual* utilities should be maximised in order to maximise allocative efficiency (Coast 2008). This approach assumes that individuals are best placed to judge their own utility and if one individuals utility can be improved without impacting that of another individual, then that decision will increase overall utility and represents a rational allocation of resources. However, this approach fails to recognise that it is rarely possible to increase individual utility without having an effect on others when resources are finite, as is the case in healthcare. Allocating health budgets to one service or patient group typically means that other services or patients are denied funding. In this scenario, it would be inappropriate to rely on the judgement of individuals to determine how resources should be allocated. Extra-welfarism moves the objective function from the individual to society and assumes that decision makers can allocate resources in a way that reflects societal preferences. Cost utility analysis, reported in the form of quality adjusted life years (QALYs), was intended to be a framework to inform these resource allocation decisions by bringing together the costs of an intervention with outcomes based on societal preferences. Whilst the principles of this approach are sound, in practice there is evidence to suggest that health maximisation is not the sole objective of decision makers and that even if this were the case, cost effectiveness evidence on the majority of routinely provided healthcare interventions is not available, meaning decision makers can not rank interventions in an informed, orderly way (Coast 2009).

These methods for the economic evaluation of healthcare interventions have developed largely through their application to pharmaceuticals and medical technologies which are typically supported by robust clinical trial evidence to illustrate their effectiveness. Their application to non-pharmaceutical interventions, and specifically public health interventions, is associated with some major challenges. Weatherly et al (2009) summarised these challenges in four main categories:

- Attribution of effects;
- Measuring and valuing outcomes;
- Identifying intersectoral costs and consequences;
- Incorporating equity considerations.

Public health interventions are often associated with a paucity of data or significant uncertainty around their effectiveness and an inability to control for confounding variables. This is compounded by the fact that many of the outcome benefits may be accrued many years in the future and there may be uncertainty in the relationship between short-term proxy endpoints captured in studies and longer term outcomes (for example: a change in physical activity and the future incidence of cardiovascular disease).

Thirdly, both the costs and benefits of public health interventions may accrue to health and non-healthcare decision makers. Adopting a narrow, health service perspective and outcome, such as the QALY, fails to capture the full benefits of many public health programmes and is likely to be poorly understood by stakeholders from non-health sectors. Such an approach also assumes that the objective function of all decision makers is health maximisation. For some decision makers, their objectives may be very different, for example, whilst changes to the built environment might consider the potential to improve physical activity levels the primary intention might be environmental improvements which are not reflected in the QALY. Similarly, on the cost side of the equation it is important to consider how costs should be allocated across sectors.

These challenges to the evaluation of public health interventions are less of a concern in the evaluation of healthcare interventions, such as medical devices or pharmaceuticals, where the primary outcome of the intervention is an improvement in health outcomes. Whilst there may be some indirect benefits, such as improving productivity through improved health, these benefits are typically marginal to the primary benefit and are often excluded from the assessment of their value.

Finally, the adoption of a cost utility framework assumes that the objective function of decision makers is to maximise health gain across a population, regardless of who benefits. In many cases, public health interventions are designed to target individuals with the greatest ability to benefit and outcomes should be equity-weighted to reflect this (Cookson et al 2009). This is neatly illustrated in one of the case studies presented herein which considers the use of activity trails to promote physical activity. Whilst data illustrate that such trails are associated with an increase in net physical activity, it is impossible to determine whether the beneficiaries are individuals who were already active or whether these are newly active individuals and the degree to which this might impact health inequalities. Incorporating qualitative research methods into the evaluation process may offer some valuable insights that help to address these issues. Preferences for the distribution of health benefits, perceptions of what constitutes a medical need and the degree to which

behaviour change should be the responsibility of the state or the individual could all be explored more effectively through qualitative research (Coast 2017). Others have suggested that qualitative research techniques could also provide improved understanding of real world decision making processes to inform how methods and outcomes should be presented (Smith 2009). Despite this, health economics remains dominated by quantitative research methods.

Many commentators have expressed concerns that the application of cost effectiveness analysis and particularly cost utility analysis may be inappropriate when considering complex, population level interventions due to the inter-sectoral nature of the costs and benefits (Marsh et al 2012)(Lung et al 2017)(Brousselle et al 2016). However, Weatherly et al (2009) found that around a quarter of all economic evaluations of public health interventions were cost utility analyses reporting outcomes in a QALY or DALY and the volume of cost utility studies continues to increase driven by guidelines for economic evaluation.

2.4 Guidelines for economic evaluation of public health interventions

Whilst there is an abundance of guidelines on methods for conducting economic evaluations these typically apply to pharmaceuticals and/or medical technologies and assume that these interventions are supported by robust, trial based evidence (Gold et al 1996) (Huserau et al 2013) (Drummond & Jefferson 1996). A number of reviews have considered the applicability of these methodological guidelines to public health interventions and typically concluded that they may have limited relevance (Lung et al 2017).

A systematic review to identify guidelines specific to the economic evaluation of public health interventions identified 16 relevant guidelines, 12 of which were from UK or international bodies and 4 were independently authored (Tudor-Edwards et al 2013). These guidelines included recommendations specific to healthcare as well as guidelines for a broader range of public sector investment decisions. There were also a number of guidelines which relate to evaluation methods more generally, such as social return on investment models.

From a UK perspective, the NICE methods for public health guidance provide recommendations for economic evaluations (National Institute for Health & Care Excellence 2012). This recommends that economic evaluation should be conducted if there is no existing, reliable economic data and there is an expectation that there will be a net benefit associated with the intervention. The preferred method of evaluation is cost utility analysis, in line with other work programmes conducted by NICE, with the QALY being the preferred endpoint. The guidance does acknowledge that other approaches may be relevant, including cost benefit analysis and cost consequence analysis, particularly where far-reaching societal impacts may occur.

A second review article (Lung et al 2017) considered two guideline documents for economic evaluation of public health; the NICE guidance referred to above (National Institute for Health & Care Excellence 2012) as well as guidance from the Centres for Disease Control and Prevention (CDC) in the United States (Department of Health and Human Services Assistant Secretary for Planning and Evaluation, 2006). As with the NICE

guidance, the CDC promotes the adoption of CUA as the primary method, with cost benefit analysis and cost effectiveness analysis also considered. A more recent discussion paper on behalf of the CDC (Russell & Sinha 2016) has explored this issue further, highlighting that health economists, with their adherence to CUA principles, should learn from cost benefit analysis methods to ensure that they can capture non-health impacts more effectively. The guidance continues to point towards CUA as the preferred methodology, albeit with some caution.

Guidelines can play a powerful role in methods development and application. As a result of the NICE guidelines there has been a significant increase in the volume of cost utility analyses of public health interventions over the last decade. The methods guidance also creates a risk of systematic bias in published evaluations, by suggesting that economic evaluations should only be carried out where there is an expected net benefit of the intervention. A review paper by staff from NICE made the bold claim that the majority of public health interventions are '*highly cost effective'* based on analyses conducted as part of guidance development (Owen et al 2018). This fails to acknowledge that the methods guidance recommends that evaluations were only developed where there was an intrinsic belief that the interventions would deliver a net benefit to the health service – the guidance states that economic evaluation is not required where there may be challenges in estimating costs and benefits – resulting in an inherent bias in analyses conducted for guideline development. This study also reports the aggregated cost per QALY ratio and fails to consider the absolute incremental differences in costs and QALYs that were identified. In the majority of case studies reported herein, the perils of the cost per QALY ratio will be explored, highlighting that a point estimate can be fundamentally unstable when the absolute differences in costs and/or QALYs are close to zero or negligible. In such cases, there is a danger that spurious accuracy in the measurement of the costs and/or health benefits may not be fully acknowledged in the point estimate of the ICER. Even where sensitivity analysis is conducted, this often involves applying an arbitrary distribution to a point estimate which may not address the fundamental uncertainty of the point estimate value.

These challenges in applying cost utility analysis to public health interventions will be explored in the applied economic evaluations presented in the following chapters.

2.5 Chapter Summary

This chapter highlights the importance of public health interventions in addressing the determinants of health but acknowledges that one of the causes of limited investment in such interventions is the absence of highquality economic evidence to illustrate their value. Some of the theoretical challenges associated with applying cost utility analysis to public health programmes are introduced were introduced and these will be explored in more depth through applied research in the following chapters. The case studies presented will

consider the relative merits of alternative approaches to economic evaluation, specifically cost consequence analysis, and whether this might help to improve the quality and accessibility of public health evaluations.

Before introducing the applied economic evaluations the next chapter will provide further context for the thesis by examining an early publication by the author. This study sought to understand the relevance of economic methods to decision makers and was influential in the shaping how the author approached applied economic evaluations throughout their career.

Chapter 3: Research into the relevance of health economics to decision makers

Publication 1: Duthie T, Trueman P, Chancellor J, Diez L. Research into the use of health economics in decision making in the United Kingdom--Phase II. Is health economics 'for good or evil'? Health Policy. 1999 Jan;46(2):143-57.

Available at: https://www.sciencedirect.com/science/article/abs/pii/S0168851098000578

This chapter considers research into the use of economic evaluation by health service decision makers. Although not restricted to public health, the research considers the applicability of multiple economic evaluation methods and the degree to which decision makers can understand the findings. This research was a powerful motivation in attempting to conduct applied economic evaluations that are accessible and easily understood by decision makers and helped to shape not only the evaluations presented herein but the overall objectives of the thesis.

3.1 Study context

The raison d'etre of health economics is to inform healthcare decision makers faced with demands which exceed the available resources. Economic evaluation has the potential to inform decisions on the value of competing investments and ensure that budgets are prioritised to those interventions which are proven to be cost effective (Russell et al 1996). In certain instances this is done in a systematic and explicit fashion, such as through the use of health technology assessment (Culyer 2018), whilst in other cases its application may be less transparent or less explicit which might result in less efficient allocation of resources (Torbica et al 2020).

Whilst the volume of economic evaluations in healthcare has increased exponentially over recent decades (Pitt et al 2016) there has been relatively little research to assess the impact of these evaluations and whether they meet the needs of healthcare decision makers.

One of the few studies to do so was a qualitative research study conducted by the author (Duthie et al 1999) which sought to understand whether the typical outputs of health economic evaluations are relevant to decision makers and how the methods and presentation of health economic research could be improved to increase their impact. This was a critical study in the authors development, as it highlights that many of the concepts, methods and outcomes used by health economists are poorly understood by healthcare decision makers. The outcomes of this study informed the methods applied in later chapters.

3.2 Methods

A qualitative research study was conducted with a purposive sample of stakeholders from the English NHS. The stakeholders were selected on the basis that they influence or contribute to decisions on the adoption of healthcare interventions. Participants included primary and secondary care physicians, pharmacists, and hospital and community care managers. Whilst attempts were made to capture stakeholders from across the geography of the NHS, the resulting sample of 34 participants might be considered a purposive sample of relevant stakeholders. Semi-structured interviews were conducted face-to-face with stakeholders in pairs lasting approximately 90 minutes.

For the purposes of the study, a series of 44 vignettes describing the outcome of hypothetical economic and outcome studies were developed (for example: 'Antibiotics A and B are equally effective but when all costs are taken into account, A works out cheaper despite costing more per tablet'). In most cases, the vignettes included a perspective on both costs and benefits to provoke conversation about how useful these would be in allocating scarce resources. However, in a few cases outcomes referring to just cost or benefits were stated to see if this led to participants raising the issue of scarce resources (for example: 80% of patients said they preferred Treatment A to Treatment B). These outcome vignettes were selected randomly as a basis for discussion between the interviewer and the participants to explore the relevance of the outcomes to participants and understand positive and negative reactions to the concepts presented.

3.3 Data

A total of 34 participants were included in the study, 14 from general practice, 14 from secondary care and 6 from regional managerial positions. In total 17 healthcare professionals comprising primary and secondary care physicians and pharmacists participated and 17 managerial professionals although it should be noted that in some instances the healthcare professionals also had budgetary responsibility whilst some of the managerial professionals had previously practiced medicine.

Given the semi-structured nature of the research and the relatively small sample size, formal qualitative synthesis methods, such as key word searches were not applied. However, methodical qualitative analysis of interviews resulted in thematic responses to the economic outcomes presented and there was some degree of consensus amongst participants to many of the messages. Following thematic analyses, an attempt was made to categorise the vignettes into *'some degree of relevance'* to participants and *'no degree of relevance'*.

3.4 Results

Of the 44 economic vignettes presented, 29 were felt to have *'some degree of relevance'* to the participants, with remaining 15 being regarded as irrelevant by decision makers. Of the 15 irrelevant cases:

- 9 were rejected on the grounds that the benefit was not considered worthwhile – these included patient convenience/preference, patients returning to social functioning or emotional well-being;
- 3 were rejected because they were not understood – these included outcomes presented as numbers needed to treat, quality adjusted life years and cost-benefit ratios;
- 3 more were rejected by the method was deemed questionable – these included outcomes of willingness to pay and time-trade off studies.

Whilst the participants were, in some cases, critical of economic methods and the presentation of outcomes there was a consensus that some form of economic evaluation was required in a resource constrained health system. There was some frustration expressed at the methods for attempting to quantify all resources (such as staff time) in monetary units and the resulting difficulty to realise any *'savings'* on a balance sheet. Related to this, participants suggested that health economists needed a better understanding of the mechanics of health service financing mechanisms to ensure that findings were presented in a way that could be put into practice.

When interpreting the messages, healthcare professionals were typically more attracted to outcomes presented at an individual level, rather than outcomes aggregated across a population. Similarly, stakeholders tended to be more attracted to outcomes which were of direct relevance to their practice or facility. For example, primary care physicians were less interested in outcomes which may benefit the secondary care provider. One over-arching comment was the mistrust of 'jargon' and the tendency for health economists to use complex terms to quantify the outputs of their studies, such as QALYs.

3.5 Strengths & weaknesses

It was recognised at the time that the qualitative, in-depth interview methods adopted in this study would limit the number of participants. As such, it would be difficult to include a sample of participants that would truly represent the NHS. However, some attempts were made to stratify the sample across healthcare professionals and managers, the geographical regions of the NHS and primary and secondary care. Furthermore, the semistructured interview format was adopted to allow for wide-ranging conversation and generate ideas on how health economic methods and reporting might be improved. The downside of such an approach is that the interpretation relies on thematic analyses rather than more formal, qualitative research methods.

3.6 Critical appraisal

This study was influential in considering the applicability of health economics to decision makers and was widely referenced by subsequent studies which further explored the theme (Hoffman & von der Schulenberg 2000). The study illustrated that many of the methodological constructs used in health economics, including

cost utility analysis and willingness to pay, were alien to front-line health service decision makers and the presentation of the outcomes in this fashion was unhelpful to informing resource allocation. The findings were prescient in concluding that more standardised approaches to health economics may help to improve applicability and understanding amongst decision makers. Shortly after this publication, a professional group task force was developed to explore this issue (Ramsey et al 2005) and the National institute for Health & Care Excellence (NICE) established their 'reference case' for health economic evaluations(National Institute for Health & Care Excellence 2013). Undoubtedly, such initiatives helped to drive more consistency in the methods applied and, in doing so, improve familiarity with health economics amongst healthcare decision makers.

Whilst consistency is helpful it needs to be accompanied by improved understanding to avoid decision-makers adopting a *'tick-box'* approach to evidence. Where an economic evaluation is conducted in line with guidance decision makers may be inclined to accept the methods as robust and consider only the outputs, such as the cost per QALY and determine whether this falls within an acceptable threshold. Although NICE was initially reluctant to define a threshold for what constitutes a cost effective intervention, a number of studies sought to identify the *de-facto* threshold by examining the cost effectiveness of interventions that were recommended for routine use in the NHS and those that were restricted (Devlin & Parkin 2004). The danger of such an explicit threshold is that decision makers blindly 'accept' interventions that are deemed to fall below it without fully understanding how the cost effectiveness ratio has been derived and the level of uncertainty around a point estimate.

Examination of the public health interventions in this thesis will highlight a number of examples where the incremental cost effectiveness ratio was deemed to be *'acceptable'* but both costs and/or outcomes were close to zero and subject to significant uncertainty. The result is that the point estimate of cost effectiveness is sensitive to small changes in input parameters which can result in a range of outcomes, from cost neutrality to cost effectiveness to cost ineffectiveness depending on assumptions about critical inputs.

The study also highlights some of the practical challenges with interpreting the commonly used outcomes of economic evaluations. Aggregating costs and outcomes into a single vector (an ICER value) creates two significant problems for decision makers. Firstly, decision makers typically operate with budget silos and need to know how their budget will be affected, rather than the aggregated health service (or even societal) budget. As such, it is important to illustrate where costs and outcomes are accrued. Secondly, the ICER is essentially a linear function which may provide the same ratio for two interventions that provide very different absolute levels of cost and benefit.

In spite of the results of this study, and several other studies conducted around the same time with similar conclusions (Walley et al 1997) (Williams & Bryan 2007) (Eddama & Coast 2008), health economists have continued to promote the use of advanced methods of health economics, particularly cost utility analysis, through best practice guidelines. Indeed, over time the complexity of these methods has developed further

arguably driven by academic pursuits rather than a desire to make the findings more applicable to decision makers, for example through probabilistic sensitivity analyses and value of information analyses (O'Hagan et al 2005). A more recent qualitative study looked specifically at the use of health economics in local authority decision making on public health interventions (Frew 2020). Whilst this suggests that familiarity with health economic concepts may have improved since the author's publication, there remain some significant challenges in applying economic evaluations to real-world policy decisions, mainly due to the narrow perspective, protocol driven events and long time horizons that are typically adopted. It is frustrating that health economists have failed to react to these studies by improving the accessibility of their methods and outputs. The remainder of this thesis will reflect on this issue and explore the practical application of multiple methods of economic evaluation to public health interventions.

3.7 Chapter summary

The study in this chapter is presented as context to the following chapters. This research was pivotal in forming the ideas which make up much of the remainder of this thesis. The desire to produce economic outcomes which resonate with the end-user and inform decision making underlies the majority of the studies which are discussed herein. This is particularly pertinent in public health planning where multiple stakeholders are involved in planning and deployment.

Chapter 4: The application of cost utility methods to weight management interventions.

Publication #2 Trueman P, Haynes SM, Felicity Lyons G, Louise McCombie E, McQuigg MS, Mongia S, Noble PA, Quinn MF, Ross HM, Thompson F, Broom JI, Laws RA, Reckless JP, Kumar S, Lean ME, Frost GS, Finer N, Haslam DW, Morrison D, Sloan B; Counterweight Project Team. Long-term cost-effectiveness of weight management in primary care. Int J Clin Pract. 2010 May;64(6):775-83.

Available at: https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1742-1241.2010.02349.x

This chapter presents the author's first applied case study of an economic evaluation of a public health programme to promote weight loss. Throughout the case studies, I will consider not only the applicability of the methods adopted but also the accessibility of the results, reflecting on some of the lessons learned from the study reviewed in the previous chapter. This chapter considers two alternative approaches to the evaluation of a weight management intervention. The first is a cost utility analysis with a lifetime horizon whilst the second is an attempt to provide a more granular estimate of the short-term impact of the intervention, recognising that decision makers typically operate under short-term budget constraints.

4.1 Study context

The prevalence of obesity in the majority of Western countries is increasing, leading to the Organisation for Economic Co-operation and Development (OECD) to refer to an 'obesity epidemic' (OECD 2017). In their latest report on the issue, the OECD estimates that nearly one in two adults and one in six children living in OECD member countries are obese or overweight. Obesity is a recognised risk factor for a number of long-term conditions including diabetes mellitus, coronary heart disease and a number of cancers (Kinlen et al 2018).

Unsurprisingly, given these trends, there has been significant interest in the economics of weight management. A number of studies have attempted to quantify the economic burden of obesity to the NHS and society more broadly (Allender & Rayner 2007) (UK Government Office of Science Foresight 2007) (Scarborough et al 2011). As well as studies seeking to quantify the economic burden of obesity, there has been a significant body of evidence published assessing the clinical and economic effectiveness of weight management interventions (Loveman et al 2011).

4.2 The Counterweight Programme

Counterweight is an evidence-based weight management programme, delivered in general practice settings for patients who are at risk of weight gain or already considered overweight or obese (The Counterweight Project Team 2004). The programme was established in 2000 through a collaboration between leading

academics with expertise in weight management, nutrition, endocrinology and behavioural sciences. The programme is provided by practice nurses or primary care staff, supplemented by specialist weight management advisors qualified in diet and/or nutrition. The programme consists of behavioural strategies intended to help participants to manage their diet and lifestyle, with the goal of achieving a realistic weight loss of 5-15% of body mass. Critically, the behavioural strategies employed are intended to produce a sustained impact, unlike other weight management interventions which have been shown to result in cycles of weight loss followed by weight gain (Chambers & Swanson 2012).

A number of robust, clinical trials have shown the Counterweight programme to be effective in promoting weight loss (The Counterweight Project Team 2008). Indeed, the programme has recently garnered significant attention due to the DiRECT study results which indicated that a more intensive form of the Counterweight programme can help sustain remission of diabetes (Lean et al 2019).

Despite the quality of the clinical evidence to support the programme, there remain challenges to funding such an intervention, particularly given the number of potentially eligible participants. An economic evaluation was conducted to provide insights into the cost effectiveness of the Counterweight programme (Trueman et al 2010). This study built upon an economic model that was originally developed to inform the development of NICE guidelines on weight management interventions. The model was adapted to consider the cost effectiveness of the Counterweight programme by incorporating evidence from the trials referred to above.

4.3 The model structure

The economic model attempts to estimate the long-term impact of weight gain on outcomes and healthcare resource use. A micro-simulation model was designed to predict weight change over time and the resulting impact on long-term outcomes. Micro-simulation models essentially model the trajectory of an individual and then repeat this multiple times, simulating a cohort of individuals, to recognise the uncertainty around many of the variables that may affect outcomes. The average results for the cohort of individuals are then presented.

In the current simulation, an individual either gained weight, lost weight or remained in a stable weight over time. However, the trend across the overall cohort was for weight gain, reflecting the trend across the population as a whole. The weight of each individual is simulated in the model on a 6 monthly basis – hence an individual whose weight remained stable over one 6 month period could gain or lose weight in the following six monthly period. This is illustrated in the schematic below.

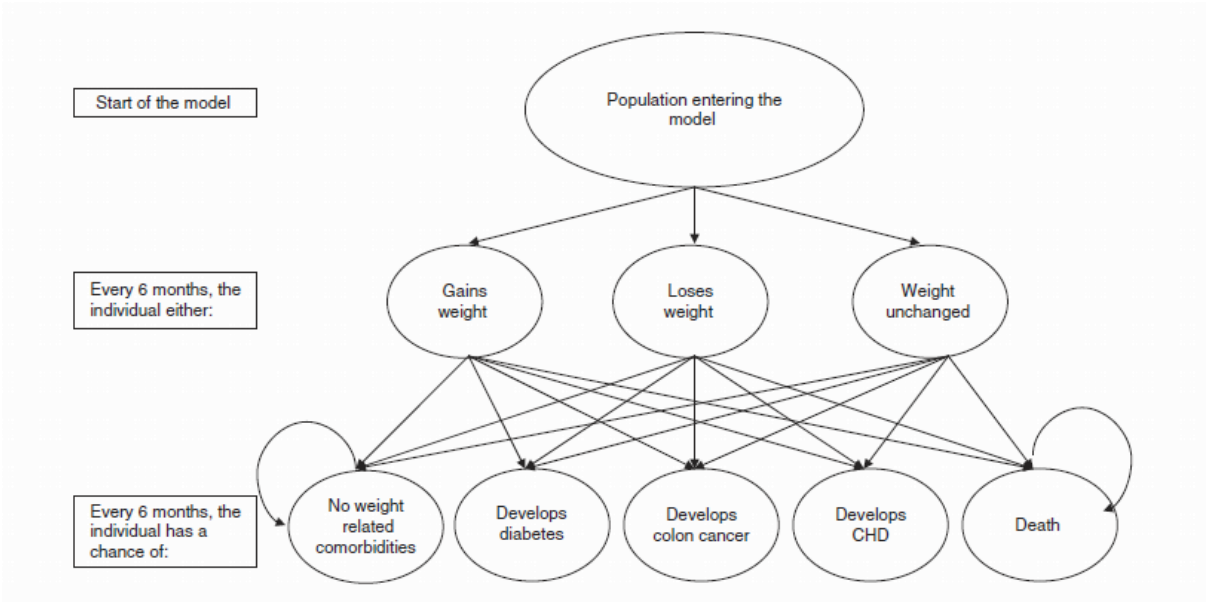

Figure 4.1: Schematic of the model of weight management interventions (reproduced from Trueman et al 2010)

Changes in weight impact on the healthcare resource use of individuals, their quality of life (utility) and their likelihood of developing obesity related conditions. Conditions considered in the model were limited to diabetes mellitus, coronary heart disease and colon cancer. Whilst other studies have pointed to an association between weight gain and other conditions, the evidence on the lifetime risk of these conditions was deemed to be insufficient to include in the model. Where an individual develops an obesity related condition, disutilities and healthcare resource use associated with this condition are factored into the model along with any impact on mortality.

4.4 Data

Simulation models offer some distinct advantages for modelling long-term conditions which have complex relationships with multiple potential outcomes. However, it should be recognised that simulation models are also *'data-hungry'*, demanding multiple data points. Critical data inputs in the current model are detailed below.

1. Population characteristics: these were derived from the Office of National Statistics and the Health Survey for England.
2. Data on underlying weight gain: the absolute weight gain adopted in the model was an average of 1kg/yr, based on observational studies from Denmark and the United States.
3. Data on the impact of weight gain on long-term conditions: the relationship between BMI and the obesity related conditions considered in the model were all derived from published sources.

4. Data on effectiveness of Counterweight programme: Data on the effectiveness of Counterweight were derived from clinical trials. (The Counterweight Project Team 2008)

5. Data on unit costs and utilities: both were derived from previous studies.

A number of scenarios were modelled which considered alternative assumptions about the duration of effect of the intervention and the degree to which any weight loss was sustained.

4.5 Outcomes

In the base case, the Counterweight programme is assumed to result in an average of 3kg weight loss at 12 months, as illustrated in the clinical trial data. It was assumed that any participants that did not present for follow-up in the Counterweight programme (55%) did not lose any weight. Furthermore, it was assumed that any weight loss over the 12 month period would be gradually regained over the following 2 years, so any impact on healthcare resource use and outcomes was time limited. The resulting cost effectiveness analysis suggested that under these scenarios the Counterweight programme was a dominant intervention. Compared to no intervention it resulted in a lifetime saving of £27 and an increase in utilities of 0.06.

Sensitivity analyses were conducted around some of the structural and parameter uncertainties in the model. Two major aspects of the model were varied in sensitivity analyses – firstly, the assumed underlying trend for weight gain in the general population and secondly the degree to which any benefit from the Counterweight programme lasts beyond the 12 month period reported in the trial data. In the first case the underlying weight gain was reduced from an average of 1kg/yr to 0.5 kg/yr and then 0.3kg/yr. In the latter case, the base case model assumes that any weight lost as a result of the Counterweight intervention is regained over 2 years whilst a 'best case' scenario assumes that weight loss is sustained over the individual's lifetime.

Sensitivity analyses resulted in the expected changes – reducing the underlying weight gain in the population worsened the cost effectiveness of the intervention (from dominant to ~£2000/QALY, whilst the best case of sustaining weight-loss from the intervention improved the cost effectiveness (dominant).

Table 4.1: Summary of sensitivity analyses (reproduced from Trueman et al 2010)

	Incremental cost	Incremental QALYs	Incremental cost-effectiveness ratio (ICER)
Base-case scenario*			
1 kg/year background weight gain	−£27	0.06	Dominant†
0.5 kg/year background weight gain	£52	0.03	£2017
0.3 kg/year background weight gain	£74	0.03	£2651
Best-case scenario*			
1 kg/year background weight gain	−£80	0.09	Dominant†
0.5 kg/year background weight gain	−£51	0.08	Dominant†
0.3 kg/year background weight gain	−£31	0.07	Dominant†

Footnote:

*Base case assumes any weight loss at 2 years is regained over 1 year following intervention; Best case assumes any weight loss at 2 years is maintained following intervention.

†Dominant indicates improved outcomes at lower cost than comparator

4.6 Strengths & weaknesses

The cost effectiveness of the Counterweight programme was a significant economic study of weight management interventions. Whilst previous economic studies had been published, the Counterweight study utilised robust randomised controlled trial evidence as its source data. Furthermore, the efforts to incorporate the risk of future, obesity related conditions ensured that the model provided a holistic view of the costs and benefits associated with obesity. This is important as the costs of managing obesity per se are relatively modest compared to the cost of managing obesity related conditions, such as diabetes and coronary heart disease.

A number of obvious limitations were acknowledged at the time of developing the model. Firstly, the assumption about the rate of underlying weight gain in the population was derived from an observational cohort assumed to be representative of the UK adult population. Secondly, the number of conditions associated with obesity was limited to three to reduce any material uncertainty in the model. Whilst a number of other conditions are known to be associated with obesity, the data on this relationship at the time of model development was limited so these were excluded. Finally, the disutilities and costs associated with each of these conditions were derived from previously published sources, again, assumed to be of relevance to the NHS treated population. In some cases, these were derived from international literature or studies which may have limited external validity.

4.7 Critical appraisal

In addition to the limitations acknowledged at the time of the study a number of important methodological and policy lessons were derived from the study. Methodologically, simulation modelling was a practical solution to the challenges inherent in modelling lifetime costs and outcomes. However, from a face-validity

perspective it can create some challenges in interpreting and communicating results to a non-economist. The model is incapable of applying a *'memory'* to an individual's weight trajectory. As such, over any 6-month cycle an individual may lose weight, gain weight or remain at a stable weight, regardless of their previous 6 months. This is modified by running the model for a large cohort of individuals (in this case 10,000) which results in 'average' weight trends across a population. However, difficulties remain in explaining that the model will generate individuals with unpredictable – and some might say, unrealistic – weight patterns over their lifetime.

The second major challenge associated with simulation modelling is the unpredictability of the outcomes. The model generates a cohort of 10,000 individuals each time it is run, with distributions around each parameter value for these individuals. The result is that running a model twice, with the same input value, will result in two different outcomes. Now this is not a major issue if there is a significant difference in costs and outcomes between the intervention and the comparator. However, it becomes more meaningful when the differences are marginal – are the differences occurring due to a material improvement from the intervention or simply as a result of the model sampling unevenly from the parameter distributions? In the case of the current analysis, this is a genuine concern as the lifetime differences in costs and utilities were both marginal and some would argue, close to zero. In this case, minor changes in parameter distributions used in the model could move the outcome from being dominant to cost effective or even cost ineffective.

Related to the above, are challenges in communicating the outcomes of the analysis. The clinical data on the Counterweight programme are powerful. Most clinicians would agree that a 3kg weight loss over the course of a year is clinically meaningful. However, to extrapolate this over the course of a lifetime requires some gross assumptions and in doing so may actually undermine the value of the intervention. Arguably, the absolute weight loss reported in the trial may be more impactful to decision makers than a lifetime QALY gain of 0.06 which may be hard to comprehend and seem negligible over the course of a lifetime. Similarly, the estimated lifetime cost saving of the intervention was £23 in the base case which may be considered as negligible.

Whilst economic data are necessary to support further investment in public health programmes, the danger in this instance is that an intervention with high quality clinical data is undermined by economic methodologies. In attempting to estimate lifetime benefits, a number of gross assumptions were required which could be open to criticism. Furthermore, whilst the composite outcome (a dominant ICER) appears favourable, both the lifetime difference in costs and QALYs is marginal – some might say negligible.

In light of this, a second study of the Counterweight programme – described below - was conducted with the intent of identifying short-term, tangible savings that may result from improved weight management.

Publication #3: McQuigg M, Broom JI, Laws R, Reckless J, Noble P, Kumar S, McCombie L, Lean M, Lyons F, Mongia S, Frost G, Quinn M, Barth JH, Haynes S, Finer N, Haslam DW, Ross H, Hole D, Radziwonik S, Sloan B, Trueman P, O'Reilley J. Influence of body mass index on prescribing costs and potential cost savings of a weight management programme in primary care. J Health Serv Res Policy. 2008 Jul;13(3):158-66.

Available at: https://academic.oup.com/fampra/article/29/suppl_1/i139/532263

4.8 Study context

A second evaluation of the Counterweight programme adopted a narrower and shorter-term perspective (The Counterweight Project Team 2008). This partial analysis considered the impact of obesity and weight gain on prescribing costs. This narrow perspective was adopted as the Counterweight programme was typically funded through the prescribing budget, hence any cost savings identified through the analysis might be used to offset the cost of the intervention. This also recognises that prescribing costs might be considered a flexible cost that can be changed with immediacy, whereas many other healthcare costs, such as labour and hospital costs, might be considered sunk costs which can only be changed over a longer period. This approach was also intended to provide potential short-term savings to healthcare budgets, acknowledging that decision makers can rarely invest now to save later, as predicted by models which adopt lifetime horizons.

4.9 Methods

This analysis estimated the relationship between prescribing costs and BMI, with a view to then estimating how the Counterweight programme can reduce prescribing costs. Attempts were made to generate a sample of patients that were broadly representative of the UK population. Records were derived from a random sample of 23 general practices, stratified geographically across the UK health service regions (at the time). A random sample of obese patients (BMI>30) was derived aged between 18-75 year. Following this, a sampling framework was developed to generate cohorts of patients with normal weight (BMI<25) and overweight (BMI 25-30). Cohorts were matched by age and sex in an attempt to improve comparability. The resulting cohort included 3,400 patients across the three BMI categories. Data on prescribed items over an 18 month period between 2000-2002 was then derived from patient notes. The costs of prescription items were derived from the National Formulary. Multivariate regression analyses were used to determine the probability of prescribing and the associated costs based on reported BMI.

Based on the above, the cost effectiveness of the Counterweight programme was modelled. This assumed that individuals without access to Counterweight would gain 1kg per year on average, whilst outcomes for those on the Counterweight programme were based on the reported trial results. The costs of the

Counterweight programme assume that participants attended at least 6 sessions over a 12-month period. Prescribing of medications primarily intended for the treatment of obesity (as distinct from the management of obesity related conditions) were also included, based on rates reported in the trials. Outcomes considered whether the incremental costs of providing the Counterweight programme could be offset by savings in the prescription budget. A base-case considered all prescribing costs whilst a secondary analysis considered only the *'top-ten'* most commonly prescribed items.

4.10 Outcomes

There was a clear relationship between the incremental cost of prescription items and BMI. In men, the prescription cost increased from £50.71 in men with a BMI of 18.5-20 to £198.66 in men with a BMI >40. Similarly, in women the costs increased from £62.59 to £160.73.

The impact of the Counterweight programme was estimated by considering a sample of patients with BMI of 37 (similar to those in the Counterweight trial). The Counterweight programme was estimated to cost £60 per participant. The analysis predicts their prescribing costs with and without the Counterweight programme over a 1 and 2-year follow-up. The results suggest that savings on prescribed items would equate to around £6.35 for men and around £3.75 for women or approximately 8% of the cost of the Counterweight intervention at one year follow up. Extending the analysis to two years the savings on prescribed items increased further, offsetting around 18% of the intervention cost. Assumptions about improved compliance with the programme increased this further to 22%. Scaling these results to the UK population resulted in potential savings of between £40M and £52M in obesity related prescribing costs.

4.11 Strengths and weaknesses

A number of limitations were recognised at the time of the analysis. Efforts were made to ensure that the sample of patients considered were broadly representative of those treated by the UK NHS. However, the degree to which the sample could be stratified for co-variates, such as multiple morbidities, was limited by the completeness of the data. Similarly, matching the cohorts of patients categorised as 'normal' weight, overweight and obese faced the same challenge. With regards to the prescribing rates and costs, data were based on reports from patient records and as such are subject to some degree of uncertainty with regards to accuracy of the reporting of prescriptions, the fill rate and the degree to which these prescriptions were actually used by patients. However, these limitations were unavoidable given the retrospective nature of the analysis. Finally, the estimate of the cost effectiveness of Counterweight assumed that patients not participating in the programme would – on average – gain weight over time. The estimate of a 1kg increase in weight per year mirrors the assumption adopted in the cost utility analysis and is open to the same criticisms raised above.

4.12 Critical appraisal

Compared with the cost utility analysis reported above, this second analysis of the Counterweight programme adopts a narrower, partial analysis perspective, seeking only to quantify the impact of the programme on prescription costs. Whilst a partial analysis explicitly excludes some of the broader impacts of the Counterweight programme and the patient benefits, it can help in defining impacts which are material and can be realised by decision makers within realistic timeframes. In this instance, it was recognised that the Counterweight programme would be *'prescribed'* to patients and covered through prescription pharmacy budgets. The intent of the study was to show that whilst the cost of the programme would increase prescribing costs, some of this increase could be offset through reductions in other prescribed items. Furthermore, the study avoided any attempt to model future savings which can not readily be offset against investments in the current budget year.

Whilst the partial analysis is considered more applicable for decision makers, the presentation of the results remain very complex and it is unlikely to provide the clarity required by decision makers. The multiple analyses and assumptions (for example, partial uptake, full uptake, underlying weight loss) make interpretation of the findings challenging for any non-economist. These assumptions were necessary to acknowledge shortcomings in the available effectiveness data and also an attempt to provide transparency about the potential benefits. However, in an attempt to be transparent about the uncertainty in the model inputs there is a degree of over-compensation which results in far too many scenario analyses to provide a clear message for decision makers. In hindsight, a more succinct outcome could have been generated by limiting the number of assumptions and generating a clearer outcome – e.g. approximately 30% of the cost of the programme could be offset through savings in prescriptions in the short-term.

The short-term, partial analysis is believed to offer practical insights into the net budgetary impact of the programme to healthcare decision makers. It is also an attempt to move from a lifetime, cost utility analysis with limited applicability to decision making to a more pragmatic cost consequence type approach, albeit with a narrow perspective limited to prescribing budgets.

4.13 Chapter Summary

This chapter provides the first case studies of applying economic evaluation to public health programmes, in this case a weight management intervention. Although the intervention was supported by robust clinical evidence, adopting a lifetime perspective in the cost utility analysis resulted in marginal costs and benefits which are unlikely to be impactful to decision makers. The short-term analysis sought to address this by presenting more discrete estimates of the impact on the prescribing budget although, in hindsight, the outcomes could have been presented in a more easily digestible format. These studies illustrate how the use of a shorter-term economic evaluation, with a narrower perspective may provide results which are more

applicable to decision makers than standard cost utility methods. This contrast is further explored in the following chapter.

Chapter 5: The application of cost effectiveness analyses to environmental interventions to promote physical activity.

Publication #4. Beale SJ, Bending MW, Trueman P, Naidoo B. Should we invest in environmental interventions to encourage physical activity in England? An economic appraisal. European Journal of Public Health, 2012; 22(6): 869-873.

Available at: https://academic.oup.com/eurpub/article/22/6/869/542542

This chapter examines a case study of applying economic evaluation to environmental interventions to promote physical activity. The research was commissioned by NICE to inform development of public health guidance. Whilst methods were largely dictated by the NICE guidelines for economic evaluation, attempts were made to incorporate some of the lessons learned from the previous chapter. In contrast with the previous chapter, which considered a targeted, individual level intervention, this chapter considers a population level intervention which brings with it further complexities for evaluation, particularly in relation to attribution of effect.

5.1 Study context

Physical inactivity is associated with increased risk of a number of long-term health conditions, including coronary heart disease, diabetes and some cancers. Min-Lee et al estimated that the global attributable mortality associated with physical inactivity is comparable to smoking, accounting for around 6% of coronary heart disease cases, 7% of diabetes cases and 10% of breast and colon cancer cases (Min Lee et al 2012). Estimates from the UK suggest that the health impacts of physical inactivity cost the NHS over £7billion annually (PHE 2014).

The benefits of pursuing an active lifestyle – even through moderate physical activity such as walking - are well documented (PHE 2014). However, it is important that the built environment is designed in a way that allows and even promotes physical activity. The World Health Organisation (WHO) has suggested that around 25% of people are insufficiently physical active and that environmental and social conditions contribute to this (Guthold et al 2018). A number of studies have examined the effectiveness of specific interventions designed to promote physical activity, including walking and cycling trails (Goodman et al 2014) and group activities (Burke et al 2006). Whilst many of these have suggested that they represent good value for money, they have also highlighted the methodological issues inherent in evaluating programmes of this type.

In order to recognise the importance of physical activity, the NICE sought to develop guidance for public health stakeholders on the importance of environmental interventions to promote physical activity (National Institute for Health & Care Excellence 2018). The author was responsible for leading a programme of economic

research to inform the development of the guidance. Building on the methods employed in earlier studies, a multi-methods approach was adopted in an attempt to present the findings as clearly as possible to multiple stakeholders.

5.2 Methods

The study involved evidence synthesis from multiple sources to evaluate the effectiveness of cycling and walking trails intended to promote physical activity. Such trails may be developed with multiple objectives, including reducing traffic congestion, improving air quality and promoting physical health. For the purposes of the study two extreme cases were considered to determine how the costs of developing and maintaining trails should be attributed. In the first case, this assumed that all the costs were attributable to healthcare, which assumes that the primary intent of the trails is to improve the levels of physical activity. In the second example, this assumed that the objectives were primarily around improvements to the environment and that any health benefits would be secondary outcomes. In this case, only 5% of the cost was attributable to the health service decision maker.

Three discrete analyses were undertaken to estimate the health benefits and combine these with the costs of the intervention.

Cost utility analysis

A simulation model was developed to quantify the long-term health benefits of increasing physical activity. The model was designed to predict the risk of developing coronary heart disease and stroke, based on the Framingham risk equations, and diabetes, based on the Diabetes Risk Score. Treatment costs for each condition were derived from published sources and then annualised. A time horizon of 10 years was adopted, reflecting the predictions generated by the risk equations above. The impact of long-term conditions was captured in terms of life-years lost as well as quality of life. All costs and outcomes were discounted at prevailing rates (3.5%) and presented in 2007 values. The resulting outcomes were presented in the form of a cost per QALY.

Regression analysis

The second method used large-scale panel data to estimate the health benefits of increasing physical activity. Health Survey for England data were used to correlate the relationship between physical activity (measured in 30-minute units) and self-reported health-related quality of life, measured by the EQ-5D. Regression analyses were used to control for possible confounding demographic variables (age, sex, ethnicity, employment/education status) as well as behavioural variables (smoking status, alcohol consumption, body mass index). The outputs estimate the incremental gain in health-related quality of life resulting from an increase of one unit of physical activity. This relationship was assumed to be linear – that it is 5 units of physical

activity would generate an increment in utility 5 times greater than a single unit of physical activity. These were then used to generate a cost per QALY by combining evidence on the effect of interventions on units of activity with the estimated cost of building and maintaining a trail. The two extreme values approach was adopted for costing purposes, assuming that 5% or 100% of the costs were attributable to health.

Cost benefit analysis

The third method was a review of cost-benefit analyses. Heterogeneity amongst the published research made direct comparisons and meta-analysis impossible. As such, an attempt was made to standardise the costs and benefits reported across the studies which necessitated a number of simplifying assumptions around the use of the cycle trail and the costs of maintenance. The output of the analysis was a 'societal' cost benefit ratio.

5.3 Data

The majority of the data used in the study were derived from published research identified in an accompanying systematic review conducted to inform the guideline development. Models for predicting long-term health outcomes were derived from well-established risk models, such as the Framingham equation. Cost data on the development, build and maintenance of cycling trails was scarce and in many cases not relevant to the UK. What data were available were used to inform the model although some significant simplifying assumptions were necessary.

5.4 Outcomes

Unsurprisingly the cost utility analyses suggest that access to a cycling trail results in improved health benefits, with QALYs gained estimated to be 0.042 and 0.227 over the 10-year time horizon. These occur as a result of a lower incidence of long-term conditions that are associated with physical inactivity.

The second method estimated that QALY gains over a 30-year time horizon depending on the levels of participation in physical activity. Individuals who participated in one 30-minute session of physical activity per week were estimated to benefit from a 0.078 QALY gain. The relationship between participation and health benefits was assumed to be linear, so individuals who participated in 5 sessions per week were predicted to benefit from a 0.390 QALY gain. Cost per QALY calculations were based on a number of assumptions about the proportion of the cost of the intervention that was attributable to health. The cost per QALY remained below £10,000 in all scenarios. Assuming that 5% of the costs of the trail were attributed to the health budget then the cost per QALY fell below £500 in all cases.

The final method attempted to standardise cost benefit ratios reported from previous studies. The resulting cost benefit ratio was estimated to be 1:11 – that is, for every £1 spent on the development and maintenance of the trail, society would accrue £11 in benefits. The majority of the reported benefit was accrued in the form of health benefits.

5.5 Strengths & weaknesses

The paucity of detailed and accurate data, relevant to a UK setting, on the costs and benefits of environmental interventions to promote physical activity was the primary acknowledged challenge to the research. Whilst a number of studies reported overall levels of physical activity there was insufficient detail to establish whether this activity was *'new'* physical activity amongst users who had previously been sedentary or substituted other activities that were already being conducted. This makes estimation of the societal impact very challenging – in the worst-case scenario, where the activity simply replaces another existing activity, the net societal benefit could be zero.

The regression analysis assumed a linear relationship between physical activity and HRQOL whereby an individual who undertook 5 sessions of physical activity would receive five times the utility increment. Significant questions were raised over this at the time of the research and, in hindsight, this assumptions seems implausible. There is likely to be an incremental gain in utility in moving from a physically inactive state to a physically active state as a result of health benefits and the so-called process benefit (as explored in Chapter 7). Whilst this utility gain may further increase with increased levels of participation in exercise the relationship is unlikely to be linear and more will more likely display some degree of diminishing returns.

Estimating the cost side of the equation is equally challenging. Environmental interventions often have multiple objectives including improving air quality, reducing traffic accidents and improving well-being. The health benefits may be a primary or a secondary benefit. This made it necessary to make an arbitrary assumption about the proportion of the costs that should be attributable to health in a cost effectiveness analysis.

The cost benefit analysis sought to address some of these challenges by taking a societal perspective. In doing so, it considers the cost to the economy as a whole – regardless of who pays – and the holistic benefits including the environment, well-being and physical health. The results indicate a favourable cost benefit ratio.

5.6 Critical appraisal

The cost utility analysis was conducted as a default approach as this research was commissioned as a direct input to the NICE guideline on interventions to promote physical activity. Whilst the author and the research team had concerns about this method, it was felt that adopting the NICE reference case should be the default approach to maximise the relevance to the NICE decision-making committee. However, it is important to recognise that the intervention under consideration – environmental interventions to promote physical activity – have far-reaching benefits with health being only one of these. This was reflected in the findings of the cost utility analyses which indicated that the QALY gains over 10 years were modest and close to zero in some scenarios.

The alternative methods considered are believed to provide some additional insights that cannot be conveyed in the CUA ratio. Cost benefit seeks to quantify outcomes in monetary terms, rather than in natural units or QALYs. Whilst there are well documented challenges to defining monetary values for variables such as improved health or wellbeing, the outcomes generated are intrinsically appealing for many decision makers (McIntosh et al 2019). The methods adopted and resulting outcome (a cost benefit ratio) are expected to be more relevant to the majority of public sector decision makers, mirroring the methods that are commonly used in economic evaluations of transport, housing and environmental funding decisions. Whilst this may have some benefits over a QALY based ICER, it still suffers from being a composite endpoint which masks the absolute changes in the costs and benefits and where these are accrued.

The research was commissioned to support the development of public health guidance by NICE so the application of cost benefit analysis was a deviation from standard economic evaluation methods that are recommended by NICE. The outcomes were influential in forming the basis of the recommendations that were included in the NICE guidance on physical activity and the environment. Furthermore, as one of the first public health economic evaluations commissioned by NICE, the methods are believed to have influenced the development of methodological guidelines which recognise the challenges of applying cost utility analysis and permit the use of alternative methods of cost benefit analysis.

5.7 Chapter Summary

This chapter seeks to further illustrate the potential shortcomings of applying cost utility analysis to population level public health programmes which are characterised by challenges in attributing effects and costs. Whilst the headline ICER was considered favourable, the use of a composite outcome masks some of the uncertainty in the derivation of the costs and outcomes, for example, assumptions about linearity in benefits associated with physical activity which seems like an unreasonable assumption.

The cost benefit analysis presents an intrinsically accessible outcome for non-specialist stakeholders: for every £1 spent society gains £11 of benefit. However, this also suffers from being an aggregated, composite outcome which fails to present how the costs and benefits are accrued. A more granular presentation of these elements – in the form of a cost consequence – would help decision makers. The following chapter builds on the insights from this chapter by introducing a disaggregated cost consequence analysis.

Chapter 6: The application of cost-benefit analysis to interventions to promote breastfeeding.

Publication #5: Pokhrel S, Quigley MA, Fox-Rushby J, McCormick F, Williams A, Trueman P, Dodds R, Renfrew MJ. Potential economic impacts from improving breastfeeding rates in the UK. Arch Dis Child. 2015 Apr;100(4):334-40.

Available at: https://adc.bmj.com/content/100/4/334

Previous chapters have considered the application of cost utility analysis as the default for economic evaluation and introduced alternative methods, such as cost benefit analysis. This chapter will consider the application of cost benefit analysis to interventions designed to promote breastfeeding and introduces further granularity to the presentation of the findings, intended to address some of the shortcomings of the previous analyses.

6.1 Study context

There is an inverse association between the rate of economic development and breastfeeding, with very low rates now reported in many Western countries (Victora et al 2016). There appears to be a growing preference for breast-milk substitutes, driven partly by societal norms, the perception of increased convenience and promotion from the manufacturers. This is despite a significant body of evidence which points to the positive effects of breast-feeding, compared to the use of milk-substitutes, both for the mother and the child. A systematic review conducted alongside this economic evaluation, confirmed the results of earlier studies and illustrated that breast-feeding provides a lasting protective effect against a number of conditions, including gastro-intestinal infection, lower respiratory tract infections and acute otitis media in infants as well as breast cancer in mothers (Renfrew et al 2012). Although less robust, there are also statistical associations with a number of other conditions including cognitive development, obesity and sudden infant death.

Estimates from the United States in 2007 report that increased breastfeeding rates could result in savings of over US$3billion, much of which relates to healthcare costs (Bartick & Reinhold 2010). Whilst similar studies have been conducted in Australia (Drane 1997) and the Netherlands (Buchner et al 2007), there was a dearth of high quality economic data relating to the UK. The current study was funded by UNICEF UK with the intention of generating robust economic data on the financial impact of breastfeeding in the UK. The study sought to estimate the costs and benefits associated with interventions to promote breastfeeding in the UK.

6.2 Methods

A partial cost benefit framework was established to capture the costs and benefits of alternative feeding regimes. The association between feeding and outcomes was established through an accompanying systematic review. Four childhood conditions were considered in the analysis: gastro-intestinal illness, lower respiratory tract infections, acute otitis media and necrotising enterocolitis. Whilst there are statistical associations with other conditions, these four conditions were selected based on the strength of the data available. In addition to this, maternal breast cancer was also considered as an outcome.

The costs of managing these conditions were derived from published sources. The time horizon for infant conditions was limited to one year whilst a lifetime horizon was adopted for the maternal outcomes. Only costs falling on the health service were considered – wider societal costs were excluded due to the challenges of quantifying these with any accuracy.

Two separate approaches were adopted to quantify the impacts to children and mothers. Risk models, based on the evidence from the literature review, were used to estimate the incidence of each condition amongst a cohort of children. The lifetime risk of breast cancer amongst mothers was derived through a simple Markov model which applied the risks of developing cancer based on the whether they breastfed children or not. These analyses, when combined, generated an estimate of the costs associated with current levels of breastfeeding in the UK. Further analyses then sought to estimate the costs and benefits of interventions designed to increase the duration or exclusivity of breastfeeding.

6.3 Results

In the base-case analysis, the costs to the NHS of treating infant conditions occurring as a result of sub-optimal rates of breastfeeding was estimated to be ~£90million per year. The cost of treating incremental cases of breast cancer as a result of current rates of breastfeeding was estimated to be £960million.

Unsurprisingly, interventions to increase the rates/duration/exclusivity of breastfeeding were found to reduce the incidence of infant and maternal conditions and, in turn, reduce the costs to the health service. Extending the proportion of women breastfeeding exclusively at one week to 4 months was estimated to result in a saving of around £11million per year. Increasing the rates of breastfeeding in neonatal units, arguably a more achievable target, had the potential to save ~£6million per year whilst doubling the proportion of women breastfeeding could result in savings of approximately ~£21million in the management of breast cancer. A net benefit calculation was also undertaken which valued any QALY gains resulting from improved breast cancer rates at £20,000 each; this resulted in a further benefit of £10million.

The table below summarises the scenarios considered in the analysis and reports the potential savings in treating conditions included in the analysis for each policy scenario. The first row reports the estimate of the average treatment cost per person of each condition considered based on current levels of breastfeeding.

Table 6.1: Estimated average costs per individual of treating identified diseases and potential cost savings associated with increased breastfeeding rates in the UK (£2009–2010 prices). (Reproduced from Pokhrel et al 2015).

	Gastrointestinal illnesses*	Lower respiratory tract infection*	Acute otitis media*	Necrotising enterocolitis†	Maternal breast cancer‡
Current treatment costs	17.02	75.52	4.88	171.13	3057.51
Savings with:					
Policy A1	0.92	3.12	0.35		
Policy A2	2.49	8.48	0.96		
Policy A3	3.81	12.94	1.47		
Policy B1	0.43	1.45	0.16		
Policy C1	1.52	6.05	0.79		
Policy D1				29.02	
Policy D2				77.39	
Policy D3				125.75	
Policy E1					48.88
Policy E2					67.46
Policy E3					88.59

*Cost per infant.
†Cost per neonatal admission.
‡Cost per primiparous woman.

The table highlights the need for multi-component interventions if changes in breastfeeding behaviour are to address both childhood and maternal conditions.

6.4 Strengths & weaknesses

Despite the original nature of the research there are a number of limitations with the methodology, some of which were recognised at the time of the study. Given the paucity and uncertainty of data, it was only possible to include a small number of conditions which are associated with breastfeeding. The accompanying systematic review suggests that breastfeeding may impact the incidence of a range of other conditions, including cognitive development and behavioural outcomes (Quigley 2012). As a result of this, the resulting estimates might be considered under-estimates of the true financial impact.

It should also be noted that the evaluation failed to incorporate the costs of interventions. The study estimated the potential savings that might occur as a result of hypothetical improvements in breast feeding rates and duration. However, no estimate of the costs of achieving these rates were considered in the publication. Further consideration was given to this in the full report provided to the study sponsor (Renfrew et al 2012).

6.5 Critical appraisal

This was recognised as an important contribution to the evidence base on breastfeeding and sought to provide a more robust economic rationale for investing in interventions to improve breastfeeding rates. As the first UK study to do so, the outcomes garnered significant attention from the press (The Guardian n.d.), broadcast

media and decision makers and continue to be referenced in policy recommendations in England (Public Health England n.d.) and overseas (Davanzo et al 2015).

Building on the previous case studies considered in this thesis a number of methodological improvements were incorporated into the design to improve the relevance to stakeholders. Firstly, a narrow perspective was consciously adopted, which meant any potential financial benefits accrued would be directly applicable to the health service decision maker, who was deemed to be the major funder of the intervention. Secondly, the short-term cost impacts (acute childhood infections) were reported in a disaggregated way from the long-term cost impacts to the mother. Again, this improves the relevance by identifying short-term costs which may be improved as a result of investment in public health interventions thereby allowing the decision maker to determine a net financial benefit. Finally, outcomes were reported in disaggregated, natural units wherever possible (for example number of cases avoided/100,000 popn). Where this was not possible, an estimate of the direction of the effect was included in an attempt to capture the full range of benefits, even where these could not be quantified.

The core analysis is relatively easy to interpret: breastfeeding is associated with a reduced risk of a number of childhood and maternal conditions. Therefore, improving breastfeeding rates will reduce the incidence, and associated costs, of these conditions. However, the analysis does become more complex as a result of the number of scenarios that are modelled. It was necessary to model scenarios that:

1. Affect the rate of any breast-feeding;
2. Affect the rate of breast-feeding prior to discharge from the neonatal unit;
3. Affect the rate of exclusive breastfeeding;
4. Affect the duration of any breastfeeding.

The result was that 11 separate hypothetical interventions were modelled in the analysis resulting in a multitude of outcomes.

A clearer solution might have been to identify a smaller number of *'most likely'* scenarios that could be referenced to published evaluations of interventions. This could have provided a clearer indication of the feasible savings that might be achieved and furthermore, allowed for an estimate of the cost of the intervention to be included thereby generating a better comparison of the costs and benefits.

The approach adopted in this analysis does offer some guidance to how future evaluations of public health interventions might be presented to increase their impact. The logic framework used in this analysis was intended to firstly illustrate the scale of the problem to the health service (and society more generally) before considering how this might be improved. This is a critical step in justifying investment in public health. In previous analyses, the focus was on the incremental improvements in outcomes but there was limited reporting of the financial and human burden associated with current behaviours. For many public health

interventions, this burden might be considered avoidable where it results from behavioural trends or decisions, such as the choice of whether to breastfeed or be physically active. Illustrating and quantifying the 'do-nothing' scenario is seen as an important step in engaging decision makers prior to evaluating interventions.

The methods adopted are believed to provide a pragmatic approach that should meet the needs of multiple decision makers. By starting with a disaggregated CCA, decision makers can easily understand the costs and benefits of the intervention, whilst CUA and CBA elements provide QALY gains and an estimate of net benefit for decision makers more used to these outcomes. The first step of presenting the outcomes in a disaggregated fashion before moving to composite ratio outcomes is an important one in improving transparency.

6.6 Chapter summary

This chapter explores an alternative approach to the economic evaluation of public health interventions, by adopting a quasi-cost benefit analysis with outcomes also presented in a disaggregated cost consequence analysis. The cost consequence analysis also allows for directional reporting of a wider range of impacts even where these cannot be adequately quantified in monetary terms or health benefits. Complexity was added due to the number of scenarios modelled and in hindsight this could have been further improved. The next chapter will continue to contrast the use of alternative methods of economic evaluation, concluding with a cost consequence analysis.

Chapter 7: The application of economic evaluation to exercise referral schemes to promote physical activity.

This chapter comprises the final case study, applying economic evaluation to exercise referral schemes. The research was commissioned by the NIHR HTA programme and allowed sufficient scope to explore the application of multiple methods of economic evaluation, building on the lessons learned from the studies presented in earlier chapters. These alternative methods were applied in an attempt to make the results as accessible as possible to decision makers and provide an illustration of alternative approaches to economic evaluation for other researchers working in the field of public health. The chapter includes 4 separate papers produced as part of the research programme.

7.1 Study context

Physical activity plays a critical role in the prevention and management of many medical conditions through multiple biological and psychological mechanisms. There is an obvious relationship between physical activity and weight gain which in turn is associated with the risk of long-term conditions, such as coronary heart disease and diabetes mellitus (Department of Health 2004). In addition to the biologic effects, physical activity has also been shown to be correlated to mental health (Stephens 1988), depression (Rebar et al 2015) and even dementia (Blondell et al 2014).

Government endorsed guidelines recommend that adults should undertake at least 30-minutes of exercise of moderate intensity at least five times a week (Department of Health 2004). However, public health data suggest that many people fail to achieve this level of activity due to increasingly sedentary life-styles and an over-reliance on transport (Craig et al 2009).

Chapter 5 considered public health programmes designed to *'nudge'* people to a more active lifestyle by developing built environments more conducive to exercise. An alternative approach to promoting physical activity is a more targeted, individualised intervention focussed in individuals who are recognised as physically inactive to an extent that it could harm their long-term health. Exercise referral schemes (ERS) were first introduced into general practice around 1990 with guidelines being introduced for best practice at a later stage (British Heart Foundation National Centre n.d.). Under these schemes, individuals with a recognised cardiac risk factor are prescribed an exercise programme, typically provided by a third-party service, such as a sport centre or gym. The service provider then works with the individual to define a programme of exercise and monitor their adherence to the programme.

A number of previous studies have sought to establish whether exercise referral schemes can increase physical activity levels in individuals who were previously sedentary (Morgan 2005) (Williams et al 2007). These studies

considered only short-term outcomes (physical activity) and did not consider the impacts on health outcomes nor did they consider the cost effectiveness of such interventions.

This chapter considers four publications which were developed as part of a NIHR HTA programme of research. The research was commissioned to address a specific evidence gap identified by the NICE guidance on physical activity (National Institute for Health Care & Excellence 2006) which questioned the clinical and economic value of exercise referral schemes.

Publication #6: Pavey TG, Taylor AH, Fox KR, Hillsdon M, Anokye N, Campbell JL, Foster C, Green C, Moxham T, Mutrie N, Searle J, Trueman P, Taylor RS. Effect of exercise referral schemes in primary care on physical activity and improving health outcomes: systematic review and meta-analysis. BMJ. 2011 Nov 4;343.

Available at: https://www.bmj.com/content/343/bmj.d6462

A systematic review and meta-analysis of exercise referral schemes was conducted as a foundation for the programme of research (Pavey et al 2011). This study sought to update previously conducted systematic reviews and also address some of their limitations, notably quantifying the impact of these schemes on health outcomes and providing data to support a cost effectiveness analysis.

7.2 Methods

A comprehensive search strategy was defined to capture all relevant studies on exercise referral schemes. Searches were limited to English language and 1990 onwards, which was deemed to be the time at which such schemes were introduced into the NHS. The search sought to identify studies based in primary care settings to improve their relevance to the overall programme objectives. Only comparative studies were included in the analysis, although in recognition of the challenges of randomisation and blinding in studies of public health interventions, non-randomised study designs were included, such as cluster studies. PICO criteria were developed with critical components being:

Population: individuals with and without a prior medical diagnosis meaning individuals considered 'at-risk' would be included;

Intervention: comprises a) referral from a primary care professional to a third party provider; b) physical activity programme tailored to individual needs, as opposed to a population intervention; c) initial assessment and monitoring throughout the programme.

Comparator: any control, typically no intervention or usual care comprising lifestyle and behavioural advice;

Outcomes: physical activity, self-reported or objectively measured, but also clinical outcomes such as the incidence of coronary heart disease and diabetes mellitus, health related quality of life and adverse events.

7.3 Data

A significant number of relevant articles were reviewed but only 8 studies were considered suitable for inclusion. The majority of studies were excluded on the basis of limited information on how individuals were referred to physical activity programmes, causes for the referral and a lack of details of the provider of the programme. Of the 8 studies included, 6 were completed, published studies and 2 were study protocols, one of which was associated with an unpublished study report made available by the investigators. The studies included 5190 participants, with six of the eight included studies being conducted in the UK, one in Denmark and one in Spain. Study duration was between 2-12 months and 6 of the 8 studies compared exercise referral schemes with usual care/no-intervention whilst two studies compared exercise referral with alternative physical activity interventions, such as walking programmes.

7.4 Outcomes

Physical activity outcomes were the most consistently reported outcome across the studies included, typically reported as the proportion of individuals achieving the recommended levels of activity of 90-150 minutes of activity per week. The pooled data identified a 16% increase in the relative risk of achieving this outcome amongst individuals who participated in exercise referral schemes compared to usual care at 6-12-month follow-up. No differences were found in outcomes between exercise referral schemes and alternative interventions designed to promote physical activity whilst the addition of a behavioural change intervention to the exercise referral scheme had a detrimental effect of physical activity levels. The Forrest plot below summarises these findings. Notably, in the comparison of exercise referral schemes vs usual care the confidence intervals of the four studies considered all cross 1. An adjusted analysis considered only those participants that agreed to randomisation (a per protocol analysis compared to the ITT analysis of the baseline) resulted in a further weakening of the result. The comparison of exercise referral schemes with other interventions to promote physical activity show even greater uncertainty over whether there is any beneficial effect of ERS.

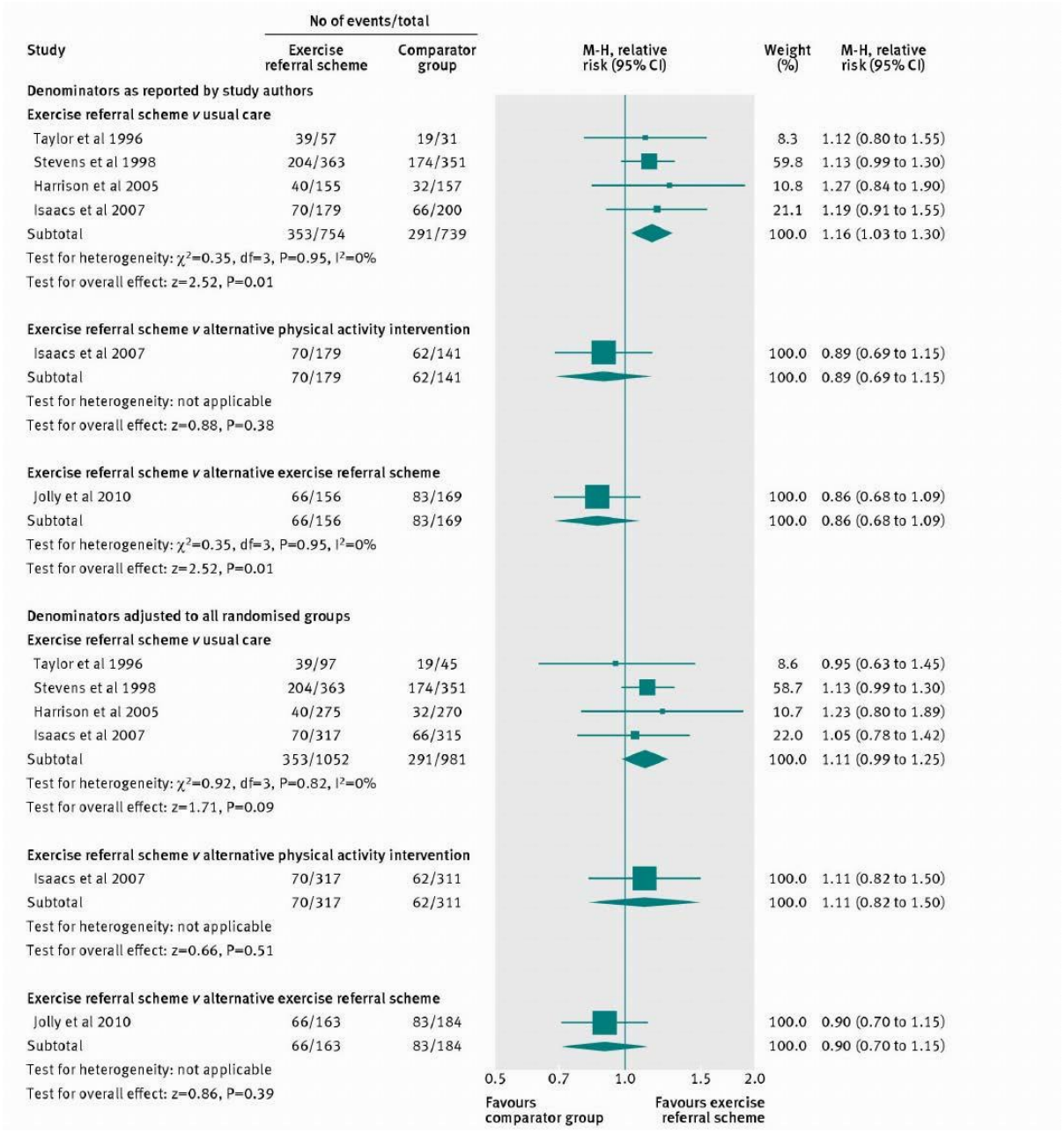

Figure 7.1: Meta-analysis of patients achieving 90-150 minutes of physical activity of at least moderate intensity per week, using denominators as reported by study authors and denominators adjusted to all randomised groups (reproduced from Pavey et al 2011).

Of the studies that considered psychological well-being there were significant improvements in physical selfworth and perceptions of physical condition and physical health in the exercise referral scheme participants. Single studies also showed improvements in depression scores.

The impact of exercise referral schemes on HRQOL was difficult to interpret due to different measures and follow-up periods. One study failed to show any difference on the SF-36 whilst a second study reported a significant improvement amongst exercise referral participants using the EQ-5D measure.

Overall, the study concluded that there was *'weak'* evidence of a short-term increase in physical activity to meet recommended levels and a reduction in levels of depression in individuals that participated in exercise referral schemes compared to individuals managed through usual care. However, there was no statistically significant difference in clinical outcomes, such as blood pressure, obesity and glycaemic control. Furthermore, exercise referral schemes were not found to offer incremental benefits above other, less structured physical activity interventions, such as walking programmes.

7.5 Strengths & weaknesses

Extensive efforts were made to screen evidence to ensure that only studies that considered the specific intervention were included in the analysis which generated a robust systematic review. The downside of such a narrow definition is that there was significant attrition in the literature screening process, excluding a number of potentially relevant studies due to lack of detail on referral pathways and interventions, resulting in a small number of studies being included in the review.

A further limitation of the study was the heterogeneity amongst the studies and inconsistency in the reporting of outcomes. The result was that only measures of physical activity, physical fitness and clinical outcomes levels could be meaningfully pooled in a meta-analysis. Even where pooling was possible, caution should be taken in interpreting the pooled results due to heterogeneity amongst studies. Differences in outcomes measures meant that it was inappropriate to pool other outcomes such as psychological wellbeing and HRQOL meaning findings were often based on individual studies.

7.6 Critical appraisal

This programme of research was intended to address a very specific question raised by NICE in guidance on physical activity which suggested that there was insufficient evidence to support the widespread adoption of exercise referral schemes and recommended that such schemes should be restricted to controlled trials. Despite this guidance, it was recognised that exercise referral continued to be prescribed widely in primary care outside of controlled trials and there was a pressing need to determine whether such schemes are justified. Although previous systematic reviews had been conducted, the study included a number or more recent studies and also expanded the range of outcome measures considered to provide a more relevant assessment of the impact on health.

Somewhat controversially, the study concluded that the case for continued investment in exercise referral schemes should be reviewed and that the limited effect identified in the study may even make a case for disinvestment. This is a somewhat unique outcome for evaluations of public health interventions which typically find that due to the low-per capita cost of the intervention, even a modest effect results in a cost effective outcome, as reported in the Owen paper (Owen et al 2018). In this case, a robust assessment of effectiveness found little evidence to suggest that individualised interventions resulted in any meaningful

health impact. The best case is that the use of such interventions should remain restricted to controlled trial environments to provide further evidence and address some of the gaps and inconsistencies in the evidence identified in the current study.

The findings of this study were directly applicable to NICE guidance on physical activity and were also shared with public health professionals in the Department of Health to inform the development of future policy.

Publication #7: Anokye NA, Trueman P, Green C, Pavey T, Hillsdon M, Taylor RS. The cost effectiveness of exercise referral schemes. BMC Public Health2011; 11:954.

Available at: https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-11-954

Building on the systematic review and meta-analysis reported above, an economic evaluation of exercise referral schemes was conducted (Anokye et al 2011). This sought to answer the question of whether referrals to ERS represent value for money in individuals with a pre-existing health condition, such as coronary heart disease or depression. Given the uncertainty over the effectiveness of such interventions, their cost effectiveness becomes even more important to decision makers concerned with making the best use of available NHS resources.

The systematic review identified 4 previous studies that had sought to estimate the cost effectiveness of ERS programmes. Of these, three were economic evaluations alongside clinical trials (Gusi et al 2008) (Isaacs et al 2007) (Stevens et al 1998) and one was a modelling study based on evidence synthesis (National Institute for Health & Care Excellence 2006). In all cases, these had suggested that such interventions are cost effective although there were limitations in terms of the data on efficacy and the use of a sedentary but healthy population. The latter is a particular problem as exercise referral is unlikely to be prescribed by the NHS for healthy individuals and is more typically targeted towards individuals who have a pre-existing condition.

7.7 Methods

A simple, decision analytic model was developed which considered the impact of physical activity on the development of coronary heart disease, stroke and diabetes. The model structure and many of the inputs were derived from the model used to evaluate trails discussed in chapter 4. These conditions were chosen due to the availability of robust data on their correlation with physical activity. The model considers a cohort of sedentary individuals and the effect of exposure to an exercise referral programme on their physical activity levels. Activity was considered to be a binary endpoint – active or non-active – based on whether an individual meets guideline recommendations of 90-150 minutes of at least moderate physical activity per week.

Evidence on the effectiveness of ERS programmes was derived directly from the systematic review which provided an estimate of the relative risk of moving from a sedentary state to an active state. Where individuals became active they were assumed to remain active for a sufficient time to provide long-term health benefits, a so-called *'fully engaged'* population. Evidence on the relationship between physical activity and long-term outcomes was derived from the systematic review and Health Survey for England data.

The costs of the ERS intervention were derived from a previous publication whilst treatment costs for long-term conditions were derived from previous publications. Annual costs were estimated for coronary heart disease and diabetes as long-term, chronic conditions, whilst the cost of stroke was considered as a one-off event. A cost utility analysis approach was adopted which reported outcomes in the form of incremental cost per quality adjusted life year (ICER).

7.8 Outcomes/Results

The base-case analysis generated an ICER of £20,876. This was based on an incremental life-time cost £170 per person in the ERS group and an incremental QALY gain of 0.008. The ICER might be considered to be 'borderline' cost effective according to criteria applied by NICE. The point estimate of the ICER masks small changes in both lifetime costs and QALY gains. The marginal QALY gain – 0.008 over a lifetime – is unsurprising given the limited effect of the interventions identified in the systematic review. In sensitivity analyses, which explored the impact of a range of scenarios based on the systematic review, the incremental QALY gain ranged from -0.01 (that is, worse outcomes than usual care) to 0.015. The cost of the intervention was also varied in sensitivity analyses and resulted in a range of values from ERS being dominated by usual care (more costly with inferior outcomes) to an ICER as low as £679.

Probabilistic sensitivity analyses attempted to address the uncertainty, estimating that there is a 51% chance of ERS being cost effective with a threshold of £20,000 per QALY and a 88% chance of it being cost effective at a £30,000 level. Of course, the probabilistic analysis reflects the assumptions made about the input parameters which may be subject to significant uncertainty. The meta-analysis produced an estimate of effectiveness of 1.16 in favour of ERS, with a range of 1.03 to 1.30. Estimates of effectiveness derived from individual studies considered in the meta-analysis included values below 1, indicating no positive effect of ERS.

Sub-group analyses considered the cost effectiveness of ERS when targeted at individuals with pre-existing longterm conditions. In these cases, the ICER decreased from the baseline of approximately £20,000 per QALY to between £8,000 - £14,000 per QALY.

7.9 Strengths & Weaknesses

Challenges associated with the model include a) limitations in the data on the effectiveness of ERS derived from the systematic review and b) the adoption of a lifetime model based on short-term effectiveness data.

The limitations of the effectiveness data are discussed in the previous section which appraised the systematic review and noted significant uncertainty and a weak effect size. The decision to adopt a lifetime model was taken to capture the impact of physical activity on long-term conditions, namely coronary heart disease and diabetes. Whilst there is a robust relationship between physical activity and these conditions, this time horizon demanded that some fairly gross assumptions were made about the long-term effectiveness of ERS. The model assumes that any individual who moves from a sedentary to an active status remains active for a sufficient period to affect their risk of developing long-term conditions. Given that the majority of the data from the systematic review reported outcomes between 6-12 months and provided little in the way of evidence on adherence to ERS programmes, this assumption is open to significant scrutiny. A further issue arose in the analysis of subgroups with underlying conditions that elevate the risk of long-term health conditions. Whilst these groups are typical of the population prescribed ERS and therefore should be the group considered by the model, there was a dearth of detail in the underlying literature to determine whether the effectiveness of ERS differs in these groups. As such, any outcomes relating to these groups should be considered hypothetical and treated with significant caution.

On the strengths side it should be noted that there are some areas where the model adopted a cautious approach, including limiting the number of long-term conditions to three and excluding any process benefits from physical activity which might benefit mental health and well-being.

7.10 Critical appraisal

This study sought to address a critically important question that had been raised by previous NICE guidance, namely are ERS cost effective. As an adjunct to the systematic review this was intended to provide clear guidance to decision makers on whether investment in ERS should be expanded or discontinued.

Unfortunately, the study was undermined by the quality of the effectiveness data identified in the systematic review. Having found a very modest positive effect of ERS which was associated with considerable uncertainty it was somewhat unsurprising that ERS were also found to be of questionable economic value. As with previous examples reported herein, the results identified marginal – some would say almost negligible – differences in lifetime costs and outcomes associated with ERS which make the ICER unstable. This was illustrated in the discussion which showed that in the base case analysis the QALY change of 0.008 resulted in a cost effectiveness ratio which might be considered borderline acceptable. Changing the QALY gain by one hundredth to 0.007 would shift the ICER to being unacceptable. Again, this illustrates the dangers inherent in a composite ratio as an outcome measure. On face value, decision makers might take the ~£20,000 per QALY as a favourable basis on which to make investment decisions. Indeed, this was one of the evaluations considered *'highly cost effective'* by Owen at el in their summary paper. However, disaggregating the ratio provides a clearer picture and helps understand the absolute impact of the intervention to the patient. In order to better comprehend the uncertainty it might be worth asking how an individual would describe the

difference between the base case QALY gain of 0.008 over a lifetime and a QALY gain of, say 0.005. The reality is that such small changes in outcomes are likely to be difficult to comprehend for the majority of people and highlight the peril of the ICER.

It should be noted that the study considers exercise referral as an input to improved outcomes. No attempt was made to capture the process benefits that might result from participation in physical activity. Incorporating benefits to mental well-being may improve the cost effectiveness ratio. The next study conducted as part of this research sought to address this issue and determine whether this would have a favourable impact on the outcomes.

Publication #8: Anokye NA, Trueman P, Green C, Pavey T, Taylor RS. Physical Activity and health related quality of life. BMC Public Health 2012; 12:624.

Available at: https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-12-624

It is widely recognised that the act of engaging in physical activity may provide immediate, process benefits in terms of improved mental well-being, as well as longer term health benefits. Indeed, there are studies which have sought to assess whether participation in exercise programmes can improve mental health and wellbeing (Gusi et al 2008). The current study sought to use panel data to establish the correlation between physical activity levels and health related quality of life (Anokye et al 2012) in order to address the gap recognised in the previous study.

The assessment of both physical activity and health related quality of life are both subjective to some extent. Quality of life can be captured by using standardised questionnaires which provide some degree of confidence about what is being measured and reported by individuals. Whilst physical activity levels can be measured objectively, for example, through the use of accelerometers, in many cases data are self-reported and as such, are subject to some degree of reporting bias. This study sought to include both subjective and objective measures of physical activity.

7.11 Methods

Panel data from the Health Survey for England were used to identify health related quality of life data and information on physical activity levels. The Health Survey for England includes a representative cross section of the English population and explores different health and lifestyle behaviours in each survey. For the purposes of our study, the 2008 survey results were used which includes a sample of over 9,000 households with over 15,000 adults and 7,000 children. The focus of the 2008 survey was physical activity and fitness and

included subjective measurement of physical activity, through self-reporting, and objective measures through the use of accelerometers. Physical activity was considered to include a walking, housework, occupational activity and sports & exercise. For the purposes of our study, it was important to determine whether the types of physical activity used in exercise referral programmes would lead to an improvement in health-related quality of life so the definition of physical activity was limited to walking and sports & exercise. Physical activity was treated as a binary variable with individuals who achieved 90 of more minutes per week being classed as 'active' and individuals with less than 90 minutes per week of activity being classed as 'inactive'.

The objective assessment of activity was measured in a sub-sample of participants who agreed to use the accelerometers over a 7-day period for a minimum of 10 hours per day. Participants also completed a diary to detail their activities.

Health related quality of life (HRQOL) was measured through use of the EQ-5D. Scores were translated into utility scores using the tariff which generates a score between 0 (death) and 1 (full health).

Regression models were developed to determine the relationship between HRQOL and physical activity levels. Dummy variables were defined for missing data whilst methods were put in place to handle censoring of HRQOL data (limiting it to a maximum of 1 according to the utility score) and co-variates linked to HRQOL such as sociodemographic variables).

Four regression models were run to consider the different definitions of physical activity:

Model 1 – walking only

Model 2 – sport & exercise

Model 3 – objective assessment through accelerometer data

Model 4 – subjective assessment of physical activity.

In each case, two versions of the model were run, one with missing data excluded and one with imputed missing data values.

7.12 Results

The proportion of individuals reported as physically active was 12% for both sports & exercise and objective measurement; 16% for walking and 44% for subjective measurement. Whilst subjective measurement includes a broader definition of physical activity, incorporating housework and occupational activities, this does suggest that individuals over-estimate their levels of physical activity. The mean utility score was 0.86. The majority of individuals were considered to be over-weight (34%) or obese (26%); 22% self-reported as smokers and 85% consumed alcohol.

Individuals who self-reported as physically active were associated with improved health related QOL scores. This positive association was consistent across all definitions of physical activity, including walking, sports and exercise and objective outcomes. Self-reported walking and sports & exercise were associated with a modest impact on HRQOL, possibly reflecting the propensity for over-reporting of subjective measures of activity. The regression analyses identified a greater effect of objective measures of physical activity than subjective, selfreported measures (co-efficient of 0.072 vs 0.047). This was confirmed through the descriptive statistics that reported a marginally higher self-reported HRQOL amongst objectively measured physically active individuals compared to self-reporting (0.918 vs 0.916).

7.13 Strengths & weaknesses

The study was based on a cross-sectional cohort of individuals reporting their physical activity and HRQOL which creates a number of limitations. Whilst cross-sectional data allow for associations to be determined, it is not possible to determine causality. As such, it is impossible to state whether HRQOL is improved as a result of physical activity or there is a higher likelihood of physical activity in individuals with higher HRQOL. As a cross sectional study, it is also impossible to determine whether the increased HRQOL is sustained over a period of time as the analysis is based on point estimates at the time of the survey. Finally, as with all cross-sectional studies, there may be limitations on generalising the results beyond the population in the sample. In this case, our sample comprised individuals aged 40-60 and whilst some efforts were made to control for confounding variables in the comparisons, there may still be characteristics of the study population which prevent widespread generalisation of the results.

On the positive side, this is one of the few studies to attempt to quantify the process benefits of taking part in physical activity which have been overlooked in previous studies, including those reported herein. Furthermore, the study attempted to determine whether objective or subjective reporting forms the most appropriate basis for such an evaluation and identified that subjective reporting may be open to reporting bias. This is an important contribution to the evidence on this issue, particularly given the challenges associated with extrapolating long-term health benefits from short-term measures of participation in physical activity.

7.14 Critical appraisal

This study was intended to provide further insights into the benefits of taking part in physical activity and act as a supplement to the earlier study which considered physical activity as an input to long-term health. The relationships between physical activity, mental wellbeing and the downstream association with longer-term health benefits are complicated and poorly understood. Whilst it is widely accepted that physical activity is associated with improved well-being there remains difficulty in establishing the nature of this relationship.

As a contribution to decision making these data further develop the initial cost utility analysis presented earlier in this section. The cost utility analysis found ERS to be of questionable effectiveness when viewing it as a determinant of long-term conditions. Adding in the short-term HRQOL benefits provides a slightly more favourable perspective and a more holistic view of the potential benefits of ERS programmes. These benefits could be added into the cost utility analysis to supplement the health benefits identified earlier or alternatively could be presented separately as a cost consequence analysis which reports both short- and long-term health benefits. Given the uncertainty in many of the underlying data points and the difficulty in extrapolating these to long-term impacts on life expectancy, cost utility analysis runs the risk of producing spuriously accurate outcomes. In light of this, the decision was made to undertake a cost consequence analysis to complement the CUA and provide a more granular view of the costs and outcomes which is presented in the next section.

Publication #9: Trueman P & Anokye NA. Applying economic evaluation to public health interventions: the case of interventions to promote physical activity. J Public Health. 2013 Mar;35(1):32-9.

Available at: https://academic.oup.com/jpubhealth/article/35/1/32/1589870

The final article in the programme of work examining exercise referral schemes sought to build on the initial research methods and test a more pragmatic approach to economic evaluation (Trueman & Anokye 2013). This was intended to recognise some of the shortcomings of the previous methods highlighted in the critiques presented above. The study sought to provide both a cost utility analysis and a cost consequence analysis of exercise referral schemes based on data derived from the systematic review and modelling exercises. CUA might be considered a composite outcomes that brings together costs with clinical outcomes and quality of life in the form of a ratio, namely the incremental cost per QALY. As highlighted throughout this thesis, the use of such a composite ratio can be misleading as it may disguise marginal, even negligible, differences in outcomes or may be subject to significant uncertainty. In contrast, CCA presents a disaggregated outcome with costs and impacts reported separately and typically in 'natural units', such as the number of cases of heart disease. In doing so, it can provide a more granular view of the programme impacts and address the needs of stakeholders with different perspectives.

7.15 Methods

The decision-analytic model described previously was adopted for the cost utility analysis. A decision analytic model was preferred to a Markov model or more sophisticated simulation model on the basis that it addresses the decision problem – namely what impact access to an ERS programme would have on individuals – in the simplest methodological approach. Whilst a more sophisticated simulation model could have been adopted

prior experience suggests that in the absence of robust data these often require gross assumptions. Inputs to the model were derived from the systematic review reported earlier in the chapter. Evidence on the effectiveness of ERS programmes was derived from the systematic review and reported in the form of a relative risk of becoming active compared to individuals who did not participate in a referral programme. The reported relative risk was 1.16 although it should be noted the lower confidence interval was below 1, indicating that there is a possibility that ERS do not change the incidence of physical activity participation. Health outcomes considered were the same as the original modelling exercise, namely coronary heart disease, diabetes and stroke. Costs of ERS were derived from a published study (Isaacs et al 2007) as per the original model.

For the CCA, the outcomes were reported in natural units, such as cases of CHD. For the purposes of the CCA, other morbidities associated with physical activity were also included in the analysis. However, given that the magnitude of effect between physical activity and these conditions was poorly defined (which is why they were excluded from the original modelling exercise) it was only possible to give an indication of the direction of change that might be expected from increased participation in physical activity.

7.16 Outcomes

As previously reported, the estimated ICER of ERS programmes was £20,876, based on an incremental lifetime cost of £170 and an incremental benefit of 0.008 QALYs. Given the small increment to lifetime benefits (0.008 QALYs), the ICER is very sensitive to any changes in assumptions about the effectiveness of ERS and the cost per participant. In sensitivity analyses, the ICER ranged from dominant to cost ineffective (>£30,000 per QALY).

The CCA outcomes were reported in a tabular format for ease of use. Outcomes were presented for an illustrative cohort of 100,000 people who might be considered suitable for ERS. The cost of ERS provision for this cohort was estimated to be ~£22M to the prescriber and a further ~£12M to the participants, generating a societal cost of around £33M in total.

The impact on outcomes that can be quantified were reported first and indicated that offering ERS to this cohort of individuals would result in:

- An additional 3,900 individuals becoming physically active;
- 51 cases of CHD avoided;
- 16 cases of stroke avoided;
- 86 cases of diabetes avoided.

The CCA also indicates that there may be beneficial, if unquantified, health benefits in terms of the incidence of cancer, improvements in hypertension and improvements in a number of musculoskeletal conditions (osteoporosis, osteoarthritis, rheumatoid arthritis, low back pain and falls prevention). Whilst these

improvements were not quantified, there may be some lasting effects associated with them, such as a risk of reduction in falls which may reduce the need for long-term care and even reduce mortality. The CCA also highlighted some of the benefits in terms of mental health outcomes that were identified in the previous study. Finally, the CCA also indicated that ERS programmes should reduce absenteeism at work which may benefit both participants and their employers.

7.17 Strengths & Weaknesses

The CUA reported in this analysis is identical to the one reported earlier in the chapter and is subject to the same limitations, notably, a) limitations on the range of conditions affected by physical activity that were included in the model; b) the estimate of effect size for ERS being close to zero and c) the resulting instability in the ICER.

The CCA approach sought to address some of these points by a) considering a broader range of impacts of physical activity and b) reporting outcomes in a disaggregated fashion thereby overcoming the weaknesses of using a ratio with a small denominator. It should be acknowledged that the inclusion of more physical activity related outcomes meant that in many cases it was only possible to report a directional impact rather than an estimate of effect. However, this was intended to provide a more rounded picture for decision makers by illustrating how far-reaching the effects could be.

7.18 Critical appraisal

This final study of the ERS programme benefited from the extensive research already conducted on the effectiveness of ERS programmes and the cost utility analysis. The study sought to acknowledge some of the recognised weaknesses in the application of CUA to this intervention and address these through the application of an alternative methodology, namely CCA. In my view, the CCA provides a much more granular picture of the impact of ERS programmes and attempts to provide a more holistic view of the impact. Furthermore, the use of natural units seems more intrinsically appealing to decision makers from both health and non-health sectors by indicating where costs and benefits are accrued. Compared to the original CUA which suggested that ERS provide an incremental benefit in QALYs at three decimal places per participant over their lifetime, the CCA estimated that this would translate to over 150 fewer episodes of CHD, diabetes of stroke. Further benefits are expected to be accrued in the form of improvements in mental health and musculoskeletal disease, although these could not be quantified, as well as improvements in absenteeism. This dashboard of costs of outcomes is intrinsically easier to comprehend that the composite ratio of the ICER and provides much more colour on the findings. The one remaining challenge which is common to both the CUA and CCA approach is the issue of the time horizon and when events might occur. The majority of public body decision makers operate with shortterm, often annual, budgets, which need to be balanced. Whilst the

CCA provides a more granular view of the outputs it still falls short of being able to illustrate when any benefits may materialise and how these might impact short-term budgets.

This final study is one of the few examples of a comparison between alternative methods of economic evaluation. Whilst it was not possible to continue the research to explore decision makers attitudes to these different approaches, it seems intrinsically likely that the transparency and ease of interpretation of the CCA are likely to appeal to a broader range of decision makers than the narrowly defined CUA which relies on an indepth understanding of economic concepts and an ability to interpret ratios effectively.

7.19 Chapter Summary

The four studies relating to exercise referral schemes presented in this chapter are intended to provide an illustration of how the author's understanding of economic evaluation of public health interventions has developed over time and, in particular, how outputs can be presented in a granular fashion to improve their accessibility. The application of cost consequence analysis is considered to provide the most widely accessible format for evaluation, providing a granular view of the costs and benefits and indicating where these are accrued.

The next chapter will provide a summary of the author's learnings from these studies and some broad guidance for future evaluations of public health interventions.

Chapter 8: Summary, recommendations & conclusions

8.1 Thesis summary

To recap, the stated objectives of this thesis were as follows:

- Consider the challenges associated with the economic evaluation of public health interventions;
- Critically assess the application of economic evaluation methods to public health through a series of case studies based on the author's published outputs;
- Develop evidence-based recommendations for how future evaluations of public health interventions might build on the critique presented.

The raison-d'etre of economic evaluation in healthcare is to address the challenges of scarcity and choice. Health service resources (budgets, staff, facilities) are limited whilst demands for health services continue to grow, driven by demographic trends, changes in patterns of morbidity and increasing expectations about what constitutes a medical need. As a result of this, decision makers need to make choices on how healthcare resources are allocated and acknowledge the opportunity costs associated with any investment. The attractiveness of a 'common currency' that allows decision makers to compare interventions on equal terms is obvious and explains why cost utility analysis, reporting outcomes in the form of a cost per QALY, rapidly expanded over recent decades. As a theoretical framework, cost utility analysis allows decision makers to prioritise investments based on their return on investment, using societal health outcomes as the objective function. Unfortunately, in practice, this theoretical framework is a poor reflection of how the majority of healthcare investment decisions are made, particularly at a sub-national, provider level. The qualitative research presented in Chapter 3 illustrates that many of the concepts and outcomes of formal economic evaluations are alien to front-line healthcare decision makers that operate in a much more pragmatic fashion. A more recent qualitative study of the use of health economics in local authority decisions on public health investments (Frew 2020) suggests that many of the issues identified have not improved over time. Whilst there may be a greater familiarity with health economic concepts their applicability to real-world decision making remains limited. The majority of healthcare resources are essentially 'sunk' – for example, staff and infrastructure costs - with limited opportunities for wholesale re-allocation in the short-term. The rational cost utility framework assumes that innovative, cost effective interventions are funded through disinvestment in less effective services to release the necessary funds. To do so assumes, firstly, that the cost effectiveness of all current interventions is known allowing less effective interventions to be identified and secondly, that disinvestment in existing services is feasible. This is particularly relevant to public health interventions where

the evidence on clinical and cost effectiveness may be limited and where it may be politically challenging to remove a service/intervention even where there is uncertainy over the value-for-money.

As a result of these issues, many health service investments are made using more pragmatic approaches, often involving marginal re-allocations of resources to permit access to innovative health interventions. Whilst some degree of resource allocation is required to release resources, this is often achieved through a 'salami-slicing' approach, where resources may be taken from multiple services to support a new intervention, rather than wholesale removal of a less cost effective intervention. Whilst this approach falls short of the robust principles of cost utility analysis and extra-welfarism discussed in Chapter 2, it is still incumbent on decision makers to attempt to adopt an informed approach to resource allocation that considers the costs and benefits of an intervention prior to investment.

The applied economic evaluations considered herein are intended to illustrate how health economics can be presented in a way that is both informative but also pragmatic for decision makers. The evaluations consider a range of public health interventions, including targeted, individual level interventions to promote breastfeeding, weight management and physical activity, as well as population level interventions to the environment. These case studies address the first objective and highlight some of the challenges inherent in the economic evaluation of public health interventions which are summarised below.

1. A paucity of robust data on the effectiveness of public health interventions. The difficulties of conducting high-quality studies of the effectiveness of public health interventions, that illustrate attribution of the effect to the intervention, undermine the ability to conduct cost effectiveness analysis. As a result, many of the studies presented herein adopt gross assumptions to estimate cost effectiveness. Examples included in the evaluations herein include assumptions that improvements in physical activity levels are sustained over a lifetime based on limited follow-up information or weight loss is sustained beyond the duration of an intervention. Multiple scenarios are often used to address uncertainty. Whilst this may help to improve the transparency of the findings it does add significant complexity to interpreting the results, as is the case in the studies of breastfeeding and weight loss programmes presented herein.
2. The reliance on a composite outcome, such as the incremental cost per QALY, can be misleading. Guidelines for economic evaluation have promoted the use of cost utility analysis and the use of the incremental cost per QALY as the preferred endpoint. Several of the studies reported herein suggest that the point estimate of the cost per QALY is dominant or within acceptable levels and the intervention should therefore be considered cost effective. However, disaggregating this composite outcome illustrates that in some instances the lifetime benefit is small or even negligible. For example, the evaluation of exercise referral programmes generated a lifetime QALY gain of 0.008, which is approximately 3 days of incremental full health per year over an entire lifetime. Any small change in

the outcome will have a notable effect on the resulting cost effectiveness and may even change an intervention from being considered cost effective to cost ineffective. This begs the question of whether a model containing incremental differences between the control and intervention arm to three decimal places, coupled with significant assumptions about the duration of effect, should be considered to be spuriously accurate and a suitable basis for investment decisions.

3. Economic evaluations of public health interventions need to be accessible to multiple stakeholders with different perspectives. In some of the instances presented herein, health is the primary outcome, as in the case of interventions to promote weight management, and a cost utility framework that assumes a health maximisation objective may be appropriate. However, in other cases, such as the activity trails to promote physical activity, impacts may be more widespread and the decision to invest will typically involve multiple agencies, including health, social care, local authorities and even private sector businesses. Presenting the results in a tightly defined 'health' framework may be confusing for decision makers who are unfamiliar with the concept of the QALY and concerned that it does not take into account the full range of costs and benefits associated with an intervention.

The case studies compare and contrast alternative approaches to economic evaluation of public health programmes and some of the challenges associated with cost utility analysis are discussed at length. Cost benefit analysis is widely used in non-health sectors, including local planning and environmental management and is recognised in guidelines for economic evaluation of non-health investments (HM Treasury n.d.). There is something intrinsically appealing about a simple ratio that states for every £1 spent, £11 of benefits will accrue to society. However, this still faces the same issues that relate to cost utility analysis described above, namely that the ratio may hide small changes in costs and/or outcomes and may be susceptible to uncertainty. When presented as an aggregated cost benefit ratio it also fails to provide clarity on when, where and to whom costs and benefits accrue which may be problematic for public health interventions which have inter-sectoral approaches.

The cost consequence analyses presented herein are believed to provide a more granular view of both costs and consequences and, crucially, allow decision makers to explore where these might be accrued. Furthermore, CCA might also allow for a wider range of costs and benefits to be considered even where these cannot be quantified. In the case of exercise referral programmes, it was possible to provide an indication of which direction outcomes would be expected to move in for a range of conditions which could not be captured in the cost utility analysis.

Of course, CCA is not without it's limitations; whilst results can be presented in a granular and disaggregated way which is likely to be more accessible, it requires decision makers to interpret the relative importance of outcomes without a common denominator, such as the QALY. Using the case studies presented herein,

interventions to promote increased breastfeeding and environmental interventions to promote physical activity were both found to offer significant benefits which may outweigh the costs of these interventions. However, without reporting these in a common currency, decision makers need to make subjective decisions on their relative value to determine how resources can be allocated. Put bluntly, is a targeted reduction in childhood morbidity more beneficial than an increase in population level physical activity? Whilst this may make justification of decisions more challenging, it is actually quite representative of how decisions are made in daily practice, and reflects some of the comments on economic methods presented in the chapter 3 as well as more recently literature (Frew 2020) which highlight that robust, quantitative methods are infrequently used in frontline healthcare decisions.

Whilst health economists have developed increasingly sophisticated methods to evaluate healthcare interventions, there has been relatively little discussion of the contribution of qualitative methods which may be particularly pertinent to complex interventions, including public health interventions (Coast 2017). Several of the case studies reported herein highlight the challenges of quantifying the impact of public health interventions which could be informed by qualitative methods. Qualitative methods offer the potential to inform decisions on a number of levels, from societal preferences for the distribution of health effects, understanding trade-offs between health and other societal effects and providing further insights into how individuals perceive the benefits of health interventions. Indeed, there remain some significant macro-level considerations about the degree to which behaviour change and public health should be state initiated or the responsibility of the individual which could be informed by qualitative methods. Health economists are encouraged to consider not only their choice of quantitative method but also the potential role of qualitative methods in informing decisions.

8.2. The author's learning journey

Over the course of the case studies, the author has illustrated continuous learning and a desire to apply methods that adequately address the decision problem and provide clarity for decision makers. The author selected studies for inclusion in this thesis on the basis that they provide a coherent illustration of learning from experience and adapting subsequent methods to improve the quality and accessibility of the findings. The first study selected for inclusion, reported in Chapter 3, is included as a foundational study that provided insights into how health economics is perceived in practice and has influenced all subsequent studies conducted by the author. The need to make economic evaluations to be 'customer-centric' and reflect the needs of decision makers runs throughout the case studies presented and continues to be a central tenet to the author's research.

Early evaluations of the Counterweight programme (Chapter 4) and environmental interventions to promote physical activity (Chapter 5) sought to apply cost utility analysis, in line with prevailing methodological guidelines. However, it soon became apparent that there were limitations to this approach which lead to attempts to estimate short-term, more tangible impacts to illustrate the short-term return on investment. These narrower, short-term perspectives were considered to be in line with the typical time-horizons adopted in local authority decision making.

The further analyses of breastfeeding interventions and exercise referral illustrate further development of the methods applied, through the use of cost consequence analysis as a means of providing a more easily accessible format for the outputs. This was particularly important in the case of the evaluation of breastfeeding interventions, as the sponsor (UNICEF UK) had a clear objective to promote policy level debate and engage the wider public. The ability to report outputs in a disaggregated way, in easily understood natural units, was critical to achieving this objective.

The figure below provides an illustration of how the author has developed their methods over time.

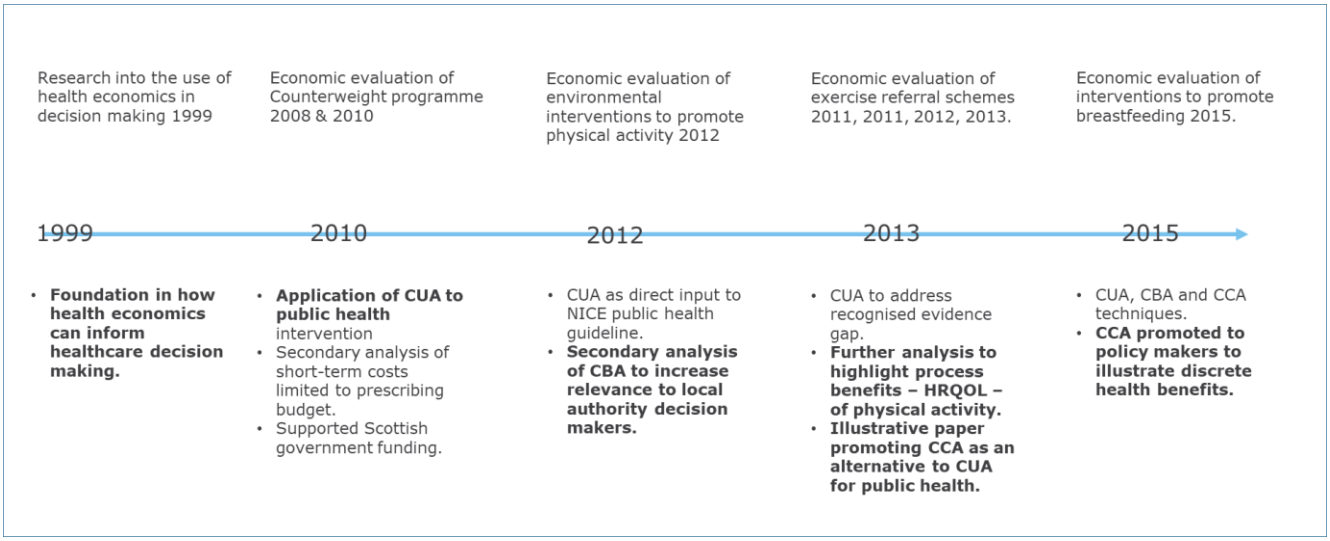

Figure 8.1: Methodolgical development over time illustrated by the studies presented in the thesis.

The following section is intended to address the third objective of the thesis by providing some recommendations for future economic evaluations of public health interventions.

8.3 Recommendations for future research

Reflecting on the initial research presented in chapter 3, it is important that the health economics community becomes more 'customer-focussed' if it wants to influence decision making rather than pursuing the academic

dogma of cost utility analysis which assumes that all investments are designed to maximise health gains. To do so, it is important that the needs of decision makers are reflected in both the methods and the presentation of results. There are a number of review articles and commentaries which have considered the shortcomings of cost utility analysis as a means of evaluating public health interventions (Tudor-Edwards et al 2013) (Weatherly et al 2009). These have largely been consensual about the nature of the challenges and have repeatedly suggested that alternative methods should be considered. However, there has been relatively little movement in guidelines for economic evaluation to reflect these concerns. The NICE guidelines comment on the use of alternative methods whilst the CDC guidance has gone further to emphasise the need for a logic framework and discuss the use of CBA techniques. Whilst cost benefit analysis allows for a holistic assessment and is widely used in other disciplines there are well documented challenges to valuing benefits in monetary terms in a consistent fashion (McIntosh et al 2019). Others have concluded that CCA should play a greater role in public health evaluations (Brousselle et al 2016)(Lung et al 2017) on the basis that it provides a more granular perspective and in doing so can meet the needs of multiple decision makers. It is important for health economists to remember the foundations of economic evaluation and the application to healthcare. Many of the earliest texts on this subject were grounded in cost benefit analysis techniques which were prevalent in non-healthcare sector decision making processes (Hutton 1992). Over time, the methods adopted in health economics seem to have become more insular, paying less attention to the broader fields of economic evaluation and their applicability to healthcare.

Based on the lessons learned from the studies presented herein, I would like to offer an alternative framework for economic evaluations of public health interventions which seeks to address methodological weaknesses and improve accessibility for decision makers. The principal tenet is that a disaggregated cost consequence analysis should be the primary, preferred method for evaluation on the basis that:

a. It is a more transparent means of presenting costs and outcomes in a disaggregated fashion than an incremental cost effectiveness ratio and, in doing so, allows decision makers to see the absolute changes in costs and outcomes and the degree to which these are meaningful;
b. It has the potential to consider health and non-health outcomes and does not start from a pre-defined view that health maximisation is the primary objective of the intervention;
c. It is accessible to a wider range of decision makers from multiple sectors and allows them to determine impacts relevant to them.

A cost consequence should be the preferred primary method. In the case of interventions where the primary outcome is a health benefit and there are relatively few non-health related outcomes, then a cost utility analysis could be presented as a secondary analysis. However, outcomes should first be presented in a disaggregated fashion in natural units. In cases where there are significant non-health benefits and/or the cost is expected to be covered by non-health sector decision makers then cost utility is not recommended as it

assumes the objective is QALY maximisation. In these instances, CBA may be considered as a secondary method to quantify the impacts where this is feasible. However, in many cases there may be some significant challenges to valuing all costs and benefits in monetary terms which may preclude a robust CBA.

The flowchart below attempts to provide guidance for economists tasked with evaluating public health interventions.

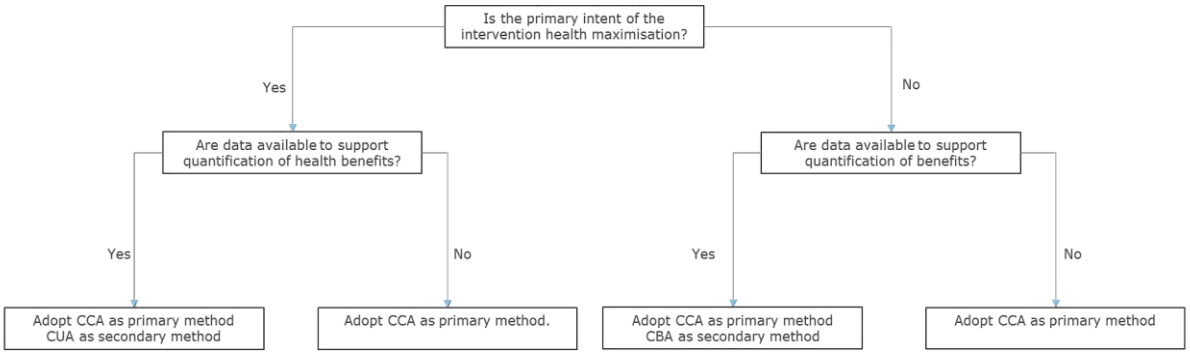

Figure 8.2: Flowchart to guide future economic evaluation for public health interventions

It is hoped that the discussion of methods in this thesis and the concluding recommendations provide some pragmatic guidance for future evaluations of public health and also contribute to the future research agenda on the appropriateness of economic methods and the accessibility of outcomes to decision makers.

8.4 Impact/originality of the thesis

The case studies presented herein represent a significant body of applied research of public health interventions. In the majority of cases, these studies were commissioned to inform the development of national guidelines (notably from NICE) or to inform policy decisions on the coverage and adoption of public health interventions (e.g. breastfeeding and exercise referral schemes). In some cases, the research had a direct impact on national guidelines, for example in the case of the evaluation of interventions to promote physical activity. In other cases, the research contributed to an advancement in knowledge around a particular issue with the intention of promoting further uptake, such as the evaluation of breastfeeding. One notable exception is the evaluation of exercise referral schemes which found the evidence to be equivocal and questioned the case for continued investment. This is unusual in the field of public health where the majority of the evidence reviewed is largely positive about the potential effectiveness and cost effectiveness. It would be interesting to conduct further research to explore publication bias in this field and whether a degree of paternalism (*prevention is better than cure*) leads to fewer studies with negative findings.

It is hoped that some of the evaluations presented above may have influenced both guidelines and other researchers. The methods guidance for public health guidelines issued by NICE does reference alternative methods for economic evaluation which may have been influenced by the research presented in chapter 4 as well as other studies conducted by the author that were commissioned to support NICE guidelines on smoking cessation and physical activity in children (not included in this thesis). Furthermore, some of the studies have been extensively referenced by other researchers, notably the research on breastfeeding (~75 citations) and exercise referral schemes (>100 citations)[1].

The critique of economic evaluation methods applied to public health interventions concurs with the findings of previous reviews which have noted the shortcomings of cost utility analysis and cost benefit analysis and promoted more pragmatic solutions, such as cost consequence analysis. However, the original element of the thesis is the use of applied examples to illustrate how these shortcomings manifest themselves in practice. The inability to accurately estimate causality and attribution to public health interventions was evidence in the population level evaluations. Similarly, several of the case studies illustrate that reliance on a composite outcome, such as the QALY, may fail to fully capture the benefits of an intervention and simultaneously narrow the applicability of the findings to select stakeholders. The attempts to apply cost consequence analysis are intended to show that this approach can result in a holistic and transparent reporting of the costs and outcomes of public health interventions and in doing so significantly increase the relevance to a wider range of stakeholders.

As with any research endeavour it is important to acknowledge some of the weaknesses of this thesis. The thesis is based on a series of applied research projects commissioned by multiple organisations across multiple interventions. Whilst there are thematic trends across the studies, it was not been possible to fully explore all the methodological issues in each applied case study due to limits on the research funding and the requirement to complete research to a schedule, for example, to input to guideline publication. Furthermore, the research spans over a decade of publications. This was necessary due to the long-term nature of some of the studies and the time-lags for publication. I should also want to acknowledge that the publications include multiple co-contributors. Whilst the author was the lead or co-lead investigator in all these research programmes it is important to acknowledge that the majority of the studies were undertaken by a research team with authorship reflecting this. In some instances, lead authorship was granted to junior researchers to support their academic development.

Finally, it was beyond the scope of this research to conduct a comprehensive, systematic review of the economic evaluations of public health interventions which would have provided a more holistic view of the prevailing methods of economic evaluation. An additional area for further research would be qualitative

[1] Citations derived from Researchgate August 2020

studies of the use of economic evaluation by decision makers. The flurry of papers produced on this topic in the mid-1990s (including the paper referenced in Chapter 3) has waned over time and there is an urgent need for the health economics community to reflect on how its methods and outputs are being used if it is to remain relevant. Further research relating specifically to public health decision making would be of particular interest given the complexity of the decision-making processes and the multiplicity of stakeholders involved.

Despite these shortcomings, it is hoped that the thesis provides original insights into the challenges of economic evaluation of public health through applied examples and provides guidance on methods that may help to improve the impact and accessibility of future economic evaluations.

8.5 Conclusions

The evaluation of public health interventions is inherently more complex than the evaluation of other healthcare interventions such as medical technologies or pharmaceuticals. The challenges inherent in generating high quality data to illustrate the attributable effect of public health interventions are very real and the multi-sectoral nature of many such interventions creates further complexity in the reporting of costs and outcomes. For these reasons, it is suggested that the most widely used methods of economic evaluation in healthcare, particularly cost utility analysis, are inappropriate. Cost consequence analysis provides a more granular approach to reporting costs and outcomes, allowing multiple decision makers to identify where costs and benefits are accrued. Where appropriate, these outcomes can be further extrapolated into a cost utility ratio or cost benefit ratio, but outcomes should always be reported in a disaggregated fashion prior to being aggregated into a composite measure. Health economists working in the field of public health are encouraged to prioritise generating evidence that meets the needs of decision makers, rather than adhering dogmatically to methodological best practice guidelines.

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Appendix 1: Authors contribution to publications.

Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

This form is to accompany an application for registration for PhD where the PhD is by Published Work. A separate form should be completed for each publication that is submitted with the proposal and should accompany the RD1 form.

1. The Candidate

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2. Title of PhD Proposal

IS ECONOMIC EVALUATION IN HEALTHCARE FIT-FOR-PURPOSE? THE POTENTIAL APPLICATION OF COST CONSEQUENCE ANALYSIS TO PUBLIC HEALTH INTERVENTIONS TO INCREASE ACCESSIBILITY OF HEALTH ECONOMIC EVIDENCE TO DECISION MAKERS.

3. Title of Research Output

Duthie T, Trueman P, Chancellor J, Diez L. Research into the use of health economics in decision making in the United Kingdom--Phase II. Is health economics 'for good or evil'? Health Policy. 1999 Jan;46(2):143-57.

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Duthie T (30%), Trueman P (30%), Chancellor J (10%), Diez L (30%). Study design, interpretation and manuscript preparation.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

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Jeremy Chancellor		

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: Date:

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7. Signature of Faculty Research Degrees Administrator

Signature: Date:

(Faculty Research Degrees Administrator)

Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

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PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

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3. Title of Research Output

Trueman P & The Counterweight Project Team. Long-term cost-effectiveness of weight management in primary care. Int J Clin Pract. 2010 May;64(6):775-83.

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Trueman P (50%): designed the cost-effectiveness model, interpreted the outputs, manuscript preparation. Counterweight Project Team (50% combined): defining model parameters, interpreting outputs, manuscript preparation.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

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6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

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7. Signature of Faculty Research Degrees Administrator

Signature: (Faculty Research Degrees Administrator) Date:

Research and Knowledge Exchange

Graduate School

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3. Title of Research Output

The Counterweight Project Team & Trueman P, O'Reilley J. Influence of body mass index on prescribing costs and potential cost savings of a weight management programme in primary care. J Health Serv Res Policy. 2008 Jul;13 (3):158-66.

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Trueman P (20%): study design and interpretation; O'Reilley J (40%) study design, statistics, interpretation, Counterweight Project Team (40% combined): study design, interpretation & manuscript preparation.

5. Co author(s):

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6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: _____ Date: 15/07/19

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: _____ Date: _____

(Faculty Research Degrees Administrator)

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Graduate School

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First Name(s):	Paul	Preferred Title:	Mr
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2. Title of PhD Proposal

IS ECONOMIC EVALUATION IN HEALTHCARE FIT-FOR-PURPOSE? THE POTENTIAL APPLICATION OF COST CONSEQUENCE ANALYSIS TO PUBLIC HEALTH INTERVENTIONS TO INCREASE ACCESSIBILITY OF HEALTH ECONOMIC EVIDENCE TO DECISION MAKERS.

3. Title of Research Output

Beale S, Bending M, Trueman P, Naidoo B. Should we invest in environmental interventions to encourage physical activity in England? An economic appraisal. European Journal of Public Health, Volume 22, Issue 6, 1 December 2012, Pages 869–873.

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Trueman P (20%): study design, interpretation & manuscript development; Beale S (30%): study design, statistics, interpretation & manuscript development, Bending M (30%): study design, statistics, interpretation & manuscript development; Naidoo B (20%): study design, interpretation & manuscript

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

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Dr Matthew Bending		matthew.bending@gmail.com
Sophie Beale	Sophie Beale	s.beale@liverpool.ac.uk
Dr Bhash Naidoo		bhash.naidoo@nice.org.uk

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: _____ Date: 15/07/19

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: _____ Date: _____

(Faculty Research Degrees Administrator)

Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

This form is to accompany an application for registration for PhD where the PhD is by Published Work. A separate form should be completed for <u>each</u> publication that is submitted with the proposal and should accompany the RD1 form.

1. The Candidate

First Name(s):	Paul	Preferred Title:	Mr
Surname:	Trueman		
MMU e-mail address:	paul.trueman@stu.mmu.ac.uk	Contact Number:	07912 064550
Personal e-mail address:	paul.trueman@smith-nephew.com	Student ID Number:	19043008

2. Title of PhD Proposal

IS ECONOMIC EVALUATION IN HEALTHCARE FIT-FOR-PURPOSE? THE POTENTIAL APPLICATION OF COST CONSEQUENCE ANALYSIS TO PUBLIC HEALTH INTERVENTIONS TO INCREASE ACCESSIBILITY OF HEALTH ECONOMIC EVIDENCE TO DECISION MAKERS.

3. Title of Research Output

The application of partial cost-benefit analysis to interventions to promote breastfeeding. Potential economic impacts from improving breastfeeding rates in the UK. Pokhrel S, Quigley MA, Fox-Rushby J, McCormick F, Williams A, Trueman P, Dodds R, Renfrew MJ.Arch Dis Child. 2015 Apr;100(4):334-40.

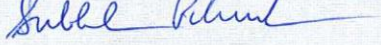
4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Trueman P (15%): study design, interpretation; Pokhrel S (40%): statistics, interpretation & manuscript; Fox-Rushby J (15%): study design, interpretation; Renfrew MJ (15%): study design, interpretation & manuscript; Quigley MA (5%) Dodds R (5%) Williams A (5%): interpretation & manuscript.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

Name	Signature	Current e-mail address
Dr Subhash Pokhrel		subhash.pokhrel@brunel.ac.uk
Prof. Julia Fox-Rushby		julia.fox-rushby@kcl.ac.uk
Prof. Mary Renfrew		

6. Statement by Director of Studies/Advisor

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Personal e-mail address:	paul.trueman@smith-nephew.com	Student ID Number:	19043008

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3. Title of Research Output

Pavey TG, Taylor AH, Fox KR, Hillsdon M, Anokye N, Campbell JL, Foster C, Green C, Moxham T, Mutrie N, Searle J, Trueman P, Taylor RS. Effect of exercise referral schemes in primary care on physical activity and improving health outcomes: systematic review and meta-analysis. BMJ. 2011 Nov 4;343.

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Pavey TG (30%) Taylor RS (15%): searches, review, data extraction & manuscript preparation; Taylor AH, Fox KR, Hillsdon M, Anokye N, Campbell JL, Foster C, Green C, Moxham T, Mutrie N, Searle J, Trueman P (5%): interpretation & manuscript review.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

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Prof Rod Taylor		R.Taylor@exeter.ac.uk
Dr Nana Anokye		nana.anokye@brunel.ac.uk

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: (Director of Studies/Advisor) Date: 15/07/19

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Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

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1. The Candidate

First Name(s):	Paul	Preferred Title:	Mr
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Personal e-mail address:	paul.trueman@smith-nephew.com	Student ID Number:	19043008

2. Title of PhD Proposal

IS ECONOMIC EVALUATION IN HEALTHCARE FIT-FOR-PURPOSE? THE POTENTIAL APPLICATION OF COST CONSEQUENCE ANALYSIS TO PUBLIC HEALTH INTERVENTIONS TO INCREASE ACCESSIBILITY OF HEALTH ECONOMIC EVIDENCE TO DECISION MAKERS.

3. Title of Research Output

Anokye NA, Trueman P, Green C, Pavey T, Hillsdon M, Taylor RS. The cost effectiveness of exercise referral schemes. BMC Public Health2011; 11:954

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Anokye NA (30%), Trueman P (20%), Green C (15%), Taylor RS(15%): study design, interpretation & manuscript preparation. Hillsdon M (10%), Pavey T (10%): input parameters and interpretation.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

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6. Statement by Director of Studies/Advisor

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Signature: Date: 15/07/19

(Director of Studies/Advisor)

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(Faculty Research Degrees Administrator)

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Manchester Metropolitan University

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1. The Candidate

First Name(s):	Paul	Preferred Title:	Mr
Surname:	Trueman		
MMU e-mail address:	paul.trueman@stu.mmu.ac.uk	Contact Number:	07912 064550
Personal e-mail address:	paul.trueman@smith-nephew.com	Student ID Number:	19043008

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3. Title of Research Output

Anokye NA, Trueman P, Green C, Pavey T, Taylor RS. Physical Activity and health related quality of life. BMC Public Health 2012; 12:624

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Anokye NA (40%), Trueman P (25%), Green C (15%), Taylor RS(15%), Pavey T (5%): study design, interpretation & manuscript preparation.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

Name	Signature	Current e-mail address
Dr Toby Pavey		toby.pavey@qut.edu.au
Prof Rod Taylor	Rod Taylor Digitally signed by Rod Taylor Date: 2019.07.07 23:43:54 +01'00'	R.Taylor@exeter.ac.uk
Dr Nana Anokye		nana.anokye@brunel.ac.uk

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Signature: [signature] Date: 15/07/19

(Director of Studies/Advisor)

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(Faculty Research Degrees Administrator)

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Personal e-mail address:	paul.trueman@smith-nephew.com	Student ID Number:	19043008

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3. Title of Research Output

Trueman P & Anokye NA. Applying economic evaluation to public health interventions: the case of interventions to promote physical activity. J Public Health. 2013 Mar;35(1):32-9

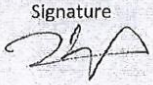
4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Trueman P (50%), Anokye NA (50%).

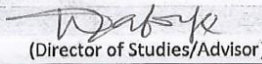
5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

Name	Signature	Current e-mail address
Dr Nana Anokye		nana.anokye@brunel.ac.uk

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature:  Date: 15/07/19

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: Date:

(Faculty Research Degrees Administrator)