

Allocating healthcare resources on the basis of
personal responsibility for ill-health:
what role (if any) should public opinion play?
A socio-ethical analysis

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ABSTRACT

The suggestion that individual responsibility for ill-health, and consequent healthcare need, should be a factor in healthcare priority-setting is increasingly debated. The adoption of such a principle within UK healthcare distribution policy would be both socially and ethically contentious.

This study examines the concept of a 'responsibility principle' within healthcare priority-setting and explores the contribution of the views, values and preferences of the public to the ongoing discussions. The ethical justification for seeking public participation in this type of debate is explored.

Within this thesis, a range of issues are critically evaluated, including healthcare distribution via the 'QALY' approach, the incorporation of distributional weighting of health benefits and the influence of social values on healthcare provision. It is concluded that an enhanced public contribution could be attained by systematically investigating how members of the public reason and construct ethical arguments regarding 'responsibility' as a priority-setting principle and that such an investigation would demand a clear, empirically-based and ethically-sound methodological approach. The means by which this may be accomplished is investigated, and a conceptual and practical basis for eliciting and examining the ethical reasoning and arguments of members of the public is presented in a detailed proposal that represents an innovative approach to research in this area.

A range of socio-ethical issues inform this study, including social value judgements, placing limits on what may be perceived to be socially justified entitlements, and questions of the citizen's role in contributing to ethically important social policy. The study employs a conceptual approach to these issues and identifies, evaluates and applies ethical arguments to the relevant topics.

This study contributes to both methodological and empirical knowledge regarding public participation in healthcare debates and assists the interpretation of existing evidence of the public's views in this area.

CONTENTS

ABSTRACT	2
CONTENTS	3
FIGURES AND TABLE	9
1 INTRODUCTION	10
1.1 BACKGROUND	10
1.1.1 ORIGINS OF THE STUDY	10
1.1.2 OUTLINE OF THE STUDY	11
1.1.3 RATIONALE	12
1.2 CONTEXT	13
1.2.1 CHALLENGES FACED BY HEALTHCARE PLANNERS	13
1.2.2 HEALTHCARE DISTRIBUTION AND THE QALY APPROACH	14
1.2.3 QALY-WEIGHTING	14
1.2.4 RESPONSIBILITY FOR HEALTHCARE NEED	15
1.2.5 PUBLIC PARTICIPATION	15
1.3 RESEARCH QUESTION	16
1.4 AIMS	16
1.5 OBJECTIVES	17
1.6 METHODOLOGY	17
1.7 THESIS STRUCTURE	18
1.7.1 SECTION A: HEALTHCARE PRIORITY-SETTING	18
1.7.2 SECTION B: PUBLIC INVOLVEMENT	19
1.7.3 SECTION C: EXAMINING REASONING AND ARGUMENTS	20

SECTION A: HEALTHCARE PRIORITY-SETTING

2 DISTRIBUTING HEALTHCARE: THE QALY APPROACH	22
2.1 INTRODUCTION	22
2.2 HEALTHCARE DISTRIBUTION	22

2.3	THE QUALITY-ADJUSTED LIFE YEAR	23
2.3.1	BACKGROUND TO THE QALY	25
2.3.2	THE QALY METHOD	26
2.3.3	GENERATING UTILITY VALUES	28
2.4	EVALUATION OF THE QALY APPROACH	30
2.4.1	EFFICACY	30
2.4.2	EQUITY AND JUSTICE	31
2.4.3	A UTILITARIAN APPROACH	34
2.4.4	QALYS AND AUTONOMY	35
2.4.4.1	RELATIONAL AUTONOMY	35
2.5	THE QALY: A NEED FOR ADJUSTMENT	37
3	WEIGHTING HEALTH BENEFITS	39
3.1	INTRODUCTION	39
3.2	WEIGHTING HEALTH BENEFITS: 'QALY-WEIGHTING'	39
3.2.1	WEIGHTING CRITERIA	40
3.2.2	HOW QALY-WEIGHTING COULD BE ACCOMPLISHED	41
3.2.3	DETERMINING WEIGHTING VALUES	41
3.2.4	PUBLIC SUPPORT FOR QALY-WEIGHTING	42
3.2.5	NICE AND QALY-WEIGHTING	44
3.2.6	POTENTIAL CHALLENGES	45
3.2.7	ETHICAL JUSTIFICATION	46
3.2.7.1	EQUITY	47
3.2.7.2	RIGHTS	48
3.2.7.3	AUTONOMY	48
4	RESPONSIBILITY FOR HEALTHCARE NEED AS A RESOURCE-LIMITING PRINCIPLE	50
4.1	INTRODUCTION	50
4.2	PRIORITY-SETTING AND RATIONING	50
4.2.1	PRIORITY-SETTING	50
4.2.2	RATIONING	51

4.3	RESPONSIBILITY AS A RESOURCE-LIMITING PRINCIPLE	53
4.4	PUBLIC SUPPORT	54
4.5	ADVANTAGES/JUSTIFICATIONS	55
4.6	POTENTIAL CHALLENGES	57
4.7	THE ARGUMENTS	58
4.8	RESPONSIBILITY	59
4.9	RIGHTS	60
4.9.1	A RIGHT TO HEALTHCARE?	60
4.10	AUTONOMY	62

SECTION B: PUBLIC INVOLVEMENT

5	SOCIAL VALUES	66
5.1	INTRODUCTION	66
5.2	SOCIAL VALUES	66
5.3	ELICITING PREFERENCES FOR QALY UTILITY VALUES	68
5.4	HOW NICE HAS ADDRESSED SOCIAL VALUES	70
5.4.1	NICE	70
5.4.2	NICE 'SOCIAL VALUE JUDGEMENTS'	72
5.4.2.1	'SOCIAL VALUE JUDGEMENTS': QALY-WEIGHTING	72
5.4.2.2	'SOCIAL VALUE JUDGEMENTS': AN 'ETHICAL FRAMEWORK'	73
6	PUBLIC PARTICIPATION	77
6.1	INTRODUCTION	77
6.2	PUBLIC PARTICIPATION	77
6.2.1	HOW PUBLIC PARTICIPATION IS ACHIEVED	78
6.2.2	ARGUMENTS FOR PUBLIC PARTICIPATION	79
6.2.3	ARGUMENTS AGAINST PUBLIC PARTICIPATION	80
6.2.4	PUBLIC PARTICIPATION – SUMMARY	83
6.3	LITERATURE OVERVIEW	83
6.3.1	DELIBERATIVE APPROACHES	85

6.4	NICE CITIZENS COUNCIL	86
6.5	ENHANCING PUBLIC PARTICIPATION	88
7	ETHICAL REASONING AND ARGUMENTS	90
7.1	INTRODUCTION	90
7.2	ETHICAL REASONING AND ARGUMENTS	90
7.3	RATIONALE FOR EXAMINING REASONING AND ARGUMENTS	93
7.4	A LACK OF AVAILABLE EVIDENCE	95
7.5	EXAMINING ETHICAL ARGUMENTS: A COMPARISON	96
8	EXAMINING ETHICAL REASONING AND ARGUMENTS: A LITERATURE REVIEW	99
8.1	INTRODUCTION	99
8.2	SEARCH METHODS	99
8.2.1	SOURCES	99
8.2.2	SEARCH TERMS	99
8.2.3	INCLUSION CRITERIA AND ARTICLE SCREENING	100
8.3	FINDINGS	107
8.3.1	METHODS OF DATA COLLECTION	107
8.3.1.1	FOCUS GROUPS	107
8.3.1.2	INTERVIEWS	107
8.3.1.4	MIXED QUALITATIVE METHODS	108
8.3.1.5	DELIBERATIVE METHODS	108
8.3.2	EXAMINATION OF REASONING AND ARGUMENTS	108
8.4	DISCUSSION	110
 <u>SECTION C: EXAMINING REASONING AND ARGUMENTS</u>		
9	EMPIRICAL ETHICS: A METHODOLOGICAL APPROACH	114
9.1	INTRODUCTION	114
9.2	APPROACHES TO ETHICAL INQUIRY	114
9.2.1	EXAMPLES OF ETHICAL CONCEPTS	114

9.2.2	NORMATIVE ETHICS	115
9.2.3	DESCRIPTIVE ETHICS	116
9.2.4	NORMATIVE OR DESCRIPTIVE?	116
9.2.5	MORAL RELATIVISM	117
9.3	ETHICS AND HEALTHCARE	117
9.3.1	MEDICAL ETHICS AND BIOETHICS	118
9.4	EMPIRICAL ETHICS	119
9.4.1	COMPARISON WITH TRADITIONAL APPROACHES	121
9.4.2	EXAMPLES OF EMPIRICAL ETHICS STUDIES	124
9.4.3	A PROCEDURAL ATTITUDE	125
10	EXAMINING ETHICAL ARGUMENTS: A RESEARCH PROPOSAL	127
10.1	INTRODUCTION	127
10.2	PURPOSE OF THE PROPOSED STUDY	127
10.3	RATIONALE	129
10.4	RESEARCH QUESTION(S)	130
10.5	RESEARCH AIMS AND OBJECTIVES	131
10.5.1	AIMS	131
10.5.2	OBJECTIVES	131
10.6	RESEARCH DESIGN AND METHODOLOGY	132
10.6.1	A QUALITATIVE APPROACH	132
10.6.2	GROUNDING THEORY	133
10.6.3	COMBINING QUALITATIVE METHODS	133
10.6.4	DATA COLLECTION	135
10.6.4.1	PHASE ONE (PILOT STUDY)	135
10.6.4.2	PHASE TWO	135
10.6.4.3	INTERVIEWS – PROCESS	136
10.6.4.4	FOCUS GROUPS – PROCESS	138
10.6.5	RECRUITMENT	139
10.6.6	DATA ANALYSIS	140

10.6.6.1	CODING	140
10.6.6.2	ETHICAL ANALYSIS	142
10.7	ENSURING DATA TRUSTWORTHINESS	144
10.8	ETHICAL CONSIDERATIONS	145
10.8.1	CONSENT	145
10.8.2	CONFIDENTIALITY	146
10.9	POTENTIAL BENEFITS	146
10.10	DISSEMINATION STRATEGY	147
11	CONCLUSIONS	148

REFERENCES & BIBLIOGRAPHY

REFERENCES	152
BIBLIOGRAPHY	174
APPENDICES	
APPENDIX ONE: ARTICLES EXCLUDED FROM LITERATURE REVIEW	179
APPENDIX TWO: EXAMPLES OF INTERVIEW GUIDE QUESTIONS	182
EXAMPLE OF INTERVIEW SCENARIO	183

FIGURES

FIGURE 2.1	THE BASIC QALY CALCULATION	27
FIGURE 2.2	INCREMENTAL COST-EFFECTIVENESS RATIO (ICER)	28
FIGURE 10.1	THE PROCESS OF DATA ANALYSIS	141
FIGURE 10.2	HYPOTHETICAL EXAMPLE OF A CODING PARADIGM	142

TABLE

TABLE 8.1	ARTICLES INCLUDED IN LITERATURE REVIEW	101
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1 INTRODUCTION

This chapter introduces the study and provides an overview of its background, aims, objectives and methodology. The thesis contents are described in an outline of the individual chapters.

1.1 BACKGROUND

1.1.1 ORIGINS OF THE STUDY

This thesis arose from two distinct but closely related aspects of my academic and clinical experience and interests. As a registered nurse, I have spent many years working within a healthcare environment in both clinical practice and professional development roles. As an academic, I have focused on the ethical aspects of healthcare practice. In various roles, I have encountered issues that have raised questions about how healthcare resources are allocated and how priorities are established.

At a time of intensifying financial constraints, a prominent source of debate in both healthcare and academic settings, is the need to establish clear, comprehensible and effective principles that would enable the justifiable – and socially acceptable – identification of healthcare priorities.

In recent years, the suggestion that individual responsibility for healthcare need could be considered as a factor in healthcare priority-setting, or as a healthcare resource-limiting principle has been increasingly discussed.

It is evident that the formal integration of such a principle within UK healthcare distribution policy would be highly contentious and it is therefore unlikely to be considered without clear evidence and confirmation of societal support. However, the notion of 'public participation'¹ – increasingly advocated as a means of involving the public in such important social policy – demands a clear, empirically-based and

¹ For the purposes of this thesis, 'public' is defined as: "*of, relating to, or affecting all or most of the people of a country, state, etc.*" (merriam-webster.com). The concept of a 'member of the public' is less easily defined as it potentially encompasses all citizens. However, in broad terms, for the purposes of this investigation, a member of the public is defined as 'a citizen who has no direct professional involvement with healthcare distribution activities' (see Chapter 10)

ethically sound basis upon which the public's views may be determined.

As I am uncertain whether existing approaches to evaluating 'public opinion'² regarding healthcare distribution offer a sufficiently firm basis for determining societal views on such a potentially controversial strategy, I decided to investigate, from a socio-ethical perspective, the concept of responsibility for healthcare need and its potential incorporation within UK healthcare (NHS) priority-setting. I also wished to explore both the role of public participation in the ongoing debate, and the extent to which existing strategies for examining 'what the people think' about this issue are able to determine empirically-based and ethically defensible social objectives.

1.1.2 OUTLINE OF THE STUDY

This socio-ethical study examines the suggestion that responsibility for ill-health and consequent healthcare need should be a factor in healthcare priority-setting. Central to this examination is the belief that, if such a proposal were deemed feasible – in both practical and ethical terms – its implementation would demand a clear, evidence-based understanding of what members of the public think about it, and effective public participation would be needed to inform the debate. This study therefore explores the role that public participation plays in informing healthcare distribution policy and examines the influence of social values on how healthcare distribution is realised and priorities identified.

The ethical justification for seeking the public's opinion is examined and it is contended that public participation would be enhanced by adopting a more critical and comprehensive approach to eliciting and examining the public's views, values and preferences concerning responsibility for healthcare need as a priority-setting (or resource-limiting) principle. Furthermore, it is argued that this could be achieved by examining how members of the public reason and construct arguments regarding this issue. This would demand a means of effectively and systematically eliciting and analysing members of the public's arguments i.e. their validity and underlying reasoning and premises, in relation to healthcare distribution, priority-setting and the incorporation of a 'responsibility principle'. In view of the acknowledged need for public participation to be based on ethically-defensible social objectives this

² The term 'public opinion' is applied within this study to describe a range of terms, such as 'views', 'values' and 'preferences' that refer to the perspective of members of the public

examination would need to specifically address the processes of *ethical* reasoning and arguments.

A review of the relevant literature indicates that this type of investigation has not been undertaken in relation to members of the public's views on healthcare distribution and priority-setting, and this study explores a means by which this may be achieved. The concept of empirical ethics is examined in terms of its suitability to guide the elicitation and examination of the public's reasoning and arguments. A practical means by which this may be accomplished is then detailed in a comprehensive research proposal that demonstrates an empirical ethics methodological approach.

As the leading organisation in matters relating to this study, the National Institute for Health and Care Excellence (NICE) provides insights into many of the study's key features. The critical examination of how NICE has addressed issues of relevance to this study is therefore a key component of this thesis.

1.1.3 RATIONALE

This study is founded on a belief that important aspects of social policy that have significant ethical consequences should be subject to vigorous ethical debate and critical ethical inquiry. This, it is contended, would provide a more substantial empirical basis for ethical and policy debates.

The rationale for this study therefore has four distinct elements:

- Evidence of increasing societal interest in a more explicitly defined and ethically-justified approach to healthcare priority-setting
- The need to examine the concept of responsibility for healthcare need as a priority-setting principle
- A concern that public participation in healthcare priority-setting is insufficient due to limitations in the existing evidence-base
- A need to identify a means by which public opinion can be more effectively examined

1.2 CONTEXT

1.2.1 CHALLENGES FACED BY HEALTHCARE PLANNERS

For a publicly-funded healthcare system, such as the UK National Health Service (NHS), within which budgets are by necessity predetermined, the distribution of resources is a primary concern and a complex and challenging policy issue (Tsuchiya *et al*, 2003; Persad *et al*, 2009; Winkler *et al*, 2012). Demand for NHS services far exceeds the level of provision that can realistically be provided (Newdick, 2005) and the distribution of NHS services must therefore be achieved in a manner that is comprehensible, economically viable, socially acceptable and, given the moral significance of healthcare, ethically defensible (Daniels and Sabin, 2008; Mason *et al*, 2011).

All (publicly-funded) healthcare systems must confront the challenge of providing a reasonable quality of healthcare to the maximum number of people via a finite healthcare budget (Winkler *et al*, 2012). Increasing demand for (and expectations of) healthcare, combined with the competing claims of discrete clinical services, patient groups and even individual patients, is intensified by the cost of expensive 'high tech' medicine, longer life expectancies and the growing rates of chronic illness (Marmot and Wilkinson, 2009; Martin *et al*, 2010).

In the context of the present UK economic climate and anticipated levels of public spending (Appleby, 2008), 'hard choices' are demanded – within healthcare as elsewhere – and, in the absence of unlimited public funding, access to effective healthcare may need to be restricted or even denied (Martin *et al*, 2002; Ham and Robert, 2003; Newdick, 2005; Green and Gerard, 2009). Priority-setting is therefore an increasingly common, possibly essential, feature of healthcare distribution (Benatar, 2003; Singer, 2009; Robinson *et al*, 2011). Furthermore, in addition to estimations of economic efficiency and technical/scientific efficacy, priority-setting decisions must also take into account the increasingly significant role that social values play within healthcare distribution

1.2.2 HEALTHCARE DISTRIBUTION AND THE QALY APPROACH

Those responsible for determining healthcare distribution policy must take into consideration the level of healthcare demand and balance this against available resources. Such resources may include tangible assets such as staff, facilities and equipment or, as is increasingly the case, the rather less discernible 'health benefits' – calculated via economic evaluation – that indicate the overall health gains achieved from a healthcare budget (Brazier *et al*, 2007). In order to contextualise this study and to enable arguments to be examined in light of a genuine, empirically-based and effectual healthcare distributional paradigm. The issues are examined with particular reference to the distribution of health benefits via the quality-adjusted life year (QALY) approach (Weinstein *et al*, 2009).

The QALY is a standardised measure of health outcome that was specifically developed to enable clear, impartial healthcare distribution and priority-setting decision-making. The aim of the standard QALY model is to maximise the number of QALYs gained in order to derive the most benefit from a healthcare budget and, for over 30 years, QALYs have enabled cost-effective priority-setting (Wailoo *et al*, 2009).

However, a criticism of the impartial QALY approach is that, as equal 'weight' is attached to all QALYs, it is insensitive to variances in people's healthcare needs or the specific circumstances of individual patients i.e. it is "...*blind to health conditions and personal characteristics*" (Whitehead and Ali, 2010: 14). There is also growing concern that such an objective approach does not fully reflect the views of the public regarding how healthcare should be distributed and that it conflicts with many people's interpretations of a reasonable approach to this process (Anand and Wailoo, 2000).

1.2.3 QALY-WEIGHTING

There is evidence of increasing public support for incorporating a degree of distributional bias into healthcare resource allocation and for enhancing equity within the QALY approach by adjusting, or 'weighting', QALYs in accordance with the individual characteristics or attributes of their recipients (Olsen, 2000; Wilmot and Ratcliffe, 2002; Wailoo *et al*, 2009; Lancsar *et al*, 2011).

Therefore, a range of criteria – such as the age of the patient or the initial severity of their illness – that could be used to justify adding or subtracting 'weight' to or from the QALY, to enable a more subjective approach to its distribution, have been proposed (Brazier *et al*, 2007). However, as attaching additional weight to the health gains of some patients carries the logical implication that lower weight should be given to the health gains of some others (Shah *et al*, 2011), QALY-weighting remains a potentially contentious and debatable strategy (Bobinac *et al*, 2012; Van de Wetering *et al*, 2013).

1.2.4 RESPONSIBILITY FOR HEALTHCARE NEED

One possible 'weighting criterion' provides a focus for this study. This is the suggestion that the health gains of those considered to be in some way responsible for their ill-health – and consequent healthcare need – should be weighted lower than those of other, 'non-culpable', individuals. In other words, lower priority should be given to those whose illness is in some sense 'self-inflicted' (Sharkey and Gillam, 2010; Walker, 2010); the estimated degree of personal responsibility being balanced against an individual's access to healthcare treatment for that particular illness. For the purposes of this study, this potential weighting criterion will be referred to as the/a 'responsibility principle'.

1.2.5 PUBLIC PARTICIPATION

It is recognised that, in a publicly-funded healthcare system, distribution policy should reflect public views and values (Menzel, 1999; Richardson and McKie, 2005), and that there should be greater public consultation in healthcare priority-setting (McKie *et al*, 2009; Mitton *et al*, 2009). It is therefore essential to obtain a clear and informed view of what the public think about how healthcare resources are allocated, and how priorities are established.

Although there is evidence of public support for distributional weighting of health benefits the evidence of public views on this and other approaches to priority-setting is only partial. Whilst a range of qualitative studies have investigated the public's views and preferences regarding how healthcare resources are distributed, the majority of studies of 'public opinion' on this issue employ a quantitative approach, the findings of which consist primarily of unsupported responses. However, many of these studies demand measurable outcomes or seek to expose statistical

differences, and therefore a quantitative approach to the issues is both sensible and effective. However, an argument sustained throughout this thesis is that ensuring effective public participation in diverse and ethically-sensitive healthcare distribution strategies – such as the incorporation a 'responsibility principle' – demands a more substantial and detailed evidence-base than that which is obtainable via quantitative methods.

Eliciting public opinion in relation to healthcare distribution, it is contended, demands a more in-depth examination of what lies behind people's stated views, values and preferences; it requires the identification of empirically based and ethically defensible social objectives (Richardson and McKie, 2005) which may be aligned to the process of priority-setting. The identification of such objectives, it is contended, may be assisted by eliciting the arguments used by members of the public and subjecting these to systematic analysis that explores their validity and underlying reasoning. There is little evidence that this has previously been undertaken in this area and, it is argued, this represents a significant gap in the existing knowledge-base.

This study will contribute to both methodological and empirical knowledge regarding public participation in healthcare debates and assist the interpretation of existing evidence of the public's views in this area.

1.3 RESEARCH QUESTION

This study sought to answer the following research question:

How can public participation effectively inform the debate on the social and ethical acceptability of individual responsibility as a healthcare priority-setting principle?

1.4 AIMS

- To critically examine the role of public participation in relation to healthcare priority-setting on the basis of responsibility for healthcare need
- To identify how such public participation may be enhanced

1.5 OBJECTIVES

- To ethically evaluate the processes of healthcare distribution, priority-setting and the QALY approach
- To consider the notion of responsibility for healthcare need as a priority-setting/QALY-weighting principle
- To examine the role of public participation in relation to the application of a 'responsibility principle' to healthcare priority-setting
- To examine the concepts of ethical reasoning and arguments as a means of enhancing public participation in healthcare priority-setting
- To propose methods by which the examination of the public's ethical reasoning and arguments may be effectively accomplished

1.6 METHODOLOGY

The research question has been explored without attempting to adhere to one specific academic discipline. The category into which this study most appropriately fits is that of bioethics and, possibly, empirical ethics. However, there is considerable debate with regard to what constitutes an empirical ethics approach and clarification of this debate is offered in Chapter 9 of this thesis. Nevertheless, it is generally agreed that bioethics is (or should be) an interdisciplinary field that allows for a variety of academic approaches. In addition, many of the relevant academic sources for the study lie within the field of health economics and considerable use is made of sources from within this discipline.

Overall, the study examines a range of socio-ethical issues, which include issues of societal welfare, placing limits on what may be perceived to be socially justified entitlements, and questions of the citizen's role in contributing to ethically important social policy. In accordance with my academic background, I have taken a largely conceptual approach to these issues and have sought to identify, evaluate and apply ethical arguments to topics that are relevant to the study as a whole. This approach is demonstrated throughout this thesis but is particularly evident in the penultimate chapter within which a detailed research proposal is presented.

The reason for adopting this approach is that there is no existing evidence, within either the bioethics or health economics literature, of the central proposition of this

study – that the ethical reasoning and arguments of members of the public, with regard to the incorporation of a 'responsibility principle' into healthcare priority-setting decision-making should be examined – having been systematically investigated. I therefore sought, within this study, to focus on providing a conceptual and practical basis for this to be achieved.

I have attempted to evaluate the ethical themes and arguments raised by various stakeholders – where necessary applying documentary analysis to their identification – not solely from an ethical perspective, but also on the basis of other claims or attributes related to them.

The study draws upon primary data sources including: Reports, Policy Documents and Consultation Papers. Secondary sources include academic monographs, journal articles and other published material. Due to the nature of the subject matter, additional research has included media sources such as newspapers and professional publications. Tertiary sources of material have included the internet. Where direct access to primary sources has been unobtainable, but these have been accessed through secondary sources, the materials are cited accordingly.

1.7 THESIS STRUCTURE

The thesis consists of eleven chapters and is divided into three sections:

1.7.1 SECTION A: HEALTHCARE PRIORITY-SETTING

Following this introductory chapter, **Chapter 2** examines the concept of healthcare distribution and offers a critical ethical evaluation of the QALY approach to distributing health benefits.

Chapter 3 explores the idea that weighting the QALY in consideration of the characteristics of its recipients would allow for a more equitable approach to healthcare distribution and priority-setting. Evidence of public support for such an amendment to the QALY method is presented and the way in which the National Institute for Health and Care Excellence (NICE) has approached weighting is critically evaluated. QALY-weighting is also subjected to critical ethical appraisal.

Chapter 4 examines the proposal that responsibility for healthcare need should be

formally recognised as a priority-setting principle. Priority-setting and rationing healthcare are examined and the 'responsibility principle' is ethically appraised.

1.7.2 SECTION B: PUBLIC INVOLVEMENT

Chapter 5 addresses the concept of social values and their role within health distribution policy. The ways in which social values and social value judgements are reflected in the work of NICE, and the extent to which NICE identify social value judgements within an overall 'ethical framework' for their activities is critically evaluated.

In **Chapter 6**, The process of 'public participation' – the means by which attempts are made to engage with the public on issues requiring public input – is critically explored. A narrative overview of the relevant literature is presented and the role of NICE's 'Citizens Council', an advisory body made up of members of the public, is considered in light of its contribution to public participation in healthcare distribution and priority-setting. The need for enhancement of public participation is emphasised and the elicitation and systematic examination of ethically-defensible public views, values and preferences regarding priority-setting is identified.

Chapter 7 examines the concepts of ethical reasoning and arguments; exploring their potential contribution to enhancing understanding of public opinion and promoting public participation. A lack of available evidence of the public's ethical reasoning and arguments regarding healthcare distribution is highlighted. Two 'non-healthcare distribution' studies of arguments are critically appraised in order to demonstrate differing approaches to the task.

Chapter 8 presents a literature review that sought to identify studies that have examined public attitudes and preferences regarding healthcare distribution and/or priority-setting and to evaluate these with regard to the extent to which they have elicited and/or examined participants' ethical arguments. A lack of such examination is identified and the need for an effective methodological approach to this subject is highlighted.

1.7.3 SECTION C: EXAMINING REASONING AND ARGUMENTS

Chapter 9 examines the concept of empirical ethics, a methodological approach that integrates ethics and empirical findings to reach a normative outcome, as a means of effectively guiding the examination of the public's reasoning and arguments.

In **Chapter 10** a detailed hypothetical proposal for a qualitative research study, guided by an empirical ethics methodological approach, to investigate the ethical reasoning and arguments of members of the public is presented.

Finally, **Chapter 11** presents the overall conclusions to be drawn from this thesis.

SECTION: A

HEALTHCARE PRIORITY-SETTING

2 DISTRIBUTING HEALTHCARE: THE QALY APPROACH

2.1 INTRODUCTION

'Healthcare distribution' – the process by which a finite healthcare budget is apportioned in order to meet healthcare needs – requires consideration of a wide range of potentially competing factors. Given the moral significance of healthcare, its distribution also demands critical ethical consideration.

Developed via the processes of economic evaluation, the QALY (quality-adjusted life year) has become a widely accepted means of guiding healthcare distribution and was specifically developed to enable clear, impartial distribution and priority-setting decision-making.

This chapter examines the process of allocating healthcare via the distribution of QALYs and offers a critical ethical evaluation of the QALY approach.

2.2 HEALTHCARE DISTRIBUTION

Once it's established what a society should spend overall on health care, then it must also be decided who should have that care, and on what basis it should be allocated (Dworkin, 1993: 885)

The effective distribution of healthcare is a challenging process. It involves making the best use of available resources and, where competing demands are made upon those resources, ensuring the most beneficial, fair and socially acceptable use of a limited budget. Distributional decisions must be economically viable, but they must also be socially and ethically justifiable; balancing the needs and interests of a range of stakeholders that includes healthcare providers, patients and the public.

The distribution of healthcare, as a morally significant feature of social policy, therefore demands well-considered ethical judgements and a coherent moral framework (Dolan and Olsen, 2002; Newdick, 2005; Kenny and Joffres, 2008; Daniels and Sabin, 2008; Mason *et al*, 2011). The topic has been extensively explored within both health economics and bioethics literature (e.g. Newdick, 2005; Morris *et al*, 2007; McMillan and Hope, 2010) and the means by which priorities are

identified and met has been a particular source of ethical debate (Bærøe, 2009; McMillan *et al*, 2006; Ridderstolpe *et al*, 2003).

In general, healthcare distribution must satisfy two key ethical criteria. Firstly, it should be effective – limited resources should be apportioned in a way that benefits the specific population and minimises harm (Williams *et al*, 2012). Secondly, healthcare distribution should be fair and just (Marmot, 2007). This criterion indicates the largely subjective aspect of the process, as perceptions of what is 'fair' or 'just' will vary according to individual and/or societal perspectives.

Ensuring that citizens have equal access to and an equal share of healthcare resources could be regarded as an indication that healthcare distribution incorporates considerations of fairness and justice. Paradoxically however, appeals to fairness and justice are frequently the foundation of calls for changes to what are ostensibly, egalitarian approaches to healthcare distribution (see below).

Additional ethical justification for a distributional strategy may be evident if the ethical theories upon which it is based or the ethical principles that guide its implementation can be clearly defined (Richardson and McKie, 2005; Persad *et al*, 2009).

2.3 THE QUALITY-ADJUSTED LIFE YEAR

In health care, 'doing good' means improving people's life expectancy and the quality of their lives. Since people value both of these fundamental attributes of life, we need a measure of outcome which incorporates both, and which reflects the fact that most people are willing to sacrifice some quality of life in order to gain some additional life expectancy, and vice versa. This is precisely the role of the Quality Adjusted Life Year (Williams 1995: 222)

The justifiable deployment of finite healthcare resources is a complex undertaking that requires a means of determining how resources should be allocated and, if necessary, which treatments and services should be prioritised. Decision-makers are assisted in this process by the use of economic evaluation methods, which enable the comparative analysis of interventions in order to identify the most economically defensible use of available resources (Jefferson *et al*, 2000).

Cost-effectiveness analysis (CEA) is a form of economic evaluation in which both the costs and consequences of a healthcare intervention are examined in order to

assess the extent to which it provides 'value for money'. CEA may be applied to healthcare when the costs and consequences of different interventions (that may vary in terms of process or clinical setting) can be measured in identical *natural units* such as life-years gained, deaths prevented or heart attacks avoided. Competing interventions may then be compared in terms of cost per 'unit of effectiveness' (life-years gained etc.). However, although CEA is useful when there is a natural dimension along which to measure health outcomes; to enable cost-effectiveness analyses across different areas of healthcare – and between diverse clinical services such as, for example, cancer treatment and hip-replacement surgery – it was recognised (in the late 20th century) that a more collective measure was needed:

To be of practical use, such a measure must be reducible to a single index, even though it may – indeed should – be made up of components which reflect the multi-dimensional nature of health (Williams and Kind, 1992: 21)

Cost-utility analysis (CUA) – "a sibling of CEA" (Jefferson et al, 2000: 7) – was developed in response to the need for a composite measure of health outcome. By applying CUA, the outcomes of healthcare ('health benefits') may be assessed in terms of the quantity and quality of life delivered by a given treatment when compared to the alternatives. These outcomes, when given a numerical value that represents a measure of an individual's projected length of life weighted by a valuation of their quality of life over that period, can then be combined with the financial cost of the treatment to provide a commonly applicable measure – the quality-adjusted life year (QALY) – against which health interventions can be compared.

Loomes and McKenzie (1989: 299) described the QALY approach to balancing quantity and quality of life:

A basic notion which underlies the QALY concept is that, for any individual, the prospect of living Y years in less than full health may be 'equated' to a prospect of living X years in full or perfect health, when $X < Y$

The primary objective of the QALY method is to evaluate the costs and consequences (benefits, potential complications etc.) of healthcare, in order that interventions may be prioritised (based on their cost-effectiveness) and overall benefits (obtained from a healthcare budget) optimised, via the process of 'QALY maximisation'.

QALYs enable the relative cost-effectiveness of competing interventions, which, in terms of their clinical aims and outcomes may be unrelated, to be explicitly defined, projected, quantified and compared in terms of 'cost per QALY'. In so doing they provide a clear and comprehensible means of determining which treatments, services and, more contentiously perhaps, individual patients, should be prioritised (Weinstein, *et al*, 2009; Neumann and Weinstein, 2010).

QALYs are increasingly used to inform policy decisions regarding the appraisal of health technologies, the issuing of clinical guidelines and the implementation of public health measures:

Health effects should be expressed in terms of QALYs... Given its widespread use, the QALY is considered to be the most appropriate generic measure of health benefit that reflects both mortality and HRQL [Health-related quality of life] effects NICE, 2008a: 33)

The QALY has become the dominant measure of healthcare benefit assessment and has established a significant role as healthcare prioritisation measure in many jurisdictions (Wailoo *et al*, 2009).

2.3.1 BACKGROUND TO THE QALY

It was developed in the 1960s and early 1970s with a view to resolving the problem of comparing "apples and oranges" in priority setting in health care (Nord, 1999: 18)

The development of the QALY took place at a time when healthcare was progressing from narrow, disease-based models, to encompass broader psychological, social and economic aspects of patients' lives. This led to the increasing recognition of the patient's role in the provision of effective healthcare and gave rise to the development of more comprehensive health assessment techniques, which were sensitive – to some extent at least – to the psychological and social impact of ill-health and healthcare treatment. Prior to the development of the QALY, 'quality of life' issues were rarely an explicit factor within healthcare decision-making and 'best choice' prioritisation decisions were most likely to be based on appraisals of symptoms and cure and perhaps that most definite of outcome measures: survival rates (Axtell, 1963).

2.3.2 THE QALY METHOD

As a unit of measure the standard, unweighted QALY represents one year in full health. Years spent in less than full health are 'quality adjusted' (Weinstein *et al*, 2009) so that one QALY equals two years of 50 per cent health; four years of 25 per cent health etc. (NICE, 2008a). Alan Williams, a prominent health economist who helped shaped the development, thinking and practice with regard to QALYs (Kind, 2008) described its fundamental approach:

... it takes a year of healthy life expectancy to be worth one, but regards a year of unhealthy life expectancy as worth less than one. Its precise value is lower the worse the quality of life of the unhealthy person (which is what the "quality adjusted" bit is all about (Williams, 1985, as cited by Harris, 1987: 117)

The central premise is that individuals move through health states over time and that each health state should have a 'utility value' attached to it (a numerical score that reflects the desirability of living in that state)³. (Hausman, 2010). Utility values represent the 'quality of life' component of the QALY by locating dissimilar health outcomes within a single measurable frame of reference. They are produced by identifying the strength of people's preferences for a range of pre-determined health states (see below).

The number of QALYs gained via a healthcare intervention is calculated by multiplying the utility value of a particular health state by the length of time it is predicted that an individual may experience that health state⁴. This is the basic 'QALY calculation' (**Figure.2.1**) that enables the overall value of a particular intervention to be determined.

³ "Utility is a term that was developed by economists (it actually derives from the work of the early nineteenth century economist and philosopher Jeremy Bentham, who developed the "utilitarian" school of thought), which refers to the subjective satisfaction that people derive from consuming goods and services. In the health care context, it is used to refer to the subjective level of wellbeing that people experience in different states of health" (Robinson, 1993: 672)

⁴ Utility values may be charted over a selected time period (for example, the anticipated life-span of a patient) to produce a series of value-weighted health states

Calculating the number of QALYs gained is reasonably straightforward. The utility value of a health state is multiplied by the length of time that the individual is in that health state (NICE, 2008b: 27)

For example:

Intervention A: four years in a health state valued at 0.75 = 3 QALYs

Intervention B: four years in a health state valued at 0.5 = 2 QALYs

Additional number of QALYs generated by intervention A = 1 QALY

Figure 2.1: The basic QALY calculation

This value is subsequently combined with the economic cost of an intervention to determine its 'cost per QALY' (Richardson *et al*, 2009). The measure of effect therefore is 'cost per QALY gained', which is the cost of treatment divided by the total number of QALYs gained:

For example, let's say that a hip replacement improves the utility of the average arthritic person from 0.8 to 0.9 (gain of 0.1). Let us say that, again on average, people have their hip replaced at the age of 65 years; and that their average life expectancy, at this age, is 15 years. They therefore gain $0.1 \times 15 = 1.5$ QALYs from the operation. If the cost of a hip replacement is £5,000 then the cost per QALY is: $5,000 \div 1.5 = \text{£}3,333$ per QALY (NICE, 2008b: 27)

Decision-makers are able to maximise the overall number of QALYs gained – and thereby increase aggregate health across the population – by comparing the 'QALY-gains' of different health interventions (Warner and Luce, 1982; Loomes and McKenzie, 1989; Weinstein *et al*, 2009).

Alternative interventions are compared via the calculation of an Incremental Cost-effectiveness Ratio (ICER) (**Figure 2.2**). The results of these analyses are assessed against a cost-per-QALY 'threshold' above or below which an intervention may or may not be funded⁵.

⁵ The 'cost-per-QALY threshold indicates the monetary value of QALY

The ICER is the ratio of the difference in the mean costs of an intervention compared with the next best alternative (which could be no action or treatment) to the differences in the mean health outcomes. ICERs are expressed as cost (in £) per QALY gained (NICE, 2008c: 18)

For example:

Cost of Intervention A = £50,000 –
Cost of Intervention B = £20,000
£30,000

Number of QALYs produced by intervention A = 10 –
Number of QALYs produced by intervention B = 4
6 QALYs

Incremental Cost-Effectiveness Ratio (ICER) or cost per QALY gained via intervention A = £5,000 (£30,000 ÷ 6)

Figure 2.2: Incremental Cost-Effectiveness ratio (ICER)

QALYs therefore provide a 'common currency' that enables measureable comparisons between competing healthcare interventions (of whatever type) plus unambiguous, defensible prioritisation decision-making across all areas of healthcare. The QALY approach allows resources to be directed towards interventions that provide better QALY-value-for-money. Alan Williams expressed this succinctly:

The general idea is that a beneficial health care activity is one that generates a positive amount of QALYs, and that an efficient health care activity is one where the cost per QALY is as low as it can be. A high priority health care activity is one where the cost-per-QALY is low, and a low priority activity is one where cost-per-QALY is high (Williams, 1985, as cited by Harris, 1987: 117)

2.3.3 GENERATING UTILITY VALUES

To generate utility values, a practical and reliable means of determining the strength of people's preferences for specific health states is required. This is achieved by defining a set of health states and measuring the extent to which they are valued. This demands careful consideration of which aspects of health, illness, psychological and social functioning should be included, as to value *all* potential health states would not be possible. Therefore, in order to construct representative

health state sets that embrace the majority of possible health states, validated generic health status measures, such as EQ-5D⁶, which enable the construction of a range of healthcare outcomes, are employed and studies of individual preferences regarding these outcomes are used to develop 'value sets' for use within the QALY calculation⁷.

In total there are 243 possible health states (3^5) formed by combining one level from each of the EQ-5D dimensions. As it would be unrealistic to expect respondents to value all these health states directly, health economists measure preferences among only a small number of alternatives. To generate value sets they estimate a multi-attribute utility function from which the values of the remaining health states can be calculated (Hausman, 2010). By a process of statistical modelling, the results are then:

...converted into a single summary index by applying a formula that essentially attaches values (also called weights) to each of the levels in each dimension (EuroQol Group, 2013b: 11)

The summary index score is used to *weight* the QALY calculation. It indicates the overall utility value of a particular health state (Hausman, 2010) and is used to predict utilities for health states not valued directly.

Utility values range from 0 (the equivalent to being dead) and 1 (best possible health state)⁸. The more preferred health states have greater utility value. To permit aggregation of the numbers of QALYs gained, the value range has interval scale properties, where the distances between the categories are identical across the range of categories (Bryman, 2008) so that, for example, a QALY gain from 0.2 to 0.4 is equally valuable as a gain from 0.6 to 0.8.

Preference elicitation is undertaken via both direct and indirect methods, and it has been observed that different methods may produce different results (Loomes and

⁶ EQ-5D is a generic, preference-based utility instrument developed by a collaborative team of European researchers, which provides a descriptive profile and single index value for health status and is NICE's preferred measure of health-related quality of life (HRQoL) in adults (NICE, 2008a). It consists of five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) each of which can take one of three responses recording differing levels of severity (no problems/some or moderate problems/extreme problems) (EuroQol Group, 2013a)

⁷ It is acknowledged that pre-scored generic preference-based measures (such as EQ-5D) may not incorporate all gains from a particular healthcare intervention. For example, as Dolan *et al* (2009: 372) observed: "*The EQ-5D does not capture the benefits of treatment experienced by the families and carers of patients*".

⁸ Some health states are regarded as being worse than 0 and are given a negative value

McKenzie, 1989; Tsuchiya *et al*, 2006). Direct methods that tend to be used most regularly for valuing health states include the visual analogue scale (VAS)⁹, the time trade-off (TTO)¹⁰ and the standard gamble (SG)¹¹. Direct methods are often used to value discrete, condition-specific health states; the valuation usually being performed by patients themselves. Indirect methods involve the use of pre-scored generic preference-based summary measures such as EQ-5D.

In developing the UK EQ-5D value set in 1993¹², approximately 3000 members of the UK public were asked to assign a value, i.e. assess their preference for (or extent to which they have 'problem' with), a subset of states constructed from the instrument's five dimensions (Dolan *et al*, 1995). Both TTO and VAS valuation methods were used in the elicitation process (EuroQol Group, 2013b).

2.4 EVALUATION OF THE QALY APPROACH

The ethical validity of the QALY approach is appraised by considering it in light of the broad ethical framework for healthcare distribution outlined earlier in this chapter:

Since we are talking about comparing different goods, the choice of unit is not merely a scientific or economic question but an ethical one (Singer, 2009)

2.4.1 EFFICACY

The ethical requirement that healthcare distribution should be effective requires an acceptable means of determining 'efficacy'. For example, a pragmatic definition of

⁹ The visual analogue scale is a form of rating scale: The top of the scale indicates the 'best imaginable health', whereas the bottom of the scale indicates the 'worst imaginable health'. Individuals are asked to indicate where on the scale they consider their own health state or the health state being valued to be located

¹⁰ Within the Time trade-off (TTO) approach, an estimated utility score for a particular health state is derived by asking subjects to consider the relative amounts of time (for example, number of life-years) they would be willing to sacrifice to avoid a certain poorer health state. For example, if an individual indicated that they would be willing to sacrifice 5 of an estimated 20 years of remaining life in order to live in complete health this would produce a TTO score of 0.75 for the particular health state being considered. Weinstein *et al* (2009: S7) noted the unique conceptual relationship of the TTO method to QALYs: "*because it is explicitly a trade-off of time with an impaired health state relative to healthy time - quality-adjusted time*"

¹¹ The SG approach is the classic method of measuring preferences in economics under conditions of uncertainty (Tolley, 2009). Subjects are presented with a choice between two alternatives: a health state (for example, chronic arthritis) that is certain and a gamble, with one better health outcome (for example, full health) and one worse (for example, death) possible. Subjects are asked to state what probability of the better outcome would make them indifferent between remaining in the current health state (chronic arthritis) for certain or going for the worse option. For example, if they are indifferent between the current health state and a gamble with a 0.8 probability of the better outcome (but 0.2 probability of the worse outcome), 0.8 represents the utility of the chronic arthritic state

¹² Discrete national EQ-5D value sets have been developed in several countries

effective healthcare distribution may perceive it in terms of its operational functionality i.e. with regard to its ability to respond to healthcare demand within the confines of a limited budget. However, a more inclusive definition may require consideration of other determinants of effectiveness, such as, for example, how well the distributional process is able to balance competing demands and interests whilst acknowledging the disparate healthcare needs of individual patients.

Distributing healthcare by means of the QALY approach enables the practical demands of an effective distributional process to be met as QALYs enable the comparative analysis of interventions in order to identify the most economically defensible use of available resources. However, this is not only a pragmatic or economic concern; it is an essential ethical consideration that is concerned with optimising benefit and minimising harm via the use of a limited healthcare budget. The maximisation of health benefits – as demonstrated by the QALY approach – is based on a utilitarian or consequentialist approach; the morally correct act being one that aims to achieve the best overall outcome for all concerned (Smart and Williams, 1973) and ethical principles for healthcare distribution typically take the need to benefit the majority or maximise health benefits as their starting point. Therefore, the efficacy of the QALY approach to healthcare distribution, it may be argued, is most clearly evaluated in terms of its ability to satisfy the second aspect of the broad ethical framework – that it should be both fair and just.

2.4.2 EQUITY AND JUSTICE

QALYs are unfair because they do not take into account who gains the QALYs (Hope *et al*, 2002: 178)

Cost-utility analysis involves the aggregation of QALYs across individual healthcare recipients (at for example, strategic or local levels) (Cubbon, 1991) with the aim of maximising the number of QALYs gained and thereby optimising overall health benefit achieved across the population (Weinstein *et al*, 2009). This aids 'allocative efficiency'¹³ (Eddama and Coast, 2008) by prioritising interventions that will accrue the most QALYs. However, QALY maximisation is undertaken under the implicit assumption that: "A QALY is a QALY is a QALY no matter who gets it" (Williams, 1992: 10) and equal weight is attached to all QALYs. Such an unrestricted approach

¹³ 'Efficiency' = "The minimum cost of producing a given outcome or the maximisation of outcomes from a given budget" (Maynard, 1987: 1539). 'Allocative efficiency' = "Selecting services that have the least cost per unit of health outcome" (Richardson and McKie, 2005: 270)

is therefore impartial to the individual circumstances of patients or to whom healthcare resources are allocated, providing the overall benefits are of equal magnitude (Dolan *et al*, 2005; Whitehead and Ali, 2010). What matters in this process is the sum total of population health. Therefore In terms of how and to whom healthcare is distributed, providing a net QALY-gain is achieved, the standard QALY model is unbiased; it focuses only on the overall benefit produced – as determined by the number of QALYs gained – and disregards any differences between peoples' healthcare needs:

... the age of recipients does not matter, as long as the QALY gain is the same. Likewise, the standard model assumes that equal QALY gains are of equal value regardless of how severely ill the patients are prior to treatment (Baker et al, 2010: 35)

However, impartiality does not automatically satisfy the requirements of a fair or equitable system of healthcare distribution and it is acknowledged that QALY-maximisation may sometimes be "... *at the expense of fairness*" (NICE, 2008c: 9). Furthermore, although prioritising healthcare for the majority may be undertaken in the interests of 'fairness'; 'justice', it may be claimed, cannot be satisfied solely by ensuring the greatest benefit for the greatest number of people.

A frequent criticism of the QALY approach is that, in relying on objective economic evaluation and promoting allocative efficiency by maximising benefit, it disregards what might be termed 'real life' concerns regarding how healthcare resources are allocated (Johannesson, 2001). Its impartial objectivity gives rise to one of the fundamental criticisms of the QALY approach i.e. that in seeking to optimise health benefit it fails to acknowledge healthcare 'need' and disregards factors that might affect the value of health gains, such as the individual characteristics or attributes of patients. It could therefore be argued that the QALY approach is inequitable in that it disregards individuals' differing claims to healthcare (Cookson *et al*, 2009).

In practice, the principle under which the QALY has developed impedes recognition of individuals' claims to healthcare based on their health-related or other personal attributes. Thus, what has been termed 'QALY egalitarianism' (Culyer, 1992) – indicated by the fact that the value of a QALY gained is the same for all – is its sole concession to the demands of equity and fairness, which do not otherwise feature within QALY reckoning:

The QALY approach is 'egalitarian' in the sense that, if all else is equal, a QALY gain to one person is of the same value as a QALY gain to anyone else, not in the sense that it advocates the equal distribution of resources regardless of benefit (McKie et al, 1998: 41)

McMillan *et al* (2006) cited the principle of justice as the overriding moral consideration when setting healthcare priorities, particularly when comparing one clinical service or treatment programme against another under conditions of scarcity. Within Rawls' 'Theory of Justice' (Rawls, 1971) a just system of distribution of 'goods' (such as healthcare) is one in which those members of society who are worst off will be better off under this system than any other. It is arguable whether the standard QALY approach meets this criteria for justice as those who are 'worst off' i.e. with the most severe illness or disability who may require an unequal proportion of healthcare, will not be considered independently within the QALY approach.

The unbiased distributively-neutral QALY approach has therefore been criticised for discriminating against particular groups of healthcare recipients, such as children, the severely ill, and, to a lesser extent, the socio-economically disadvantaged (Cookson *et al*, 2009), and those with a chronic illness:

If, for instance, a chronically ill patient is in a health state with a QALY weight of 0.5, his/her added life years will only receive half the value of added years for an individual in full health (Johannesson, 2001: 573)

It may also give rise to other, arguably, prejudicial distributional decisions. For example, in theory, the QALY method does not support the provision of very expensive treatments for small numbers of patients, or support expensive services that, by their nature, do not generate large numbers of QALYs:

If a healthcare system were to take QALY-maximisation as its only goal it would not just be hyper-expensive treatments it would have to give up onmany areas of medical care, such as palliative care, which do not generate many QALYs for their cost, would have to be dropped (Hunter and Wilson, 2011: 10)

An early and vociferous critic of the QALY, the bioethicist John Harris, reflecting concerns that the egalitarian, objective QALY was both ageist and discriminatory against those with least capacity to benefit, declared (somewhat provocatively) that the QALY was "a life-threatening device" (Harris, 1987: 117). Harris based his criticism primarily upon the QALY requirement to value life-years rather than individual people's lives, and stated:

If what matters most is the number of life-years the world contains, then the best thing we can do is devote our resources to increasing the population. Birth control, abortion and sex education come out very badly on the QALY scale of priorities (ibid: 119)

2.4.3 A UTILITARIAN APPROACH

Utilitarianism is obviously this method's philosophical parent (Menzel, 1999: 254)

The QALY approach emphasises the efficient distribution of health benefits and, as noted, overlooks individual claims to healthcare. In doing so it acknowledges one of the principal edicts of utilitarianism i.e. that:

Once note has been taken of the person's utility, utilitarianism has no further direct interest in any information about himPersons do not count as individuals in this any more than individual petrol tanks do in the analysis of the national consumption of petroleum (Sen and Williams, 1982: 4)

A utilitarian basis for distributing health benefits has been critically explored by many authors, including for example, Sen (1979), Olsen (1997) and more recently, Coast (2009). In pursuit of a reasonable approach to healthcare distribution and priority-setting, a utilitarian approach, it is argued, offers insufficient ethical justification for the deployment of resources and does not reflect the multiplicity of factors that dominate the way in which the public think about decision problems in this area (Anand and Wailoo, 2000). As Newdick (2005: 30) commented:

No-one will argue that considerations of cost and efficiency are irrelevant. But if they become the dominant or only concern, can they be described as ethical?

It has been argued that to overlook the needs of some patients, particularly those in evident need, is both counter-intuitive and inequitable. Richardson and McKie (2005: 269) observed that:

...there is a fact about the human psyche that will inevitably trump the utilitarian rationality that is implicit in cost-effectiveness analysis

Furthermore, a utilitarian approach to healthcare distribution can:

... allow the interests of minorities to be overridden by the majority; and it may not help in eradicating health inequalities (NICE, 2008c: 9).

It has been proposed that to produce a more ethically justifiable system of healthcare distribution, specific normative determinants of healthcare entitlement – such as those based on choice and causation – should be considered (Anand and Wailoo, 2000).

2.4.4 QALYS AND AUTONOMY

Many of the most widely debated ethical issues within healthcare relate to the concept of autonomy and the freedom, or otherwise, of individuals to decide what they do and what is done to them (this is a common understanding of autonomy; an alternative construction is discussed below). People are increasingly aware of (and prepared to claim) their right to be treated as self-determining individuals, free from the controlling interference of others and able to engage in informed decision-making with respect to their own healthcare, in other words, to be *autonomous* (O'Neill, 2002).

Logically perhaps, with regard to healthcare distribution, respecting an individual's autonomous preferences requires acknowledging (at least) their healthcare choices, bearing in mind that being autonomous and respecting autonomy also demands consideration of the autonomous choices of others. However, the principle inevitably comes into conflict with other important ethical values such as equity and justice. (UKCEN, 2013) and does not accord with the overriding ethical stimulus for the QALY approach: the need to benefit the majority. Therefore, a policy of aggregated health-maximisation does not allow for individual engagement in the process of healthcare distribution and, in this sense, the standard QALY method has little regard for the principle of respect for autonomy (in its individualistic sense), as it is unable to accommodate a need to respect individual choices regarding healthcare.

2.4.4.1 RELATIONAL AUTONOMY

A relational account of autonomy (Verkerk, 2001; Ho, 2008) possibly offers a more adaptable means of considering the relationship between autonomous choices and healthcare distribution.

It is increasingly argued that the traditional individualistic concept of autonomy that acknowledges individuals as free and independent autonomous agents is inadequate and that autonomy is better understood in the context of personal and

institutional relationships that facilitate or possibly impede the making of real choices:

This new understanding of autonomy – known as ‘relational’ autonomy – claims to be a more accurate description of the actual basis for autonomous action, as well as a better grounding for our obligation to respect each other’s autonomy (MacDonald, 2002: 195)

For example, in a clinical healthcare setting, the individualistic notion of autonomy considers illness as a problem of individual patients (Sherwin, 1998) and assumes that patients regard family involvement or their respective interests as being in conflict.

Donchin (1995) claimed that an idealised image of the otherwise healthy patient, self-sufficient and accustomed to making decisions about what they do and what is done to them is symptomatic of a "*pervasive distortion in moral thinking that arises from a false conceptualisation of individuals as capable of existing apart from any social relationships*" (*ibid.*: 45). Therefore, the traditional approach to autonomy, overlooks the many contextual features of patients' lives that may prevent them from undertaking real choice, even if they fulfil the accepted requirements for being 'autonomous' – being informed, having capacity, not being coerced etc.

Much of the available literature on relational autonomy has arisen via feminist scholarship and the work of academics such as Donchin (1995), Sherwin (1998) and Christman (2004) that has highlighted the networks of social relationships and interdependencies that facilitate autonomous action (MacDonald, 2002). Such relationships, it is maintained, are generally neither chosen nor optional and therefore, to perceive autonomy solely as an individualistic concept is erroneous.

It has been claimed that a relational perspective on autonomy has implications for a wide range of issues, such as our understandings of informed consent, advocacy and confidentiality (MacDonald, 2002). With regard to the QALY approach, a relational understanding of autonomy suggests that QALYs, health maximisation and autonomy may not necessarily be mutually exclusive concepts. Relational autonomy acknowledges self-determination within an overall context of interdependency and therefore enables the structure by which particular actions can be deemed autonomous – or by which an individual can be regarded as autonomous with respect to particular actions – to be more broadly articulated (IEP,

2014). Such (relational) autonomous actions are most effectively realised when the social conditions that support it are in place. These include the supportive structures – both personal and political – that give one the confidence to take charge of choices (Sherwin, 1998). This has implications for a proposed adjustment to the standard QALY approach that is discussed below and examined in detail in Chapter 3.

2.5 THE QALY: A NEED FOR ADJUSTMENT

By taking into account both the quantity and quality of life generated by a health intervention, the QALY approach to healthcare distribution reflects a contemporary view that mere survival is an insufficient measure of health benefit - the expected *quality* of life years gained must also be considered. By offering a 'common currency', the QALY approach enables the relative cost-effectiveness of competing healthcare interventions to be explicitly compared in terms of 'cost per QALYs gained' and facilitates transparency within healthcare distribution and prioritisation decisions.

However, healthcare must be distributed in a way that balances morally competing arguments (Edlin *et al*, 2011) and healthcare priorities must be determined in an ethically defensible way. The QALY model – particularly the principle of QALY-maximisation – has been subjected to on-going critical appraisal (Dolan *et al*, 2005; Shah, 2009; Hunter and Wilson, 2011). A persistent criticism is that, in its standard form, the QALY approach does not offer an ethically defensible (normatively desirable) approach to distributing healthcare (UKCEN, 2013).

As noted by Shah (2009) and others, the purpose of a healthcare system should not be to simply maximise health benefit. For example, a range of commitments, values and principles (Department of Health, 2009, 2010) guides NHS provision. It has therefore been argued that the achievement of maximum overall aggregate health benefit is not a sufficiently equitable basis upon which to determine healthcare distribution. Such apparent lack of fairness has been a key stimulus for exploring alternative approaches to QALY distribution (Nord *et al*, 1999; Sassi *et al*, 2001; Schwappach, 2002; Bleichrodt *et al*, 2004; Cookson *et al*, 2009) and has led to proposals that the QALY approach be amended – via 'QALY-weighting' – in order to increase equity and to enable a more transparent and equitable approach to healthcare priority-setting (Nord, 1999; Olsen *et al*, 2003; Johannesson, 2001;

Richardson and McKie, 2005; Baker *et al*, 2010).

The next chapter examines the concept of weighting health benefits and, specifically, weighting the QALY, in pursuit of a more equitable system of healthcare distribution and priority-setting.

3 WEIGHTING HEALTH BENEFITS

3.1 INTRODUCTION

It is increasingly argued that the equitable distribution of NHS services demands an explicit approach to priority-setting. A possible means of achieving this, it is claimed, would be to weight health benefits (QALY gains), in circumstances where the predicted health outcomes are the same, in accordance with one or more pre-determined criteria. This, it has been maintained, would offer a fairer approach to healthcare distribution and enhance transparency and objectivity within priority-setting decisions (Wailoo *et al*, 2009).

This chapter explores the concept and process of 'QALY-weighting' and critically evaluates its ethical legitimacy and its potential to enhance healthcare priority-setting.

3.2 WEIGHTING HEALTH BENEFITS: 'QALY-WEIGHTING'

It is essential that publicly-funded healthcare resources be deployed effectively and efficiently. In order for this to be achieved, a measureable system of quantifying the outcomes of healthcare is required – hence the widely established use of QALYs. However, as discussed in the previous chapter, the concept of 'QALY-maximisation', which aims to achieve the maximum QALY gain at the least financial cost, has attracted substantial criticism due to the fact that, in focusing on the overall benefit gained from a healthcare intervention, it disregards any differences between the recipients' (individuals or groups of patients) healthcare needs. A fundamental problem presented by the standard, unweighted QALY is that a QALY accrued has the same value regardless of its recipient. In other words, an increase of one QALY is valued equally if it is gained by an individual "*who is already 'rich' in years*" as it is to "*someone whose life in the absence of treatment will be short and miserable.*" (Bleichrodt, *et al*, 2004: 158). Consequently, there has been considerable debate about whether QALYs gained by different beneficiaries of healthcare should be weighted equally (Donaldson *et al*, 2011).

Weighting QALYs would – in circumstances where the predicted health outcomes are the same – require attaching a degree of 'distributional weight' to health gains

accrued by some healthcare recipients, in other words, assigning differential weights to QALYs by mathematically adjusting the QALY by a factor that takes into account, for instance, the individual characteristics or attributes of their recipients (Williams, 1997; Nord, 1999; Johannesson, 2001; Richardson and McKie, 2005; Wailoo *et al*, 2009). Weighting may mean that 'weight' is *added* to the standard QALY – in effect giving its recipient higher priority for healthcare – or *subtracted*, thereby implying lower priority.

Efficiency, in terms of 'allocative efficiency', is at the heart of the conventional QALY approach. Nonetheless, increased efficiency is one of the perceived advantages of QALY-weighting. For example, a simple if highly contentious efficiency-based argument would be that, if the current system of distributing income is justifiable, then a QALY gain for those who make the greatest contribution to the society through their higher productivity (higher productivity = higher taxes paid = higher contribution) should be weighted higher than a QALY gain for those who contribute less. Alternatively, in the interest of efficiency, it could be deemed acceptable to weight the QALY gains of those who, regardless of income, make a greater contribution:

...those who have more to contribute to society should be rewarded more extensively...since the fruits of human capital and productivity of such people could trickle down and contribute to a richer society overall
(Dolan and Tsuchiya, 2006: 383)

3.2.1 WEIGHTING CRITERIA

The suggestion that the QALY should be weighted demands consideration of criteria that could be used to validate the incorporation of a distributional bias into an otherwise impartial system of healthcare distribution. Several authors have discussed the theoretical, practical and ethical issues concerning attaching distributional weights to the QALY (e.g. Nord *et al*, 1996; Nord, 1999; Dolan and Olsen, 2002) and a range of methods have been used to identify 'equity weights'. This has been mainly achieved by eliciting preferences from the general population regarding various possible weighting criteria. Examples of potential weighting criteria (Brazier *et al*, 2007: 290) include:

- *Severity of health before receiving treatment*
- *Severity of health should patients not receive treatment*

- *Age and life stage of a typical patient*
- *Socio-economic background of a typical patient*
- *Whether or not patients brought the ill health on to themselves*
- *How long patients have had the condition for*
- *The number of patients involved and whether or not they are 'identifiable'*

3.2.2 HOW QALY-WEIGHTING COULD BE ACCOMPLISHED

Although the concept of the unweighted, aggregated, egalitarian QALY is deep-rooted and, it has been claimed, the incorporation of weighting would complicate the QALY distribution process, thus obstructing transparency (Drummond *et al*, 2009), Alan Williams, one of the QALY's chief advocates indicated that weighting, within a system of collective prioritisation, would not necessarily be at variance with the original strictures of the QALY method:

....there is nothing in the QALY approach that requires QALYs to be used in a maximising context...more complex rules will almost certainly be needed if collective priority-setting is to reflect the views of the general public (Williams, 1995: 224)

The process of QALY-weighting, it is asserted, would be fairly straightforward and would simply require the standard QALY model to be modified by the assignment of weights to health utility gains – thereby adjusting the number of QALYs generated by a particular health intervention. The number of weighted QALYs could then be compared with the relevant cost-per-QALY threshold:

*For example, an intervention generating 5 additional QALYs in a patient group for whom a weight of 1.5 was considered applicable would generate 7.5 equity-weighted QALYs. Provided the additional cost was no more than £150 000, then this would be considered a cost-effective intervention, assuming a threshold of £20 000 (£150 000 per 7.5 QALYs) (Wailoo *et al*, 2009: 985)*

Alternatively, the cost-per-QALY threshold itself could be adjusted in accordance with whatever weighting was attached to the QALY.

3.2.3 DETERMINING WEIGHTING VALUES

The specific values to be accorded to the weighted QALY, it has been claimed, could be determined by seeking people's views and preferences on collective

priority-setting from behind a Rawlsian 'veil of ignorance' (Rawls, 1971). The process was effectively detailed by Williams (1995: 223):

We have to imagine ourselves outside the society of which we are members, and then choose that set of rules for collective priority-setting which would be most likely to achieve the distribution of health benefits that we think best for our society. Then, and only then, will we be assigned, by lottery, an actual place in that society. We may find ourselves favoured by our rules, or we may be one of the unfortunate people who are disadvantaged by them, but we would have achieved a set of rules which we would have to accept as fair. The question which I would ask the reader to consider is whether, under these conditions, you would choose a set of rules which would maximise the health of the community as a whole, as measured in QALY terms, and, if not, why not?

3.2.4 PUBLIC SUPPORT FOR QALY-WEIGHTING

In both the UK and beyond, there is evidence of public backing for weighting QALYs, or for at least taking personal characteristics or attributes into consideration when allocating limited healthcare (Wilmot and Ratcliffe, 2002; Anderson *et al*, 2011). This is supported by evidence of increasing societal willingness to trade efficiency for a more explicitly equitable – i.e. weighted – distribution of healthcare resources (Schwappach, 2003).

From the evidence available, it does not appear that members of the public's views on 'weighting health benefits' or 'QALY-weighting have been explicitly sought. This is perhaps unsurprising given the complexities of weighting per se and the public's unfamiliarity with the terminology. Evidence of the public's views, values and preferences on weighting has been extrapolated from studies of public views on various aspects of resource allocation; data being obtained via quantitative methods such as stated preference surveys (e.g. Buxton and Chambers, 2011).

An impartial utilitarian approach, it is claimed, overlooks the multiplicity of factors that dominate how the public think about decision problems in this area (Anand and Wailoo, 2000; Schlander, 2008), and evidence suggests that a system of QALY-maximisation is at odds with many people's views on the equitable distribution of healthcare:

...a number of studies have shown that the public would not naturally choose the most efficient allocation of resources and aim simply to maximise QALYs gained (Buxton and Chambers, 2011: 287)

Baker *et al*, (2010) reported that members of the public appear to be open to the

possibility of using separate QALY weights for different groups of beneficiaries, and Richardson *et al* (2011) found that respondents to a survey of members of the public preferred to share resources between patients rather than maximising life years – 'sharing' being interpreted in terms of a more equal distribution of resources than would occur with an exclusive focus upon efficiency.

Nord *et al*, (1995) reported that survey respondents rejected a policy of maximisation and distributive neutrality when the consequence was a loss of equity, and Schlander (2008) found that there was little, if any, evidence that an emphasis on maximisation is shared by the general population. Anand and Wailoo (2000) report that some citizens are guided by multiple perspectives, including the protection of individual rights and embedded community values.

It appears therefore that there would be substantial public support for introducing a system of weighting health benefits in accordance with the individual characteristics or attributes of their recipients (Olsen, 2000; Wilmot and Ratcliffe, 2002; Lancsar *et al*, 2011). This, it is claimed, would more accurately reflect societal preferences concerning how healthcare resources should be allocated. For example, for many people arguments in favour of treating children over older people maintain an instinctive plausibility as do considerations for those with dependents. As Williams (1995: 225) observed:

....there is ample evidence that most people (including the elderly) would give extra weight to benefits accruing to young people over the same benefits accruing to old people. There is a similarly widespread view that people with young children should have some priority over their childless contemporaries

There is also evidence to suggest that, when informed of the fact that individual patients find two health improvements to be of identical benefit, members of the public generally express a strong preference for prioritising those with the worst initial health state (Richardson and McKie, 2005), and are willing to sacrifice aggregate health gains, and to include a degree of bias within the allocation of resources, in order to give priority to certain groups of patients, such as the severely ill (Shah, 2009).

However, public support for QALY-weighting is not unequivocal. For example, Bryan *et al* (2002) found some broad public support for the QALY-maximisation model, and Lancsar *et al* (2011) observed that focus group respondents were

reluctant to weight QALYs based on the characteristics of their recipients except in a small number of specific cases. Anderson *et al*, (2011) observed that when asked, members of the public initially favour giving priority to healthcare interventions that produce the most life years of the highest quality, and that:

It is only when it is pointed out that this will disadvantage the elderly, the permanently disabled and chronically ill, and others with a limited capacity to benefit that members of the public begin to have misgivings (ibid: 143)

3.2.5 NICE AND QALY-WEIGHTING

The national Institute for Health and Care Excellence (NICE) is an independent organisation, established in 1999, that is responsible for providing UK national guidance on promoting good health and preventing and treating ill health (NICE, 2013a). The various reports of NICE's Citizens Council¹⁴ provide evidence of how QALY-weighting considerations – and public participation – contribute to NICE activities.

The report of one Citizens Council meeting: *Quality Adjusted Life Years (QALYs) and the severity of illness* (NICE, 2008b) provides the clearest evidence of how NICE approach QALY-weighting.

Addressing the need to either take severity of illness into consideration, alongside cost and clinical effectiveness evidence *or* include severity of illness within the calculation of the QALY i.e. weight the QALY in accordance with the severity of a patient's ill-health, the Citizens Council report recommended that NICE and its advisory bodies should only take severity of illness '*into consideration (ibid: 4)* when making decisions. It was concluded, if not unanimously agreed by Council members, that taking this approach (as opposed to QALY-weighting) would give NICE appraisal committees greater flexibility.

Throughout the QALYs report, and other reports of the Citizens Council, NICE repeatedly acknowledges the need for its committees and advisory bodies to take potential weighting criteria '*into consideration*', but does not appear ready to commit itself to formal weighting or, as the QALYs report puts it: "*modifying the QALY*" (*ibid*; 14). Interestingly, one of the expert speakers at the Citizens Council 'QALYs' meeting suggested that, as NICE appraisal committees already have a degree of

¹⁴ The role and influence of NICE's Citizens Council is examined in Chapter 6

flexibility and the discretion to take account of clinical need:

They could be mandated to give more weight to social value judgements, and proportionately less to cost-effectiveness (ibid: 9)

However, it appears that NICE's current approach is to avoid mandatory QALY-weighting and to rely on the discretion of its committee members¹⁵.

3.2.6 POTENTIAL CHALLENGES

Although QALY-weighting may be achievable and the advantages can be defined, the practicalities of weighting health gains, in the interest of both equity and efficiency, would be expected to raise considerable societal concerns as such an approach would inevitably result in the sacrifice of health gains by some in order to meet the health needs of others.

How to reflect preferences over efficiency and equity in a reliable manner is a fundamental difficulty in the realisation of QALY-weighting. It has been suggested that an 'equity-efficiency trade-off' may be necessary (Bleichrodt *et al*, 2005).

Whitehead and Ali (2010: 15-16) illustrated an example of such a trade-off:

For example, it may be more efficient (in terms of lives saved) to implement an intervention in easy-to-reach affluent areas rather than hard-to-reach poor areas; however, a decision-maker may trade-off equity versus efficiency to promote distributional equity of health outcomes

Although weighting may be intuitively appealing, the procedural issues involved in both the weighting process and its application have yet to be determined. It has so far been deemed impractical because of the perceived technical challenges of incorporating weights in a manner that respects societal preferences over efficiency and equity (Wailoo *et al*, 2009). These include uncertainties about the identification of relevant characteristics and a lack of agreement on which methods would be most effective in determining the necessary weights.

Dolan and Tsuchiya (2006) considered the process of '*eliciting distributional judgements*' and discussed at some length the practicalities of undertaking a study aimed at determining publicly supported equity weights. Baker *et al* (2010) highlighted three significant challenges faced by those attempting actually identify

¹⁵ Social value judgements are examined in Chapter 5

QALY-weights, these are:

identifying characteristics of beneficiaries over which weights should be derived; designing and presenting questions so that respondents can understand complexities and make choices; and elicitation of quantitative preference data from members of the general public to allow the estimation of QALY weights (ibid: 3)

According to some observers, one of the fundamental barriers to the inclusion of weighting criteria has been the relative obduracy of traditional health economics (Dolan *et al*, 2005; Richardson and McKie, 2005). As has been noted, a system of healthcare distribution that promotes the principle of health maximisation does not necessarily concur with the attitudes of the public. One reason for this, it has been argued, is that within a cost-utility analysis (QALY) approach, there is an inherent supposition that people's preferences are commonly applicable. In other words, society's values are assumed, despite the range of evidence that indicates wide variations in people's preferences (Dolan *et al* 2005).

There is a need for a more comprehensive understanding of what the public think about the possibility of weighting health benefits. Although there are indications of members of the public's apparent support for weighting, there is not, as yet, any secure evidence base for introducing such a system (Baker *et al*, 2010).

3.2.7 ETHICAL JUSTIFICATION

Ethical concerns, relating to, for example, equity, justice, rights and autonomy, permeate the QALY-weighting and priority-setting debate, and the ethics-related literature concerning these concepts is substantial (e.g. Jecker and Pearlman, 1992; Dworkin, 1993; Williams, 1995; McKie *et al*, 1998; Butler, 1999; Dolan and Olsen, 2002; Newdick, 2005; Daniels and Sabin, 2008).

The ethical justification for weighting QALYs lies primarily in its potential to respond more effectively to the diversity of healthcare needs. As has been discussed, a system of egalitarian impartiality is the principal ethical weakness of a health-maximisation approach to healthcare distribution.

3.2.7.1 EQUITY

Health equity is one of the main avowed objectives of public health policy across the world. Yet economic evaluations in public health (like those in health care more generally) continue to focus on maximizing health gain. Health equity considerations are rarely mentioned (Cookson et al, 2009: 231)

It is increasingly contended that, in certain circumstances, there may be a need to forego health maximisation and to combine considerations of cost and efficiency with a greater concern for equity within healthcare distribution. As Bleichrodt *et al* (2005: 656) observed:

Several authors have raised concerns about the equity implications ...and have argued that it may be necessary to differentiate between individuals based on, for example, age, health status or previously enjoyed health

'Equity' in this context implies justice' rather than simple impartiality or even-handedness. Differentiating between patients (who stand to benefit equally from a particular intervention) necessitates the incorporation of a degree of explicit partiality into healthcare distribution decision-making and, as already noted, has been the main motivation for exploring the feasibility of weighting QALYs in accordance with pre-determined criteria (Baker *et al*, 2010). Equity, it is claimed,' necessitates that some individuals (or groups) receive more, even if the recipients' overall health gain is less than that of others who, although greater in number, are less ill (UKCEN, 2013).

The addition of 'equity weights' to the QALY model, it has been argued, would, to some extent counter the discriminatory nature of the conventional QALY approach¹⁶. In other words, the perceived lack of 'fairness', inherent within the QALY model – indicated by its disregard for individual needs – could be corrected if the QALY were to be adjusted to a value enhanced (or diminished) by the specific circumstances and/or characteristics of its recipient(s). QALY-weighting would, therefore, enhance the equitable distribution of health benefits across the population.

¹⁶ Paradoxically, the conventional QALY is weighted in that the length of time spent in a health state is *weighted* by its utility value

3.2.7.2 RIGHTS

Rights are justified claims (entitlements) that demand action or restraint from others i.e. rights impose duties on other people to either act or refrain from action (Gillon, 1986). The existence of a 'right to healthcare' has been widely debated (e.g. McCarrick, 1992; Eleftheriadis, 2012)¹⁷ and the extent to which such a right may impose (on governments for example) a duty to provide certain healthcare services has also been subjected to critical appraisal (Gauri, 2004). QALY-weighting would, if undertaken in accordance with individual characteristics and attributes, appear to sit well within a broad rights-sensitive approach to healthcare distribution. The duties imposed on decision-makers to act in accordance with the rights of those who may access healthcare services i.e. all citizens, would imply that the right of the individual patient to receive healthcare imposes a duty (upon providers) to ensure that such healthcare as is required is made available. However, a significant and perhaps obvious proviso to such a rights-based justification for weighting is that the imposed duty to provide healthcare could, in practice, extend only so far as is possible within the confines of a limited healthcare budget. A consideration of QALY-weighting and rights can therefore offer only partial acknowledgement weighting's ethical justification.

3.2.7.3 AUTONOMY

The ethical principle of 'respect for autonomy' requires that rational individuals should be free to think, act and make decisions independently (O'Neill, 2002) and, according to this principle, autonomous individuals should be free to make informed choices. However, as previously discussed, the standard QALY model, limits individual choice and potentially inhibits the exercising of autonomy – at least with regard to commonly perceived, individualised understandings of autonomy.

As has been discussed, weighting QALYs would enable resources to be directed towards individuals or groups of individuals in accordance with their individual characteristics or attributes. This, in itself, offers the possibility of enhancing the autonomous choices of recipients of the 'weighted QALY': a basic illustration of enhanced autonomous choice brought about by weighting health benefits was

¹⁷ A right to healthcare is discussed in Chapter 4

presented by NICE's decision (made in 2009) to accept higher incremental cost-effectiveness ratios for some end-of-life treatments¹⁸.

A relational account of autonomy¹⁹, which acknowledges autonomous choice in the context of personal and institutional relationships, could further extend the potential for autonomy to play a meaningful role in (weighted) QALY distribution. This is because such a view asserts that autonomous choice is essentially linked to the wider contextual features of an individual's existence and acknowledges the interests and involvement of others within individual choices (Ho, 2008). Therefore, QALY-weighted healthcare distribution, which recognises healthcare recipients' attributes and characteristics (possibly including, as noted above, relationships such as dependents) could potentially enhance the range of autonomous choices by acknowledging that the respective interests of the individual patient and those close to them, are not necessarily in conflict.

A relational autonomy perspective does not, in itself, indicate that autonomy would inevitably be enhanced by QALY-weighting; but that if the range of individual choices in relation to healthcare distribution were to be improved – however marginally – such choices might be further enhanced from a relational autonomy perspective.

Overall, the incorporation of weighting into the QALY approach appears to possess ethical credibility. This examination now proceeds to consider a contentious potential QALY-weighting criterion, one that, at its heart, invokes concerns for the social and ethical integrity of healthcare distribution and priority-setting: responsibility for healthcare need.

¹⁸ This is discussed further in Chapter 5

¹⁹ An overview of relational autonomy is provided in Chapter 2

4 RESPONSIBILITY FOR HEALTHCARE NEED AS A RESOURCE-LIMITING PRINCIPLE

4.1 INTRODUCTION

When demand for healthcare services exceeds available resources, the application of resource-limiting strategies – such as priority-setting and rationing – becomes inevitable. The terms 'priority-setting' and 'rationing' are often applied synonymously within the healthcare literature (Coulter and Ham, 2000). Each implies:

...the withholding of potentially beneficial health care through financial or organizational features of the health care system in question
(Norheim, 1999: 1426)

In the interests of delivering an equitable healthcare service, the rationale for limiting resources must be clear, effective and defensible. In addition to the strategic withdrawal of services and reducing funding for one service or another, a range of criteria have been proposed that, it is claimed, could be applied to validate resource-limiting strategies. One particularly contentious suggestion is that healthcare should be limited in accordance with the extent to which a patient is deemed to be responsible for generating their own healthcare need.

This chapter examines this suggestion and, in light of relevant ethical concerns, considers whether a valid ethical argument can be made for the incorporation of a 'responsibility principle' within healthcare distribution policy.

4.2 PRIORITY-SETTING AND RATIONING

4.2.1 PRIORITY-SETTING

Priority-setting is an accepted feature of healthcare provision. For example, within an emergency/trauma setting it is generally understood that patients with an immediate need for treatment should have priority over others. However, in situations where a clinical distinction between patients is less easily made i.e. where there are no obvious medical reasons for giving priority to one patient, or group of patients, over another as each will benefit to the same degree (respond equally well

to treatment), other factors must be considered to help decision-makers identify priorities (Baltussen and Niessen, 2006; Sibbald *et al*, 2009; Arvidsson *et al*, 2010).

Strategic priority-setting is founded within NHS decision-making, delivery and performance management systems (Robinson *et al*, 2012) where the extent to which healthcare services and treatments are provided is determined. It takes place at various planning stages – from government to clinical commissioning group levels (Williams *et al*, 2012). Prescribed economic goals, such as the NHS target of delivering up to £20bn in efficiency savings by 2015 (Ball and Sawyer, 2009), inevitably initiate priority-setting, and guidance from national organisations such as NICE may also contribute to resource-limiting decisions (Green and Gerard, 2009).

At whichever level decisions are undertaken, priority-setting derives from the need to strike a balance between available resources, predicted healthcare need and the amount of benefit it is anticipated can be produced from a healthcare budget. This may result in priority-setting strategies such as the closure of a particular healthcare service or reducing in-patient hospital bed numbers (Robinson *et al*, 2011).

4.2.2 RATIONING

Given that the finite nature of a healthcare budget is generally understood (although not necessarily accepted), healthcare 'priority-setting' is perhaps a more comprehensible and socially acceptable concept than healthcare 'rationing'. For many people the word 'rationing' may have negative, emotive meanings. Rather than identifying a hierarchy of access to healthcare based, to some extent at least, on logical criteria (as in priority-setting), the term may have connotations of unfairness and imply placing restrictions on access to healthcare or withholding treatment that is perceived to be beneficial (Norheim, 1999). Dickinson *et al* (2011: 363) highlighted the distinction between the terms:

... 'rationing' usually relates to the withholding of resources to the cost of individual patients, whereas 'priority-setting' has less starkly negative connotations, referring more to populations than individuals, without directly alluding to punitive resource allocation

Placing limits on healthcare is a long-standing source of debate (Owen-Smith *et al*, 2010; Weinstein and Skinner, 2010; Hicks, 2011; Kelly and Cronin, 2011). However, without some kind of resource-limiting criteria it is unlikely that effective and

defensible distribution decisions would be possible. For example, justifiable decisions regarding the allocation of scarce resources such as organs for transplantation *demand* clear and effective rationing criteria (Neuberger, 2012).

Healthcare rationing has been subjected to considerable scholarly investigation (e.g. Newdick, 2005; Morris *et al*, 2007; McMillan and Hope, 2010, Neumann, 2011), and stories concerning the funding of healthcare treatment – for example, restrictions being placed on non-urgent treatments such as fertility treatments and cosmetic surgery – are a continuing source of debate in print, broadcast and online news media (e.g. Aziz, 2011; BBC News, 2012; Smith, 2012).

A distinction can be made between the explicit rationing of healthcare services ('macro-rationing') and the rationing of healthcare treatment to an identified patient or group of patients – sometimes referred to as 'bedside rationing' ('micro-rationing') (Strech and Danis, 2012). Explicit rationing is undertaken according to established 'rules' of entitlement. For example, in the UK, national funding thresholds determine the extent to which costly treatments will be supported. NICE currently applies a funding threshold range of £20,000 to £30,000 per QALY gained (Claxton *et al*, 2013).

The application of funding thresholds often attracts adverse publicity (BBC News, 2008, BBC News 2010; Hope, 2013) but other more implicit forms of rationing – undertaken at the discretion of gatekeepers, such as doctors and nurses, and more reliant upon professional judgement and clinical decision-making than on policy demands – are less overt and consequently receive less public exposure. It has been noted that, if rationing is inevitable, then explicit, rule-based rationing – such as the application of funding thresholds – is preferable to implicit, case-based rationing at the bedside (Daniels and Sabin, 2002; Winkler *et al*, 2012).

The very notion of 'rationing' signifies limits being established on the amount of a particular resource that one individual or group receives. The diversity of individual health needs: "*the multi-dimensional nature of health* (Williams and Kind, 1992: 21), indicates therefore that, when rationing decisions are made, some patients – whether implicitly or explicitly – must concede healthcare gains to others. Consequently, criteria (determinants, parameters and considerations) must be identified and principles (values, rules and assumptions) established that underpin rationing and enable decisions to be taken in as clear and objective a manner as

possible.

4.3 RESPONSIBILITY AS A RESOURCE-LIMITING PRINCIPLE

The consequence of acknowledging responsibility as a resource-limiting principle would be that healthcare could justifiably be constrained, or even wholly withheld, in proportion to the estimated culpability of a patient for their own ill-health. At the heart of the 'responsibility principle' debate therefore is the question of whether or not individuals deemed to be personally responsible for their ill-health should receive lower priority for healthcare (Buyx, 2008).

One of the founding principles of the NHS was that high quality care should be freely available to all on the basis of clinical need. Although this value-driven aim may have been compromised by the mounting disparity between available resources and demand, there persists, among the UK public, a widespread belief that what may be regarded as 'essential' NHS services will be available if and when required (Ziebland *et al*, 2011).

It is perhaps conceded – if not always willingly – that patients may be denied treatment that is not clinically indicated i.e. where there is no prospect of it benefitting the patient; while such decisions may contradict a patient's perceptions of their own healthcare need, they are regarded as an appropriate function of a clinician's role (Lockwood and MacFie, 2012). However, a suggestion that healthcare should be rationed or lower priority given to those whose ill-health is in some sense 'self-inflicted' both conflicts with the original goals of the NHS and invokes a range of practical and ethical concerns. For example, unlike most other criteria for limiting healthcare resources – such as financial restrictions or clinical diagnoses – applying this principle could not be undertaken on economic or scientific evidence alone; it would demand the application of explicit social value criteria to priority-setting²⁰. From this perspective therefore, the 'responsibility principle' can be seen as a proposal of particular moral concern; it would, for example, possibly invoke social determinants of 'blame', 'punishment', 'desert' and, of course, 'responsibility' itself.

²⁰ Social value judgements, an increasingly influential factor in healthcare distribution policy, are examined in Chapter 5

Smoking and alcohol use are the most commonly cited examples of 'self-inflicted' illness-causing behaviours, others conditions that it has been claimed should affect priority for health care include obesity, drug abuse and lack of physical exercise (Moss and Siegler, 1991; Bikhchandani *et al*, 2007; Grice, 2006; Glantz, 2007; Feiring, 2008).

The topic has been extensively debated in the academic literature (e.g. Bowling, 1996; Dolan *et al*, 2005; Steinbrook, 2006; Buyx, 2008; Browning and Thomas, 2009; Sharkey and Gillam, 2010; Snelling, 2012; Persson, 2013). Although it remains, with a few notable and well-publicised exceptions, such as stories of obese patients being denied priority treatment if they do not change their lifestyle (Grice, 2006), a primarily theoretical debate:

Scholars are only at the beginning of exploring what a 'responsibility principle' may imply for healthcare allocation (Bringedal and Feiring, 2011: 357)

However, it is a proposition that increasingly appears to be gaining credibility with both healthcare professionals and the public. For example, in 2012, the findings of a survey reported that a majority of doctors support measures to deny treatment to smokers and the obese. Respondents to the survey were asked "*Should the NHS be allowed to refuse non-emergency treatments to patients unless they lose weight or stop smoking?*":

Some 54% of doctors who took part said the NHS should have the right to withhold non-emergency treatment from patients who do not lose weight or stop smoking. Some medics believe unhealthy behaviour can make procedures less likely to work, and that the service is not obliged to devote scarce resources to them (Campbell, 2012)

4.4 PUBLIC SUPPORT

The requirement for healthcare policy to reflect public views is increasingly acknowledged (Menzel, 1999; Richardson and McKie, 2005; NICE, 2008a), and indicates a need for public consultation in value-based distributional decision-making (McKie *et al*, 2009; Mitton *et al*, 2009):

For a particular value judgement to be incorporated into the methodology it must demonstrate 'social legitimacy' – that is, there must be systematic evidence of societal support for the change (Shah, 2009: 78)

As is maintained throughout this thesis, consideration of the 'responsibility principle' demands effective public participation.

In an extensive review of the literature pertaining to people's preferences regarding the maximisation of health benefits, Dolan *et al* (2005) reported on a wide range of views, noting that:

There is some evidence to support the view that people who are considered to be responsible for their ill health should be given lower priority ...it is certainly an issue that generates much controversy (ibid: 205)

This was confirmed by Edlin *et al*, (2011) who reported that responsibility plays a significant but not necessarily pivotal role in the public's view of priority setting.

Walker (2010) describes a feeling that those whose ill health is in some sense self-inflicted should be given lower priority for health care as "*a common and recurring intuition.*" This 'intuition' has been examined by a number of authors (e.g, Ubel *et al*, 2002; Dolan and Tsuchiya, 2006; Sharkey and Gillam, 2010).

4.5 ADVANTAGES/JUSTIFICATIONS

The justifications for adopting a 'responsibility principle' are most often expressed in terms of either enhanced equity or with regard to the perceived economic benefits.

The equity benefits are explained with reference to a potential increase in justice and fairness – rather than simply equality – within healthcare distribution (Olsen *et al*, 2003). Personal responsibility for ill-health is one of a range of potential QALY-weighting criteria (see Chapter 3), the application of which, it has been claimed, would demonstrate a fairer approach to both healthcare distribution and priority-setting (Walker, 2010). Identifying responsibility as a priority-setting factor would increase equity by compelling those individuals deemed to be 'morally culpable' to be held accountable for their actions – in the sense that their actions ('self-inflicted ill-health') have a potentially negative impact on other 'non-culpable' individuals,

In addition to the financial need to identify acceptable priority-setting criteria due to limited resources, one economic justification for incorporating the principle is the increasing costs of 'lifestyle-related' illness. For example, it is estimated that a continuing trend in obesity will present a loss of 2.2 to 6.3 million QALYs in the UK

during 2010–30 (Wang *et al*, 2011).

In 2012, a report by the NHS Future Forum recommended the NHS to:

...use every contact with patients and the public to help them maintain and improve their physical and mental health and wellbeing
(Department of Health, 2012: 8).

The report was regarded by some as part of a strategy to reduce related healthcare costs, which Campbell (2011) labelled "*An exploding timebomb of bad lifestyles*".

Responsibility may be evaluated from the perspective of several theories of justice. In the context of an examination of the 'responsibility principle', it may be considered most effectively from the perspective of distributive justice – concerned with the socially just allocation of goods – that is ordinarily reflected within the economic framework used to distribute economic benefits and burdens across members of society (Roemer, 1996).

Acceptance of a 'responsibility principle' may also accord with a concept of social justice as described by Rawls (1971 & 1999) who notably advocated the concept of 'justice as fairness', achieved by advancing 'ends' through cooperation. Rawls' first principle of justice claimed that "*Each person is to have an equal right to the most extensive total system of equal basic liberties compatible with a similar system of liberty for all*" (Rawls, 1999: 266) and his second principle stated that "*Social and economic inequalities are to be arranged so that they are both: (a) to the greatest benefit of the least advantaged, consistent with the just savings principle, and (b) attached to offices and positions open to all under conditions of fair equality of opportunity (ibid)*". These principles indicate the potential for philosophical recognition (at least) of a 'responsibility principle'. For example, the first principle may be considered in light of access to healthcare services (an equal right for all); the second, and more applicable, principle indicates that individuals believed to have directly brought about their healthcare needs may have weaker claims on social resources to meet those needs than 'non-culpable' individuals (achieving benefit to the least advantaged).

Clearly, the reliability of such an evaluation of the 'responsibility principle' from the perspective Rawls' principles of justice would be reliant on how the notion of 'least advantaged' is defined in this context. In order to determine fair principles of social

justice, Rawls offered a model of a fair choice situation (the 'veil of ignorance'); a hypothetical choice of mutually acceptable principles of justice taken from a position from outside of the society of which the chooser is a member²¹. Rawls claimed that people would adopt principles to govern the assignment of rights and duties and regulate distribution of social and economic advantages across society and that, by choosing from behind the 'veil of ignorance', they would have to accept these principles as fair. It would, it is contended, be desirable that the public's support for the 'responsibility principle' be evaluated from such a hypothetical position.

4.6 POTENTIAL CHALLENGES

Conceptually at least, it may be possible to accept that, when healthcare resources are limited, individuals should accept some responsibility for their use of these resources.

Distinguishing between patients – which implies denying treatment to one in favour of another – on the basis of whether they are considered responsible for their ill-health, challenges the conventions of NHS care. The degree to which an individual should be considered to be 'responsible' for their ill-health is both debatable and indeterminate. Healthcare professionals could therefore be asked to adopt a judgemental role with regard to determining the extent to which a patient has knowingly ignored a known risk.

There are convincing moral arguments for exercising caution before allowing healthcare priority-setting to be influenced by perceptions of patients' responsibility for their healthcare needs (Wikler, 2002) and for favouring a system that focuses on meeting patients' needs rather than asking whether they 'deserve' to be treated. One of the main difficulties would be ensuring that resource allocation, according to this principle, is undertaken fairly. Four broad conditions would have to be met:

1. The need for healthcare must have arisen as a direct, identifiable, result of an individual's actions
2. Such actions should have been undertaken autonomously
3. The individual should have been aware that the actions would create a healthcare need

²¹ See section 3.2.3

4. The individual should have been aware when they acted that their healthcare needs resulting from it would receive lower priority

Satisfying such conditions would be extremely difficult as each is open to interpretation and potential challenge. Brock and Wikler (2006) outlined the difficulties associated with one commonly cited source of 'self-inflicted' illness – smoking:

Smoking is typically begun when individuals are young adolescents, and ... it is highly addictive, which undermines the voluntariness of continuing to smoke. Individuals in industrial countries are now generally familiar with the health risks of smoking, but this is less true among less educated populations in developing countries, where smoking is an increasing problem. No one anywhere has been informed before they smoke that, if they do, their health needs from smoking will receive lower priority for treatment than will other health needs. Thus, it would generally be unfair to give smokers lower priority for treatment of smoking-related diseases on the grounds that they were morally responsible for those health needs

4.7 THE ARGUMENTS

Sharkey and Gillam (2010) reported that the 'responsibility debate' commenced in 1991 with the publication of opposing papers concerning alcoholic patients and liver transplantation (Cohen and Benjamin, 1991; Moss and Siegler, 1991). The debate intensified with the publication, two years later, of opposing papers regarding smokers and access to coronary artery bypass surgery (Underwood and Bailey, 1993; Shiu, 1993). In a helpful review, Sharkey and Gillam (2010) mapped out the relationship between, twelve key arguments – and counter arguments – relating to what they termed "*the lower priority debate*". These were divided into arguments that lie within three broad areas: *medical*, *policy* and *moral*. Sharkey and Gillam (2010) reported that most of the identified arguments had been refuted and that the debate (on self-inflicted illness) has therefore stagnated. However, this view was, itself, refuted by Bringedal and Feiring (2011: 357) who stated that:

Far from being stagnated, or stalled...the debate about responsibility for health is flourishing and is also offering alternatives to the luck egalitarian version of the principle of health responsibility

With regard to the current study, it is contended that the debate is ongoing but that it has not progressed due to the limitations of inquiry conducted into the key issues that lie within the spheres of public perceptions and social values.

4.8 RESPONSIBILITY

Of the many questions raised by a consideration of the 'responsibility principle', perhaps the most fundamental yet most insoluble relates to the concept of 'responsibility' and, in particular, how it should be defined in this context.

The extent to which it is reasonable to declare an individual 'responsible' for his or her actions is the subject of long-standing ethical and legal debate, which is predicated on the concept of responsibility itself. I.e. what does it mean to be 'responsible' for the commission of an act? How is such 'responsibility' determined? Any justification for a responsibility principle must respond to such questions by clearly defining responsibility and acknowledging both the degree of responsibility an individual should bear (for their ill-health) and how this might be evaluated (Strawson, 1994; Speak, 2013). For example, which illness-inducing factors should be considered relevant to identifying ill-health as 'self-inflicted'? Which of these might people be held responsible for and to what extent? (Anand and Willoo, 2000; Sharkey and Gillam, 2010). For, as has been noted, an individual can only be considered blameworthy for actions that are within their own control and therefore, 'self-inflicted' ill-health cannot be solely aligned with 'responsibility':

...not every smoker develops cancer; indeed, 80% do not. The fact that he [the smoker] is in the 20% that do is not solely a question of choice but, at least in one sense, of bad luck. Hence his health in such a situation is in large part an outcome of a random "lottery" and thus beyond his control-except insofar as he chose to enter the lottery (Le Grand, 1987: 271)

It could be argued, for example, that the heavy smoker is a 'victim' of their addiction and, as a result, should not bear responsibility for their ensuing healthcare needs (Martin, 2001).

The issue of clearly determining the degree of responsibility upon which a 'weaker claim' may be based may ultimately prove insurmountable. The relevance and legitimacy of personal responsibility in priority-setting is, therefore, far from conclusive (Cappelen and Norheim, 2005; Daniels, 2011) and the question of whether it maintains social or ethical validity persists and is a central feature of this study.

4.9 RIGHTS

Acceptance of the 'responsibility principle' would depend on responses to rights-based questions such as:

Do those who fail to take care of their own health have a lesser right to treatment for resultant diseases? (Steinbrook, 2006)

Is a claim to healthcare less legitimate if the individual contributes to their illness than if no such correlation is established? (Bringedal and Feiring, 2011).

The view that individuals are accountable to the other members of the society to which they belong offers some justification for the inclusion of a 'responsibility principle'. If an individual is considered to be accountable in this way, it may suggest an attendant duty to behave in a certain manner in accordance with the conditions of that accountability. It may further imply that other people ('society') have a 'right' (a justified entitlement) to expect that duty to be fulfilled and, where it is not, a corresponding right to act (or not act), by for example, limiting the accountable individual's access to healthcare.

It is conceivable therefore to translate this view into an argument that accepting responsibility for ill-health or healthcare need means having a positive duty – in accordance with the rights of society – to 'look after yourself' healthcare-wise.

Broadly, rights may be divided into three categories: *moral rights*; *legal rights* plus what may be described as *special* or *institutional rights* that are created as a result of prior action such as contracts or membership of a group or society. The concept of moral rights lies at the heart of the 'responsibility debate'. However, it is in terms of enforceable 'legal' rights that any practical measure to incorporate responsibility as a priority-setting or weighting principle criterion would be established. Currently, a legal right to healthcare is only limited by the availability of healthcare services or by clinical judgement.

4.9.1 A RIGHT TO HEALTHCARE?

The existence of a 'right to healthcare', and whether or not such a right can possibly be absolute or unconstrained, has long been the subject of considerable debate (Buchanan, 1984; Eleftheriadis, 2012).

The first guiding principle of the NHS is that it provides a "comprehensive service available to all" (NHS for England, 2013) and this principle applies:

... irrespective of gender, race, disability, age, sexual orientation, religion, belief, gender reassignment, pregnancy and maternity or marital or civil partnership status.....It has a duty to each and every individual that it serves and must respect their human rights (ibid: 3)

The concept of rights in relation to the 'responsibility principle' is centred on whether any right to healthcare could (or should) be diminished by the degree to which a person is considered to have contributed to their own ill-health. In other words, could society's duty to provide healthcare be weakened in relation to people's self-chosen actions?

If we assume that all citizens enjoy a right to a decent minimum of healthcare, can particular individuals forfeit that right even when they wish to preserve it?When people engage in such actions, does society have the same obligation to provide healthcare to them as it does to patients who need care because of bad luck in life's lottery of health? (Beauchamp and Childress.2001: 358)

An argument in support of this view would be that a lifelong smoker, for example, has created a need for healthcare treatment that arises as a direct result of their smoking, by their persistent and apparently autonomous actions. As a result, the argument proceeds, the smoker must accept that their right to healthcare is diminished and society's duty to provide healthcare is reduced accordingly²².

In this sense, a right to healthcare is conditional on acting in accordance with identifiable duties. For example, a duty to not deliberately harm oneself to the point where others would be required to intervene (financially or in other ways). Or a duty to maintain optimal health and therefore minimise one's need to utilise finite healthcare resources²³. The smoker, it may be argued, has diminished their claim to treatment when compared with the non-smoker who requires the same healthcare intervention through *no fault of their own*. The argument is not that an individual should lose the right to all forms of healthcare. It is that their right to certain forms of healthcare – arising as a direct result of their actions – is diminished i.e. it is weaker than the right of those whose ill-health is not 'self-inflicted' (Anand and Wailoo, 2000).

²² Although this argument and its conclusions may be valid, it is purely theoretical, and as has been highlighted already, it would present many practical challenges

²³ Therefore, this argument proceeds, in order to justify an entitlement to healthcare, individuals have a moral duty to safeguard their own health

4.10 AUTONOMY

A key issue in appraising responsibility (in any circumstances) is determining the degree to which an individual may be considered responsible for their actions. This, it may be argued should include an appraisal of the extent to which they have acted autonomously.

There are, potentially, numerous social and cultural factors that may enhance or inhibit the exercising of autonomy and it is questionable whether all lifestyles, lifestyle choices and any related ill-health are necessarily a direct consequence of fully autonomous choices (Devisch, 2011).

It is acknowledged for example, that an individual's socioeconomic status has implications for autonomous action and the expression of personal preference through choice. A potential by-product of higher socioeconomic status is the enhanced ability to exercise control, self-efficacy, and self-direction (Snibbe and Markus, 2005). In other words:

...some people get more of what they want, more of the time, than others (ibid: 703)

Level of education may also influence an individual's ability to exercise autonomy and, possibly, to perceive the extent of individual choice. Also, issues of addiction and other mental disorders may cloud the objective evaluation of a fully autonomous choice. For example, how 'free' is the smoker (or alcoholic) with regard to their actions? Is it possible that he or she may be regarded as 'victims' of their addiction and therefore not wholly accountable for their health care needs?

It is also acknowledged that autonomy requires more than mere freedom from interference (MacDonald, 2002). Sherwin (1998) emphasised the importance of supportive social conditions for nurturing autonomous action and noted that an individual's relationships with others and with institutions must be constituted in such a way as to facilitate genuine opportunities for choice²⁴.

The implication of such apparent enhancement or reduction of autonomy in accordance with factors such as socioeconomic status, education and addictions, or

²⁴ The concept of 'relational autonomy' is discussed in Chapter 2

with regard to personal and institutional relationships, is that the notion of autonomy – with regard to determining the degree of responsibility an individual should bear for their actions – is not clear-cut.

Where an individual persistently lacks the capacity for rational thought, decisions and action – as with a progressive condition that diminishes mental capacity such as dementia – overriding their autonomy (to the extent to which they are perceived capable of having or exercising autonomy), may be claimed to be ethically justifiable (Rabins and Black, 2010). Their autonomy is diminished (or absent) and therefore the requirement to respect autonomy is correspondingly reduced. The concept of 'best interests' is frequently invoked as moral justification for making decisions on behalf of those unable to exercise autonomy (Bingham, 2012).

However, circumstances where overriding autonomy is most clearly defensible is where someone's actions may cause harm to others. For example, if an individual's actions generate the need for a costly or scarce healthcare resource – an organ transplant due to liver damage caused by alcohol consumption for example – it may be claimed that their autonomous actions threaten harm to others who, through no fault of their own – liver damage due to infection for example – require the same limited resource and who may be unable to obtain it due to their place in the (egalitarian) queue. At the heart of the pro-responsibility autonomy argument is that overriding the first individual's autonomy is morally permissible as their entitlement to healthcare treatment is less valid than that of the less 'blameworthy' individual to that same treatment.

As has been demonstrated, the debate on the incorporation of a 'responsibility principle' is both complex and contentious. Although it is possible to perceive a number of valid theoretical ethical arguments in support of the proposal, many of the answers to questions it raises are not easily found. However, one issue that emerges is that, in order to progress the debate, there is a need for greater public involvement. There is empirical evidence that suggests that members of the public do wish to give less priority to those who are considered to be in some way responsible for their ill health and it is therefore essential that the 'responsibility principle' be systematically investigated in light of the public's views, values and

preferences. The next section of this thesis examines the role of public participation in healthcare priority-setting.

SECTION: B

PUBLIC INVOLVEMENT

5 SOCIAL VALUES

5.1 INTRODUCTION

The concept of social values plays an increasingly significant role in healthcare distribution. It is no longer the case that distributional planning can be predicated solely on considerations of cost and efficiency; social values – represented by the qualities and beliefs shared by and within a society – are now a fundamental consideration when determining healthcare distribution and priority-setting.

This chapter examines the concept of social values and social value judgements in relation to weighting health benefits and priority-setting.

The explanatory focus of this examination is the manner in which the National Institute for Health and Care Excellence (NICE) has identified social values as a key component of its role.

5.2 SOCIAL VALUES

It is acknowledged that within a publicly-funded healthcare system, distribution policy should reflect shared values that incorporate recognisable social concepts (e.g. 'generosity') and context-dependent moral sentiments (e.g. 'pride') that are believed to be commonly applicable to members of a society. These are generally defined as 'social values' (NICE, 2008c; Zahn *et al*, 2009). Social values:

...constitute preferences or evaluative claims about an aggregate or community of persons (Menzel, 1999: 250)

Social values are increasingly referred to within healthcare planning and distribution decisions and there is:

*...growing interest in involving citizens in policy development to ensure that decisions are legitimate, and reflect the broad social values of the public (Bombard *et al*, 2011: 135)*

There is also recognition of the need to incorporate the non-scientific, non-quantifiable but increasingly relevant aspects of healthcare delivery:

Values such as justice, equity, dignity, non-discrimination, autonomy, and solidarity figure prominently in debates about priority setting. The way in which these values are weighed in decision making varies widely between different countries, but policy makers the world over increasingly must grapple with the problem of how to strike a balance between the values in a way that is socially and ethically justifiable (UCL, 2013)

The perceived social value of a QALY – as opposed to its monetary equivalent – has been subjected to considerable empirical investigation (Baker *et al*, 2010; Donaldson *et al*, 2011). The social value derived from applying the QALY approach to healthcare distribution is generally determined via the estimation of health gains (in quality of life, length of life and number of persons treated) and, as previously observed (Chapters 2 and 3), is the same regardless of the characteristics of the individual(s) to whom the QALY relates. For example, an intervention that results in a small loss of QALYs for some but a greater gain of QALYs for others will result in net efficiency gains – and thus social improvement. Therefore, the social value of the standard unweighted QALY is commonly explained in terms of the QALY's health-generation and/or maximisation function.

However, it is generally acknowledged that social values cannot be evaluated simply in terms of incremental changes in health reflected in the standard QALY-maximisation approach i.e.:

QALY gains cannot be directly interpreted as a measure of social value (Gyrd-Hansen, 2004: 1102)

Dolan *et al* (2005) queried what they termed the "*descriptive validity*" of QALY-maximisation, noting "...a *diminishing marginal social value*" associated with changes in both health state and length of life determined by a number of factors, such as severity of illness and age.

Evidence from the literature suggests that many people would support using societal preferences to construct values for weighting QALYs in accordance with the individual characteristics or attributes of their recipients (Olsen, 2000; Wilmot and Ratcliffe, 2002; Lancsar *et al*, 2011).

Gyrd-Hansen (2004) identified a number of potential sources of social value, each of which reflects possible criteria for weighting QALYs (see chapter 3). Relating, for example, to factors such as age, social role and health-related lifestyle. As healthcare and healthcare distribution affects, to some degree, the lives of all

citizens and encompasses fundamental ethical concerns, the range of potential social values is wide. Baker *et al* (2013) found that there was a plurality of social values but noted:

...a paucity of rigorous research investigating the views of the general population in relation to the social values that should underpin healthcare resource allocation

5.3 ELICITING PREFERENCES FOR QALY UTILITY VALUES

Preference elicitation, regarding various health states, is one of the key features of the QALY method. It enables the quantifiable representation of 'quality of life' in the form of utility values and offers an insight into the practicalities of eliciting social values:

The bulk of the empirical work involved in making the concept operational is concerned with eliciting the values that people attach to different health states, and the extent to which they regard them as better or worse than being dead (Williams, 1995: 222)

Identifying the population from which preferences should be sought when seeking to obtain collective value judgements about a state of health has been the subject of considerable debate (e.g. Dolan *et al*, 2003; Brazier *et al*, 2004). For example, should preferences be sought from the perspective of individuals who are currently experiencing (or have experienced) a particular health state, or from those on whose behalf resource allocation decisions may be made but who may not (nor ever have been) in the health state at the time they assess its value?:

*The trouble is that these hypothetical preferences often bear little resemblance to the real experiences of those in the health states (Dolan *et al*, 2009: 371)*

It could be argued that the preferences of sub-groups – for example, patient groups such as inpatients, outpatients or recipients of cancer care, stroke, maternity, emergency care or mental health services – rather than individuals, would provide more collective judgements. However, it is generally accepted among health economists that preferences from general population samples should be used rather than those of discrete sub-groups (Conner-Spady *et al*, 2000). One frequently argued rationale for using members of the public is that, in a publicly-funded healthcare system, the views of the general population are most appropriate and most relevant (Gudex, 1986; Drummond *et al*, 2005; NICE, 2008a; EuroQol Group, 2013a; Tolley, 2009).

Respondents are normally asked to value health outcomes in terms of how they feel about it for *themselves* rather than in terms of how they feel about the health of others or of the community as a whole. Arguably, such individual, self-interested perspectives are insufficiently robust to provide (when aggregated) a collective 'social value judgement' about a state of health.

It has been suggested therefore, that the adoption of a broader more community-focused perspective, that considers the desirability of health states or health state changes to others, would be better able to incorporate broader social value concerns such as those relating to 'fairness' (Weinstein *et al*, 2009). Although Richardson and McKie (2005: 272) warned that:

The process of community consultation confronts a familiar problem. Encouraging subjects to adopt the "caring-for-others perspective" paves the way for judgments based on "fairness" and "justice". But it also paves the way for biased, intolerant, and dogmatic preferences

However, Menzel (1999) supported a view that most individuals would have preferences about what is good for society as a whole and would express relational or distributive values:

These would be societal values as expressed by individual members of the society – "individual social welfare functions," we might say (ibid: 250)

Morris *et al* (2007: 24) provided some reassurance for the aggregatability of individual preferences in terms of identifying social preferences and social values. Whilst acknowledging that the utility function within consumer choice theory *is* subjective and idiosyncratic and the utility obtained depends entirely on individual preferences – essentially the consumer's likes and dislikes – they noted that:

The consumer is, however, assumed to be rational, which essentially means that their behaviour is consistent with their aims. We assume that individuals behave as if they make decisions with the aim of maximising their well-being

Weinstein *et al* (2009: S7) stated that the individual-based approach to measuring value "...is consistent with the principle of consumer sovereignty, the keystone of welfare economics" that underpins the QALY process.

A number of authors, for example, Baker *et al* (2010) have discussed one of the inherent challenges of eliciting quantitative preference data i.e. the elicitation and explanation of values that arise from the non-medical, non-scientific features of a

health state. For instance, preferences for certain health states, at both individual and societal levels, may be dependent on a multiplicity of psychosocial considerations relating to influential factors such as personal relationships and employment status. Generic health status measures such as the EQ-5D (EuroQol Group, 2013a) may fail to capture all of these factors.

The process of eliciting preferences (the context, descriptions of health states, instructions etc.) may influence the preferences declared (Dolan *et al* 2005). Patrick *et al* (1994) discussed the 'cognitive burdens' involved in preference decisions, and Loomes and McKenzie (1989) referred to two phenomena that are of practical and theoretical concern with regard to the accurate elicitation of preferences. These are 'framing effects' – individuals' stated preferences between alternatives are liable to be substantially affected by the way in which the alternatives are framed – and 'utility effects' whereby different procedures for eliciting preferences, or even different variants of the same procedure, produce systematically different estimates of utilities for the same sets of outcomes²⁵.

5.4 HOW NICE HAS ADDRESSED SOCIAL VALUES

An examination of the role of social values in relation to weighting health benefits is aided by considering how NICE has addressed these concepts. The key point of reference for this evaluation is the NICE publication: *Social Value Judgements: Principles for the development of NICE guidance* (NICE, 2008c) – henceforth referred to as *Social Value Judgements*.

An exploration of NICE's approach also helps to further illustrate some of the ethical aspects of the QALY-weighting debate as *Social Value Judgements* has been described as an attempt by NICE to "...create an explicit ethical framework for funding decisions" (McMillan *et al*, 2006: 127).

5.4.1 NICE

Since being established in 1999, a particularly contentious feature of NICE's work has been its role in determining the cost-effectiveness of healthcare treatments. The organisation's approach to funding decisions has been frequently criticised; chief among these criticisms has been that NICE's funding threshold is inappropriate and

²⁵ A number of methods used to value health states are outlined in Chapter 2

that its evaluations fail to capture patients' personal experiences of their condition and treatments (Devlin *et al*, 2003). The need for an empirical basis for NICE's funding threshold of £20,000 to £30,000 per QALY gained has been highlighted (Donaldson *et al*, 2011; Claxton *et al*, 2013). NICE has also been accused of inconsistency in its approach to cost-effectiveness decisions; thereby exacerbating inequalities in access to healthcare (Cookson *et al*, 2001)²⁶.

In its early years, NICE faced increasing demands to acknowledge the impact of social values on its decision-making processes.

In 2009, in a significant development, NICE announced that, providing certain criteria were met, it would accept higher incremental cost-effectiveness ratios for some medicines over others, signifying that its appraisal committees would in future assign additional weight to health gains from life-extending end-of-life treatments (NICE, 2009a).

The change in NICE policy took place against "*a background of legal action by patients, attendant publicity and political discomfort*" (Raftery, 2009: 271). It represented an explicit departure from the distributive neutrality of the standard, impartial QALY model and was made in response to mounting concern that effective new drugs for end-stage cancer frequently failed NICE's funding threshold or 'cost per QALY' test. It also followed the publication of the 'Richards Review' (Richards, 2008), in which it was stated that:

Many stakeholders believe that the value society places on supporting people nearing the end of their life is not adequately reflected when the cost-effectiveness of drugs is appraised (ibid: 4)

A public consultation on the amendment to NICE policy found that the majority of respondents supported it on the grounds that rejecting proven life-extending treatments on the grounds of cost-effectiveness alone was not acceptable (NICE, 2009b).

²⁶ The bioethicist John Harris, in a critical exposition of NICE's approach to cost-effectiveness decisions which, he claimed, discriminate against the old and those with diminished life expectancy, stated that "*NICE should not be in the business of evaluating patients rather than treatments; to do so is contrary to basic morality and contrary to human rights*" (Harris 2005: 375)

5.4.2 NICE 'SOCIAL VALUE JUDGEMENTS'

Prior to this significant threshold change, the first edition of *Social Value Judgements* (NICE, 2005a) emerged following extensive consultation and a revised (current) edition was published in 2008 (NICE, 2008c). The aim of the publication is to offer guidance on the non-scientific aspects of NICE decision-making and to describe:

*...the principles that NICE should follow when applying social value judgements to the processes it uses to develop guidance. It is particularly concerned with the social value judgements that NICE should adopt when making decisions about effectiveness and cost-effectiveness (NICE, *ibid*: 5).*

The document as a whole summarises NICE's approach to value judgements relating to society (as opposed to scientific value judgements).

5.4.2.1 'SOCIAL VALUE JUDGEMENTS': QALY-WEIGHTING

The notion of QALY-weighting, either directly or by implication, is not a prominent concern of *Social Value Judgements*, which promotes a view that distributive fairness and an obligation to serve the interests of the entire population limit the capacity for subjective weighting of health benefits. Issues relating to cost-effectiveness – and, by implication, priority-setting – are addressed within a section entitled "*Evidence-based decision-making*". Although a number of possible weighting criteria ('Individual choice', 'Rare conditions', and the 'Rule of Rescue') are considered (albeit briefly), their potential contribution to NICE's decision-making is largely rejected. *Social Value Judgements* illustrates NICE's view that any attempt to restrict the use of a healthcare intervention to a particular sub-group, for example, according to a patients' age or gender, must be supported by:

...clear evidence about the increased effectiveness of this intervention in this subgroup (NICE, 2008c: 25)

Therefore, although the need to consider factors other than the relative costs and benefits of a particular treatment i.e. social values, is the focus of this publication, its central proposition is 'fairness', or the:

*...need to distribute health resources in the fairest way within society as a whole (*ibid*: 22)*

5.4.2.2 'SOCIAL VALUE JUDGEMENTS': AN 'ETHICAL FRAMEWORK'

In describing the social value principles (also described as "*broad moral principles*" (NICE, 2008c: 26)) that NICE should follow in developing its guidance – particularly with regard to the social value judgements that it should adopt when making decisions about effectiveness and cost-effectiveness (*ibid*) – it appears that NICE is attempting to provide a degree of ethical resilience for its procedures whilst offering a reasonably coherent manifestation of what the organisation terms its "*moral obligations to the people it serves*" (*ibid*: 29), and a degree of ethical sensitivity is therefore evident throughout *Social Value Judgements*.

Throughout the publication, issues such as fairness, equality, inclusiveness and support are emphasised and what might be regarded as 'ethical indicators', for example, terms such as 'principles', 'discrimination', and 'equality' are prominent. Reducing health inequalities, "*including those associated with sex, age, race, disability and socioeconomic status*" (*ibid*: 28) is a key ethical imperative for NICE and a short section of *Social Value Judgements* is dedicated to outlining the impact of NICE guidance on health inequalities (*ibid*: 28).

It may be argued that NICE's commitment to equality (as demonstrated within *Social Value Judgements*) highlights the need for equality within its own processes rather more than the need for equality within healthcare distribution. However, NICE's equality guidelines indicate that considerations of equality within resource allocation decisions (and not simply the processes involved in making these decisions) do contribute to NICE activities.

The second section of *Social Value Judgements* describes the core of NICE's ethical approach. NICE has adopted the 'four principles' approach to bioethics (Beauchamp and Childress, 2008):

Because they provide a simple accessible and culturally neutral approach that encompasses most of the moral issues that arise in healthcare
(NICE, 2008c: 8).

The section outlines the four principles - respect for autonomy, non-maleficence, beneficence, and justice, their relationship to healthcare and, to a lesser extent, their impact on NICE activity.

Reference to the four principles method is unsurprising given that it is a popular and influential approach to ethical analysis, however it should be noted that its ubiquity and extensive acceptance has been subjected to criticism (Campbell, 2003; Lee, 2010). NICE acknowledges the inherent tensions within and between the four principles and points out that:

These guidelines are, to a considerable extent, concerned with attempting to resolve the inherent tensions between them within the context of the social value judgements that NICE and its advisory bodies have to make (NICE, 2008c: 8)

The principle of autonomy, previously identified as an essential component of NICE's ethical approach, is constrained within *Social Value Judgements*. This is, perhaps, unsurprising given the organisation's role. As McMillan *et al*, (2006: 127) noted:

...the very mention of the principle of autonomy in a document such as this [Social Value Judgements] can give a very misleading impression

Although "*a well ordered society confirms the autonomy of persons*" (Rawls, 1999: 456) and the concept of the autonomous patient is an accepted tenet of 'good' healthcare, *Social Value Judgements* acknowledges that respect for autonomy "*cannot be applied universally or regardless of other social values*" (NICE, 2008c: 8) and states that individual's expectations of receiving treatment:

...should not impose a requirement on NICE's advisory bodies to recommend interventions that are not effective, or are not cost-effective enough, to provide the best value to users of the NHS as a whole (ibid: 20)

In outlining its ethical approach, *Social Value Judgements* emphasises the principle of justice. The "*problem*" (perhaps NICE's use of quotation marks here is illuminating – see below) of *distributive justice* is introduced and two approaches to distributive justice that can be used to resolve problems arising from the mismatch between demands and resources in healthcare are outlined (*ibid*: 9):

1) *The utilitarian approach (maximising the health of the community as a whole)*

and

2) *The egalitarian approach (to allow each individual to have a fair share of the opportunities available)*

The strengths and weaknesses of utilitarian and egalitarian approaches are acknowledged and it is stressed that NICE does not subscribe fully to either. Instead, it gives emphasis to 'procedural justice', ensuring that its decision-making process is transparent and its decisions explicit.

What amounts to an effective rejection of distributive justice as a key principle within this document is surprising, particularly in so far as NICE dismisses the egalitarian approach which, it states "*...cannot be fully applied when there are limits on resources*" (*ibid*: 9).

The conclusion drawn from such a reluctance to engage with the complexities of distributive justice is that NICE regard demonstrating its internal 'ethical processes' – as evidenced by transparency etc. – to be easier than ensuring external 'ethical practice', which would entail making multifaceted and potentially controversial recommendations. An impression is therefore conveyed that, despite a number of references to 'fairness' within *Social Value Judgements*, NICE is less concerned with ensuring that health resources are distributed fairly, or that they be maximised, than it is with confirming that it is, in itself, operating in an ethically justified manner. Although NICE declares the "*need to distribute health resources in the fairest way within society as a whole*" (*ibid*: 18), responsibility for ensuring distributive fairness it seems, lies with individual NICE committees and advisory bodies:

NICE and its advisory bodies must use their own judgement to ensure that what it recommends is cost effective and takes account of the need to distribute health resources in the fairest way within society as a whole (*ibid*: 22)

Reference is made to the work of Daniels and Sabin (2002) on the importance of "*accountability for reasonableness*". Referring to the consultation that preceded the publication of *Social Value Judgements*, McMillan *et al* (2006: 128) noted an apparent inconsistency in NICE's support for Daniels and Sabin's approach:

These authors [Daniels and Sabin] recognise that while justice is the overriding ethical concern for priority setting, it is not possible to describe a set of principles that will guarantee a just outcome. They think this is because we live in a pluralistic country and cannot expect there to be consensus about the principles that are relevant to prioritisation NICE has used the Citizens Council to do precisely what Daniels and Sabin think we cannot do – generate unproblematic principles that will automatically produce a just prioritisation

This 'inconsistency' remains within the current edition of *Social Value Judgements* in

which evidence from NICE Citizens Council reports²⁷ is implicitly accepted as a valid representation of mutually acceptable principles for decision-making.

Social Value Judgements appears to be an attempt to establish the ethical resilience of NICE processes whilst providing a reasonably coherent manifestation of NICE's "*moral obligations to the people it serves*" (NICE, 2008c: 29). It provides a broad 'ethical framework' for NICE advisory bodies and assists in an understanding of the ethical basis for NICE guidance.

A consideration of social values and how they may influence healthcare distribution decisions helps to elucidate the rationale for reflecting a 'public voice' within healthcare distribution policy. Healthcare priority-setting, it is asserted, is significantly aided by reference to social values, and this view is comprehensively supported by the available literature. The incorporation of a 'responsibility' principle within priority-setting, it is further contended, *demand*s the critical exposition of social values.

The increasing relevance of social values and social value judgements to healthcare distribution indicates a need for enhanced public participation to inform decision-making. The concept and impact of public participation are examined in the next chapter.

²⁷ The role of NICE Citizens Council is addressed in Chapter 6

6 PUBLIC PARTICIPATION

6.1 INTRODUCTION

It is increasingly argued that healthcare distribution policy should reflect public views, values and preferences and that there should be greater public involvement in priority-setting. The process of 'public participation' is the means by which decision-makers seek to engage with the public on such issues.

This chapter examines the role of public participation in healthcare priority-setting, with particular emphasis placed on how evidence of the public's views has been sought. A narrative overview of the literature identifies strategies for achieving public participation. Studies into deliberative approaches to public engagement are increasingly prominent, and the role of NICE's Citizens Council is examined as both an example of a deliberative focus group approach and a means by which public participation is sought.

A proposition is made that public participation in relation to healthcare priority-setting would be enhanced by understanding the ethical reasoning and arguments used to support the stated views, values and preferences of members of the public.

6.2 PUBLIC PARTICIPATION

As noted in earlier Chapters²⁸, the need for healthcare priority-setting to incorporate a valid public perspective is increasingly acknowledged (Menzel, 1999; Richardson and McKie, 2005; McKie *et al*, 2009; Mitton *et al*, 2009). In the current policy context, within which concerns about quality and accountability are increasingly considered, publicly-funded health systems wish to be seen as responsive to the expectations, needs and priorities of the public, and public participation (or public involvement²⁹) has become a key feature of UK health policy (Department of Health, 1999; Green and Gerard, 2009; *Health and Social Care Act, 2012*):

²⁸ The requirement for healthcare policy to reflect public views is noted in Chapters 1 and 4 (Section 1.2.5 and Section 4.4)

²⁹ The term 'public participation' and public involvement' are often applied interchangeably (e.g. Donovan and Coast, 1996; Litva *et al*, 2002)

Scholars have argued the need for public input to enhance the legitimacy of priority-setting decision-making, and governmental reports have advocated greater public input in health care priority-setting (Martin et al, 2002).

6.2.1 HOW PUBLIC PARTICIPATION IS ACHIEVED

Various mechanisms exist for involving the public in health policy, and public participation generally involves members of the public adopting one of two substantive roles: either as public *representative*, directly participating in decision-making processes, or as public *consultant* whose views are solicited to inform decisions (Abelson et al, 2007).

The roles are fulfilled in several ways. Examples include: NICE's Citizens Council, described by Abelson et al (2007: 42) as "...the highest profile example of an institutionalized public involvement model" (discussed in section 6.4 below); the increasing use of patient representation (Martin et al, 2002), for example in health technology appraisals and the formulation of clinical guidelines (NICE 2013b) and the use of patient and public involvement forums, which have become an integral part of the governance structures of NHS providers (Baggott, 2005). Within these settings, members of the public may directly participate in decision-making whilst also informing the on-going public debates on, for example, priority-setting and rationing medical treatment (Wright, 2011; Campbell, 2012).

Besides government-led initiatives that facilitate public involvement, there is considerable consumer-led activity. Structured patient groups, interest groups and organisations such as Alzheimer's Society (alzheimers.org.uk), the Spinal Injuries Association (spinal.co.uk) and the mental health charity MIND (mind.org.uk) provide an influential public voice to the formulation of treatment guidelines and key health policy decisions (Tattersall, 2002; Landzelius, 2006). In addition, organisations, support groups and charities representing a range of subcultural groupings based, for example, on ethnicity (blackmentalhealth.org.uk) and sexual orientation (stonewall.org.uk) offer an increasingly influential and diverse representation of public views and public involvement in the formulation of health policy.

With regard to public participation and this study, it is important to note that not all forms of public participation need to be representative of the population as a whole, nor do they need to directly influence decision-making. For example, local initiatives may be focused on engaging an identified engaged section of the public in order to

inform local policy. Alternatively, the public's views, values and preferences may be sought via researchers seeking to explore concepts and shed light on them with the aim of developing theory, rather than seeking representativeness (Corbin and Strauss, 2008)³⁰, and it is this process of public participation that is of most relevance to this study.

6.2.2 ARGUMENTS FOR PUBLIC PARTICIPATION

Arguments in favour of public participation are frequently stated in terms similar to that used to justify eliciting preferences for QALY utility values from members of the general public³¹ i.e. that in a tax-funded healthcare system, services are paid for by the public and their implementation should therefore be guided by them – it is the public's assessment of benefit that matters (Florin and Dixon, 2004).

A second argument in favour of public participation concerns the potential benefits that may ensue. Public participation, it is claimed, is a means of generating trust and improving accountability within healthcare systems (Church *et al*, 2002) and has the potential to create service improvement and improve public confidence in the NHS (Health Committee, 2007; NICE, 2013b). Thus, healthcare services, it is argued, will be more responsive to the people who use them and, in turn, more responsive services will lead to improved healthcare (Wait and Nolte, 2006). This argument in favour of public participation may also make reference to the perceived benefits for those individuals at the centre of healthcare delivery whose views, values and preferences, it is argued, may frequently not be heard:

Most of the parties involved in healthcare reform debates – governments, politicians, healthcare professionals, pharmaceutical companies, special interest groups – actively work to make their desires known. Despite their obvious interest in this debate, however, it is the patients who will likely have the greatest difficulty in providing input to these discussions
(Diederich *et al*, 2012: 1)

Practical motivations for public participation include: an appreciation of untapped community resources; broadening the range of inputs to decisions or solutions to health problems, and the belief that participation may lead to more cost-effective decisions (Frankish *et al*, 2002).

³⁰ Such studies are mainly founded within the academic areas of bioethics and health economics (see section 6.3)

³¹ Discussed in Chapter 5

A further contention may be that involving the public helps to ensure that health policy decisions – that have significant ethical as well as technical dimensions – more effectively reflect the values of the community. Public involvement is therefore, according to this view, an intrinsic 'good' in itself (Florin and Dixon, 2004). With regard to the focus of this thesis, this is an applicable argument for public participation; the socio-ethical implications of the incorporation of a 'responsibility principle' within healthcare distribution would, it is contended, require the effective exploration of both individual and community values via the involvement of members of the public in their role as public *consultants*.

6.2.3 ARGUMENTS AGAINST PUBLIC PARTICIPATION

Arguments against public participation generally make reference to the perceived limitations of public contributions, the divergence between public and 'professional' knowledge and understanding and the unwillingness of members of the public to engage in health policy debates (Frankish *et al*, 2002, Abelson *et al*, 2007).

These arguments include the view that health professionals are the legitimate and superior decision makers (Scanlan *et al*, 1996) and that participation would involve those who have less skill or knowledge than those responsible for carrying out the decisions and who are less accountable for outcomes than professional decision-makers (Brownlea, 1987). Concerns have also been expressed about the apparent validity of public preferences; that they may, for instance, be based on prejudices rather than factual information (Sharkey and Gillam, 2010). It should not therefore be assumed that public participation is universally regarded as an essential component of health policy activities. Indeed, Abelson *et al* (2007: 40) describe the call for public involvement as a "*popular "motherhood" gesture*" that overlooks the conflicting interpretations of who the public is and how the public expresses values.

The promotion of public participation may also overlook the fact that many members of the public may not actually wish to be involved in informing health policy. For example, the perceived importance of autonomy to the effective delivery of healthcare³² may encourage healthcare planners to believe that members of the public wish to be more involved in healthcare, or even that the public *expect* to be consulted about the quality of healthcare services and how the healthcare budget is

³² Autonomy is discussed in Chapters 2, 3 and 4

allocated. However, such an "*apparently seamless link between individuals as [autonomous] patients and individuals as citizens*" (Wait and Nolte, 2006: 155) should not be presumed. Members of the public may be less motivated to participate in health policy than professional healthcare decision-makers as a result of the divergence of their interests; the contrast in available information and levels of understanding concerning healthcare planning and policy and, perhaps most significantly, the fact that most members of the public ordinarily have only infrequent and unplanned contact with the healthcare system. This suggests that, despite the claims of those who promote public participation, the planning of and distribution of healthcare services may not be of particular concern to a significant proportion of the population.

Concerns regarding representation and influence may also affect members of the public's willingness to formally contribute to health policy initiatives³³. There may be a perception of limited representation by members of subgroups and subcultures and by those involved with the 'less glamorous' healthcare services such as mental health care (Donovan and Coast, 1996). In an assessment of guiding principles for the design of public involvement processes, Abelson *et al* (2004) reported citizens' concerns about:

... the unbalanced power relationships between participants and consultation organisers; and the exclusivity of processes with respect both to the selection of participants (i.e. who is invited/who is not invited) and the degree of content knowledge necessary to be able to participate meaningfully (ibid: 210)

Furthermore, although the public voice is increasingly influential, within most public participation initiatives, the role of the public in contributing to policy discussions is generally a reactive rather than proactive one. Authority rests with the policy-makers to determine how public input should inform healthcare decisions.

Although not strictly an argument against public participation, a particular difficulty faced by those wishing to facilitate public involvement is that definitions of 'the public' may vary³⁴ and 'members of the public' may assume different roles according to how they interact with the healthcare system. For example, contemporary users of NHS care have been claimed to assume concurrent roles of (among others)

³³ Representation concerns may deter public involvement in formal activities, such as patient and public involvement forums, rather more than participation in consultative approaches such as surveys

³⁴ Definitions used within this thesis are outlined in Chapter 1

'decision-maker', 'care manager', 'co-producer of health', 'taxpayer' and 'active citizen' (Coulter, 2002) and the means by which individuals traverse these different roles has implications for how they perceive both the healthcare services and their own involvement.

There is also extensive diversity within what is commonly termed 'public opinion'³⁵ as there is diversity among the individuals, groups and sub-groups that comprise the 'public'. One of the key factors in conceptualising public participation is to determine how such diversity could, or should be, managed. One of the inherent challenges of public participation is ensuring that – in its *representative* sense at least – it is able to draw together these different roles.

Ensuring meaningful public participation requires determining the extent to which individuals or groups can legitimately be regarded as representative of 'the public' (if generalisable representation is sought rather than representation via a consultative role³⁶). It also necessitates dealing with a range of stakeholders that include large organisations and smaller interest groups and ensuring that elicited views on societal distribution of healthcare are distinguishable from that of a self-interest perspective. Identifying the means by which public participation is facilitated – surveys, interviews, focus groups, for example, and ensuring a well-considered framework for analysis – are therefore important both in relation to eliciting views and in the interpretation of findings.

Although opportunities exist for participation across a range of healthcare-related organisations and settings, and the ways in which public participation is realised are many and diverse, there appears to be no single conceptual framework underlying public involvement (Wait and Nolte, 2006). Consequently, its aims demand clarification. Is it, for example, concerned with achieving *instrumental* goals i.e. to inform policy decisions? Or, more concerned with *process-oriented* goals that seek to improve the legitimacy of decision-making? (Abelson *et al*, 2007). Therefore, the evidence-base needed to support and enhance public participation is deficient (Staniszewska *et al*, 2008) and research is needed to investigate the rationale, aims and objectives applied within various public participation contexts. Greater

³⁵ See Chapter 1

³⁶ 'Generalisable representation' is used here to refer to participation processes that seek to demonstrate some generalisable aspects of public views, values etc.

transparency is also required regarding how public participation activities align with the general healthcare policy-making process.

6.2.4 PUBLIC PARTICIPATION – SUMMARY

From the above discussion it is evident that public participation/involvement in health policy activities is an ongoing and increasingly employed strategy that offers members of the public an opportunity to contribute in a variety of roles both directly (via representation) and indirectly (via consultation) in how healthcare services are planned and resources allocated. It has the potential to make a valuable contribution to health service policy decisions and may ultimately lead to improved healthcare.

However, the differences in lay-professional knowledge and the extent to which each is valued must be considered, and it should not be routinely accepted that members of the public wish to 'participate'. There is also need to ensure that diversity (of both the 'public' and 'public opinion') is effectively managed within a clearer conceptual framework for public participation activities.

With regard to the current study, the category of public participation under examination is that of public consultation and how the views, values and preferences of members of the public can contribute via this approach to the debate regarding a 'responsibility principle'. It is contended that such consultative participation, in which public participants may be purposively recruited, offers a significant degree of flexibility and adaptability to the diversity of public opinion and individuals' background, needs and expectations. Arguably, the methods used by researchers seeking 'public opinion' into healthcare policy issues – whether via quantitative or qualitative methods – can effectively enable the voices of otherwise unrepresented individuals and groups to be expressed within participation activities. A key consideration in this regard, is to the process of participant recruitment³⁷

6.3 LITERATURE OVERVIEW

The following is a brief narrative overview of the literature that outlines the theoretical and contextual framework of public participation in this area.

³⁷ This is discussed further in Chapter 10

There is a substantial body of literature exploring questions of public participation in priority setting and resource allocation Mitton *et al* (2011). Anderson *et al* (2011) noted an increasing trend to include the public in decision making and there is evidence that members of the public believe that their views ought to be considered with regard to setting health priorities (Mitton *et al*, 2011).

Policy and decision makers have acknowledged that the public's views should constitute an important, although not necessarily determining, input into priority-setting (Mitton *et al*, 2009; Mitton *et al*, 2011). The integration of public views with other perspectives is clearly required – rather than regarding the public view as the sole determinant of how healthcare resources should be allocated and priorities identified:

In the health field, theorists stress that citizens need to express their values to health policy-makers in order to assist them in setting health goals
(Murphy, 2005: 173)

However, the view that the public must be involved in healthcare distribution does not have total support. Robinson *et al*, (2011) reported that some NHS areas had taken a conscious decision not to involve the public in their priority-setting activities, arguing that:

...there was a need to get the process established in-house and that organisations from across the health economy needed to agree on decisions before involving patients or the public (ibid: 49)

A range of studies have examined the views, values and preferences of members of the general public in relation to various aspects of healthcare distribution, including: QALY-maximisation (Bryan *et al*, 2002; Dolan *et al*, 2005) priority-setting (Mason *et al*, 2011; Anderson *et al*, 2011), and QALY-weighting (Baker *et al*, 2010). Some have examined the views of members of the public together with those of health professionals (e.g. Coast, 2001a), and others have explored the reasons behind people's preferences (e.g. Dolan and Cookson, 2000; Madden *et al*, 2005).

The majority of studies appear to have employed quantitative methods and have therefore produced generalisable statistical evidence obtained via, for example, stated preference surveys (Buxton and Chambers, 2011). Some have been used to generate data that may be used to estimate relative QALY weights (e.g. Baker *et al*,

2010; Lancsar *et al*, 2011). Some studies have employed a mixed methods approach i.e. using both quantitative and qualitative methods (e.g. Bombard *et al*, 2011), whilst others have applied qualitative methods only. Various qualitative methods, using both individual and group-based approaches, have been used. These have included: focus groups (e.g. Dolan and Cookson, 2000; Block *et al*, 2001) and semi-structured interviews (e.g. Coast, 2001a; Dolan and Shaw, 2004). The findings of these studies offer the most substantial evidence available of public participation in relation to healthcare distribution.

6.3.1 DELIBERATIVE APPROACHES

Citizen deliberation has been identified as a key means for setting health-care priorities that aim to promote individual and community health
(Murphy, 2005: 173)

Enabling effective public participation in priority-setting requires the identification of empirically-based and ethically defensible social objectives (Richardson and McKie, 2005). Various strategies have been used in the design of more proactive public participation processes (Abelson *et al*, 2003) in an attempt to achieve meaningful citizen engagement in decision making. These have included deliberative strategies aimed at achieving more 'informed involvement', such as via 'citizens' juries' (Lenaghan, 1999; Mullen, 2000).

Mitton *et al*, (2009) suggested that authors of deliberative processes – such as citizens' juries' – find them to produce better results and that there appears to be increased satisfaction with the process when there are opportunities for face-to-face contact between the public and decision-makers. Abelson *et al* (2003: 239) observed that:

A common thread weaving through the current participation debate is the need for new approaches that emphasize two-way interaction between decision makers and the public as well as deliberation among participants.

Kim and De Vries (2009) proposed the practice of 'deliberative democracy' – involving ordinary citizens in deliberative political issues (Steiner, 2012) – as a means to overcoming the challenge of eliciting informed and considered ethical opinions from members of the public.

Robinson *et al* (2011) reported that the use of citizens' forums allowed members of the public to influence the planning of services. Issues regarding service-provision were highlighted at the forums and subsequently, action was taken to resolve these issues:

Although limited as a means of involvement in specific decisions, these forums were seen as beneficial in helping to address the broader issue of resource constraints and the need for priority setting (ibid: 50).

Mitton *et al*, (2009) undertook a scoping review to examine public engagement in priority setting and resource allocation. They reported that there appears to be growing interest in deliberative approaches to public engagement, which are more commonly on-going rather than one-off and more apt to involve face-to-face contact.

Citizen deliberation, where the public are "*exposed to the arguments of others*" (Dolan *et al*, 1999: 916), is a prominent theme in health policy literature:

...as citizens articulate their values, they may guide policy-makers to choose health services that respond to health inequalities associated with social contexts (Murphy, 2005: 172)

The Citizens Council of the National Institute for Health and Care Excellence (NICE)...

...where thirty people – from all walks of life and with no particular background in the subjects to be discussed or experience in public life – were recruited to advise a national level health policy agency on the value judgements that underpinned its decisions (Davies *et al*, 2005)

...was developed as a result of the increasing popularity of deliberative approaches in public engagement.

6.4. NICE CITIZENS COUNCIL

NICE's Citizens Council an advisory body made up entirely of members of the public (NICE, 2013c) seeks to enable public participation in the wide range of issues the organisation must respond to. The Council was established in 2002 to provide advice about the social values that should underpin NICE guidance and in order that such guidance should:

...broadly reflect the values of the population who both use the service (as patients) and who ultimately provide it (as taxpayers) (NICE, 2005b)

The Council represents a deliberative approach to public participation (Davies *et al*, 2005) and meets once a year to address pre-determined issues relevant to NICE's work. Meetings are usually held over two days during which Council members hear presentations from a range of experts and subsequently address the topic under discussion in various ways (within breakout groups, plenary sessions etc.) with the intention of producing recommendations submitted to the NICE board.

The aim of expert presentations, breakout groups and plenary sessions within Citizens Council meetings is to encourage Council members to communicate with one another and to explain their views on the issues.

A question or series of questions is posed for the Citizens Council to consider and Council members' views on a range of statements are sought via a 'tracking survey' at various stages within their deliberations. For example, at the start of the meeting, following exposure to expert presentations and at the end of the meeting. The Council's conclusions are usually presented, in the form of an 'Executive Summary' that includes examples of their discussions and data relating to the 'tracking survey'.

Council meetings operate in accordance with a deliberative focus group approach. Focus groups are used to explore a range of phenomena (e.g. Block *et al*, 2001; Wilmot *et al*, 2002; Abelson *et al*, 2009). Emphasis is placed on interaction within the group and the joint construction of meaning (Bryman, 2008). The aim is to capitalise on communication between participants in order to generate data (Kitzinger, 1995).

Since its inception, the Citizens Council has specifically addressed a number of topics relevant to the distribution of healthcare, priority-setting and rationing. These have included Age (NICE, 2004), Ultra-orphan drugs³⁸ (NICE, 2005c), The 'rule of rescue' (NICE, 2006a) and, in 2008, the Council considered QALYs and the severity of illness (NICE, 2008b).

The process of Council meetings and reports is recognition of the need for, although not necessarily clear evidence of, public involvement in formulating NICE guidance. The extent to which NICE seeks to assimilate public preferences within its guidance

³⁸ "Ultra-orphan drugs" is a term used to describe a drug indicated for a very rare disease. "NICE uses the term for conditions occurring in less than 1000 people in the UK" (NICE 2005c: 28)

is not fully articulated, within the Council's reports. It is not possible for instance to ascertain the degree to which empirically based social objectives were sought, empirical data being limited to results of the tracking surveys³⁹.

A further limitation of the reports is that there is little indication that the influence of group dynamics, such as the development and articulation of group norms that may inhibit dissenting voices, has been considered. In addition, the involvement and influence of the moderator(s) is not well defined.

Overall, with regard to the NICE Citizens Council, the impact of public participation is not clearly defined and there seems to be a lack of integration of the Council's findings into the wider activities of the organisation.

6.5 ENHANCING PUBLIC PARTICIPATION

It has been reported that within conventional approaches to healthcare economic evaluation there is a general assumption that people's preferences are commonly applicable (Richardson and McKie, 2005), despite evidence suggesting that such methodological dogma may lead to widespread public attitudes being overlooked, misrepresented or even ignored (Dolan *et al*, 2005).

Many policy analyses proceed from an assumption what ordinary people want, assumptions about the effect of different kinds of intervention, or assumptions about the motivation of different actors. Unfortunately, such assumptions may be wrong, and the whole analysis thereby misleading. It is not sufficient to assume what the 'person on the Clapham omnibus' thinks, believes, or wants, at least not if it is a matter that could be investigated (Holm, 1997: 30)

Unsupported survey results may offer an insufficient understanding of what the public feel about how resources should be allocated. Such evidence is susceptible to criticism that it is unsupported by evidence of valid arguments (Harris, 2005).

Therefore. A more in-depth approach to eliciting and analysing the views, values and preferences of members of the public regarding healthcare priority-setting is required in order to both improve the depth of understanding and to enhance the influence of public participation.

³⁹ There is little evidence of how the Council's recommendations were attained other than by the on-going voting system reflected within the tracking survey of opinions.

Deliberative approaches to public engagement may enable the elicitation and analysis of social objectives. However, for these objectives to be ethically valid, they must be ethically defensible. The process of eliciting and analysing *ethically defensible* public views, values and preferences regarding priority-setting therefore demands systematic examination.

It is contended that this may be achieved by exploring the underlying ethical reasoning used by members of the public in relation to priority-setting, and by examining how such reasoning is applied in the form of ethical arguments. There is little evidence in the available literature to suggest that this has been undertaken (see Chapter 8).

The next chapter examines the concepts of ethical reasoning and argumentation and considers how these concepts have been examined in relation to healthcare distribution.

7 ETHICAL REASONING AND ARGUMENTS

7.1 INTRODUCTION

In order to enhance public participation in healthcare priority-setting, and to improve both the understanding and influence of the views, values and preferences of members of the public in this area, it is necessary to identify and examine empirically-based, ethically-defensible social objectives that may helpfully inform policy debates.

It is contended that the elicitation and examination of ethical reasoning and arguments used by members of the public to support their stated views, values and preferences regarding healthcare priority-setting – particularly in relation to the application of a 'responsibility' principle – would contribute to the identification of such ethically-defensible objectives.

This chapter explores the concept of ethical reasoning and argumentation and considers how they have been elicited and analysed. The rationale for exploring reasoning and arguments in relation to healthcare priority-setting is defended, particularly in relation to how their elicitation and analysis could increase awareness of the public's views, values and preferences and enhance public participation in healthcare priority-setting. A lack of available evidence of the examination of ethical reasoning and arguments is identified.

7.2 ETHICAL REASONING AND ARGUMENTS

The technical notion of an argument reflects the process of deductive reasoning (Overton, 1990; Fisher, 2004); it is typically represented by an ordered pair, consisting of premises and a conclusion that directly results from the premises (Parsons, 1996). Its validity relates to its adherence to a logical form, i.e. "*the conclusion follows from the reasons as a matter of logic*" (Thomson, 1999: 39), the truth of its premises and the extent to which it is able to withstand objective scrutiny and be justified. In surveys where unreasoned preferences are sought (e.g. "*State how strongly you agree with the following...*"), there is no potential for reasoning or arguments to be elucidated so any 'conclusion' offered is unsupported.

An ethical argument is distinguished by a conclusion that makes some sort of moral claim: that may be an imperative i.e. "You should do x, for a, b and c reasons" or that something is (morally) *right* or *good* (Thomson, 1999). The conclusion therefore functions as an authentic reasoned ethical preference.

Ethical arguments are distinct from simple expressions of values or preferences; they are more representative of a 'process' within which reasoning may be exposed (Lawrence and Helm, 1987). Therefore, in addition to arguments that accord with the traditional technical-logical framework it is possible to discern ethical arguments from within the evaluative processes people employ to justify their views and preferences. Banks *et al* (2006) identified some of the components of such evaluative processes, including:

- Expressing an instinct or gut feeling; making distinctions;
- Reference to ethical principles
- Use of personal experience
- Use of analogies, parallels and examples
- Slippery slope arguments

The processes of ethical deliberation can therefore produce recognisable ethical arguments that do not necessarily arise from rational, logical forms of argumentation. For example, if an initial, possibly intuitive, reaction to a question or topic is referred back to within a process of ethical reflection (applying one or more of the components of ethical evaluation described above) which ultimately leads to a conclusion; and a coherent link can be made between the two positions (starting point and conclusion) i.e. there is evident coherence between the intuition, components of evaluation and conclusion, it may be possible to identify a justified, valid, ethical argument (Banks *et al*, 2006).

An example of an ethical argument is evident within a frequently cited priority-setting principle – the 'rule of rescue':

...the imperative people feel to rescue identifiable individuals facing avoidable death (McKie and Richardson, 2003: 2407)

Its application is evident within such life-saving, but costly, interventions as renal dialysis and major organ transplantation. It is broadly based – within a healthcare

context – on an ethical argument constructed as follows (premises^A and conclusion (moral claim)^B indicated):

- Allowing a person to die when interventions that may save their life are available is morally wrong^A
- Lifesaving interventions (e.g. renal dialysis) are available^A
- Therefore, people must not stand idly by if such rescue measures are available^B

This argument implies that greater weight should be attached to the health gains of the severely ill or those facing the threat of imminent death. Jonsen (1986) claimed that the 'rule of rescue' argument derives from an instinctive rather than utilitarian imperative, and Hadorn (1991) as cited by Richardson and McKie (2005: 269) observed that:

...any plan to distribute health care services must take human nature into account if the plan is to be acceptable to society

However, as McKie and Richardson (2003: 2411) argue, the 'rule of rescue' can also be *defended* from a utilitarian point of view: "*...on the basis of the utility gained by the individual from the knowledge that an attempt to help has been made*". To this may be added a further utilitarian justification: that overall well-being is increased if people believe that they live in a society in which such a 'rule' is applied. Subjecting ethical arguments to even rudimentary examination therefore, reveals underlying – and possibly contradictory – views, motivations and obligations.

One of the basic requirements for examining ethical reasoning and arguments is that the examination should produce findings that are objective and able to withstand scrutiny. This means identifying evidence and valid arguments in support of stated views, values and preferences that are objective and justifiable:

If that support is strong, and if it is not culture bound, that is, accepted by people in one specific culture and not generally accepted in other cultures, then anyone at any time should follow the argument and accept the claim that comprises the argument's conclusion. If the claim commands our consent because of the compelling nature of the support for that claim, then we can say with some confidence that the claim is not simply a matter of personal opinion or cultural perspective: It is 'objective'. As the British philosopher Karl Popper has said, "objective means justifiable, independently of anybody's whim": a justification is 'objective' if in principle it can be tested and understood by anybody. What we seek in ethics are precisely those elements and features of an ethical argument that we are compelled to accept whether we want to or not, 'independently of anybody's whim' (Curtler, 2004: xvii)

7.3 RATIONALE FOR EXAMINING REASONING AND ARGUMENTS

To identify empirically-based and ethically defensible social objectives that will helpfully inform policy discussions, the reasoning that underpins people's stated views, values and preferences must be examined and the arguments used to construct and defend these judgements must be effectively analysed.

Examining the ethical reasoning and arguments that underpin members of the public's views, values and preferences would, it is contended, enhance public participation within healthcare priority-setting. It also offers the potential to examine 'public opinion' regarding a contentious proposal such as that presented by the 'responsibility principle', to a greater and more explanatory depth than has hitherto been achieved.

For example, it is possible that the existing evidence of support for (or opposition to) QALY-weighting may be flawed if stated preferences are based on conflicting or inconsistent reasons. Recognising possible conflicts and inconsistency in reasoning are important factors in arriving at a well-considered decision (Hardman, 2009), i.e. only when it is acknowledged that, in reasoning terms, "*you can't have it both ways*", is a valid decision possible. Effectively exploring preferences therefore involves the identification and, hopefully, resolution of conflicts and inconsistencies in reasoning (Thomson, 1999). Most importantly, and what existing studies have tended to overlook (see below), examining reasoning and arguments would allow the exploration of the reasons *why* people regard certain issues (in relation to 'responsibility' and priority-setting) as important.

In order to identify logically valid arguments, the ways in which members of the public seek to resolve both logical and ethical conflicts, inconsistencies and

contradictions in their responses should be considered. For example, are reasoning strategies and arguments contradicted or rejected in response to contrasting prioritisation strategies? Or are moral distinctions made between types of 'self-inflicted' ill-health? By exploring the processes of ethical reasoning and argumentation, it may be possible to identify which ethical principles, theories and concepts are used to underpin people's views, and whether or not some moral concepts are dominant.

If ethically defensible preferences can be identified from forms of ethical reasoning and argument that are distinguishable from self-interest, a social perspective might be a legitimate one (Dolan *et al* 2003). Dolan and Tsuchiya (2006: 387) explained how a legitimate societal perspective may be obtained:

The societal perspective can be operationalized in two ways. One is by indicating that the respondents themselves are not directly affected by the scenarios, and the other is by indicating that they are to imagine themselves making decisions for a community to which they themselves belong. The latter is sometimes called the societal inclusive perspective. In order to establish whether the social perspective is being achieved, the effect of self-interest on the results can be tested

However, concern has been expressed that ethical arguments proposed by members of the public lack philosophical contemplation. Scully *et al* (2006a: 751), commenting on the view that many expert scientists and bioethicists find lay people's ethical judgements less trustworthy than those of professional ethicists, stated:

These experts suggest that, instead of weighing the evidence and the arguments, non-philosophers usually have an immediate response to an issue, and then search for reasons to legitimate their intuitions

Such concern may also reflect a perception of public views and values regarding health-related ethical issues as inconsistent and poorly defined, thereby making their elicitation and analysis – beyond quantitative approaches – both problematic and ultimately, an inapplicable basis for public policy (Levitt, 2003; Harris, 2005).

However, this perception has been refuted and it has been argued that publicly-stated arguments should be valued as much as those within professional bioethical discourse (Scully *et al*, 2006b, Partridge *et al*, 2009). Nonetheless, a comparison of ethical arguments put forward by members of the public with those applied within professional discourse could potentially make a valuable contribution to the public

participation/priority-setting debate.

7.4 A LACK OF AVAILABLE EVIDENCE

A range of studies – chiefly within health economics⁴⁰ – have examined public views, values and preferences concerning various aspects of healthcare distribution, including for example: QALY maximisation (e.g. Bryan *et al*, 2002); priority-setting, either in accordance with health gain (e.g. Mason *et al*, 2011) or based on patients' individual characteristics (e.g. Anderson *et al*, 2011); and QALY weighting (e.g. Baker *et al*, 2010), and there is evidence that public attitudes towards healthcare distribution are influenced by various ethical concerns. For example, Olsen *et al* (2003) reviewed the ethical reasons underlying people's views on incorporating personal characteristics within healthcare priority-setting and reported that utilitarian and egalitarian explanations appear to be frequently used, in addition to justifications based on individual desert and merit.

However, confirmation of 'what the public think' about how healthcare is distributed and how priorities are identified is mostly founded on generalisable statistical evidence obtained via, for example, the self-completion of questionnaires (e.g. Dolan and Shaw, 2003) or interviews in which participants were asked to state and explain preferences in order to assist the further development of quantitative measures of preferences (Shaw *et al*, 2001). Obviously, the primary purpose of such studies has not been to examine reasoning and arguments. Olsen *et al* (2003: 1171) noted the lack of research aimed at distinguishing "*ethically based considerations from prejudices*" and called for increased qualitative research designed to probe people's beliefs and their ethical bases.

A number of studies have examined 'lay', or 'non-expert', ethical reasoning and arguments relating to topics other than healthcare distribution, including: medical genetics (Banks *et al*, 2006) and the use of technologies to extend human lifespan (Partridge *et al*, 2009).

Banks *et al*, (2006) examined the processes by which non-professionals make

⁴⁰ Hasman (2003:43) reviewed the empirical literature on priority setting in healthcare and explained that the differing aims of researchers are dependent on their professional focus: "*Economists tend to elicit the preferences people have in the priority choice situation, political scientists look for political incentives and public opinion, whereas ethicists traditionally focus on the principles or values, which people hold*"

ethical evaluations in relation to a contested area in medical genetics. The authors examined participants' reasoning and arguments and highlighted the role played by the use of personal experience, analogies and examples, noting that:

The issues that lay people find important, and the ways they express and develop their opinions and arguments, constitute an important dimension in policy decisions (ibid: 300)

Partridge *et al* (2009) conducted interviews and focus groups with 'lay' participants in order to examine ethical concerns about life-extension research. The authors found that participants made explicit reference to ethical concerns:

...often using words such as "ethical", "moral", or "philosophical", to identify these key issues for them, while at other times, participants only implicitly referred to key ethical themes (ibid: 71)

7.5 EXAMINING ETHICAL ARGUMENTS: A COMPARISON

An overview of two studies that have examined ethical arguments offers an indication of differences in how such an examination may be undertaken. The studies on which this comparison is based are McKie *et al* (2009)⁴¹ and Scully *et al* (2006b)⁴². Each demonstrates a different approach to exploring ethical arguments.

McKie *et al* investigated people's beliefs about a particular topic (priority-setting with regard to treatment costs). The authors stated that they sought to "...explore the values, arguments and rationalisations underlying those views" (*ibid*: 2), although this exploration was mainly a descriptive process that identified and discussed a range of themes arising within the study and a number of positions taken by participants. As the authors themselves stated, they offered an *overview* of participants' reasons and arguments, and this was presented in a narrative, rather than analytical form.

McKie *et al* also sought to enhance the strength of the views obtained by eliciting "*underlying values rather than unreflective preferences*" (*ibid*: 1). Participants were asked to consider alternative principles for resource allocation and given the opportunity to deliberate and discuss the issues and verbalise the underlying values

⁴¹ McKie, J., Shrimpton, B., Richardson, J. and Hurworth, R. (2009) Treatment costs and priority setting in health care: A qualitative study, *Australia and New Zealand Health Policy*, 6 (11).

⁴² Scully, J. L., Banks, S. and Shakespeare, T. W. (2006b) Chance, choice and control: Lay debate on prenatal social sex selection, *Social Science and Medicine*, 63 (1), pp. 21-31.

and reasons. This appears to have been done primarily to elicit 'strong evaluation' (involving reflection on one's own preferences) rather than 'weak evaluation' (simple weighing of alternatives, expression of preferences etc.). Therefore, the rationale for identifying values and reasons was to enhance the views obtained and to emphasise the importance of deliberation and reflection in preference elicitation. It was not done so that the values and reasons themselves could be subjected to systematic analysis.

In contrast, Scully *et al* set out to explore the processes by which non-professionals make ethical evaluations and to examine the evaluative processes of reasoning and argumentation used in relation to a given topic (prenatal social sex selection). Rather than requiring participants to solely give their views or make a choice between alternatives, the researchers sought to identify the implicit or explicit normative framework that gave rise to participants' opinions. They used a brief scenario to initiate and focus the discussion and asked participants to articulate and discuss their reasons for their opinions.

Scully *et al* analysed their participants' arguments – particularly the form of moral reasoning applied, its coherence, the predominant rationales offered, the moral values espoused, and the way in which participants verbalised their ethical views. In a further report of the same study (Banks *et al*, 2006) the authors described how they also explored morally relevant concepts that underpinned people's views – components of ethical reasoning such as expressions of instinct; making distinctions; rational/logical argument; reference to principles; use of personal experience; analogies and examples; slippery slope arguments and meta-reflections.

Scully *et al* also investigated how participants framed a problem; they undertook data analysis to identify ethical content and arguments and made the comparison between participants' ethical reasoning and that which is evident within the bioethics literature.

In summary, McKie *et al* (2009) undertook a study of public views, an aspect of which was the description of the underlying reasons, values and arguments. Scully *et al* (2006b)'s paper was based on a study which explicitly sought to examine how the public make ethical evaluations, including the role of rational argumentation within this process.

The extent to which evidence is available of the ethical reasoning and arguments supporting the public's views, values and preferences regarding healthcare distribution and priority-setting is considered in the next chapter.

8 EXAMINING ETHICAL REASONING AND ARGUMENTS: A LITERATURE REVIEW

8.1 INTRODUCTION

Economics is commonly defined in terms of the relationship between people's unlimited wants and society's scarce resources. The definition implies a central role for an understanding of what people want, i.e. their objectives (Richardson and McKie, 2005: 265)

The purpose of this literature review is to identify studies that have examined public attitudes and preferences regarding healthcare distribution and/or healthcare priority-setting and to evaluate these with regard to the methods employed and the extent to which they have elicited and/or examined participants' ethical arguments. The study is restricted to qualitative studies in consideration of the limitations of a quantitative approach to this subject discussed in Chapter 7. The methodological literature regarding qualitative reviewing and synthesis (Barbour, 2001; Britten *et al* 2002; Major and Savin-Baden, 2010) indicates that this literature review has been undertaken with the application of a "systematic approach" but does not represent a fully formed qualitative systematic review.

8.2 SEARCH METHODS

8.2.1 SOURCES

Four online bibliographic databases were searched for the years 1985–2013: Medline, EconLit, CINAHL, Applied Social Sciences Index and Abstracts (ASSIA) and Web of Knowledge. It was felt that these databases struck a balance between those containing primarily healthcare-focused articles and those that draw upon broader social science content. Subsequently, reference lists of articles were hand-searched to detect articles that were not identified in the computerised search.

8.2.2 SEARCH TERMS

Search terms, applied separately, in combination and with appropriate truncation symbols, included: 'QALY', 'priority-setting', 'rationing', 'public participation' and 'argument'. Searches were undertaken in 2013 and restricted to items published

since 1985. Rather than focusing on title and abstracts, search terms were applied to 'all text' as

...the indexing of qualitative research on existing electronic databases is generally inconsistent, and there is often no methodological information in the study's title or abstract to allow it to be clearly identified as a qualitative study (Petticrew and Roberts, 2006: 86)

8.2.3 INCLUSION CRITERIA AND ARTICLE SCREENING

The following specific inclusion criteria were applied: peer reviewed articles reporting qualitative primary research involving members of the public, published in the English language and limited to a timespan of 1985 to 2013.

The initial searches yielded a large and unmanageable number of results. This number was reduced to approximately 250 by applying qualitative search terms: 'qualitative' OR 'qualitative research' OR 'qualitative study' OR 'qualitative method*' OR 'grounded theory' OR 'interviews' OR 'focus group*' OR 'discussion group*' OR 'deliberative'

This number was further reduced by applying to the results the additional search terms: 'reasoning', 'values' and 'preferences'.

Articles were reviewed for relevance; those covering unrelated topics – for example, the elicitation of health utilities – or those that did not describe qualitative research were excluded from the review. Subsequently, 51 potentially relevant articles were identified, and they were obtained and reviewed for possible inclusion. Of the 51 papers, 33 were excluded (Appendix One) leaving 18 articles to be included within this review. Table 8.1 briefly summarises the papers that were selected via this process, the methods used, the outcomes of these research studies and whether there is evidence that a specific attempt was made to examine ethical reasoning and arguments.

TABLE 8.1: ARTICLES INCLUDED IN LITERATURE REVIEW

Author(s)	Study design / methods	Aim(s) of study	Participants	Ethical reasoning / arguments examined	Main findings
Abelson <i>et al</i> (2009)	'Modified grounded theory approach.' Focus groups (plus telephone survey)	To examine people's values toward a health care system and to develop conceptualisations of trust	Public. Age: 18-79	Addressed 'values'. No attempt made to explore reasoning or arguments	Thematic findings regarding 'trust'
Block <i>et al</i> (2001)	Focus groups (x14) Content analysis of perceived benefits	To identify the range of benefits that are significant for a wide cross-section of social groups	Multiple countries. Public - 122 participants	Not explored	Identification of a means of measuring health systems performance
Bombard <i>et al</i> (2011)	'Citizens' Reference Panel'. Five, one-day sessions over a two year period Pre and post-panel questionnaires	To elicit a set of ethical and social values to be used to guide a Health Technology Assessment review and appraisal process To explore the feasibility of using participatory approaches to elicit these values	14-person Citizens' Reference Panel on Health Technologies Age range = 18 to 71+	Discussed the elicitation of ethical and social values into the evaluation of health technologies. Identified core values via group deliberation. Coding of data included 'Patient autonomy' and 'Challenges to social values and arrangements'.	Identification of 'core values' across a variety of health technologies

TABLE 8.1: ARTICLES INCLUDED IN LITERATURE REVIEW (continued)

Author(s)	Study design / methods	Aim(s) of study	Participants	Ethical reasoning / arguments examined	Main findings
Coast (2001a)	Semi-structured interviews Initial fieldwork undertaken via focus groups Data analysis via constant comparison	To consider the application of the theoretical notion of a principal-agent relationship to societal health care decision making	'Citizens' – 13 members of UK public 'Agents' (working in a health service role) Interviewees purposively selected based on comments made in focus groups	Arguments reported but not analysed	With regard to the 'citizen-agent' relationship, it appears to operate as a system of equivocation Questions the perceived 'typicality' of citizen informants
Coast (2001b)	Semi-structured interviews Data analysis via constant comparison	To explore people's views about whether they would want to know about any rationing of their own health care.	'Citizens' – members of the UK public (plus 'informants' – members of interest groups, elected representatives, health service workers)	Arguments reported but not analysed Reasons for responses elicited	Majority of participants wanted to know about rationing

TABLE 8.1: ARTICLES INCLUDED IN LITERATURE REVIEW (continued)

Author(s)	Study design / methods	Aim(s) of study	Participants	Ethical reasoning / arguments examined	Main findings
Cookson and Dolan (1999)*	<p>Focus groups</p> <p>Used 'rationing exercises'</p> <p>Categorised responses corresponding to five rationing principles. Participants' reasons were then subcategorised – coded into 'principles' and 'factors'</p>	To investigate public support for ethical principles of health care rationing	<p>60 public participants. Ten focus groups – approximately six participants in each.</p> <p>Age range 18-70</p>	<p>Reported participants' arguments e.g. 8% argued that it is unethical to make explicit rationing choices – but these arguments were not analysed</p> <p>Offered some analysis of participants' reasons for decisions – e.g. the most common justifications given for decisions</p> <p>Provided summary statistics of participants' responses</p>	Identified public support for three rationing principles: (1) a broad 'rule of rescue', (2) maximising the health of the whole community and (3) reducing inequalities in people's lifetime experience of health.
Dicker and Armstrong (1995)	<p>Semi-structured interviews</p> <p>Thematic analysis</p>	To explore the assumptions underlying responses to questions of resource priorities in the NHS.	Patients x16	Participants' responses reported and some arguments stated but not analysed	Identified recurring themes within the interviews e.g. Participants' reluctance to use their own needs as a basis for determining preferences - balanced by the use of others' needs as justification for service priorities.

TABLE 8.1: ARTICLES INCLUDED IN LITERATURE REVIEW (continued)

Author(s)	Study design / methods	Aim(s) of study	Participants	Ethical reasoning / arguments examined	Main findings
Dolan <i>et al</i> (1999)*	Focus group	To investigate the extent to which people change their views about priority setting in healthcare as a result of discussion and deliberation	60	Arguments not discussed or analysed	Public views about priority-setting are systematically different when people have been given an opportunity to discuss the issues.
Dolan and Cookson (2000)*	Focus group	To elicit the general public's views about the extent to which health gain matters	60 respondents	Aim of focus groups: to enable participants to " <i>raise, discuss, and reflect upon, different arguments</i> " Participant responses analysed but arguments not examined	Support for the view that equality of access should prevail over the maximisation of benefits
Dolan and Shaw (2004)	Focus groups Variant of Grounded Theory	To explore whether and how people wish to give differential priority based on certain characteristics of potential donor kidney recipients	23 participants meeting in four groups of five or six	Group discussions described Arguments not analysed	People are willing and able to distinguish between potential recipients according to a range of characteristics beyond expected treatment benefits.

*Cookson and Dolan (1999); Dolan *et al* (1999) and Dolan and Cookson (2000) are papers based on the same study

TABLE 8.1: ARTICLES INCLUDED IN LITERATURE REVIEW (continued)

Author(s)	Study design / methods	Aim(s) of study	Participants	Ethical reasoning / arguments examined	Main findings
Kuder and Roeder (1995)	Focus groups Scenario-based discussions Thematic analysis	To assess public views on age-based rationing of healthcare	46 participants	Identified common themes Participants' arguments presented but not examined	Reluctance to withhold treatment on basis of age
Litva <i>et al</i> (2002)	Focus groups and follow-up semi-structured interviews Thematic analysis	To examine the public's preferences for being involved in particular types of rationing decisions	34 members of the public (plus others)	Arguments presented and quotations are used " <i>to illustrate the themes presented and to allow the reader to judge the veracity of the interpretation</i> "	Findings demonstrate variations in the willingness of members of the public to be involved in health care decisions
McKie <i>et al</i> (2009)	Semi-structured group discussions	To investigate whether the public believes high cost patients should be a lower priority for public health care than low cost patients	41 participants	Sought to " <i>...explore the values, arguments and rationalisations</i> " –, exploration was mainly a descriptive process that identified and discussed a range of themes arising within the study and a number of positions taken by participants. Considered participants' conclusions as well as their reasoning	Demonstrated the tendency for people to disregard costs in prioritising health care

TABLE 8.1: ARTICLES INCLUDED IN LITERATURE REVIEW (continued)

Author(s)	Study design / methods	Aim(s) of study	Participants	Ethical reasoning / arguments examined	Main findings
Owen-Smith <i>et al</i> (2009) And Owen-Smith <i>et al</i> (2010)	Interviews Data analysis via constant comparison	To examine how patients react to explicit rationing decisions	31 patients (plus 21 healthcare professionals)	Arguments elicited and justifications for arguments discussed	Found that nearly all patients wanted to know about rationing decisions and regarded implicit rationing as paternalistic
Werntoft <i>et al</i> (2007a) And Werntoft <i>et al</i> (2007b)	Interviews Content analysis	To describe the views and reasoning of people aged 60 years and over about prioritization in health care with regard to age and willingness to pay	446	Categorised and analysed participants' reasoning Quotations, including arguments, used to illustrate categories	Views expressed indicated contradictory opinions and experiences
Wilmot and Ratcliffe (2002)	Focus groups	To investigate public preferences in the allocation of donor liver grafts for transplantation	22 members of the public	Quotations, including a range of arguments, used to illustrate the discussion. Arguments not analysed	Participants approach was flexible and thoughtful – occasionally resorting to arguments based on what is 'obvious' and 'natural'. Suggesting that members of the public would be able and willing to respond positively to a more open and consultative system of donor liver prioritisation

8.3 FINDINGS

8.3.1 METHODS OF DATA COLLECTION

8.3.1.1 FOCUS GROUPS

Focus groups were the most frequently used approach to data collection. Abelson *et al* (2009) applied what they termed a 'modified grounded theory approach', using focus groups (plus telephone survey) to examine the public's values toward a health care system and to develop conceptualisations of trust. Block *et al* (2001) used a series of focus groups (n=14) in order to identify the range of health benefits that are significant for a wide cross-section of social groups. Also using focus groups, Cookson and Dolan (1999) and Dolan and Cookson (2000) investigated public support for ethical principles of health care rationing identified in the literature. 60 participants within an age range of 18 to 70, took part in the focus groups (n=10). Focus groups were also used by Wilmot and Ratcliffe (2002) to investigate public preferences in the allocation of donor liver grafts for transplantation. In addition, focus groups were employed by Dolan and Shaw (2004) and Kuder and Roeder (1995). McKie *et al* (2009) used what they termed "*semi-structured group discussions*" to investigate whether the public believes high cost patients should be a lower priority for public health care than low cost patients.

8.3.1.2 INTERVIEWS

Dicker and Armstrong (1995) interviewed 16 participants in order to explore the assumptions underlying responses to questions of resource priorities in the NHS. Owen-Smith *et al* (2009 and 2010) conducted interviews with patients (n=31) and healthcare professionals (n=21) to examine how patients react to explicit rationing decisions. Interviews were also used by Werntoft *et al* (2007a & 2007b) to describe the views and reasoning of people aged 60 years and over about prioritisation in healthcare with regard to age and willingness to pay. Coast (2001b) conducted semi-structured interviews with members of the public to explore people's views about whether they would want to know about any rationing of their own health care.

8.3.1.3 MIXED QUALITATIVE METHODS

Following initial fieldwork undertaken via focus groups, Coast (2001a) conducted semi-structured interviews with members of the public and health service personnel. The interview sample was purposively selected on the basis of their comments during focus groups. Using focus groups and follow-up semi-structured interviews, Litva *et al*, (2002) examined the public's preferences for being involved in particular types of rationing decisions.

8.3.1.4 DELIBERATIVE METHODS

Bombard *et al* (2011) sought to elicit a set of ethical and social values to be used to guide a Health Technology Assessment review and appraisal process and explored the feasibility of using participatory approaches to elicit these values. They utilised a 'Citizens' Reference Panel' plus pre and post-panel questionnaires.

8.3.2 EXAMINATION OF REASONING AND ARGUMENTS

Arguments not explored:

Block *et al* (2001) examined people's expectations and experiences of healthcare systems, but participants' reasoning and arguments were not explored. Dolan and Shaw (2004) investigated whether and how people wish to give differential priority based on certain characteristics of potential donor kidney recipients. They reported that people are willing and able to distinguish between potential recipients according to a range of characteristics beyond expected treatment benefits. Participants' arguments were not examined. In the study by Abelson *et al* (2009), no attempt was made to explore reasoning or arguments, but the authors did provide some, fairly lengthy, quotes – including arguments – from participants in order to inform the discussion.

Arguments identified but not explored:

Cookson and Dolan (1999) identified public support for three rationing principles: (1) a broad 'rule of rescue', (2) maximising the health of the whole community and (3) reducing inequalities in people's lifetime experience of health. The findings included reports of the arguments participants used, for example, 8% of participants argued

that it is unethical to make explicit rationing choices, but these arguments were not analysed. The authors also indicated some analysis of participants' reasons for decisions by identifying the most common justifications given for decisions. In a further report on this study, Dolan and Cookson (2000) stated that the group discussions were designed to enable participants to "*raise, discuss, and reflect upon, different arguments*" (*ibid*: 19). Participants' responses were analysed but arguments were not examined. An additional aim of Dolan and Cookson's study was to investigate the extent to which people change their views about priority setting in healthcare as a result of discussion and deliberation. It was found that public views about priority-setting are systematically different when people have been given an opportunity to discuss the issues (Dolan *et al*, 1999).

Dicker and Armstrong (1995) identified recurring themes within the interviews. For example, participants' reluctance to use their own needs as a basis for determining preferences. This was balanced by the use of others' needs as justification for service priorities. Participants' responses were reported and some arguments stated but not analysed.

Kuder and Roeder (1995) assessed public views on age-based rationing of healthcare. Their focus group participants, it was reported, were reluctant to withhold treatment on the basis of age. Common themes were identified and participants' arguments were presented within the paper, but not subjected to analysis. The authors emphasised the value of statements and opinions being presented in participants' own words.

Wilmot and Ratcliffe (2002) reported that participants' approach was flexible and thoughtful; occasionally resorting to arguments based on what is 'obvious' and 'natural'. Quotations, including a range of arguments, were used to illustrate the discussion but the arguments themselves were not analysed. Coast (2001a; 2001b) identified arguments but these were not subjected to analysis.

Other:

Bombard *et al* (2011) discussed the elicitation of ethical and social values into the evaluation of health technologies and identified core values via group deliberation. The authors reported that panel members felt ill-equipped to reflect on ethical and social values. In their findings, Bombard *et al* (2011) used participant responses to

illustrate the expressions of 'values'.

Litva *et al*, (2002) and their findings demonstrated variations in the willingness of members of the public to be involved in health care decisions. Participants' arguments were presented and, interestingly, Litva *et al* included quotations from participants "*to illustrate the themes presented and to allow the reader to judge the veracity of the interpretation*" (*ibid*: 1829).

McKie *et al* (2009) sought to "*...explore the values, arguments and rationalisations*" (*ibid*: 2). However, the exploration was primarily a descriptive one that identified and discussed a range of themes arising within the study and a number of positions taken by participants. The authors considered participants' conclusions as well as their reasoning and offered an overview of participants' reasons and arguments, which were presented in a narrative, rather than analytical form.

Owen-Smith *et al* (2009 and 2010) elicited arguments, and the justifications participants gave for these were presented and discussed. They found that nearly all patients wanted to know about rationing decisions and regarded implicit rationing as paternalistic. Werntoft *et al* (2007a and 2007b) categorised and analysed participants' reasoning. Quotations, including some arguments, were used to illustrate a number of categories.

8.4 DISCUSSION

Research into the ethical reasoning and arguments used by the general public in relation to their stated views, values and preferences regarding healthcare distribution and priority-setting is limited.

Although the primary purpose of the studies reviewed was not to examine reasoning and arguments, a number of authors indicated their intention to *explore* arguments (McKie *et al*, 2009) and some *described* participants' arguments (Wilmot and Ratcliffe, 2002) and reasoning (Werntoft *et al* (2007a) or elicited ethical and social values (Bombard *et al*, 2011). While others reviewed the literature in an attempt to, for example, identify ethical reasons that underpin public views (Olsen *et al*, 2003) or to consider the reasoning behind public preferences regarding QALY-maximisation (Dolan *et al*, 2005). It is not apparent that ethical arguments that underlie public responses regarding healthcare distribution have been subjected to

systematic examination.

The notion of identifying responsibility for healthcare need as a priority-setting principle was not a focus of any of the articles reviewed. Although the literature review did not include 'responsibility'-related search terms, it was anticipated that any existing studies into public ethical arguments relating to this principle would emerge from within the existing search criteria. However, none did.

This literature review demonstrates that various qualitative methods, using both individual and group-based approaches, have been used. These have included: focus groups (e.g. Dolan and Cookson, 2000; Block *et al*, 2001) and semi-structured interviews (e.g. Coast, 2001a; Dolan and Shaw, 2004). The findings indicate that qualitative studies have produced primarily descriptive accounts in which respondents' arguments are reported rather than being examined (e.g. Dolan and Cookson, 2000).

Therefore, although attempts have been made to illustrate the ethical justifications for public preferences regarding healthcare distribution, the arguments used; their validity and underlying reasoning and premises – described as the 'missing link' between knowledge and action (Moore and Nelson, 2010) – do not appear to have been subjected to empirical analysis.

Furthermore, there is no indication in the literature of *ethical* analysis being specifically applied to reasoning and arguments in relation to healthcare distribution issues. As Richardson and McKie (2005: 272) noted:

The embryonic state of the economics literature on questions such as the elicitation of ethical preferences is a reflection of their neglect

This review of the literature indicates that such an 'embryonic state' persists.

The absence of such examination may reflect the perceived limitations of ethical inquiry and a belief that:

...ethical questions are commonly considered to be better answered by appeal to theory rather than by practical testing (Jones, 2003: 348)

However, empirical methods of research are becoming widespread in contemporary bioethics (Ashcroft 2003; Hasman, 2003; Borry *et al*, 2005; Myser, 2009; Harvey,

2011) and offer a practical response to such concerns (see Chapter 9).

The concepts of ethical reasoning and ethical arguments provide scope for a detailed examination of what members of the public think about healthcare priority-setting and have considerable advantages over other public participation approaches – particularly with regard to a potentially contentious proposal such as the incorporation of a 'responsibility' principle.

Examining ethical reasoning and arguments demands a methodological approach that is sensitive to the often ill-defined nature of reasoning and argumentation and can enable reasoning and arguments to be understood in light of established ethical theory and principles whilst facilitating the production of justifiable outcomes via data analysis.

Empirical ethics, a methodological approach that integrates ethics and empirical findings to reach a normative outcome, offers a means of achieving these aims, and is explored in the next chapter.

SECTION: C

EXAMINING REASONING AND ARGUMENTS

9 EMPIRICAL ETHICS: A METHODOLOGICAL APPROACH

9.1 INTRODUCTION

This chapter examines the concept of empirical ethics⁴³ and its relationship to traditional approaches to ethical inquiry. Its applicability to the task of eliciting and analysing ethical reasoning and arguments is critically evaluated.

9.2 APPROACHES TO ETHICAL INQUIRY

Ethics is a branch of philosophy (*moral philosophy*) which, in its most basic and widely recognised expression, is concerned with establishing normative concepts of 'right' and 'wrong' with regard to people's thoughts, decisions and actions (Driver, 2007)⁴⁴. Traditional ethical inquiry focuses on using a method of rational argumentation in the application of principles to tangible moral questions (often expressed as 'ethical dilemmas') and therefore provides a theoretical framework for examining the morality of thoughts, decisions and actions. This necessitates a process of *moral evaluation*, a rationalistic and deductive process, in which the background, justifications, values, etc. that underpin thoughts, decisions and actions are critically assessed with reference to established ethical theories and principles⁴⁵. A range of ethical concepts may inform this process⁴⁶.

9.2.1 EXAMPLES OF ETHICAL CONCEPTS

- Avoiding harm – possibly the most fundamental and readily appreciated ethical concept ('Above all do no harm' is a basic and widely recognised principle of medical ethics)

⁴³ Evidence of the history and development of empirical ethics is mainly found within the philosophical literature. However, as its application within this study is focused on a healthcare-related topic, this examination focuses on the development and applications of empirical *medical ethics* and empirical *bioethics* which are presented here as broadly analogous approaches

⁴⁴ 'Right' and 'wrong' within a normative ethical context indicate the correct or incorrect moral norms for the guidance and evaluation of conduct (Beauchamp and Childress, 2008)

⁴⁵ For example, *why* might it be claimed that an act is 'right' or 'wrong'? *Who* decides and in what *context*? Is an assertion morally justifiable (via the application of ethical theories and principles)? Is it supported by objective *evidence* or simply a matter of *personal opinion*?

⁴⁶ Without such considered reasoning, ethical appraisal may be restricted to unsubstantiated, albeit familiar, examples of 'moral evaluation' such as: "I think that's awful!" and "It should not be allowed!" etc.

- Moral obligations and duties – identifying moral rules (that impose ethical duties) assists in guiding decisions and actions
- Assessing the consequences of actions – it may be claimed that the ethical acceptability of an act is most effectively determined by calculating its potential outcomes
- Autonomy and rights – acknowledging individual choices and entitlements provides a basis for respecting others
- Best interests – identifying and acting in accordance with the best interests of oneself or others as a basis for ethically justifying a decision or action
- Values and beliefs – from which general ethical principles are formulated to guide decisions and actions

9.2.2 NORMATIVE ETHICS

A normative approach to ethical inquiry is evident when morally evaluative terms (such as 'right' and 'wrong') are applied to decisions and actions. Normative ethics typically gives rise to questions such as: "What is the 'right' thing to do?" or "Would it be 'wrong' to do X?" It is concerned with determining how people should act⁴⁷ and with providing ethical guidance for action. The process by which normative evaluation is put into practice – 'applied ethics' – is concerned with *applying* established ethical theories and principles to specific situations so that general moral norms may be determined for particular circumstances (either in everyday life or within specific contexts such as healthcare). A popular and influential example of applied ethics is the 'four principles' approach to bioethics (see Chapter 5), incorporating the principles of respect for autonomy, nonmaleficence, beneficence, and justice (Beauchamp and Childress, 2008).

⁴⁷ 'Should' is a commonly applied indicator of normative reasoning i.e. it may indicate a view on the *right* or *wrong* way to act: *You shouldn't do that*; or represent an appeal for ethical guidance: *Should we tell truth?*

9.2.3 DESCRIPTIVE ETHICS

An alternative approach to ethical inquiry is that of *descriptive* or *comparative* ethics, which is the study of people's moral conduct and beliefs. Descriptive ethics incorporates research from the fields of anthropology, psychology, sociology and history as part of the process of understanding what people either believe, or have believed, about moral norms. It is distinct from normative ethics in that, whereas a normative approach considers standards for the rightness and wrongness of actions and how people *ought* to act, a descriptive approach seeks to empirically investigate *how* people reason and act. Its aim is to establish what factually or conceptually *is* the case, not what ethically *ought* to be the case (Borry *et al*, 2005; Beauchamp and Childress, 2008) and has therefore been used by researchers seeking empirical evidence of how people behave morally i.e. to *describe* ethics and ethical behaviour rather than to determine what is *right*⁴⁸. Although a descriptive ethics approach does not seek to identify moral norms, it is an important constituent of a focused empirical ethics approach (see below).

9.2.4 NORMATIVE OR DESCRIPTIVE?

Normative and descriptive ethics therefore offer different approaches to ethical inquiry. One is chiefly prescriptive and seeks to identify moral norms by applying theoretical concepts to real-life situations and the other is concerned with examining how people behave ethically. However, the distinction between the two approaches is possibly over-simplistic (Haimes, 2002). For example:

When sociologists and other social scientists study how doctors, nurses, patients (and other people beyond the medical setting) make decisions which involve an ethical dimension they find that: 'a rigorous separation of the descriptive and the normative is practically untenable' (Hedgecoe, 2004: 131)

The blurring of the boundaries between the two approaches is perhaps understandable as the moral evaluation of people's thoughts and decisions may also prompt consideration of their actual moral conduct. Furthermore, the separation of normative and descriptive approaches is unhelpful to an examination of an ethically significant topic that seeks to produce empirical results.

⁴⁸ A descriptive ethics approach has been used to investigate issues such as the ethical problems encountered by people living with AIDS (Cameron, 1993); professional attitudes towards specific aspects of healthcare practice (Dreyer *et al*, 2010) and the adequacy of the informed consent process within a hospital setting (Barnett *et al*, 2008)

9.2.5 MORAL RELATIVISM

Applied ethical reasoning is generally founded on a belief that there are objective, universally applicable, moral standards that can be applied to actual situations in order to determine a normative outcome. An alternative *relativist* claim is that there are no objective moral standards; only standards that apply within cultures, groups, societies etc. Therefore, a 'true' statement concerning morality cannot be said to be a statement of *facts*, it is merely a statement expressing the *values* held by a specific culture, group etc. (Lukes, 2008). From a relativist viewpoint, perceptions of *right* and *wrong* are based only on one's social, cultural, religious etc. background i.e. approaches to morality are 'relative' to the particular culture, group, society or individual from which they emerge. However, whilst acknowledging the relativist perspective, this study seeks to explore the social implications of incorporating a 'responsibility' criterion into healthcare distribution, and is therefore founded on a belief that ethical agreement (or at least understanding) *can* be achieved via the acknowledgement of some common principles – many of which can (or *should*) be universally applicable.

9.3 ETHICS AND HEALTHCARE

Although effective treatment is a priority for both healthcare providers and patients, it is generally acknowledged that the provision of 'good healthcare' is also dependent upon its ethical components, which demands consideration of issues such as respect, confidentiality, trust and rights. Ethics and ethical inquiry are as concerned with the ordinary aspects of healthcare as with its less common, although frequently challenging, features⁴⁹.

The provision of healthcare gives rise to a broad range of fundamental ethical questions concerning, for instance, its aims: do healthcare services exist principally to do 'good' or avoid 'harm'?⁵⁰ Or, with regard to individual entitlements: do all citizens have an equal 'right' to healthcare? Perhaps the primary purpose of healthcare is to help or assist people – an ethical process in itself. At a societal level, deliberation of the 'big' healthcare ethical issues, such as abortion, euthanasia

⁴⁹ Although controversial healthcare issues are regularly highlighted within the media, the 'ethical debate' often generates more passion than clarification

⁵⁰ Obviously, neither concept ('good' or 'harm') is amenable to simple definition within a healthcare context

and the allocation of limited resources is underpinned by broader meta-ethical concerns regarding the value of human life and how it should be lived.

9.3.1 MEDICAL ETHICS AND BIOETHICS

The application of ethical analysis (both in terms of normative and descriptive approaches) to healthcare issues increased significantly in the second half of the twentieth century⁵¹. Technological advances that challenged traditional medical knowledge and practice were accompanied by changes in social attitudes and an increased awareness and acknowledgement of patient autonomy, rights and justice. Innovations such as dialysis and kidney transplantation, artificial respiration, resuscitation techniques, and prenatal diagnosis extended the range of available treatment options and increased the number of potential 'ethical dilemmas' within healthcare.

The increasingly widespread application of ethical thinking to healthcare issues in the late twentieth century encouraged the expansion of the essentially analogous analytical disciplines of medical ethics and bioethics. Each has supposedly distinct characteristics. For example, *medical ethics* is founded within the field of applied ethics and is concerned with the study of moral values and judgments as they apply to medical practice, research and policy, whereas *bioethics* is concerned with morally evaluating critical aspects of healthcare provision (technological developments, abortion, euthanasia etc.). Borry *et al* (2005: 56-57) described the development of the bioethics discipline:

Initially, people from many different disciplines, such as medicine, law, theology, biological sciences, social sciences, philosophy, humanities, etc. entered the dialogue. However, in a process of professionalisation and institutionalisation, the bioethical discussions quickly became anchored in the fields of theology and philosophy

Both medical ethics and bioethics are frequently used to describe the application of ethical thinking to aspects of healthcare provision as each involves:

⁵¹ "A turning point in medical ethics is widely agreed to have occurred after the Second World War, although explanations for this vary. They include: the medical atrocities of the Nazi doctors; changing social attitudes, including less deference to authority; more assertive attitudes to individual rights and self-determination; a shift from the preoccupation of medical ethics with the individual patient at the expense of the community; the increasing plurality of cultural and religious norms within some nations, including the UK; and the development of a system of internationally recognised human rights" (British Medical Association, 2004: 4)

...the self-critical application of modes of moral reasoning, in the form of ethical theory or fundamental moral principles, to questions raised by the biomedical sciences (Green, 1990: 180)

9.4 EMPIRICAL ETHICS

During the 1970's published work in medical ethics consisted either of theoretical discussions of ethical concepts or analysis of individual case discussions. During the late 1980's, as medical ethics caught the interest of an increasing number of academic physicians, a new form of ethics paper began to appear. These works, rather than emphasizing the theoretical methods of theologians or philosophers, used the empirical methods of social scientists and especially clinical epidemiologists (Arnold and Forrow, 1993: 195)

Empirical ethics represents an emerging feature of ethical activity within both academic and professional healthcare arenas. An empirical ethics approach seeks to substantiate the philosophical basis for ethical inquiry and ethical pronouncements by integrating theoretical ethics and empirical research. It uses ethical theory to explore data in order to reach a normative conclusion with respect to a specific feature of social practice (Molewijk *et al*, 2004)⁵². Ashcroft (2003: 3) provided the following concise clarification of the empirical ethics process, indicating how the theoretical and empirical components combine.

....theorists seek to frame hypothetical imperatives (on the assumption that p is true, do X) and to supply the empirical, contingent information (p is true) which will complete the hypothetical imperative, thus specifying what ought to be done

Traditionally, ethical inquiry and empirical approaches have distinct objectives: ethics is primarily a prescriptive discipline, concerned with conceptual clarification and normative justification, and the social sciences represent a more descriptive discipline that emphasises the cultural setting and is concerned with empirical description, reconstruction, and analysis. Empirical ethics acknowledges the symbiotic nature of theoretical and empirical methods; it refutes what has been termed "the structural incompatibility" between the empirical description and analysis of the social sciences and the conceptual clarification and normative approach of ethics, and is undertaken in recognition of their basic complementarity (Zussman, 2000).

⁵² The question of whether something should be considered as 'right' or 'wrong' is undoubtedly a philosophical, rather than empirical issue. However, such normative evaluation (determining 'right' and 'wrong') is not the defining role of empirical ethics

The rationale for employing an empirical ethics approach is the desire to make effective moral judgements as opposed to theoretical moral pronouncements. Ordinarily, to assign normative status to empirical descriptions i.e. to seek to derive an 'ought' from an 'is', is to commit the 'naturalistic fallacy' (Holm, 1997). However, empirical ethics, it is claimed, seeks to do this – to use the actualities of lived experience to determine normative, value-based judgements that indicate how people *should* act (Hedgecoe, 2004). It therefore seeks to eliminate the meta-ethical distinction (between 'is' and 'ought') that has traditionally created a natural border between the social sciences and ethics approaches (Borry *et al*, 2005).

Hedgecoe (2004) highlighted the historical differences between bioethics and the social sciences and referred to a 'critical bioethics' approach to aligning the disciplines; outlining some of the traditional/historical difficulties that may have impeded the development of empirical bioethics. The role of critical bioethics in identifying the framework within which ethical issues are identified and analysed, Hedgecoe argued, is dependent on bioethicists and social scientists recognising and embracing the value of each other's discipline. Hedgecoe also noted that identifying what counts as an ethical problem is, in the first place, a socially constructed concept. A significant aspect of a critical bioethics approach is therefore concerned with acknowledging how the social sciences can actively contribute to bioethical inquiry and recognising where the apparently diverse approaches complement one another and, in places, correspondence. For example, that the 'is/ought' distinction (referred to above) is a concept *assumed* by bioethicists: "*...while social science research suggests that at the very least such an idea needs more support (ibid: 126).*

The contribution of the social sciences to ethical inquiry was examined by Haimes (2002) who noted that the social sciences have a longstanding theoretical interest in analysing the role of ethics and ethical thinking in explanations of social change, social organisation and social action. The value of empirical ethics to social scientists is, it is argued, that combining theoretical and empirical work enables them [social scientists] to: "*...enquire further into the social processes that lie behind the very designation of certain matters as being `ethical issues`" (ibid: 89).* The potential outcome to be achieved by aligning these complementary approaches to inquiry is empirical findings that are of value to both disciplines separately and in combination.

The emergence of empirical ethics, both within healthcare and beyond, has occurred in line with the requirement for 'scientific substantiation' of research studies and the identification of the appropriate evidence-base to support research findings. This has had a direct influence on the practice of bioethics and provided a pragmatic basis for the growth in empirical ethics – researchers interested in medical ethics need to find ways in which their work can be assessed and funded (Hope, 1999). In addition, many clinical ethicists and bioethicists come from a background in the empirical social sciences – from within the medical or nursing professions for example – rather than from a philosophy and theology background. They are accustomed to the processes and requirements of empirical exploration and the need to provide demonstrable, evidence-based outcomes.

9.4.1 COMPARISON WITH TRADITIONAL APPROACHES

Traditional approaches to ethical inquiry have relied on establishing a theoretical basis for establishing a normative or descriptive conclusion. The relationship of the theoretical findings to empirical evidence has been generally slight and/or undervalued. If conventional ethical enquiry is enhanced by empirical input, this is mostly an 'unintended and unavoidable outcome', described by De Vries and Subedi (1998: xvii) as a "*sociological version of the bioethical idea of double effect*"⁵³.

As medical ethics/bioethics has advanced it has gradually adopted additional features of ethical inquiry such as narrative ethics (which places a particular emphasis on the empirical aspects of the issue under consideration⁵⁴) (Zaner, 2004), and feminist ethics⁵⁵. The application of these additional ethical strategies has served to broaden the scope of traditional ethical analysis and has inspired increasingly diverse approaches, encouraging ethicists (and others) to engage in

⁵³ The doctrine of double effect may be used to morally justify an action that causes a serious harm, such as the death of a patient, as a side effect of promoting some good end. For example, a potential harm 'such as the death of a patient' is morally permissible if it is foreseen as a possible side effect (or 'double effect') of bringing about a good result, such as pain relief; the harm being a foreseen (although unintended) side-effect of the *good* act. For the doctrine to apply, the 'bad' outcome must not be the means of achieving the 'good' act i.e. if the only way analgesia relieves pain is by killing the patient, the doctrine does not apply

⁵⁴ Narrative ethics focuses on personal identity through the content of stories (what people say) and through the analysis of the stories' form (how stories are told and why it matters to the individual or group) (Charon and Montello, 2002)

⁵⁵ Feminist ethics challenges the traditional foundations of ethical inquiry – which emphasise what may be regarded as masculine cultural traits such as dealing in abstract principles and analytical reasoning – and promotes the view that ethical inquiry is best understood from a perspective that focuses on more 'feminine' cultural traits such as emotion, trust and compassion (Card, 1991). One's approach to moral reasoning (and the ethics of care) therefore, is inseparable from these traits and from the contextual circumstances and experiences within relationships (Gilligan, 1982; Kuhse *et al*, 1998, Green, 2012). [See also: Chapter 2: 'Relational autonomy']

more holistic ethical inquiry. Ashcroft (2003:5) outlined three phases of the history of medical ethics:

...a phase in which medical ethics was an internal part of the discourse and self-understanding of the medical profession; a phase in which this self-understanding is problematized and made a topic for reflection in philosophical terms; and (the most recent) a phase in which analytical methods exhaust themselves and are supplemented by various other truth-producing strategies labelled 'empirical'

Hedgecoe (2004: 130) highlighting the need for a more 'critical bioethics' summarised the chief problems of the traditional bioethics model (as viewed from a social science perspective):

- *Bioethics, founded on philosophy, gives a dominant role to idealised, rational thought*
- *It tends to position individuals as the sole judge in ethical decision-making, in that it relegates social and cultural aspects to the status of at best, curios, and worst irrelevancies*
- *The applied ethics model assumes that social reality cleaves down neat philosophical lines, with theoretical categories matching those in social reality: i.e. that what a philosopher says is the doctor-patient relationship actually represents the relationship between doctors and their patients in all settings. Consequently, bioethics does not have the right tools to resolve substantive moral problems, external to these categories themselves*

Although moral evaluation and ethical sensitivity are essential to determining what is 'good' healthcare provision (in its various manifestations), theoretical ethics and ethical inquiry are often seen as somewhat disconnected from the actual experiences of healthcare professionals and patients, insensitive to specific clinical situations and unable to adequately incorporate the complexities of diseases and the contexts in which ethical problems arise (ten Have and Lelie, 1998). Theoretical ethical inquiry, it may therefore be believed, is too abstract, too speculative, and too dogmatic to be of practical assistance to empirical examination. This conceptual gap has served to isolate ethics and ethical inquiry from healthcare practice; it undermines the validity of its claims, and reduces its contribution to policy debates concerning important ethical issues.

Conventional ethical inquiry can offer only theoretical and, by their very nature hypothetical, rules and principles upon which to appraise a particular topic. An increasing awareness of the need for 'real-life' ethics, and for ethical inquiry to be located more strongly within the actualities of healthcare practice and patients'

experience, has led to the emergence of the 'empirical turn' in healthcare ethics/bioethics (Borry *et al*, 2005) and, as the concept has developed, calls for greater empirical ethics activity in relation to healthcare and associated topics have increased (Hope, 1999; Molewijk *et al*, 2004; Richardson and McKie, 2005).

The application of empirical ethics to healthcare situations reflects an increasing awareness that the foundations for ethical analysis of most healthcare and healthcare-related issues lie within the details of real-life events concerning real people with individual experiences and discrete preferences. There are inevitable differences, for example, between the approaches used in theoretical medical ethics to analyse problems, and the realities of 'hands-on' ethical reasoning that occurs in clinical practice. An example provided by Hope (1999: 219) explains how, within healthcare settings, the rationale for seeking the morally 'right' action is intrinsically linked to matters demanding empirical evaluation:

One reason, for example, why doctors should keep patient information confidential is in order to foster patient trust and ensure that appropriate help is sought. And yet the effect of specific breaches of confidentiality is an empirical issue. Medical ethics has been shaped by empirical facts

A constructive ethical examination of such events cannot be undertaken by reference to theoretical concepts and principles alone; it must be grounded within the actualities of the situation and in consideration of, for example, the possible consequences of action or inaction.

Empirical ethics potentially offers the means to examine and resolve substantive moral problems. However, this does not imply that theoretical ethical inquiry is a meaningless endeavour. Ethical theories and principles guide actions and substantiate good judgement. They arise out of the practical contexts and dilemmas, and theory and practice, as Frith (2012: 201) observed: "are *symbiotically related*".

9.4.2 EXAMPLES OF EMPIRICAL ETHICS STUDIES

The application of empirical research and data in bioethical inquiry has been demonstrated in a broad range of studies in which a variety of methods – both quantitative and qualitative – have been employed, for example:

Levitt (2003) used an analysis of public consultation to raise questions about the role of the public in decision making about genetics and health care. The author applied ethical analysis and an exploration of available findings (large-scale surveys of opinion, consensus conferences and focus groups) to respond to the (ethical) question of whether the public *should* be consulted on important ethical issues in science and technology. This study demonstrated the application of 'empirical ethics' in relation to the process of utilising social science data to explore a specific ethical question.

Hasman (2003) offered a more reflective approach to an empirical ethics approach by examining the use of social science methodology in ethical explorations of priority setting in healthcare. The author explored values applied in priority-setting decisions and considered the weight that specific ethical values carry towards such decisions and how different reasons are balanced and traded against each other in the decision-making process. Empirical methods were reviewed and their applicability and efficacy discussed in relation to their adequacy as methods in empirical ethics. The author concluded that: "...a combination method is needed to give a comprehensive representation of values in priority setting and thus to meet the overall objectives of empirical ethics (*ibid*: 41).

Alexander and Wynia (2008) provided an indication of what an empirical ethics methodology, in a more practical sense, may look like. The authors examined what they termed "*the dynamic interplay*" between the quantitative nature of surveys and the normative theories that survey data seek to inform. The authors illustrated the components of an empirical ethics survey and gave examples of key elements of such a survey's design, administration, and analysis. They pointed out some common-sense, but essential, ethical requirements such as the need to ensure that the wording of questions is clear "*because the issues under study are often complex, conceptually inchoate, and/or sensitive or controversial*" (*ibid*:157). They concluded that surveys are an effective method to inform bioethics, clinical practice, and health policy.

9.4.3 A PROCEDURAL ATTITUDE

The preceding examples of empirical ethics studies indicate that the term has been used in a variety of ways to describe the methodological approach applied and demonstrate that, in its overarching function, empirical ethics is not a methodology in itself – it is not a way of 'doing ethics' – but that it is a basic procedural attitude to use the findings from empirical research in ethical reflection and decision-making. It represents a broad classification of ethical inquiry; encompassing different interpretations of combining ethics and empirical research or of attempting to integrate the two.

Unlike studies of ethical dilemmas solely undertaken in light of established ethical theories and principles, empirical ethics (utilising, for instance, interviews, case studies and participatory observation) focuses on 'ethics-in-action'. At its heart is the need to substantiate what may otherwise be claimed to be simply theoretical reflections on a particular issue.

An empirical ethics approach, in addition to introducing an empirical element into ethical inquiry places emphasis on the normative and descriptive ethics approaches described earlier.

Although an empirical ethics approach is reliant on being able to evaluate an empirical fact in light of theoretical ethical considerations, it is not simply the case that ethical principles or concepts are conveniently linked to the empirical data. It is essential that there is integration of data with ethical theory/principles with the aim of enhancing ethical findings:

Empirical findings contribute more than just descriptive information to which the ethicist applies their theories. They contribute to our very understanding of the principles themselves (Frith, 2012: 202)

While empirical data cannot in itself resolve moral questions, it is helpful – in terms of gaining meaningful ethical knowledge – to discover how, for example, people interpret ethical norms, pronouncements and judgements and what they think about the issues and questions that lie at the heart of ethical inquiry. Of particular interest is how people approach ethical decision making when faced with complex practical questions (Wainwright *et al*, 2010).

Empirical ethics therefore enables ethical arguments to be explored via empirical investigation and would provide an appropriate 'procedural attitude' for undertaking the elicitation and analysis of ethical reasoning and arguments. The examination of reasoning and arguments in light of an empirical ethics approach would enable empirical verification of normative claims about public views, values and preferences concerning healthcare distribution. A fundamental aim would be to provide insight into the relationship between empirical data and ethical theories and principles by adhering to a methodological attitude that allows the integration of empirical information in ethical reflection and decision-making (Borry *et al* 2005).

In order to effectively elicit ethical reasoning and arguments, and to subject data to meaningful and productive analysis, it is contended that a qualitative methodology, informed by an empirical ethics approach should be employed. This would entail adherence to the standards and requirements of qualitative research – in terms of data collection and analysis – with an emphasis, within data analysis, on exploring its relationship to a normative and descriptive ethical framework.

How this could be effectively achieved is examined in the next chapter, in which a detailed proposal for a research study, guided by an empirical ethics methodology, is presented.

10 EXAMINING ETHICAL ARGUMENTS: A RESEARCH PROPOSAL

10.1 INTRODUCTION

The preceding chapters of this thesis have examined healthcare distribution and priority-setting – using the QALY approach as an exemplar of distributional practice – and have examined the possibility of incorporating a 'responsibility principle' into priority-setting. It has been established that, in order to effectively inform the current policy context, such a potentially divisive proposition demands a clear, evidence-based account of the public's views. It has therefore been determined that, in order to achieve this, the ethical reasoning and arguments that underpin members of the public's views, values and preferences in relation to a 'responsibility principle', should be elicited and analysed.

This chapter describes a detailed hypothetical proposal for a research study to examine this hypothesis⁵⁶. The proposal is presented as a discrete stand-alone study that would effectively link with the overall aims pursued in this thesis.

10.2 PURPOSE OF THE PROPOSED STUDY

The purpose of this study is to examine ethical reasoning and arguments used by members of the general public to explain and defend their views, values and preferences in relation to identifying responsibility for healthcare need as a healthcare priority-setting and, by implication, QALY-weighting principle.

It is hoped that its findings will complement and assist the interpretation of existing evidence of the public's views, inform the current policy context and contribute to the wider debate on how responsibility for healthcare need may influence healthcare priority-setting.

Members of the public will be recruited to the study and participant data will be elicited via semi-structured interviews and focus groups. Data will be subjected to two phases of analysis: data coding and ethical analysis. The aim of data analysis

⁵⁶ Although this is presented as a discrete proposal, reference is made to the preceding chapters of this thesis where appropriate

will be to determine the nature and validity of arguments applied, identifying the reasoning and evaluative strategies participants have used in support of their arguments, and to subject reasoning and arguments to critical ethical scrutiny.

Fundamentally, this study is an ethical inquiry that seeks to explore the tension between empirical evidence and ethics (Borry *et al*, 2005) by applying an empirical ethics methodology that integrates theoretical ethical inquiry with empirical research (Molewijk *et al*, 2004). The study is explorative and interpretive; it employs a qualitative design and applies a grounded theory approach.

In consideration of the often misperceived aims of traditional (non-empirical) normative or descriptive ethical inquiry, it is important to note what this study is *not* intended to achieve. Its primary focus is not on peoples' conclusions about the ethics of priority-setting or the (moral) 'rights' and 'wrongs' of incorporating a 'responsibility principle', but on the resources and evaluative processes members of the public use to develop and express their points of view. Furthermore, although the evaluation of alternatives may be utilised within data collection, the study is not examining how participants evaluate, or rank alternatives. Neither is the study seeking to identify a broad socio-ethical consensus⁵⁷ i.e. it is not intended that its findings will reveal the 'public's view' on how scarce health care resources should be allocated; it is concerned with examining reasoning and arguments rather than soliciting opinion.

Although it is anticipated that the findings of this study will inform the broad policy context in relation to priority-setting, particularly in light of the demands for increased involvement of the public in policy formation, it is not intended that it will directly influence policy. It is acknowledged that public opinion does not always direct policy/practice and that there is not always a direct link between public opinion and policy formation.

⁵⁷ It is anticipated however, that data analysis will highlight issues of consensus and disagreement

10.3 RATIONALE

This study is founded on the belief that:

- Issues concerning the distribution of healthcare resources are fundamentally of ethical significance
- Public participation is increasingly recognised as an important factor in healthcare policy and the lack of research into the public's ethical arguments is at variance with this
- Understanding public views, values and preferences regarding healthcare priority-setting and the 'responsibility principle' cannot be achieved solely via surveys of public opinion, descriptions of preferences or by philosophical reflection. It demands the systematic examination of the underlying ethical reasoning and arguments.

The foundations of public views, values and preferences must be understood if public participation in healthcare distribution decisions is to be enhanced and if public views are to effectively inform policy discussions. The rationale for the study therefore is the need to improve the link between theoretical arguments and empirical results in order to gain a better understanding of what members of the public think about healthcare priority-setting and the concept of a 'responsibility principle'.

Within the healthcare distribution/priority-setting literature, there is considerable evidence of the professional voice and related arguments. However, although attempts have been made to elicit ethical values and describe ethical justifications for public preferences regarding how healthcare is distributed (see Chapter 8) there has been a lack of research specifically aimed at systematically examining members of the public's ethical arguments i.e. their validity and underlying reasoning and premises, in relation to healthcare distribution, priority-setting or the incorporation of a 'responsibility principle'. In fact, in terms of examining public views, values and preferences, there is no evidence of empirical studies aimed at distinguishing ethically based considerations from prejudices in this area (Olsen et al, 2003).

Given the increasing focus on social and ethical issues in the healthcare distribution literature; the on-going public debate on rationing medical treatment; the need for

more evidence to inform ethical and policy debates regarding healthcare distribution and priority-setting – such as those relating to the 'responsibility principle' – and the paucity and limitations of previous studies, there is a need for the systematic investigation of the authenticity of people's views, values and preferences, and the identification of empirically-based and ethically-defensible social objectives in relation to these issues. This, it is contended, demands the critical examination of public views that exposes and analyses their underlying ethical reasoning and argumentation.

It is anticipated that by offering lay participants an opportunity to engage with the conflicts and complexity of healthcare priority-setting, the findings of this study will complement and assist the interpretation of existing evidence of public opinion, inform the current policy context and contribute to the wider debate on how responsibility for healthcare need may influence priority-setting. The study findings will hopefully stimulate further research activity.

10.4 RESEARCH QUESTION(S)

The study will seek to *answer the following research question:*

What are the ethical arguments that underpin the views, values and preferences of members of the public when asked to consider responsibility for healthcare need as a healthcare priority-setting principle?

This question has generated sub-questions that provide a clear link to data generation and analysis (Churchill and Sanders, 2007) and provide additional value and authority to the study:

- What are the processes of ethical reasoning and moral evaluation used by members of the public to explain and defend their views, values and preferences?
- Which ethical principles and theories and concepts are used to underpin participants' responses, and are some moral concepts dominant?
- Are attempts made to synthesise different ethical approaches?
- Are valid arguments applied – defined by either their logical structure or coherence?
- How do participants seek to resolve both logical and ethical conflicts,

inconsistencies and contradictions in their responses?

- Are views, values and preferences contradicted or rejected in response to contrasting prioritisation strategies?
- Are moral distinctions made between types of 'self-inflicted' ill-health?

10.5 RESEARCH AIMS AND OBJECTIVES

10.5.1 AIMS

- To examine the ethical arguments that underpin the views, values and preferences of members of the public when considering responsibility for healthcare need as a possible healthcare priority-setting principle
- To produce empirical evidence that will contribute to the existing knowledge-base and, by complementing, enhancing and assisting the interpretation of existing evidence, inform the current policy context and the wider debate on healthcare priority-setting and the incorporation of a 'responsibility principle'

10.5.2 OBJECTIVES

- To elicit the views, values and preferences of members of the public regarding responsibility for healthcare need as a possible healthcare priority-setting principle
- To examine processes of ethical reasoning and moral evaluation
- To examine the ethical nature and validity of arguments
- To review existing sources of evidence by undertaking systematic reviews of academic literature concerning: (i) the elicitation of the views, values and preferences of members of the public regarding healthcare priority-setting in relation to responsibility for healthcare need and, (ii) the identification of moral reasoning and ethical argumentation used by members of the public in response to the distribution of healthcare

10.6 RESEARCH DESIGN AND METHODOLOGY

10.6.1 A QUALITATIVE APPROACH

The broad scope of this study is innovative and a clear choice of methodology did not immediately suggest itself. A review of empirical ethics research was undertaken to inform the methodology (Bjørn *et al*, 1999; Richard *et al*, 2005; Schildmann *et al*, 2006; Van der Vorm *et al*, 2009).

Although a quantitative approach enables public views to be identified, it is most appropriate for generating data across statistically representative samples of the population (Coast, 1999). Therefore, to effectively elicit, identify and explore participants' reasoning and arguments this study will employ a qualitative design and apply a Grounded Theory approach to data collection and analysis (Glaser and Strauss, 1967; Charmaz, 2006), which will be undertaken via semi-structured interviews, focus groups and thematic analysis.

Qualitative research emphasises words rather than quantification in the collection and analysis of data (Bryman, 2008). It allows the researcher to "*get at participants' inner experiences, to determine how meanings are formed*" (Corbin and Strauss, 2008:12) and focuses is on the *why* and *how* of decision making rather than simply *what*, *where*, *when*. Hence, smaller but focused samples are more often needed than large samples. Qualitative studies are grounded in a philosophical position that is broadly 'interpretivist', in the sense that they are generally concerned with how the social world is interpreted, understood, experienced or produced (Ritchie and Lewis, 2003).

A potential weakness of qualitative methods is their vulnerability to accusations in relation to subjectivity and the *representativeness of participants*. With regard to subjectivity, the (relatively) small number of participants and potentially large bodies of data, pose a risk of both participants and data being selected that support a particular pre-determined view, making it problematic for an external observer to tell if or to what extent this may have occurred, leading to questions such as "whose perceptions are really being described in the findings?" This, plus the potential for the researcher to lose objectivity due to the nature of analysis involved, is managed by ensuring data trustworthiness (Morrow, 2005) (see below). The representativeness of participants is not the prime requirement when the objective is

understanding social processes:

In qualitative investigations, researchers are not so much interested in how representative their participants are of the larger population. The concern is more about concepts and looking for incidents that shed light on them. And in regard to concepts, researchers are looking for variation, not sameness. Variation is especially important in theory building because it increases the broadness of concepts and scope of the theory (Corbin and Strauss, 2008: 156)

10.6.2 GROUNDED THEORY

Grounded Theory (Strauss and Corbin, 1990; Charmaz, 2006) is particularly appropriate for exploring areas where there is little existing knowledge on which to base hypotheses (Greenhalgh and Taylor, 1997; Mason, 2002). It is a comparative, iterative and interactive method that aims to develop theory that is 'grounded' in data. It is an inductive strategy⁵⁸ for generating and confirming theory that emerges from close involvement and direct contact with the empirical world (Patton, 2002). It also allows for contextual sensitivity and interpretation (Strauss and Corbin, 1990) and for differences in participants' responses to be viewed as a source of data richness and deeper understanding of emerging concepts (Priest *et al*, 2001).

Grounded Theory involves specific techniques of data collection and analysis that ensure rigour and comprehensiveness. These include concurrent data collection and analysis; subjecting data to constant comparative analysis as additional data are collected (Strauss and Corbin, 1998), and the use of a coding paradigm to ensure conceptual development and density (Corbin and Strauss, 2008). Data analysis aims to discover dominant themes and later generate a conceptual framework that underpins the emerging theory (Glaser and Strauss, 1967). This approach was selected because of the limited nature of existing knowledge of the reasoning and arguments used by the public in relation to healthcare priority-setting and the 'responsibility principle'.

10.6.3 COMBINING QUALITATIVE METHODS

Data collection will be achieved through semi-structured interviews and focus groups. A decision to combine qualitative methods has been made in order to

⁵⁸ Induction is the process of estimating the validity of observations of part of a class of facts as evidence for a proposition about the whole class i.e. a conclusion reached by this process. In inductive reasoning, the conclusion, although supported by the premises, does not necessarily follow from them (Glaser and Strauss, 1967).

increase the richness of data and facilitate data confirmation (Lambert and Loiselle, 2008).

A mixed method approach will help to identify the extent to which issues are delineated and interpreted and it is anticipated that each method will reveal complementary data. For example, interviews provide an opportunity for detailed investigation of personal perspectives of complex and potentially sensitive issues (Ritchie and Lewis, 2003; Kvale, 2007), whereas focus group discussions, which emphasise group interaction and the joint construction of meaning (Block *et al*, 2001; Bryman, 2008; Abelson *et al*, 2009), can help participants to explore and clarify their views in ways that would be less achievable within a one-to-one interview (Webb and Kevern, 2000). Combining or overlapping qualitative approaches thereby contributes to enhanced understanding and will potentially increase the depth and trustworthiness of the study's findings (Barbour, 1998; Farmer *et al*, 2006; Lambert and Loiselle, 2008). Qualitative method triangulation – generating complementary views of a concept or phenomenon – is increasingly advocated and is one of the principal ways of 'validating' qualitative research evidence (Ritchie and Lewis, 2003).

Within this 'mixed methods' approach, focus groups and interviews may be conducted in a pre-determined sequence or may be undertaken in no particular order according to the aims of data collection. For example, researchers may obtain interview data and use focus groups to follow-up or confirm their findings (Wackerbarth *et al*, 2002) or undertake focus groups followed by semi-structured interviews (Coast, 2001a; Litva *et al*, 2002). For the purpose of this study, it is proposed that semi-structured interviews will precede focus groups so that the focus groups may explore issues emerging from interview data.

It is anticipated that findings from both methods will corroborate one another but data sets from both approaches will not be regarded as equivalent i.e. it is not intended to reveal or imply a hierarchy of evidence, where one method is claimed to yield more accurate findings than the other (Barbour, 1998).

Data analysis will identify and interpret processes by which participants' views, values, preferences, reasoning and arguments emerge according to each method. Although interviews may allow systematic exploration, focus groups may not allow the exploration of all questions and may therefore provide a more partial picture. For

example, characteristics discussed in one group may not be discussed in another group. Therefore, in the analysis stage, group conversations will not be considered separately. However, when focus group data are considered together, summarised and compared with individual interview data, a more 'complete' picture of themes across groups will hopefully be obtained. It is intended that trustworthiness will be increased by this 'data convergence', enabling corroboration of views, values, preferences, reasoning and arguments across the methods.

10.6.4 DATA COLLECTION

Data collection will be undertaken in two sequential phases:

10.6.4.1 PHASE ONE (PILOT STUDY)

The aims of the first phase of data collection (the pilot study) will be to demonstrate the feasibility of data collection and analysis by i) testing the design of the interview and focus group processes, including participant recruitment and engagement and the design and functionality of the pre-prepared interview guide and focus group questions, and ii) subjecting data obtained to the process of analysis outlined below.

One-to-one semi-structured interviews with a small sample of members of the general public (it is anticipated that no more than ten interviews will be conducted for this phase of data collection) and one focus group consisting of approximately eight to ten members of the public, will be conducted. Interviews and the focus group will be audio-recorded, transcribed and analysed.

Evaluation of phase one of the study will inform the next phase of data collection.

10.6.4.2 PHASE TWO

Semi-structured interviews will be conducted with a larger sample of members of the public. Interviews will be conducted until interview data achieves 'saturation' i.e. a point where additional interviews would give rise to minimal new perspectives or concepts (Corbin and Strauss, 2008). Data analysis will be undertaken concurrent with the interviews and it will therefore be possible to identify a point at which saturation is achieved.

Interviewees will be asked if they are willing to take part in a subsequent focus group. The number of focus groups held will be determined in accordance with the requirement for data saturation, but it is anticipated that a least two focus groups will be held, each consisting of approximately eight to ten members of the public in each group.

Interviews and focus groups will be audio-recorded, transcribed and analysed.

10.6.4.3 INTERVIEWS – PROCESS

Participants will be informed about the nature and purpose of the study and invited to discuss issues related to the distribution of healthcare, priority-setting and the suggestion that responsibility for healthcare need should be considered when healthcare priorities are identified. Terms such as 'QALY-weighting' or 'weighting health benefits' are not in common use and will not be used within the interviews. However, participants' inferred views on weighting will be sought⁵⁹.

An interview guide comprising of open-ended questions, relevant prompts and probes, plus scenarios designed to explore key issues arising from the literature, will be used to guide the discussion rather than as a prescriptive means of eliciting responses (Appendix Two).

The intention will be to generate an adaptable dialogue, with the interviewer questioning, probing, seeking clarification, offering additional information and summarising. Throughout the interview, additional short, open questions (probes) will be used to elicit reasoning and arguments; to verify their consistency and to encourage participants to explain and explore their responses. For example:

- What are your reasons for thinking/believing that?
- Earlier in the interview you stated that you believe 'X' but you have now confirmed that you also support doing 'Y', what do you think of this?
- Can you give me an example?

⁵⁹ To elicit responses that may indicate a view on weighting health benefits (and not simply a preference to maximise efficiency) the predicted health outcome will be kept the same within questions and scenarios. Weighting is only applicable in circumstances where the potential health gain is equal. Therefore, if the health gain is not kept the same, the question cannot elicit a view on weighting health benefits. Statements such as "I would give priority to the most severely ill" could be about weighting benefits or may indicate a preference for straightforward efficiency, depending on how the question is framed

- Are there circumstances where that would not be the case?
- Why do you think such views are held?
- What would you recommend?
- If another person had an opposite view to your own, how would you explain to them why you believe your view to be correct?

To ensure that ethical reasoning may ensue, issues will be presented in terms of an ethical problem (or containing ethically-relevant features) (Holm, 1997: 99). Participants will be encouraged to explain and defend their views; to provide reasons or evidence to support their position and, in so doing, demonstrate morally reasoned preferences.

It has been noted that the valuations of health increments seem to be affected by whether questions are framed as individual or social choices (Gyrd-Hansen, 2004). Therefore, in order to avoid discrepancies between individual and social valuations, participants will, where possible, be encouraged to adopt a social decision-making perspective.

Self-contradictory statements or evident conflicts or inconsistencies of reasoning and the extent to which participants sustain logical arguments when challenged will be explored by encouraging participants to reflect on their responses, for example:

Interviewer: *Earlier, you said that you think that people responsible for their own ill-health should have lower priority, but you have now stated that you also believe that society shouldn't discriminate against smokers – how do you think decision-makers can resolve such opposing views?*

It is acknowledged that formulating and framing sound arguments demands considered, critical thinking, and it has been suggested that general population respondents do not have a readily articulated account of their views on complex healthcare priority-setting issues (Shah, 2009). Therefore, a conversational approach will be fostered throughout the interview. Participants will be encouraged to 'think aloud', to verbalise their reasoning and express arguments in their own words.

The interviewer will be particularly alert to the development (by the participant) of coherence-focused arguments that do not necessarily accord with the rational, logical process of deductive reasoning (outlined in Chapter 7). Participants will be

encouraged to reflect upon their initial responses to questions and to develop their evaluation and, ultimately, their ethical arguments. The interviewer will be attentive to the evaluative processes participants employ and will aim to recognise and respond to their use of:

1. moral claims, made either via recommendations ('should', 'ought' etc.)
2. evaluative terms ('right', 'wrong' etc.)
3. adjectives such as 'cruel', 'inhumane', etc.
4. components of ethical evaluation, such as analogies and parallels ("x is like 'y' so you should not do 'x'")
5. 'slippery slope' arguments ("if you do 'x' then it will eventually lead to 'y'") (Thomson, 1999).

The interviewer will aim to use these to facilitate the discussion.

Information will be presented verbally and, where necessary, via laminated card or computer laptop screen, and participants' understanding of written information will be established. Interviews will be conducted by the researcher and it is anticipated that each interview will last for approximately one hour. Interviews will be recorded using digital audio equipment and subsequently transcribed.

10.6.4.4 FOCUS GROUPS – PROCESS

Focus groups will be facilitated by the researcher and an experienced co-facilitator. Focus groups will be structured around a set of predetermined questions to examine issues emerging from interview data. Focus groups will commence with the facilitator asking one or two questions aimed at engaging participants and subsequent questions will seek to explore issues emerging from interview data.

A key feature of focus groups is the exploitation and active encouragement of group interaction among participants (Webb and Kevern, 2000) and it is anticipated that participants' comments will stimulate and influence the thinking of others. Emphasis will be placed on encouraging participants to talk to one another; asking questions, exchanging anecdotes, and commenting on the others' experiences and points of view.

Focus groups will be recorded using digital audio equipment and subsequently

transcribed.

10.6.5 RECRUITMENT

The study will seek to recruit English-speaking, adult⁶⁰ 'members of the public'. However, it is acknowledged that this term is indistinct and that, from a qualitative research perspective, the concept of a 'member of the public' may be unhelpful. This is obviously of concern with regard to the generalisability of qualitative findings and this issue is addressed in 'Data Trustworthiness' (below).

In a review of public participation in healthcare priority-setting, Mitton *et al* (2009: 223) defined three distinct categories of members of the public:

1. *the public as individual citizens speaking on their own behalf*
2. *the public as organised interest groups supposedly speaking on behalf of their membership*
3. *the public as patients or consumers of services, in those relatively few instances where they are asked to speak on issues broader than their own personal experience*

In recruiting participants, it is not intended that a 'member of the public' will be specifically defined. The expectation is that participants will be invited as 'individual citizens speaking on their own behalf'. However, it is acknowledged that this may not be possible to confirm.

In accordance with a Grounded Theory approach, the initial participant sample will be obtained from where the phenomenon occurs (Coyne, 1997). Therefore, recruitment to the pilot study will recruit adult members of the general public via advertisements placed within prominent locations (supermarkets, libraries etc.). A study website will also be established to provide further information and the website address will be included within the advertisement. No additional inclusion/exclusion criteria will be applied.

Subsequent recruitment will be based on theoretical sampling, a form of sampling that is controlled by the needs of the emerging theory, not a list of variables (Strauss and Corbin, 1998). It is anticipated therefore that a more focused sampling strategy may emerge as data is analysed.

⁶⁰ Participants age and language abilities will be checked on recruitment to the study

Members of the public who express an interest in participating in the study will be sent an introductory letter, Participant Information Sheet and Expression of Interest form plus a pre-paid envelope. Upon receipt of a completed Expression of Interest form, the researcher will contact respondents by telephone to discuss the study further and, if appropriate, to arrange a convenient date and time for their interview. Each participant will take part in one interview and receive a small payment to cover any travelling expenses.

10.6.6 DATA ANALYSIS

Interviews and focus group data will be transcribed and then organised using the qualitative data analysis package NVivo (Gibbs, 2002; Bazeley, 2007). Data from both sources will be analysed together in fulfilment of data triangulation. This will enhance data trustworthiness by data convergence, enabling corroboration of views, values, preferences, reasoning and arguments across the methods. Focus group data will also be compared with individual interview data, to identify and interpret processes by which participants' views, values, preferences, reasoning and arguments emerge according to the method of data collection. There are two aspects of data analysis for this study, i) coding, and ii) ethical analysis which, in accordance with Grounded Theory, will be undertaken concurrently (**Figure 10.1**).

10.6.6.1 CODING

Coding is central to Grounded Theory; it involves three stages: open coding; axial coding and selective coding (Corbin and Strauss, 2008).

In the *open coding* stage, categories of information are developed via line-by-line analysis of the data; examining it for concepts that appear to relate to the same phenomena. A coding framework is developed, both to facilitate analytical consistency and to reveal discursive themes and processes recurring within and across data. These categories are subsequently 'labelled' using, for example, theoretical ideas from the literature. Sub-codes are identified which represent different dimensions of the categories. For example, depending upon participants' responses, an initial label may be '*Lower priority*', this may subsequently generate such sub-codes as 'responsibility', 'alternatives', 'fairness', 'blame', 'punishment' etc.

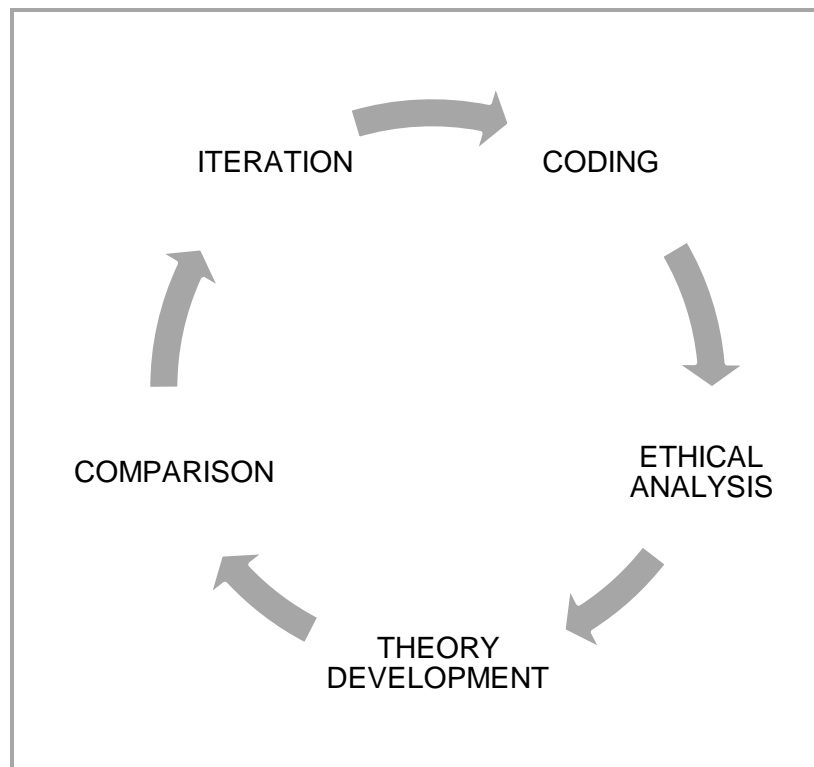


Figure 10.1: The process of data analysis

The second stage of coding is *axial coding*, in which relationships between categories and sub-codes are explored and defined. This is done by linking codes to contexts, to consequences, to patterns of interaction, and to causes (Bryman, 2008). For example, as the potential health gain will have been (where possible) held constant within interviews and focus groups, any stated preference for prioritising the youngest patients, the most severely ill etc. will not be combined into a category with preferences for prioritising these groups when the health gain is not predicted to be the same, as that could result in erroneous conclusions being drawn about arguments for weighting benefits.

A coding paradigm (theoretical model) that visually displays the interrelationships of these axial codings (Strauss and Corbin, 1998) is then developed (a hypothetical example is given in **Figure 10.2**).

The third stage of coding is *selective coding* which involves selecting a core category – such as 'Lower priority' in the example given above – as the central phenomenon, systematically relating it to other categories and filling in categories that need further refinement (Bryman, 2008).

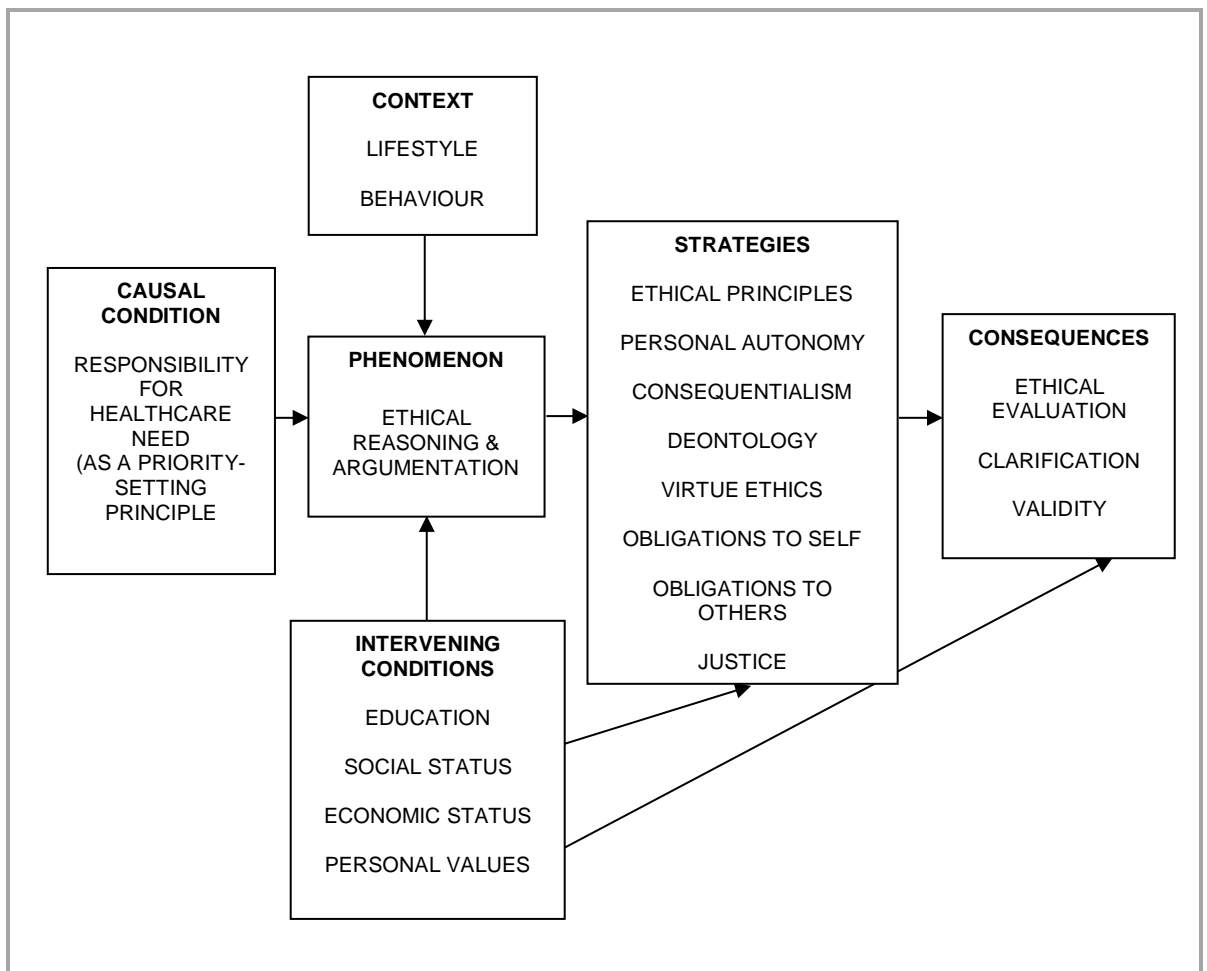


Figure. 10.2: Hypothetical example of a coding paradigm:

10.6.6.2 ETHICAL ANALYSIS

This stage of analysis will explore core categories and subject them to more detailed study of their ethical content and evidence of ethical reasoning and argumentation. A focused ethical analysis of the data will be undertaken; mapping the categories onto relevant moral theory.

To establish control over the scope of analysis (the range and complexity of theories that data could be compared against is considerable, implying a potentially limitless process of scrutiny), preliminary ethical analysis will be applied from the perspective of key ethical theories, starting with the standard bioethical approach to ethical analysis - respect for autonomy, non-maleficence, beneficence and justice, commonly referred to as the 'four principles' approach (see Chapter 5). Data will also be analysed from a consequentialist, deontological and virtue ethics

perspective. The ethical validity of arguments will be established via their adherence to a valid logical form (See Chapter 7).

Having established a practicable ethical framework, subsequent analysis will examine the process of ethical reasoning and the ways in which participants have sought to resolve both logical and ethical conflicts, inconsistencies and contradictions in their responses. For example, are moral distinctions made between 'self-inflicted' illnesses and their influence on healthcare entitlement? Are preferences contradicted or rejected when participants are asked to consider various prioritisation strategies? Are attempts made to synthesise different ethical approaches? Are some moral concepts dominant? For example, do participants support an egalitarian account, rejecting prioritisation of healthcare on the basis of perceived responsibility for healthcare need? The extent to which broad moral concepts such as 'merit', 'responsibility' and 'social value' have been used (or inferred) to support arguments will be identified.

In acknowledgment of the need to identify coherence-focused arguments⁶¹ – in addition to the rational, logical argument structure – the links between participants' initial responses, the components of the evaluative processes applied and the conclusions will be examined.

The issue of commensurability will be explored. For example, some participants may state that their ethical priority is to ensure there is as little difference between what healthcare people receive as possible, and be consistent within this. While others might argue (or infer) that maximising health benefits is the most important approach and respond consistently within that view. However, there may be identifiable inconsistencies or flaws within these arguments or there may simply be differences in what people regard as the primary ethical goal (e.g. ensuring equality, maximising benefits etc.).

All identified ethical arguments will be subjected to further descriptive analysis highlighting, for example, issues of consensus and disagreement

To assist the supplementary validation of the findings (Strauss and Corbin, 1998), a comparative analysis of ethical arguments advanced by participants, with those

⁶¹ Coherence-focused arguments are discussed in Chapter 7

advanced in the literature regarding responsibility for ill-health as a priority-setting criterion, will be undertaken.

10.7 ENSURING DATA TRUSTWORTHINESS

Establishing criteria for assessing the quality of qualitative research – its 'trustworthiness' – has been an important consideration in developing this research proposal. Qualitative research is sometimes accused of lacking the scholarly thoroughness of quantitative approaches because the presumed lack of demonstrable validity and reliability - fundamental cornerstones of the quantitative method – of its findings. Shenton (2004) described four criteria for ensuring trustworthiness, proposed by Guba (1981) that will be applied to this study. Each criterion's equivalent in quantitative research is shown in brackets (Bryman, 2008):

- a) Credibility (which parallels internal validity)
- b) Transferability (which parallels external validity)
- c) Dependability (which parallels reliability)
- d) Confirmability (which parallels objectivity)

In order to demonstrate the trustworthiness of this study's findings, the following outlines how each of these criteria will be met:

Firstly, the *credibility* of the study's findings will be established by the adoption of established research methods; the triangulation of methods (any weakness in one is compensated by the strengths of the other (Guba, 1981)); the use of a transparent and systematic approach to data analysis; reference to supporting literature to explain and confirm the data; the voluntariness of participation; and lastly by the ongoing scrutiny of the project by an experienced research supervisor.

The study will be examining a relatively small number of participants. Therefore, the generalisability and overall relevance of its findings may give rise to concerns (Coast *et al*, 2004). However, although it will not be possible to ensure that the findings of this study are applicable to other situations and populations, the *transferability* of its findings will be enhanced by providing sufficient 'thick description' of the context in which the study has been undertaken to enable others to assess the possible transferability of findings to their own situations. Morse (1999: 5) opposed the view that qualitative findings are not generalisable providing

that the sampling of participants "*ensures that the theory is comprehensive, saturated and accounts for negative cases.*" Monitoring progress towards data saturation, a key feature of Grounded Theory, will enhance the transferability of this study's findings.

The *dependability* of findings is related to some of the factors cited in support of their credibility, particularly the use of overlapping research methods (interviews and focus groups), and the adoption of an 'auditing approach' (Bryman, 2008) ensuring that complete records are kept at all stages of the research process.

Finally, with regard to *confirmability*, the researcher will seek to avoid allowing personal values or theoretical inclinations to influence the conduct of the study. Although it is recognised that complete objectivity is impossible in social research (Bryman, 2008), and Grounded Theory acknowledges the role of the researcher as an active participant in the research process (Corbin and Strauss, 2008), there has been a systematic approach to the design of this study, as there will be to its implementation, and the researcher will ensure that they are aware of the impact their role and presence will have on both participants and the data. The methods adopted for this study provide transparency, so that the influence of the researcher on the process can be identified and allowed for, and that clear connections may be drawn between the original data and the conclusions. The researcher will also be mindful of the need for reflexivity throughout the research process and will maintain a reflective journal; a personal narrative consisting of notes and responses to key events such as interviews.

10.8 ETHICAL CONSIDERATIONS

10.8.1 CONSENT

Participation will be voluntary, potential participants will be advised that if they do not wish to participate they need only not return the Expression of Interest form. All potential participants will be encouraged to make contact with the researcher to ask questions or seek further information if required before deciding whether or not to take part. Prior to commencement of an interview, participants will be asked to sign a consent form and their written consent will be retained for the duration of the study. A copy will also be given to each participant.

10.8.2 CONFIDENTIALITY

Participants will be informed that all personal information will be treated in confidence and that all data will be anonymised and not made available to anyone who is not directly involved in the study. The results of the study, or any resulting statistics or publication of direct quotes from participants, will not be made available in a form that identifies participants. Consent Forms will be stored in a locked filing cabinet. Raw and processed electronic data will be encrypted and stored on the researcher's computer which will be password protected. All data will be stored and accessible, by the researcher only, for a period of five years after the study has ended, at which point data will be destroyed.

10.9 POTENTIAL BENEFITS

It is hoped that this (hypothetical) study will provide a significant contribution to methodological and empirical knowledge, as the critical examination of ethical reasoning and arguments in the context of healthcare priority-setting represents an innovative approach to research in this area. By systematically examining ethical reasoning and argumentation and applying an empirical ethics methodology, it will help to bridge the quantitative/qualitative gap in research into the public's views regarding healthcare priority-setting.

The methods used will enable inconsistencies in reasoning to be highlighted and allow participants to deliberate on how to resolve them. This is something that is not evident within other approaches to eliciting public views in this area. By not seeking participants' unsupported views or presenting a summation of views and opinions the study acknowledges participants as reasoning moral agents rather than simply a source of stated preferences and this is considered to be a particular strength of this study.

It is recognised that there can be no certainties with regard to the outcome of this study, in fact 'uncertainty' – with regard to, for example, identifying how the public's reasoning per se (as opposed to opinion) might inform policy – is one of its key strengths. However, it is anticipated that it will produce empirical evidence to complement, enhance and assist the interpretation of existing evidence of the public's views.

It is further anticipated that the findings will have normative implications that will be articulated and evaluated and may therefore inform the current policy context; contribute to the debate on the role responsibility should play in priority-setting (Campbell, 2012) and effectively align with contemporaneous activities in this field such as the 'Social Values and Health Priority Setting' project being undertaken at University College, London (UCL, 2013).

10.10 DISSEMINATION STRATEGY

The findings of this study will be disseminated via peer-reviewed journals, such as: *The Journal of Medical Ethics*, and *Health Care Analysis*. All participants in the study will be offered the opportunity to receive a copy of its findings.

11 CONCLUSIONS

The challenge faced by the National Health Service of providing a reasonable level of healthcare to the maximum number of people via a finite healthcare budget has provided the broad context for this study. A significant aspect of that challenge is ensuring that healthcare is distributed efficiently and that it meets the need for social and ethical acceptability.

The recognition of a 'responsibility principle' within healthcare priority-setting would, as has been contended throughout this thesis, be a particularly contentious addition to NHS distribution strategy and would indicate a marked change to the manner in which NHS provision is conceived and delivered. However, as the introduction to the thesis made clear, financial limitations, combined with growing demand for NHS care, suggest that priority-setting and rationing must be regarded as pragmatic prerequisites for effective healthcare distribution. It is therefore essential that priority-setting criteria be established that enable empirically-based and ethically defensible resource-limiting strategies.

In the second and third chapters of this thesis, the way in which healthcare is distributed and priorities identified via the use of QALYs was described and subjected to critical ethical evaluation. The QALY approach is an effective, if somewhat inflexible, means of quantifying health outcomes and offers a standard method of priority-setting against which the introduction of a different approach to priority-setting – as via the introduction of a 'responsibility principle' – may be appraised. The QALY approach has been subjected to considerable criticism, particularly due to its disregard for the variations in people's healthcare needs. It has been established that the suggestion that the QALY approach should be modified and that a system of weighting – that would enable more explicit priority-setting – be introduced is gaining credibility in health economics and bioethics fields, and that it has (limited) evidence of public support.

The concept of 'weighting' the QALY in accordance with the individual characteristics or attributes of its recipients was explored and the feasibility of incorporating a distributional bias into an otherwise egalitarian approach to healthcare distribution was ethically evaluated. Proposals for weighting the QALY, it was established, are ethically valid. However, other socio-ethical influences would

need to be addressed if a substantive system of weighting were to be introduced. Chief among these are the need to identify the specific characteristics against which weight could be added or subtracted, and ensuring that weighting criteria have public support.

Responsibility for ill-health and consequent healthcare need is a particularly controversial potential weighting criterion. In light of its various socio-ethical implications, responsibility-weighting would demand a clear understanding of public views and, more importantly, effective involvement of the public and public opinion in the debate.

In chapter four, the concept of the 'responsibility principle' was investigated and subjected to critical ethical appraisal. A proposal that responsibility should be a factor in priority-setting would encounter much opposition, much of which would refer to the ethical difficulties that its implementation would inevitably encounter. A need for clear, empirically-based and ethically defensible social objectives has been promoted throughout this thesis and the 'responsibility principle' offers a clear justification for identifying such objectives.

The thesis then considered the role of the public and, more particularly, the views, values and preferences of the public with regard to healthcare distribution, priority-setting and the 'responsibility principle'. In chapter five, the influence of social values on health distribution decision-making was explored and the ways in which NICE, as the national source of guidance to decision-makers, has sought to integrate social values and social value judgements into its activities was evaluated.

Effective public participation in healthcare distribution debates, it is concluded, demands a more thorough exposition of the public's views, values and preferences. This, it is contended could be achieved by examining how the public construct ethical arguments to support their stated preferences regarding priority-setting and the 'responsibility principle'.

The concepts of ethical reasoning and arguments were explored in Chapter 7, and in Chapter 8, it was shown that there is little existing evidence of these concepts being systematically examined in relation to healthcare distribution. Therefore, it was established that an effective means of doing so should be identified.

The methodological approach of empirical ethics, discussed in Chapter 9, it is contended, would provide appropriate methodological guidance for a study seeking to elicit, analyse and identify the public's reasoning and arguments. In chapter 10, a detailed proposal was presented that would meet the need for a systematic, in-depth approach. It is anticipated that the findings of the proposed hypothetical study would enhance knowledge of public views and enable public participation in the debates to be more effectual.

The overall conclusions drawn from this study are that:

- i. the suggestion that responsibility for ill-health and consequent healthcare need should be a factor in the allocation of healthcare resources demands the input of 'public opinion'
- ii. the role and influence of public opinion in healthcare distribution policy are impeded by the inherent limitations of available evidence of the public's views values and preferences
- iii. the systematic examination of ethical reasoning and arguments would enhance public participation by adding to the existing knowledge-base on public opinion
- iv. a qualitative research study, guided by an empirical ethics methodological approach, would provide the means by which members of the public's reasoning and arguments could be systematically investigated.

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APPENDICES

APPENDIX ONE

ARTICLES EXCLUDED FROM LITERATURE REVIEW

		Reason for exclusion
1.	Anand, P. and Wailoo, A. (2000) Utilities versus Rights to Publicly Provided Goods: Arguments and Evidence from Health Care Rationing, <i>Economica</i> , 67 (268), pp. 543-577.	Survey
2.	Anderson, M., Richardson, J., McKie, J. and Iezzi, A. (2010) Personal Characteristics in Health Care Rationing: The public explanations, Monash University Centre for Health Economics Research Paper No. 56.	Survey
3.	Anderson, M., Richardson, J., McKie, J., Iezzi, A. and Khan, M. (2011) The Relevance of Personal Characteristics in Health Care Rationing: What the Australian Public Thinks and Why, <i>American Journal of Economics and Sociology</i> , 70 (1), pp. 131-151.	Survey
4.	Baker, R (2006) Economic rationality and health and lifestyle choices for people with diabetes, <i>Social Science and Medicine</i> , 63 (9), pp. 2341-2353.	Q-methodology
5.	Browning, C. J. and Thomas, S. A. (2009) Community values and preferences in transplantation organ allocation decisions, <i>Social Science and Medicine</i> , 52 (6), pp. 853-861.	Survey
6.	Bryan, S., Roberts, T., Heginbotham, C. and McCallum, A. (2002) QALY-maximisation and public preferences: results from a general population survey, <i>Health Economics</i> , 11 (8), pp. 679-693.	Interview-based survey. Statistical data analysis only
7.	Cuadras-Morato, X., Pinto-Prades, J-L. and Abellan-Perpinan, J-M. (2001) Equity considerations in health care: the relevance of claims, <i>Health Economics</i> , 10 (3), pp. 187-205.	Survey
8.	Dolan, P. and Shaw, R. (2003) A note on the relative importance that people attach to different factors when setting priorities in health care, <i>Health Expectations</i> , 6 (1), pp.53-59.	Self-completed questionnaire
9.	Dolan, P., Shaw, R., Tsuchiya, A. and Williams, A. (2005) QALY maximisation and people's preferences: a methodological review of the literature, <i>Health Economics</i> , 14 (2), pp. 197-208.	Literature review
10.	Dolan, P. and Tsuchiya, A. (2009) The social welfare function and individual responsibility: Some theoretical issues and empirical evidence, <i>Journal of Health Economics</i> , 28 (1), pp. 210-220.	One-to-one structured interviews
11.	Edlin, R., Tsuchiya, A. and Dolan, P. (2011) Public preferences for responsibility versus public preferences for reducing inequalities, <i>Health Economics</i> , doi: 10.1002/hec.1799	Statistical data analysis
12.	Furnham A, Simmons K, McClelland A. (2000) Decisions concerning the allocation of scarce medical resources, <i>Journal of Social Behaviour and Personality</i> , 15 (2), pp. 185-200.	Statistical data analysis
13.	Furnham, A., Thomson, K. and McClelland, A. (2002) The allocation of scarce medical resources across medical conditions, <i>Psychology and Psychotherapy: Theory, Research and Practice</i> , 75 (pt.2), pp.189-203.	Questionnaire
14.	Gold, M. R., Franks, P., Siegelberg, T. and Sofaer, S. (2007) Does providing cost-effectiveness information change coverage priorities for citizens acting as social decision makers? <i>Health Policy</i> , 83 (1), pp. 65-72	Questionnaire
15.	Johannesson, M. and Johannsson, P-O. (1997) Is the valuation of a QALY gained independent of age? Some empirical evidence, <i>Journal of Health Economics</i> , 16 (5), pp. 589-599.	Survey

APPENDIX ONE

ARTICLES EXCLUDED FROM LITERATURE REVIEW (Continued)

		Reason for exclusion
16.	Jones, I. R., Berney, L., Kelly, M., Doyal, L., Griffiths, C., Feder, G., Hillier, S., Rowlands, G. and Curtis, S. (2004) Is patient involvement possible when decisions involve scarce resources? A qualitative study of decision-making in primary care, <i>Social Science and Medicine</i> , 59 (1), pp. 93-102.	Interviewed GPs
17.	Lancsar, E., Wildman, J., Donaldson, C., Ryan, M. and Baker, R. (2011) Deriving distributional weights for QALYs through discrete choice experiments, <i>Journal of Health Economics</i> , 30 (2), pp. 466-478.	Statistical data analysis
18.	Madden, S., Martin, D. K., Downey, S. and Singer, P. A. (2005). Hospital priority setting with an appeals process: a qualitative case study and evaluation, <i>Health Policy</i> , 73 (1), pp. 10–20.	Participants: Professionals
19.	Martin, D. K., Hollenberg, D., MacRae, S., Madden, S. and Singer, P. (2003) Priority setting in a hospital drug formulary: a qualitative case study and evaluation, <i>Health Policy</i> , 66 (3), pp. 295–303.	Participants: Professionals
20.	Mason, H., Baker, R. and Donaldson, C. (2011) Understanding public preferences for prioritizing health care interventions in England: does the type of health gain matter? <i>Journal of Health Services Research Policy</i> , 16 (2), pp. 81–89.	Q-Methodology
21.	Mitton, C., Smith, N., Peacock, S., Evoy, B. and Abelson, J. (2009) Public participation in health care priority setting: A scoping review, <i>Health Policy</i> , 91 (3), pp. 219-228.	Literature review
22.	Murphy, N. J. (2005) Citizen deliberation in setting health-care priorities, <i>Health Expectations</i> , 8 (2), pp. 172-181.	Literature review
23.	Neuberger, J., Adams, D., MacMaster, P., Maidment, A. and Speed, M. (1998) Assessing priorities for allocation of donor liver grafts: survey of public and clinicians, <i>British Medical Journal</i> , 317 (7152), pp. 172-175.	Postal questionnaire
24.	Neuberger, J. A. and Ubel, P. A. (2000) Finding a place for public preferences in liver allocation decisions, <i>Transplantation</i> , 70 (10) pp. 1411-1413	Review
25.	Nord, E., Richardson, J., Street, A., Kuhse, H. and Singer, P. (1995) Maximizing Health Benefits vs. Egalitarianism: An Australian Survey of Health Issues, <i>Social Science and Medicine</i> , 41 (10), pp. 1429-1437.	Self-completion questionnaire
26.	Olsen, J. A., Richardson, J., Dolan, P. and Menzel, P. (2003) The moral relevance of personal characteristics in setting health care priorities, <i>Social Science & Medicine</i> , 57 (7), pp. 1163–1172.	Review
27.	Ratcliffe, R. (2000) Public preferences for the allocation of donor liver grafts for transplantation, <i>Health Economics</i> , 9 (2), pp. 137-148.	Questionnaire / survey
28.	Richardson, J., McKie, J., Peacock, S. and Iezzi, A. (2011) Severity as an independent determinant of the social value of a health service, <i>European Journal of Health Economics</i> , 12 (2), pp. 163-174.	Review
29.	Schwappach, D. L. (2003) Does it matter who you are or what you gain? An experimental study of preferences for resource allocation, <i>Health Economics</i> , 12 (4), pp. 255-267.	Questionnaire
30.	Shah, K. K. (2009) Severity of illness and priority setting in healthcare: A review of the literature, <i>Health Policy</i> , 93 (2-3), pp. 77-84.	Literature review
31.	Stolk, E. A., Pickee, S. J., Ament, A. H. J. A. and Busschbach, J. J. V. (2005) Equity in health care prioritisation: An empirical inquiry into social care, <i>Health Policy</i> , 74 (3), pp. 343-355.	Quantitative

APPENDIX ONE

ARTICLES EXCLUDED FROM LITERATURE REVIEW (Continued)

		Reason for exclusion
32.	Ubel, P. A. and Loewenstein, G. (1995) The efficacy and equity of retransplantation: an experimental survey of public attitudes, <i>Health Policy</i> , 34 (2), pp. 145-151.	Survey
33.	Ubel, P. A. and Loewenstein, G. (1996) Distributing scarce livers: the moral reasoning of the general public, <i>Social Science and Medicine</i> , 42 (7), pp. 1049-1055.	Survey

APPENDIX TWO

1 – EXAMPLES OF INTERVIEW GUIDE QUESTIONS

Sample question (i)

What do you think of the suggestion that, where priority for healthcare cannot be decided on medical grounds – who is the most ill etc. – people who are thought to be responsible for their own ill-health should have lower priority than people who require healthcare through (for want of a better phrase) 'no fault of their own'?

Probes

- It has been suggested that higher priority should be given to those who have 'looked after themselves' – what are your views on this?
 - What factors do you think influence whether a person lives a healthy lifestyle?
 - Would you say that what could be called a 'lifestyle disease' (e.g. obesity-related) is self-inflicted?
 - Do you think that there could be reasons or circumstances that may have led someone to pursue an 'unhealthy' lifestyle?
 - Is it important to you that people are free to make choices about their lifestyle – including 'unhealthy' behaviour?
-

Sample question (ii)

Imagine that the NHS is planning to introduce a policy of treating some patients before others – or even not treating them at all – based on some aspect of their 'lifestyle' such as whether they drink, smoke, take regular exercise etc. The justification for this policy would not be based on medical grounds (e.g. the risks of operating on obese patients are higher; treatment may be less effective etc.), but on the essential need – due to financial limitations – to set priorities in the allocation of healthcare resources. What would be your views on such a plan?

Probes

- Do you believe that all UK citizens have a 'right' to receive NHS treatment in all circumstances? If so, can anything affect this right?
- Do you think that giving lower priority in relation to responsibility for illness would be a particularly controversial development? If so, why?

APPENDIX TWO (Continued)

2 – EXAMPLE OF INTERVIEW SCENARIO

Question:

Based on the information in this scenario, which of the two patients do you believe should receive the available treatment?

'X' and 'Y', both aged 40, have advanced cirrhosis of the liver. Both have the same degree of liver damage and face the same risk of dying if they do not receive a liver transplant in the near future.

'X' is a 'non-drinker' and has cirrhosis due to infection and 'Y' has cirrhosis due to excessive alcohol consumption (but has now stopped drinking).

It is predicted that, following transplant, both 'X' and 'Y' could expect to live a fairly normal, healthy existence for a further 15-25 years. However, there is currently only one available liver for transplant that is a good match for both patients.

A decision must be made regarding which of these patients will:

- a) receive the available liver
- b) remain on the transplant waiting list

Prompts:

- For the purposes of this question, both patients are the same in terms of their physical condition
- A decision must be made, and both patients are expected to respond equally well to a transplant
- Suppose that 'Y' has had a previous liver transplant, following which they continued to drink, leading to their current need for a second transplant – does this affect your view on who should receive the available liver?
- Some people might claim that patient Y 'does not deserve' to receive the available liver – what are your thoughts on such a view?
- Do you believe that 'Y' is 'responsible' for their need for a liver transplant?