

Legitimate Priority-Setting: Refining Accountability for Reasonableness and its Application within NICE

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In this dissertation, I examine Daniels and Sabin's theory for fair and legitimate procedures, accountability for reasonableness (AFR), and its relationship to the National Institute for Health and Care Excellence (NICE). AFR has been widely adopted as an exemplar model of procedural decision-making for healthcare limit-setting. Despite the prominence of AFR, few institutions have fully adopted it, so NICE, which claims AFR enhances its legitimacy, is an important example of how the theory translates into practice.

The dissertation addresses challenges to AFR as a theory. I first argue that the substantive constraints in AFR's procedure are left too vague to answer criticisms of the theory. I refine the definition of relevant reasons, focusing on mutual justifiability and raise a novel problem about whether agreement on reasons to determine their relevance is based on normative objective standards or empirical agreement. I also make a new argument that the four conditions of AFR are not sufficient for legitimacy. I argue that we need a condition of fair consideration in order to ensure legitimacy in limit-setting procedures that follow AFR. Fair consideration requires decision makers to take relevant reasons seriously.

The latter part of the dissertation examines NICE's adoption of AFR. As a public body NICE needs to demonstrate the legitimacy of its decisions, and it supports its claim to legitimacy with AFR as a framework of procedural justice. I argue that NICE meets the conditions of AFR, but it also supplements AFR with additional procedural principles, demonstrating that AFR is not specific enough and does not meet the needs of an actual priority-setting body. NICE strengthens its claims to legitimacy with its procedural principles, however it fails to implement fair consideration of reasons, so it misses out on an essential element for legitimacy, as I argue the revised account of AFR requires. NICE could further enhance its legitimacy with fair consideration. NICE's application of AFR illustrates how problems in the theory translate into challenges for practice. I address some of these challenges to legitimacy with the additional requirement of fair consideration.

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1 Introduction: AFR and NICE, and problems for legitimacy

Accountability for reasonableness is a procedural solution addressing the problem of disagreement about how to distribute healthcare resources. In the twenty years since its publication by Norman Daniels and James Sabin, it has become the exemplar model of procedural decision-making. Resources to meet healthcare needs are limited, and the scarcity is not going to let up: ageing populations, expensive pharmaceuticals, and increasing activity mean greater demand on health systems. Inadequate resources to meet needs raises the problem of how to decide who to treat and what services to provide.

Norman Daniels and James Sabin first proposed “accountability for reasonableness” (AFR) in 1997.¹ AFR is a framework that requires four conditions to be met with the aim that meeting these four conditions will result in fair and legitimate procedures for limit-setting. AFR is an appealing theory: it draws on a background of political philosophy condensed into four conditions, making it a pragmatic theory to implement. AFR is considered the ‘gold standard’ and model for procedural decision-making, and it has been cited for use in projects ranging from the World Health Organization’s 3 by 5 HIV treatment program to decide how to expand HIV treatment coverage, to individual surgery units prioritising patients.²

¹ Daniels and Sabin, "Limits to health care: fair procedures, democratic deliberation, and the legitimacy problem for insurers", 1997.

² Daniels, "Fair process in patient selection for antiretroviral treatment in WHO’s goal of 3 by 5", 2005; Ashcroft, "Fair Process and the Redundancy of Bioethics: A Polemic", 2008; Ibrahim, Tymianski, and Bernstein, "Priority setting in neurosurgery as exemplified by an everyday challenge", 2013; Syrett, "Health technology appraisal and the courts: accountability for reasonableness and the judicial model of procedural justice", 2011; Biron, Rumbold, and Faden, "Social value judgments in healthcare: a philosophical critique", 2012; Sabik and Lie, "Principles versus procedures in making health care coverage decisions: addressing inevitable conflicts", 2008; Jonas, Kolbe, and Warin, "Publish or be damned: Individual Funding Requests and the publicity condition", 2013.

For the attention that AFR receives, few institutions have actually put it into consistent practice, and amongst those that have the National Institute for Health and Care Excellence (NICE) stands out as a leader in explicit priority-setting.³ NICE is a public body that makes decisions on behalf of the National Health Service (NHS) for England, NHS England. The recommendations of NICE's technology appraisals determine whether new interventions will be available through the NHS. A key problem for NICE is that with stretched budgets, its decisions have affects on opportunity costs. Opportunity cost is the concept that resources spent on one thing, A, are not available to be spent on others, B and C, for example. NICE's judgements of what should be funded raise opportunity cost problems within NHS England since with a fixed budget, funding new interventions means not funding others.⁴ Both harms and benefits result from its decisions, and as a public body, NICE must justify them. NICE claims legitimacy for its appraisal processes because it follows the principles of AFR. NICE has sought to justify its decisions and claims they are legitimate and fair because it uses the procedural justice framework of AFR.

This dissertation examines the relationship between NICE and AFR as legitimate procedures, and how the practice of AFR draws out weaknesses in the theory while the theory presents challenges for implementation. I focus on legitimacy as it is understood in AFR and by NICE. There are two forms of legitimacy that I discuss, the normative and the descriptive. Normative legitimacy is a political concept: decisions should be made with the right authority and in the appropriate manner. When decisions are normatively legitimate, the people affected by them

³ NICE was first named the National Institute for Clinical Excellence, but it has undergone name changes since although keeping the acronym. In 2005, NICE merged with the Health Development Agency and took on public health guidance, so its name changed to National Institute for Health and Clinical Excellence. In 2013, NICE's remit was extended to include social care, and its name changed to the National Institute for Health and Care Excellence. I will refer to it straightforwardly as NICE, and only distinguish the names as the publisher of reports.

⁴ Sheehan and Hope, "Allocating Health Care Resources in the UK," 2012.

recognise the decisions and their authority.⁵ Descriptive legitimacy, as I will call it, addresses the problem of what people recognise as legitimate in real practice. These are the conditions that pertain when an institution is considered legitimate. (Other descriptions of this split might be that political legitimacy is normative and descriptive legitimacy includes empirical or sociological evidence of perceived legitimacy.⁶) These two forms of legitimacy are often ambiguous—an ambiguity that we will see play out in AFR and then in its adoption into practice.

Daniels and Sabin begin their account of AFR with the “legitimacy problem”, which asks under what conditions a patient should consider a limitation on her treatment legitimate.⁷ The problem is phrased as an empirical one, but the main thrust of AFR is focused on normative legitimacy, although Daniels and Sabin also suggest that it will enhance the descriptive legitimacy of institutions. This is an important distinction, since as I will discuss in the dissertation, if AFR is to be normatively legitimate, additional conditions must be in place.

NICE draws on both normative and descriptive legitimacy to justify its decisions. NICE claims legitimacy because it follows the procedural justice framework of AFR.⁸ Its commitment to AFR and a framework of values and procedures is NICE’s attempt to establish its normative legitimacy. However, it faces challenges that these theories of normative legitimacy do not suffice to meet. The real

⁵ Syrett, "NICE work? Rationing, review and the 'legitimacy problem' in the new NHS", 2002.

⁶ I base the distinction between normative and descriptive legitimacy on Buchanan, "Political Legitimacy and Democracy", 2002.

⁷ Daniels and Sabin, 1997; *Setting Limits Fairly: Learning to Share Resources for Health*, 2008.

Daniels and Sabin have articulated AFR and its conditions in many publications, but I will use these two as my primary sources for their discussion of AFR. The initial publication of AFR was in an article “Limits to health care: fair procedures, democratic deliberation, and the legitimacy problem for insurers” (1997) and along with *Setting Limits Fairly* (2002, revised 2008) these present clear and thorough articulations of AFR. (I cite the revised 2008 edition because it is the same as the 2002 but with additional chapters.)

⁸ NICE, Social Value Judgements, 2008.

Throughout the dissertation, I will cite NICE documents by their section rather than page number since the pages vary between publication formats.

demands on NICE and the perception of its legitimacy shape additional principles and procedures NICE uses to ground its descriptive legitimacy. NICE's adoption of AFR and its additional framework to enhance its legitimacy demonstrate a disjunction between theories of normative legitimacy and descriptive legitimacy.

I will argue that AFR's four conditions are not sufficient for normative legitimacy. I offer a new argument that demonstrates that a procedure can meet the requirements of AFR yet still fail to be legitimate. In order to resolve this problem, I suggest a new and necessary condition of "fair consideration", a requirement to take reasons seriously. The value of this argument as a new approach to AFR is two-fold. First, I discuss AFR in its own terms. Rather than impose an external, additional substantive or procedural condition on AFR, as has been done by other critics of it, I develop the need for fair consideration out of what the theory of AFR already has to offer. Fair consideration is suggested in the deliberative democracy background that Daniels and Sabin draw on for their account of AFR but do not actually adopt. I recommend a revised account of AFR that includes an explicit requirement for fair consideration, which is necessary for legitimacy.

A second area of criticism I raise around AFR concerns the Relevance Condition, which places substantive constraints on the process, and the indeterminacy of what it requires. Daniels and Sabin have been criticised for excluding religious reasons from decision-making, but I argue that an alternative reading of their arguments does not exclude religious reasons but rather emphasizes the need for mutual justifiability of reasons. However, mutual justifiability is itself a problematic concept. Daniels and Sabin refer to idealised deliberators, called "fair-minded people", and it is not apparent whether we are to consider these fair-minded people as necessary only for the justification of the process or necessary for its realisation and

instantiation too. This problem raises the question of whose agreement matters: is mutual justifiability an objective normative concept or one that needs to be empirically proven?

These challenges to the theory of AFR have repercussions in the design of NICE's processes when it implements the theory. Questions like whose agreement matters play out both in the design of NICE's procedures and in practice during actual appraisal cases. NICE faces criticism and scrutiny for its decisions, and in addition to appealing to AFR, it justifies its processes with more procedural principles. The introduction of these principles demonstrates that AFR alone is not enough to secure NICE's descriptive legitimacy given the challenges it faces in the real world as a public body. Analysing NICE's procedures to promote its descriptive and normative legitimacy reflects back onto AFR as a theory for legitimate procedures, and we will see how the problems that arise in examining AFR carry on into its implementation.

Part I describes the need for a fair and legitimate distribution of healthcare and the shift to procedural approaches for making priority-setting decisions. It sets up the stakes of priority-setting: the limited resources available and the challenges faced by countries as they established their first priority-setting commissions. In the UK, a significant and prominent problem in priority-setting has been the "postcode lottery" or regional variation in the availability of specific treatments. In response, NICE was established as a centralised and national priority-setting body. NICE claims its legitimacy from the processes it uses to produce guidance, so Part I concludes with an explanation of AFR as a procedure for limit-setting.

Part II takes a critical approach to AFR, and in it I make the arguments that the Relevance Condition leaves too much undetermined and that the four conditions of

AFR are not sufficient for legitimacy. The discussion begins with an examination of Daniels and Sabin's use of deliberative democracy and their omission of it from their account of AFR. The purpose of this portion of the dissertation is to challenge the theory of AFR and suggest revisions—the inclusion of fair consideration—that will strengthen the theory in response to these concerns.

Part III examines NICE's implementation of AFR and the problems that arise when the theory is translated into practice. I first discuss NICE's adoption of AFR and its additional procedural principles, which demonstrate that more specification is needed to meet its legitimacy concerns, especially its descriptive legitimacy in practice. I then argue that NICE fails to clearly specify the process it uses to develop relevant reasons for its recommendations, focusing on the set of “social value judgements” that guide the reasoning. Part III concludes with the argument that NICE's technology appraisal process does not meet the requirement for fair consideration of reasons because of its presumptions about cost-effectiveness. This means that NICE misses out on a necessary component of AFR for normative legitimacy.

I conclude with recommendations for NICE's processes and a look to the future activities of NICE that may enhance its legitimacy. The revised account of AFR I offer need not be limited to healthcare. With this strengthened account of decision-making, AFR may be applied to other areas of public policy and decision-making where there is disagreement.

I. Principles, Procedures and Priority-Setting

Part One sets up the discussion that follows with a look at three connected problems in healthcare priority-setting. I begin with the indisputable fact of limited resources for meeting healthcare needs; there are simply more demands for healthcare than can be met, and this is true around the world in both public and private health systems. Resource scarcity means that someone must make decisions about how to use the available resources and who will benefit from them. Assuming healthcare is a matter of justice, it matters how it is distributed. From this position—we must ration healthcare and it matters how we do so—I move on to the three main sections of the chapter.

Chapter One will consider procedures as the appropriate response to limit-setting and the trend through the last two decades towards procedural priority-setting. In contrast to principled, substantive approaches, procedural accounts normatively focus on the process of deciding how to select between conflicting principles. Through the 1990s, health systems adopted approaches to priority-setting that were increasingly process rather than principle focused.

In the second chapter, I turn to the development in the UK of the National Institute for Health and Care Excellence (NICE). NHS England faces pressures both on resources and its rationing decisions. Prior to 2000, priority-setting was done at a regional and local level, but since NICE's establishment, there is an additional, centralised, and national priority-setting process. NICE has not resolved all the problems of localised rationing, but it is a body that sets national agendas and has

increased the centralisation of decision-making. As a procedural approach to priority-setting, NICE also serves as a model to other countries.

In the final chapter, I introduce accountability for reasonableness (AFR), a fair and legitimate process for priority-setting. AFR has become the exemplar model for procedural priority-setting. It builds on the shift to procedural approaches for priority-setting and introduces conditions that such procedures should meet in order to respond to the “fairness problem” and “legitimacy problem”—challenges to the process and its resulting decisions.

Unable to meet every healthcare need and with increasing demand and scrutiny on decision-making, health systems are using procedures to make difficult decisions. The shift to procedural approaches created a need to define what is an appropriate priority-setting procedure. AFR responded to this trend, consolidating concepts of democracy and deliberation into a proposed procedure for normatively legitimate decision-making.

2 Healthcare scarcity, and the turn to procedures

This chapter begins with the important claim that healthcare is a matter of justice. If healthcare is a matter of justice, then it matters that it is distributed justly. This basic claim motivates the ensuing dissertation and debates about priority-setting. Because there are limited resources for healthcare, there should be a mechanism to make decisions about how to use those resources, which is the aim of priority-setting. The first section examines the claim that healthcare is an issue of justice. The subsequent section reviews some of the signs of limitations to healthcare resources with the mounting pressure on health system services. The latter half of the chapter traces the development of priority-setting in Europe; initial attempts at formalising principles from which to derive rules for ranking interventions and priorities gave way to procedures. The shift to procedures has led to a new focus on processes and making decisions that are justified not on the grounds of substantive principles but because of the process of decision-making itself.

2.1 Healthcare as a matter of justice

Distributing healthcare resources fairly and legitimately matters because healthcare is a matter of justice. There is something important about healthcare, and that is why we need an account of how to distribute it. Some goods, like having a swimming pool or a bicycle are beneficial and desirable. A bicycle may even meet an important need like being able to travel to work, but we do not think of these as matters of justice.

In this section, I will present Daniels's argument that healthcare is an issue of justice. He argues that health is essential to protecting opportunity. The "normal opportunity range" is the array of life plans and social opportunities a person in a society may reasonably expect. Opportunity is relative to each society. A subset of the normal opportunity range is someone's "normal functioning", which is the portion of the full opportunity range available to her, and her "effective opportunity" is the share of that range actually available to her at a given time.⁹ Effective opportunity may affect people differently: a pianist will suffer a greater loss of effective opportunity from severe arthritis in her hands than a radio host who does not rely on her hands for a living. In practice, there is a great reluctance to distinguish individuals on this kind of criterion of effective opportunity though. NICE, for example, will not consider productivity from working in its decisions about making treatments available.¹⁰ A person's health affects her normal functioning and opportunity; when she is in good health, her normal functioning will not be limited by her health, but poor health reduces a person's normal functioning and her opportunities.¹¹

The importance of opportunity, Daniels pins to the principle of fair equality of opportunity, which is necessary for social justice. His account is derived from Rawls's theory of justice. (I do not think we necessarily have to buy into Rawls's account of justice to see the merit of Daniels's argument here.) Rawls's second principle of justice calls for fair equality of opportunity. Citizens should have the same opportunities—educational and economic—no matter if rich or not, the

⁹ Daniels, *Just Health*, 2008, 43-44.

¹⁰ Specifically, NICE will not include the costs of lost productivity in its economic evaluation of new interventions (NICE, Guide to the methods of technology appraisal 2013, 2013, 5.1.10, 5.5.12..)

¹¹ Daniels, *Seeking Fair Treatment: From the AIDS Epidemic to National Health Care Reform*, 1995; *Just Health*, 2008, 45.

opportunity should be the same for those who are equally endowed and motivated.¹² Rawls's principle is economic, focusing on economic opportunities and whether a person is born to wealth or poverty is morally arbitrary and should not exclude her from opportunities, neither too should other arbitrary traits like race. Daniels extends this principle to take into account those goods that are necessary for someone to achieve fair equality of opportunity. His focus is on healthcare, but the principle could be applied elsewhere too, education or personal safety, for example. Because fair equality is a principle of justice, and health allows for fair equality of opportunity (in one regard), healthcare, which restores and provides health, is a good of justice. The general obligation of fair equality of opportunity begets a specific obligation to provide healthcare services for normal functioning as a matter of justice rather than mere preference or consumerism.¹³

An important point about Daniels's account is that fair equality of opportunity does not require levelling outcomes but instead levelling the opportunities available.¹⁴ This difference allows us to account for those who are worse off as a result of genetic bad luck. Natural differences will place some people at a greater advantage, but we have a social obligation to reduce risks that may infringe on fair equality of opportunity, such as preventing disease, treating curable disease, and mitigating the

¹² Rawls, *A Theory of Justice*, 1999, 266.

¹³ Daniels, *Seeking Fair Treatment*, 1995.

Daniels limits his account of normal functioning to a biomedical definition of health, though as his work has developed he has taken into account the social determinants of health. He uses Boorse's definition of health as the absence of pathology, rejecting the World Health Organization's broader definition that encompasses well-being. The broader definition makes it difficult to address normal functioning and health equity since it covers so many factors. For Daniels, another advantage of this narrower definition is that it excludes enhancement and other social reasons for health treatment in favour of treating diseases and pathologies. One blurry line though is that Daniels does not rule out abortions for non-therapeutic reasons. ("A reply to some stern criticisms and a remark on health care rights", 1983; "Symposium on the Rationing of Health Care: 2 Rationing Medical Care — A Philosopher's Perspective on Outcomes and Process", 1998; "Equity and population health: toward a broader bioethics agenda", 2006.)

¹⁴ "A reply to some stern criticisms and a remark on health care rights", 1983; Kelleher, "Real and Alleged Problems for Daniels's Account of Health Justice", 2013.

effects of disease and disability.¹⁵ Equity of access to healthcare plays into this too. An example of equal access Daniels uses is the choice of where to situate the coffee break room. If it is up a flight of stairs, then the worker in a wheelchair cannot reach it or if it is a women-only room and excludes men, then in both cases there is not equal access. Inevitably, some people's desks will be closer to the coffee break room than others, but so long no one is unduly burdened by being too far away, then these inconsistencies in how far someone has to walk do not violate fair equality of opportunity.¹⁶ It is important for a just society to work to minimise these differences. But, any just society will face limitations due to resource constraints, its technological advancements, and even efficiency and liberty in arriving at the requirements of justice.¹⁷ Fair equality of opportunity is an important principle, but it does not determine distributions without consideration of other principles.

Fair equality of opportunity grounds Daniels's argument that healthcare is an issue of justice and as such must be distributed in a just way. If healthcare is a matter of justice, then providers of healthcare, whether private or public, have a duty to meet the social obligation to provide healthcare and promote fair equality of opportunity. How they do so is up to them, and Daniels argues they ought to share their reasoning in order that the public may evaluate whether this duty is met. Daniels's account of healthcare justice is a useful starting point since it gives a background to the ensuing discussion and the importance of distributing healthcare rightly and justly.

2.1.1 Healthcare needs and claims (a brief diversion into fairness)

¹⁵ Daniels, "Treatment and Prevention: What Do We Owe Each Other?," 2012.

¹⁶ "Equity of Access to Health Care: Some Conceptual and Ethical Issues", 1982; "Is there a right to health care and, if so, what does it encompass?," 1998.

¹⁷ "Is there a right to health care and, if so, what does it encompass?," 1998.

Before continuing the discussion, in this section I want to give a brief account of what concept of “fairness” is at play in the discussions and how healthcare needs have been understood and approached as a problem of fairness. Daniels does not define fairness in his discussion, so I look to Broome and Hooker’s accounts of fairness though I do not adopt their distributive principles. When it comes to justice and fairness, Broome argues that defining claims is at the core of fairness.

A person has a claim on a good based on criteria that we determine, and there are different reasons and features that may be used to justify someone’s claim. For example, a person may have a claim on healthcare because she has a need for it. Fairness requires satisfying claims in proportion to their strength, so fairness is about relative satisfaction; equal claims should be treated equally, and stronger claims require more than weaker claims. If we cannot satisfy all the claims, this does not affect their status as such: a claim is a claim. A stronger claim may not simply override a weaker one. The claim holds whether or not there are the resources to meet it; its status is independent of its potential or actual satisfaction. A fair decision will accommodate all the applicable and appropriate moral features of the claims.¹⁸ Claims are not the same as rights. Rights must be met, and whereas a fair outcome may mean a claim goes unsatisfied that is not the case for rights.¹⁹ Conversely, something that is not a claim should not be met simply because there are the resources to do so.²⁰

If claims are based on need, then we require a definition of need to define the claim and its strength. However, there are different views of need. It may be that ill health, falling below an individual’s normal functioning constitutes a need for

¹⁸ Broome, "Fairness", 1990. Broome’s solution to fairness is to use a lottery or weighted lottery, but I do not intend to suggest that I adopt this proposal.

¹⁹ Hooker, "Fairness", 2005.

²⁰ Loughlin, "Rationing, barbarity and the economist's perspective", 1996.

healthcare and therefore a claim.²¹ In contrast, need may be defined as something that is necessary for something else to be accomplished. Translating this into healthcare means there has to be some beneficial effect for a medical intervention to be needed. With this definition, a need for healthcare is distinct from a need for health.²² But the ability to benefit does not itself create a claim, according to Broome, which rules out claims on enhancement.²³ I will not settle on a specific definition of need, but raise the point here that it may be differently understood.

Claims and meeting needs set the scene for the problem: the claims on healthcare cannot all be met. A tangential point that I want to clear up now is that because of all these competing claims, healthcare justice and distribution does not concern autonomy. Autonomy, the backbone of 20th century medical ethics, cannot be relevant here. When patients have need, they may all autonomously choose to have the healthcare that would resolve their need. But, there is a limited supply, so they cannot all have their claims satisfied.²⁴ Therefore, I set aside the principles of autonomy and patient choice since they cannot relevantly feature in determining how to distribute resources. If the claims and need cannot be met, then we require a means to fairly resolve the claims and determine which ones to satisfy.

2.2 Limited resources and pressures on health systems

Limited resources mean that not every healthcare claim and need can be met, and this is true across health systems. Across global health systems, there are simply not the resources, whether material, human, or financial, to meet all the needs and

²¹ Harris, "More and Better Justice," 1988.

²² Culyer, "Need: the idea won't do—but we still need it", 1995.

²³ Broome, 1990.

²⁴ Sheehan, "It's unethical for general practitioners to be commissioners", 2011.

demands on them.²⁵ Budgets for healthcare have been steadily increasing, but that alone does not address the increasing costs and healthcare activity. Ageing populations, growing technology prices, co-morbidities, and increased activity all add strain to health systems. In addition, there are greater expectations of what can and will be provided, and there has been an increase in activity, i.e. use of health systems.

Despite the inability to meet all health needs, many countries spend large budgets on healthcare. The proportion of UK GDP spent on healthcare has doubled since 1960 and as of 2014 was at 9.1% of GDP. In comparison, the EU average is 10% GDP, though France and Germany spend around 11.4%, and the US tops the charts at 17.1%. At the other end, Indonesia and Bangladesh spend 2.8% GDP on healthcare.²⁶ Healthcare is one of many state obligations and social goods that must be provided for, so the proportion of GDP spent on healthcare cannot grow unchecked without sacrificing state spending on other projects. Healthcare costs, however continue to rise and are outpacing the rate of economic growth and increases in individual income.²⁷

Increasing technology costs are one contributor to the growth in health spending. New treatments, often targeted at specific patient groups, like a subset of cancer patients, come with high price tags, claimed to be the cost of innovation's research and development.²⁸ Indeed, research and development is a costly and

²⁵ Khayat-zadeh-Mahani, Fotaki, and Harvey, "Priority setting and implementation in a centralized health system: a case study of Kerman province in Iran", 2013.

²⁶ "Health expenditure, total (% of GDP)," The World Bank, <http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS>.

²⁷ In the US, for example, employee health insurance plans are expected to increase 6% in cost next year (5% for employees, 6% for employers), which is well above increases in salaries and economic growth (Braverman, "Your Health Insurance Will Cost More Next Year: Here's What's Driving Prices Higher," 2016, <http://www.thefiscaltimes.com/2016/08/10/Your-Health-Insurance-Will-Cost-More-Next-Year-Here-s-What-s-Driving-Prices-Higher>.)

²⁸ Timmins, Rawlins, and Appleby, *A Terrible Beauty: A Short History of NICE*, 2016.

lengthy process, so manufacturers look to recoup their investments.²⁹ Another driver of costs is that many “blockbuster” treatments, those given to large patient populations, like blood pressure lowering medication, are now coming off patent, so pharmaceutical companies are increasing prices of patented, new treatments to make up this deficit.³⁰

Older patients now live for longer with chronic conditions, and there is not the workforce to replace them. This leads to a skew between those contributing to and using health systems. In a trend mirrored across Europe, the UK population over eighty-five is set to double by 2032, but there will be much smaller increases in population sizes of other age groups.³¹ An ageing population leads to higher costs for public services, and a concern is that increases in life expectancy have not been matched with increases in healthy life expectancy. More people survive for longer but live with ill health for longer too, and the use of health services has increased independently of the population size. NHS England currently spends twice as much on retired households as non-retired.³² While the elderly occupy the most hospital beds, a lack of social services to support them makes discharge difficult, illustrating that the problem of how to address the population’s needs is not limited to the provision of medical services alone.³³ Demographics, healthcare, and social support are all linked; however I confine the focus of this dissertation to healthcare.

Older patients place greater strain on health systems, and so too do the chronic conditions and co-morbidities that many more people live with now and live with for

²⁹ DiMasi, Hansen, and Grabowski, "The price of innovation: new estimates of drug development costs", 2003.

³⁰ Kolata and Pollack, "Costly Cancer Drug Offers Hope, but Also a Dilemma," 2008; Langreth, "Big Pharma's Favorite Prescription: Higher Prices," 2014, <http://www.bloomberg.com/news/articles/2014-05-08/why-prescription-drug-prices-keep-rising-higher>.

³¹ "Ageing Population," <http://www.kingsfund.org.uk/time-to-think-differently/trends/demography/ageing-population>; Imison, Overview: Future Trends, 2012.

³² "Ageing Population".

³³ Stubbs, "Introduction," 2016.

longer periods of time. Chronic conditions are expensive to treat in the long-term, and increasing numbers of patients have more than one chronic condition, like hypertension or diabetes.³⁴ Taking diabetes as an example, the prevalence of Type II diabetes has increased in the UK over the last decade and is expected to continue to rise. It is a condition associated with co-morbidities and complications, meaning greater demand on healthcare resources and a predicted increase in health spending related to treatment of diabetes and its complications.³⁵

The growing pressures on health services and cost increases can be seen in the NHS. One symptom of a strained health service is cancelled operations, and in each quarter of 2015-2016, there have been between 12,000-16,000 cancelled elective operations—close to 80,000 a year.³⁶ One reason operations are cancelled is a lack of beds for post-operative patients. A lack of beds also leads to ambulances queuing outside of hospitals, an emotive image of a health system failing to serve its patients.³⁷ The queue for beds illustrates pressures on the NHS to meet the activity demands on it. At the same time, rising costs in other areas, like pharmaceuticals, create additional pressures.

Resources for healthcare are limited and the pressures on health systems look set to increase rather than slake. Globally, there are challenges to meeting healthcare

³⁴ Imison, 2012.

³⁵ Kanavos, van den Aardweg, and Schurer, Diabetes expenditure, burden of disease and management in 5 EU countries, 2012.

³⁶ Cancelled Elective Operations, 2016.

³⁷ See articles like, "One third of Hampshire's ambulances stuck in hospital queue," 2016, <http://www.actiononsugar.org/Sugar%20and%20Health/Sugar%20and%20type%20%20diabetes%20/151911.html>; "Pictured: Ambulances forced to queue and patients lined-up in corridors at Telford's Princess Royal Hospital," 2016, <http://www.actiononsugar.org/Sugar%20and%20Health/Sugar%20and%20type%20%20diabetes%20/151911.html>.

It is worth noting though that while queues for beds may be prominent, there are more efficiencies in the system overall as treatments have improved. There are fewer hospital beds in England and across OECD countries since treatments are increasingly effective and require less recovery time. From 1979 to 2011 the average days of acute hospital admission dropped from 9.4 to 3 days (Appleby, "The hospital bed: on its way out?," 2013, <http://www.kingsfund.org.uk/blog/2013/03/hospital-bed-its-way-out>.)

needs. Even in countries that spend a significant portion of GDP on healthcare, there is demand and need that goes unmet. It is against this background of scarcity, tight budgets, and increasing demand that priority-setting takes place.

2.3 Principles and procedures: trends in priority-setting

In this section, I discuss the shift from principle based priority-setting to procedures for priority-setting. I refer to Søren Holm's explanation of this change in how countries have approached priority-setting, but my focus is not the historical and political shift but rather an interest in using procedural approaches for these decisions. The change from principles to procedures indicates both a trend in policy and ethics and also a perceived weakness in principle and rule-based priority-setting in practice. Turning to procedural approaches also demonstrates a certain kind of legitimacy for priority-setting decisions, which is grounded on how decisions are made and following procedures—a normative commitment that is meant to convey descriptive legitimacy too. I break this section up into three parts: explicit rationing and its accountability advantage, the use of explicit rationing first with principled approaches and then procedures, and finally a comment on procedural approaches to priority-setting.

2.3.1 Explicit rationing and accountability

National priority-setting systems or commissions contrast with the implicit rationing that was standard before their introduction. Implicit rationing limits individuals' access to particular treatments and services without explaining that the limitation is due to rationing rather than clinical need and effectiveness. The well-

cited proponents of implicit rationing, Calabresi and Bobbitt, argue that it is the best way to make ‘tragic choices’ rather than subject people to the moral angst of rationing.³⁸ Implicit rationing may take place at the bedside when doctors make decisions about what the progression of treatment for their patients should be. But this kind of rationing seems to conflict with the physicians’ duty to best serve their patients, and it would require physicians to be consistent with their decisions so as not to unfairly discriminate between patients.³⁹ Implicit rationing occurs too when only certain health centres provide a treatment. This was the case with the introduction of dialysis into the NHS at expertise centres resulting in limited access to dialysis.⁴⁰ However, when healthcare is implicitly rationed, the public is excluded from the discussion and decision of how to ration and what principles should determine the distribution. It also limits the extent to which the decision-makers and the implementation of priorities can be held accountable since both are obscured.

An advantage is that explicit rationing allows for public accountability: stakeholders are able to judge the decisions about priority-setting and hold the decision makers accountable for their decisions. Public accountability means that there is some responsibility of the person making the decision to those affected by it—whether they are consumers purchasing insurance or taxpayers in a publicly funded system.⁴¹ Explicit rationing allows the limits on healthcare services and treatments to be scrutinised, challenged, and debated because they are acknowledged rather than being obscured within health systems or masked as clinical judgement.

³⁸ Calabresi and Bobbitt, *Tragic Choices*, 1978.

³⁹ Hunter, "Rationing: the case for "muddling through elegantly"", 1995; New and Klein, "The Rationing Debate: Defining a Package of Healthcare Services the NHS is Responsible For", 1997.

⁴⁰ Klein, Day, and Redmayne, *Managing Scarcity: Priority Setting and Rationing in the National Health Service*, 1996.

⁴¹ I take the phrase “public accountability” from Daniels and Sabin who argue it is necessary for healthcare priority-setting to be publicly accountable yet never define the concept. They claim there are two ways to be publicly accountable: either with market accountability or with accountability for reasonableness (Daniels and Sabin, *Setting Limits Fairly*, 2008, 44.).

Explicit rationing may be achieved through market based healthcare and insurance. Market proponents argue that requiring individuals to buy their own healthcare or insurance allows them to select their healthcare options based on their willingness to pay. (Such a system is also consistent with libertarian property rights.)⁴² Whether it is buying insurance or paying out of pocket for a treatment, individuals are left to make decisions about their own willingness to pay for healthcare.

However, there are problems with the market approach, especially if we believe that healthcare is a matter of justice. For proponents of markets, distributive justice is achieved by market equilibrium under perfect competitive conditions, and they are the most efficient means of distributing resources. However the problem with markets is that health wants do not equate with health needs.⁴³ Willingness to pay and ability to pay do not track onto need and claims to healthcare, so markets cannot fairly distribute healthcare. Purchasers of health insurance are also at a disadvantage because they cannot predict their future healthcare needs, so the purchase is not based on informed choice.⁴⁴ Markets will generally fail to recognise the obligation to distribute healthcare justly. However, I set aside further discussion of healthcare markets; here they illustrate an explicit rationing mechanism as a problem for just distributions and a contrast to the public health systems I now turn my attention to.

Without markets to ration healthcare, many public health systems, including the NHS, initially relied on implicit rationing (and may still do), but increasing strains

⁴² Ruger, "Ethics in American health 2: an ethical framework for health system reform", 2008; "Ethics in American Health 1: Ethical Approaches to Health Policy", 2008.

⁴³ Ashcroft 2006

⁴⁴ Daniels and Sabin, "Limits to health care", 1997. In addition, in the US system at least healthcare insurance is often a benefit of employment, but then it is the employer who picks the healthcare plan. It does not make sense to attribute consumer choice, informed choice, and willingness to pay to such market based systems.

on resources have moved many decisions into public and political discourse. Priority-setting commissions mean the decisions are explicit, so there can be public discussion of the values and decisions that guide the rationing.⁴⁵ Explicitness also allows for the involvement of the public in these decisions, whatever form that involvement takes, and including the public's voice has gained ground in policy making.⁴⁶ Explicit and acknowledged limit-setting means it is possible to have an engaged debate about how those limits ought to be set, what values should guide them, and that decision makers may be held responsible for their decisions and enforcing them.

2.3.2 The shift to procedural limit-setting

In some national health systems, the explicit approach to limit-setting began with a rendering of principles that should determine rationing decisions. Principle-based accounts look to principles and the outcome as the normative justification—the result of the decision is fair based on its substantive value. In contrast, procedural accounts derive their normative justification from the process of arriving at the outcome rather than the outcome itself. The experience of implementing principle-based systems, showed principles that give rule-based priorities did not resolve the kind of fine-grained decisions and trade-offs that need to be made. Later iterations of priority-setting saw the introduction of procedures for selecting between principles.

Norway was the first country to establish a modern priority-setting commission. Even as its economy strengthened through the 1980s, the government convened the first commission in 1985 to consider how to ration and distribute

⁴⁵ Ham and Coulter, "Explicit and implicit rationing: taking responsibility and avoiding blame for health care choices", 2001.

⁴⁶ Syrett, "Deconstructing Deliberation in the Appraisal of Medical Technologies: NICELY Does It?", 2006.

healthcare in the national health system.⁴⁷ The commission did a literature search and found that there were no ‘tools’ for priority-setting—no established methods that the national health system might adopt. The commission, known as Lönning I, published its report in 1987 highlighting the principles that should be focused on when making decisions about priority-setting in healthcare. The Lönning Commission wanted to emphasise fairness and equal rights as well as both the medical and social effects of treatments, so it used the principles of severity, equal opportunity to benefit, and efficiency to tier services. Healthcare services were ranked from essential and life-saving treatments, ones where withholding would be harmful, treatment of chronic conditions, treatments with uncertain benefit, and finally a do not fund level for treatments with no benefit or that are not needed.⁴⁸ This approach to priority-setting focused on principles and using them to justify rule-based decisions about what healthcare services should or should not be prioritised.

When the Lönning Commission reconvened in 1997, it found that its recommendations had had little effect.⁴⁹ But this time there was a growing international literature on priority-setting and decision-making. Lönning II concluded that the emphasis this time should be on the mechanisms of prioritisation and the

⁴⁷ Calltorp, "Priority setting in health policy in Sweden and a comparison with Norway", 1999.

The practice of systematic and principle-based rationing is certainly much older than Norway's Lönning commission. Consider examples like charity hospitals that required a character reference—a principle of rationing based on good moral and social character. A more recent example is the controversial "Seattle God Committee" that selected patients for dialysis and heavily weighted its decisions by social and character criteria like family life and work contribution (Fissell, "The Disappearance of the Patient's Narrative and the Invention of Hospital Medicine," 1991; Alexander, "They Decide Who Lives, Who Dies," 1962.)

⁴⁸ Bringedal, *Priority setting in Norwegian health care, Medicine, Markets, and Morals* (Birmingham, UK2015).

⁴⁹ Holm, Liss, and Norheim, "Access to health care in the Scandinavian countries: ethical aspects", 1999.

For example, although the first commission identified psychiatric patients as a high priority group, while real growth in expenditure on health grew, there was no growth in expenditures for psychiatric services.

process of priority-setting.⁵⁰ The Norwegian exercise in priority-setting shows a start with a principle based approach and the stratification of health services into the more and less urgent. These principles, like severity, are open to debate though, and do not provide clear, pragmatic answers for how to set priorities and make actual decisions.⁵¹ Norway's first priority-setting commission used a rule-based system grounded in principles, but to justify its priority-setting decisions it later turned to a process oriented system.

Other countries followed suit, like the Netherlands, Denmark, and Sweden. The Netherlands' Dunning Commission published a report in 1992 giving guidance on the principles that ought to direct national health priority-setting. The Dunning Commission focused on necessity, efficiency, effectiveness, and whether a particular health service should be something individuals rather than the state should be responsible for, i.e. considering where the state's obligations ended. Denmark and Sweden also set up priority commissions, and in general these also tiered levels of healthcare services from most essential to those that should not be provided on a national, public system.⁵² Each of these approaches to priority-setting justified the decisions based on a principle (dignity and solidarity in Sweden; necessary care in the Netherlands) from which would follow decisions about whether the healthcare service should be provided. The emphasis of priority-setting was on the normative principle and defining what did or did not fall under it.⁵³ These commissions established frameworks of values for priority-setting but lacked the means to make difficult decisions between treatments and services based on these principles. Although they

⁵⁰ Calltorp, 1999; Sabik and Lie, "Priority setting in health care: Lessons from the experiences of eight countries", 2008.

⁵¹ Holm, Liss, and Norheim, 1999.

⁵² Sabik and Lie, "Priority setting in health care: Lessons from the experiences of eight countries", 2008.

⁵³ Holm, "Goodbye to the simple solutions: the second phase of priority setting in health care", 1998.

gave accounts of values, the principles were not specified enough to solve the rationing decisions that have to be made in practice.

No discussion of priority-setting is complete without reference to Oregon's Medicaid expansion, which highlighted the problems of a single principle for a rule-based determination of priorities. In 1989, the state of Oregon sought to revise its Medicaid program, the health coverage for the poor or permanently disabled, by limiting which services were available with the aim of expanding basic coverage.⁵⁴ The initial plan used condition-treatment pairings ranked by cost-benefit (cost-effectiveness) alone, and the list was cut-off at the point at which funding was exhausted. The rankings produced counterintuitive results: procedures like tooth capping ranked ahead of surgery for ectopic pregnancy, and splints for a joint disorder listed higher than emergency appendectomy based on cost-benefit.⁵⁵ This scheme allowed small gains to many people (tooth capping) to outweigh significant, indeed life-saving, benefits to a few (appendectomy), a situation known as the aggregation problem.⁵⁶ The aggregation problem is whether benefits to many people should ever outweigh significant benefits to a few people, and if so under what circumstances?⁵⁷ Oregon answered this problem by revising its ranking list taking into account need, urgency of treatment, and the public's views. Town hall style meetings, public hearings, and surveys were used to elicit the public's view about which treatments were most important.⁵⁸ In 1991, the new rankings were published, and of 709

⁵⁴ Daniels, "Is the Oregon rationing plan fair?", 1991.

⁵⁵ Brock, "Justice and the ADA: Does Prioritizing and Rationing Health Care Discriminate Against the Disabled?," 1995; McKie and Richardson, "The rule of rescue", 2003.

⁵⁶ Daniels, "Justice, Health, and Healthcare", 2001; Kamm, "Aggregation and Two Moral Methods", 1999.

⁵⁷ Daniels, "Rationing fairly: programmatic considerations", 1993.

⁵⁸ Sabik and Lie, "Priority setting in health care: Lessons from the experiences of eight countries", 2008. There were still results in these rankings we may consider morally problematic. For example, liver transplants were ranked at 366 but liver transplants for alcoholic cirrhosis was ranked at 690, so not covered, even though the outcomes for this patient group are no worse (and may be better) than the

condition-treatment pairs, the state funded the first 587 on Medicaid.⁵⁹ The revised list combined multiple principles to produce a ranking scheme that increased the value of health produced insofar as it met more serious needs. Oregon struggled to implement this plan, but with further revisions it was introduced in 1993.⁶⁰ What Oregon demonstrates, in this instance, is the difficulty faced when the one principle was used as a rule to rank treatments and conditions. Later iterations of the plan expanded on the single principle approach to include more elements in producing the rankings.

Principles alone can be unwieldy and are indeterminate when it comes to making difficult trade-offs in a healthcare system. For example, the rationing problem of “fair chances and best outcomes” asks whether we should give everyone who might benefit a chance to receive the resource or whether we give it to those who will have the best outcomes.⁶¹ Principles like cost-effectiveness would support best outcomes, but dignity and solidarity (Sweden’s principles) would support fair chances. Conflicts between principles require a means of resolution, either by discerning how the principles may be collapsed into one another or ranking the principles. Some principles will prove to be insufficient for priority-setting since they ignore something relevant.⁶² The adoption of multiple principles demonstrates the variety of relevant moral concerns.

non-alcoholic group (Klein, "Warning Signals From Oregon: The Different Dimensions Of Rationing Need Untangling", 1992.).

⁵⁹ 1992. Once the rankings were set, the legislature was not allowed to change them in order to prevent interest groups from lobbying and affecting the rankings (Fleck, "Just caring: Oregon, health care rationing, and informed democratic deliberation", 1994.)

⁶⁰ The opposition came from concerns about how cost-benefit was calculated and the potential to discriminate against people with disabilities (Brock, 1995.)

⁶¹ Daniels, "Rationing fairly: programmatic considerations", 1993.

⁶² Persad, Wertheimer, and Emanuel, "Principles for allocation of scarce medical interventions", 2009.

Perhaps the strongest current example of principle-based approaches is countries where a right to health or right to life has been litigated as a positive right. This has happened in Brazil and Columbia, with plaintiffs in court cases arguing that the denial of an intervention by the public system violated their right to health. The concern is that these cases divert limited public resources to those

Following the introduction of principles for priority-setting, there was a shift from principles to procedures for priority-setting. Procedures built on the work of the principles in the reports and created processes that justified decisions by the process rather than the principle. In the mid-1990s the Scandinavian countries shifted from principle-based approaches to procedures. The second Lönning Commission and a 2014 iteration both focused on process for normative justifications and legitimacy.⁶³ In place of ranked principles, countries turned to processes characterised by transparency and accountability to guide their decision-making about broad policies or specific treatments.⁶⁴ A shift to procedure does not mean that principles are irrelevant; the procedure is a process for selecting amongst principles and justifying a decision based on the process of considering them. Procedures also served an important political role with the opportunity for citizens to be involved and as a demonstration of political legitimacy and fairness.

Joining the scene late was the National Institute for Clinical Excellence (NICE), which took a different approach to priority-setting. Where other countries began with principles and then procedures, NICE has always been procedurally focused. NICE's functions are process driven, as I will discuss below, and it does not tier healthcare based on principles of urgency and need. NICE was established at the end of the period Holm describes in which countries moved from principle based accounts to procedural ones for setting their health priorities and limits.

with the ability and means to litigate for their right to health. (Flood and Gross, "Litigating the Right to Health: What Can We Learn from a Comparative Law and Health Care Systems Approach?", 2014; Yamin and Parra-Vera, "How Do Courts Set Health Policy? The Case of the Colombian Constitutional Court", 2009.)

⁶³ Bringedal.

⁶⁴ Holm, "Developments in the Nordic Countries - Goodbye to the Simple Solutions," 2000.

2.3.3 Procedural and substantive approaches—resolving some concerns

Before moving on to discussing NICE in full, I want to resolve a point about procedural and substantive (principle) approaches: the two are not mutually exclusive and each will inevitably rely on the other in order to make any sort of decision. There is debate over whether procedural or substantive approaches are best, but rather than argue a side, in this section I want to clarify that procedural approaches may have substantive limits, constraints, and elements yet retain their procedural nature. That is to say that procedural approaches need not be purely procedural for the outcome of the process to be fair and legitimate.

Procedural and substantive approaches are not necessarily exclusive, but they have different normative focuses. Substantive approaches focus normative value on principles. Procedural approaches are those that place normative weight on procedures and process.⁶⁵ Substantive approaches look at specific principles and try to reconcile conflicts between them. Arguments in favour of substantive approaches look to justice as a substantive issue itself and so want to tackle head-on difficulties with principles. Indeed, substantive approaches may seem a stronger response to healthcare limits since they back specific commitments rather than retreating to procedures and debate between principles.⁶⁶ A substantive approach will seek to reconcile differences between principles or rank them so that in case of conflicts between them, there is an order to be followed. Clear-cut substantive methods are those that use a principle-based methodology to make decisions, like using cost-effectiveness analysis to determine a distribution.⁶⁷

⁶⁵ Ceva, "Beyond legitimacy. Can proceduralism say anything relevant about justice?", 2012.

⁶⁶ Mahowald, "Why retreat to procedural justice?", 2001; Ashcroft, 2008.

⁶⁷ Emanuel, "Justice and managed care: four principles for the just allocation of health care resources", 2000.

However, the problem we will face with substantive approaches, much like the principle-based priority commissions, is how to decide between principles. In both theory debates and practice, people will hold different views on which principle is most important and valuable, and they will disagree about how to distribute resources and pick between principles. Unless we hold that principles can be resolved or collapsed into a single one, we will need a means to resolve the conflicts that arise between them in order to make a limit-setting decision.

Procedural approaches focus on the process of decision-making, rather than the principles that make up the disagreement. Procedural approaches privilege the problem of how we decide over the principles that go into the process. The advantage to the procedural approach is that we look for rightness in the decisions not from the substantive principles, which will be difficult to affirm, but from the process by which we arrive at a decision.

Important to my discussion, is that procedural approaches may have substantive constraints and limitations. (Similarly, there is usually some procedure in substantive approaches.) A procedural approach to justice or decision-making does not require a commitment to pure procedure stripped of substantive elements. Procedures for limit-setting may include parameter criteria about what sorts of inputs can go into the process, i.e. what kinds of principles may be used. We must also be careful not to be too wrapped up in the procedures since ultimately the purpose of using them is to make a decision, and that needs to be done. A procedural approach is a process to arrive at a substantive outcome.⁶⁸

⁶⁸ I am grateful to Benedict Rumbold for a helpful discussion on procedural and substantive approaches in decision-making.

In this chapter, I have considered how explicit rationing allows countries to make their priority-setting decisions part of a political and public discussion around priorities. Looking at the trajectory of priority-setting from the 1980s through the 90s, the trend was to begin with principle-based approaches that then developed into procedures for priority-setting. Finally, I made the point that procedures may contain substantive elements. What is important about procedures is that the substantive elements do not dictate the outcome prior to the procedure happening—if that were the case, then it would be a substantive approach since we would already have the principled answer. Amongst the national level health systems and their commissions, NICE stands out as one that has always been procedural with a process designed to resolve concerns about priority-setting in the NHS.

3 Consistency and the need for legitimate procedures—the establishment of NICE

In this chapter, I discuss the establishment of NICE as a centralised, procedural answer to priority-setting problems in NHS England. The Blair government established NICE in 1999 to reduce regional variation in the provision of services across NHS England by producing guidance on best practice and explicitly setting priorities. In this chapter, further broken down into three sections, I discuss the need for NICE as a national body to reduce variation in access to healthcare. NICE has always been a process-focused body, and it is with a process of guidance development that it aims to shape NHS commissioning and provision. However, NICE has also introduced new problems into the NHS and a new source of variation. It is with these high stakes in mind that NICE must justify itself as a legitimate decision-maker, and so it is to fair and normatively legitimate procedures that it turns.

3.1 Postcode lotteries and the need for NICE

NICE was established to address the problem of the “postcode lottery” in the NHS: the problem of patients having different access to healthcare services based on their regional health administration. Clinical Commissioning Groups (CCGs)—prior to 2013, they were Primary Care Trusts (PCTs)—each make their own decisions about the provision of NHS services for their constituency. Local level decision-making raises two problems, which NICE is meant to address: differential coverage of patients despite being part of a *national* system and inadequate evidence review to support commissioning decisions and clinical guidelines. Through the 1990s, media

and patient attention increasingly turned to the “postcode lottery” of commissioning groups providing different services. Patients in one county would be paying privately for expensive new treatments while those a few miles away had them provided as part of their NHS coverage.⁶⁹ The postcode lottery was especially evident for expensive services and new drugs, like beta interferon for multiple sclerosis, antipsychotics, new line cancer treatments, and drugs for motor neurone disease. In addition to different prescribing practices, local variations in treatment and diagnosis of conditions, like hypertension in the elderly, resulted in different regional outcomes.⁷⁰

Even since the introduction of NICE, much is still left to CCGs to determine how they set their budgets. The argument in support of this is that it allows each CCG to be responsive to the values and clinical context of its patient population. Because CCGs make commissioning decisions for small patient populations, averaging 250,000 people, they seem better placed to know the population’s needs and how to arrange services.

Ashcroft argues that postcode prescribing is desirable because the provision of services is a question of values, and it should be up to each locality to determine its values. He goes on to argue that a centralised system, like NICE, will end up increasing inequality and is not accountable whereas local policies are founded on respect and equality so long as decision-makers are held accountable. He urges that value based questions should be ones for CCGs rather than a centralised, non-transparent national decision that is arbitrary and uses ‘medical’ reasoning to back value based and political decisions.⁷¹

⁶⁹ "NHS drug 'lottery' targeted," 1999; Jones and Irvine, NICE or NASTY: Has NICE Eliminated the 'Postcode Lottery' in the NHS?, 2003.

⁷⁰ Rawlins, "National Institute for Clinical Excellence: NICE works", 2015.

⁷¹ Ashcroft, "In vitro fertilisation for all? The question is for local purchasers to answer, not for NICE", 2003; Ashcroft, "Fair Rationing is Essentially Local: An Argument for Postcode Prescribing", 2006.

Ashcroft's condemnation of NICE's centralised decision-making relies on the assumption that local decisions are more transparent and accountable, but that is not necessarily the case. There is no reason to think that NICE will be any less transparent and accountable than CCGs/PCTs. Indeed, a survey of PCTs found that there was a range of procedures, aims, transparency, and engagement in their priority-setting processes.⁷² However, this challenge from Ashcroft illustrates why NICE relies so heavily on its process. NICE has always addressed decision-making procedurally, whereas CCGs use a mix of values and processes. Ashcroft is concerned with the perceived legitimacy of NICE—a theme I return to in Part III with a discussion of NICE's normative and descriptive legitimacy. Clarity about NICE's process and acceptance of it, will help to answer concerns like those Ashcroft raises.

NICE is an important decision-maker for the NHS because it reduces inconsistencies in the provision of healthcare services and ensures equitable access to new interventions. Equal access for patients in the NHS matters; it is a *national* system that is funded by taxpayers, who make the same kinds of tax contributions no matter where they live in England. If we accept the premise that healthcare is a matter of justice (and if it is not then we need not devote so much energy to its appropriate distribution), then we need grounds for distinguishing the claims of individuals in order to treat them fairly. Location seems inadequate to do this, and when we break down a national system into smaller segments, we deny people fair equality of opportunity when it comes to access. Inconvenience is a different matter; it may be the case that someone has to travel to the next region, but recalling the coffee break room example (at 2.1), that is akin to having the coffee far away rather than in an exclusive, female-only area of the office. Up to a point it does not infringe

⁷² Robinson et al., "Priority-setting and rationing in healthcare: Evidence from the English experience", 2012; Robinson et al., "Structures and processes for priority-setting by health-care funders: a national survey of primary care trusts in England", 2012.

on equal access.⁷³ Consistency and the need for treating people consistently in order to be fair is a theme that will recur throughout the discussion of NICE.

Making decisions on behalf of a national system and about a matter of justice means that NICE needs a good procedure to demonstrate that it makes a sound and appropriate decision. One advantage NICE has over the CCGs is that it is powered to be able to do better evidence reviews, and it is more efficient for NICE to do these reviews than for each of the 209 CCGs to do the same. Indeed, one concern about CCGs is that they may not be able to make good evidence-based decisions since they do not have as many resources for reviews; variation between them may result from poor evidence rather than intentional value-based decisions.⁷⁴

But even with good process and evidence reviews, NICE makes political decisions, and that is an area where there is disagreement and conflicting values. What Ashcroft really seems to object to in his argument in favour of postcode prescribing is that NICE, ostensibly an evidence-reviewing organisation, makes decisions that are political and value-based. Ashcroft uses the example of IVF; once its effectiveness is established, the question of providing the service is one of values and what a public health system ought to provide.⁷⁵ NICE is not mandated to settle political questions, and the basis of its guidelines remains rooted in scientific evidence (as will be discussed extensively in Chapter 7) yet its decisions are necessarily value-laden whether in how evidence is interpreted or what recommendation it makes.

⁷³ I wish to offer two further arguments against location based rationing: where someone lives is not necessarily a meaningful unit and does not indicate that the person shares the values of her neighbours. Second is that location suffers from a similar problem as market accountability: we do not know what our health needs will be, and so cannot make an informed choice of which CCG will best meet our needs. Furthermore, there are many reasons someone chooses to live in a certain place, and availability of specific healthcare services is usually not one—we don't expect someone made the choice between Dorking and Reigate because of the commissioning groups each belongs to. Someone may move if they know a centre of excellence will be closer for the treatment of a child's rare disease, for example, but when settling down, it is unlikely that someone will pick based on the possibility of being offered a certain cancer treatment in ten years time if she were to develop that cancer.

⁷⁴ Murdoch, "In vitro fertilisation for all?: Society must hear the voices of infertile people", 2003.

⁷⁵ See Ashcroft, 2003.

Variation in services, like IVF, is precisely why NICE was created and why there is a national discussion about healthcare access.⁷⁶ These decisions are difficult, and shifting them to NICE rather than the NHS or Parliament was a way to off-load unpopular political decision-making.⁷⁷ Making decisions for a public body requires using principles and values, and NICE does this with a process that is designed to produce fair and normatively legitimate decisions to meet the demands on healthcare as a matter of justice.

3.2 Consistency and guidelines

NICE fits into the problem of postcode prescribing since as a centralised agency, it issues guidance for NHS England that applies to all CCGs. If CCGs were to follow NICE guidance, postcode prescribing would be reduced. As a large and centralised institution, NICE can undertake more thorough evidence analysis than CCGs are capable of and commission large scale reviews and expert consultations.⁷⁸ In addition, NICE's guidance is also value-based with judgements on values informing how to interpret and use the available evidence and what matters in a particular case.

NICE has four areas of guidance development, and the first two in particular are focused on reducing variation in access to services.

(1) *NICE Guidelines* are guidance on clinical, public health, and social care pathways and best practices. To produce these guidelines, NICE uses clinical and

⁷⁶ Mathur, "In vitro fertilisation for all?: Local decision making has led to inequality", 2003.

⁷⁷ Jones and Irvine, 2003.

⁷⁸ Rawlins, "In pursuit of quality: the National Institute for Clinical Excellence", 1999; Pearson and Rawlins, "Quality, innovation, and value for money: NICE and the British National Health Service", 2005.

cost effectiveness information alongside extensive evidence review.⁷⁹ The clinical guidelines include explicit rationing, with recommendations of treatments to try first before moving onto more expensive, less cost-effective ones. In addition to explicit rationing, the role of the clinical guidelines is to standardise best practice across England and reduce geographical variations in clinical outcomes. NICE is powered to do large systematic reviews and publish evidence-based guidelines in a way that CCGs are not equipped, and it would be wasteful for CCGs to attempt to conduct the same scale of review.⁸⁰ The guidelines, though, are not mandatory to implement—they are recommendations for best practice rather than statutory requirements for CCGs. Because clinical guidelines are meant to standardise best practice, they are one means of addressing the postcode lottery, but because they do not have statutory weight, they have had limited success, as I will discuss below.

(2) *Technology Appraisals* are assessments of the clinical and cost effectiveness of new technologies and whether they provide value to the NHS. Technology appraisals are carried out for new interventions, including diagnostics, devices, pharmaceuticals, and procedures. Unlike the clinical guidelines, CCGs have a statutory requirement to follow the recommendations of technology appraisals.⁸¹ Technology appraisals address both aims of NICE: they reduce variation since when NICE recommends an intervention through its technology appraisal guidance CCGs must fund it. Guidance is an explicit means of rationing since it states what should regularly be made available. Although technology appraisals comprise only a small portion of NICE's overall activities, because they are the only form of statutory guidance and explicitly ration, they receive the majority of attention. In the

⁷⁹ NICE, "Types of guideline," [nice.org.uk](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/types-of-guideline), <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/types-of-guideline>.

⁸⁰ Murdoch, 2003.

⁸¹ NICE, "What we do," [nice.org.uk](https://www.nice.org.uk/about/what-we-do), <https://www.nice.org.uk/about/what-we-do>.

conclusion (10.1), I will return to the issue of NICE's wider rationing activities and how much is still left to CCGs. However, in this dissertation, the technology appraisals provide the case study of limit-setting decisions and procedures, and I will focus on them rather than NICE's other activities.

(3) *Medical technologies and diagnostics guidance* reviews specific technologies and diagnostic tests and compares them to current practice standards. These reviews will recommend the uptake of a new technology if it finds it clinically and cost effective compared to current practice. However, these recommendations do not limit the use of the old technology nor do they have any statutory weight.⁸²

(4) *Interventional procedures guidance* reviews safety and efficacy of medical interventions. This program is similar to the Medicines and Healthcare Products Regulatory Agency and focuses on safety and efficacy standards rather than comparative measures like clinical or cost effectiveness.⁸³

These forms of guidance are the tools NICE has to meet its objectives of reducing variation in access to services and rationing for the NHS. But there are problems with these means, and in the years since NICE's founding, postcode prescribing has persisted. There are several causes to the continued variation, including limitations to NICE's powers and activities. NICE's clinical guidelines are just that—guidelines on best practices rather than requirements for how CCGs must commission care and patient pathways. When NICE publishes a clinical guideline, it is a recommendation for clinically effective and cost effective treatment. But these NICE guidelines are liable to come into conflict with CCGs, which are by design

⁸² "Types of guideline".

⁸³ "What we do"; Pearson and Rawlins, 2005.

In terms of resource allocation and efficiency, this seems to be a redundant program and should not be in NICE's remit. It's likely that NICE's success with clinical guidance meant it was assigned more tasks to undertake. Given NICE's own budget strain, this program seems the weakest use of NICE's resources.

meant to make local decisions based on population needs. The very design of the system and the stated aims for CCGs and NICE guidance pose potential conflict, though certainly it is possible for NICE's clinical guidance to be a useful support and guide in CCG decision-making.

It is worth briefly stepping to the side and noting that the exact relationship of the clinical guidelines to CCGs has been somewhat illuminated in *Rose v Thanet* [2014]. In this case, in which Elizabeth Rose applied for exceptional funding for oocyte cryopreservation but was turned down by Thanet CCG, Justice Jay upheld the CCG's position. However he did rule that they had irrationally disagreed with the clinical guideline. NICE's view, as put forward in its clinical guideline, supported oocyte cryopreservation in such circumstances based on the evidence. Justice Jay noted that the CCG had rejected this guideline because it disagreed, which was not an appropriate response when there were reasonable justifications it may have given. The upshot of the judgement is that it limited how the CCG may disagree with NICE and that it was irrational for the CCG to disagree with NICE's evidence. The judgement did not benefit the claimant, Rose, as it did not require the CCG to change its decision but rather to justify it in the right ways.⁸⁴ The judgement highlights the necessity of giving reasons and appropriate reasons for decisions.⁸⁵ (Such a requirement is precisely in keeping with the Publicity Condition of AFR, which I discuss in the next chapter (4) and which requires the rationales for a decision to be published along with the decision itself.) What this case shows for CCGs is that

⁸⁴ *R (on the application of Elizabeth Rose) and Thanet Clinical Commissioning Group*, (2014); Williams, "Briefing: What does *Rose v Thanet* tell us about the status of NICE guidelines in priority setting?," 2014, http://www.mills-reeve.com/files/Publication/b41bf907-e2bd-4399-ac79-31e5f0904dc2/Presentation/PublicationAttachment/4bcc6330-b26a-4d44-a77d-3b4b2b15ec17/RosevThanet_200488838.pdf.

⁸⁵ Ranson et al., "Implementation Of NICE Clinical Guidelines (CG)—What Can Be Learned From A UK Case Study And How To Ensure That Health Services Do Not Fall Short Of Their Obligations", 2015.

although they are left to make their own commissioning and funding decisions, they must be able to justify their deviance from NICE guidance, which has authority and takes priority.

3.3 Tensions between NICE and CCGs—the persistence of postcode lotteries

CCGs do not always follow NICE's guidance, and while NICE resolves some issues of equitable access, it also introduces new inconsistencies into the NHS. When it comes to CCGs following NICE's clinical guidelines, an issue at stake is NICE's credibility.

In its early years, NICE had not yet established itself with medical professionals, who were unlikely to take up the recommendations in the clinical guidelines. Initially, there were concerns that NICE's guidance development was not rigorous enough, but the addition of more expert testimony and, it would seem, continued practice have made NICE a leader in the UK and internationally in the development of guidance.⁸⁶ Amongst the many guidelines published by the royal colleges, local health authorities, and the like, NICE needed to establish itself as an authority. In part, this was an issue of publicity and ensuring that its guidance was well disseminated.⁸⁷ In its first few years, with little media or researcher attention, NICE's guidance seems to have had little impact.⁸⁸ NICE's response to such criticisms has been to develop a robust and publicised procedure for guidance development. These procedures and their publication are important not just because

⁸⁶ For example, Mr Justice Jay acknowledges that NICE is able to carry out much better evidence reviews than Thanet CCG in his judgement on *Rose v Thanet* (2014) *R (on the application of Elizabeth Rose) and Thanet Clinical Commissioning Group*, 2014.

⁸⁷ Jones and Irvine, 2003.

⁸⁸ Summerhayes and Catchpole, "Has NICE been nice to cancer?", 2006.

of the guidance they produce but also to convince CCGs and practitioners that it is credible and ought to be followed. However, more than ten years on, there is still variation in CCG adoption of guidelines; in its 2014-15 annual review, NICE noted that only 1 in 5 CCGs followed its recommendations on IVF provision.⁸⁹ As noted above, IVF is one service over which there is value-based disagreement, and not all CCGs have adopted NICE's clinical guideline. It may be that the debate over whether IVF should be provided means it is more likely to be commissioned differently, but the example does show that the postcode lottery persists.

While CCGs are not required to follow the clinical guidelines, the technology appraisal recommendations must be implemented. Technology appraisals are an explicit means of rationing. When NICE recommends a technology or makes an "optimised" recommendation for a particular patient subgroup, CCGs have three months in which to comply with the guidance and make the technology available to the specified patient groups.⁹⁰ When NICE does not recommend a technology, CCGs are unlikely to provide it because NICE has advised that it provides poor value for the NHS, and there is no legal obligation on the part of the CCGs to make it available.⁹¹ These sorts of decisions are one reason NICE was set up: it removes the onus of making unpopular rationing decisions from politicians and, as more new and expensive treatments appear, is a way to standardise decisions across the NHS thereby

⁸⁹ NICE, "Annual Review 2014-2015," National Institute for Health and Care Excellence, <http://review2014-2015.nice.org.uk>.

⁹⁰ An "optimised" or restricted recommendation is one that limits the subgroup of patients who are recommended for treatment beyond the market authorization of the treatment in question. Another option is for NICE to 'recommend in research', giving a recommendation that a research program be established to collect more evidence on the treatment. NICE does not run the trials itself, however.

⁹¹ NICE, "NICE statistics," nice.org.uk, <https://www.nice.org.uk/news/nice-statistics>

While it is possible for a CCG to still choose to commission a treatment NICE has not recommended, it is highly unlikely: these are treatments that have been determined not to be a good use of resources, and CCGs that already struggle to meet the demands on their resources will not provide a cost-ineffective treatment that they are legally protected from not funding.

reducing the postcode variation. Reviewing NICE in 2002, the Department of Health noted:

This is a key part of the government's strategy to end postcode prescribing and fulfils a commitment in the 2001 manifesto commitment. It will mean that every patient can know that, if their doctor makes a clinical decision within the terms of NICE guidance, no one will block the decision on grounds of alleged lack of funding.⁹²

Technology Appraisals are framed as giving patients security about access to treatments. The technology appraisals can be contentious decisions, and Chapter 7 closely examines the process.

Although technology appraisals introduce new technologies across NHS England, they have not eliminated postcode variation and have exacerbated it in other areas. For those technologies that are appraised, variation in availability is ruled out since CCGs must provide them. However, during the process of appraisal, some CCGs are reluctant to fund a technology that may end up being not recommended. Appraisal takes 12-14 months, and during this time the technology under consideration may suffer from “NICE blight”, wherein some CCGs choose not to fund it while waiting on a decision, and even this varies between CCGs resulting in inequitable access.⁹³ Even with positively recommended technologies, there is evidence of variation in regional uptake and use despite the statutory requirement to implement technology appraisal guidance.⁹⁴

When a treatment is not recommended, exceptional applications for its use are left to the judgement of CCGs, again resulting in different access by region. Off-

⁹² Department of Health, "Memorandum by the Department of Health (NC 1)," 2002.

⁹³ Jones and Irvine, 2003; Jackson, "Top-up Payments for Expensive Cancer Drugs: Rationing, Fairness and the NHS", 2010.

In contrast, at the 3 February 2016 meeting of Appraisal Committee B, which I attended, to assess ibrutinib for chronic lymphocytic leukaemia, a clinical expert testified that he and his colleagues were more likely to start a patient on a new treatment, like ibrutinib, if it were being appraised out of fear that it would not be recommended. Because NICE's recommendations often grandfather clause in patients currently being treated, this is a way for a clinician to assure that his current patients receive what he believes to be best care.

⁹⁴ Summerhayes and Catchpole, 2006.

license applications for drugs and exceptional requests, via the Individual Funding Request (IFR) are handled individually by CCGs, each of which will make its own decisions.⁹⁵ These cases introduce another area of variation in the NHS even though the IFRs and off-label prescribing are for treatments NICE has appraised.

NICE's choice of appraisals to carry out has a significant effect on what will be available on the NHS, and we should see appraisals not just as a tool of rationing but as one that ensures equal access to and use of recommended interventions. Topics for appraisal are chosen by working groups from NICE and the Department of Health, and selection is based on which technologies appear likely candidates for postcode prescribing. Technologies with a poor evidence base, high cost, potentially significant benefit, and/or likely effect on NHS resources or policies, are chosen for NICE to review.⁹⁶ When a topic is chosen for selection it is because it looks like it will be a difficult case of decision-making, which means it is likely CCGs would come to different conclusions about funding it. The considerations at play in topic selection also presage the kinds of considerations that play a role in the appraisal itself, as I will discuss in Chapter 7.2.

When NICE recommends a technology, it is prioritised over whatever a CCG may consider its local priority. Technology appraisals are statutory guidance, and since CCGs must provide the recommended interventions, this means that they must limit their other services in order to meet the NICE recommendation. Technology appraisals privilege the conditions and interventions; if you have renal cell carcinoma, for example, and NICE has recommended sunitinib (which it has), even though the CCG may think that sunitinib is not cost-effective, it is required to provide it to you. But if your treatment has not been appraised by NICE, then it is still up to the CCG to

⁹⁵ Jackson, 2010.

⁹⁶ NICE, Guide to the methods of technology appraisal, 2013, 2.3.1, 2.2.3.

determine what it will fund. NICE is only able to carry out so many appraisals each year. A concern about topic selection, especially in NICE's early years when it had not assessed many interventions, was that only 'fashionable' conditions and treatments would be appraised, giving them secured funding while other areas languished. This is particularly acute for pharmaceutical budgets since most of NICE's technology appraisals are of drugs.⁹⁷ Indeed, appraisals tend to cover new, controversial, or expensive drugs, which do not encompass most of the technologies used to meet the population's health needs.⁹⁸ Additionally, NICE only reviews interventions based on the market authorisation of each, so smaller studies on expanded uses of new treatments do not inform NICE's recommendations. For example, patients with a rare cancer may be left without assured access to a new, expensive treatment if that application for it is not covered in the market authorisation.⁹⁹ Topic selection and appraisals, therefore, will result in giving priority to those patients and conditions that are considered for NICE guidance.

Because NICE only positively recommends or does not recommend new technologies with its technology appraisal program, it leaves de-commissioning to each CCG, and here too there will be variations in how decisions are made. NICE is not a budget holder, and it does not take responsibility for the NHS budget, which is the role of Parliament and the Department of Health. NICE keeps adding new treatments to a growing list of ones that must be provided, but it does not offer de-commissioning advice to CCGs, which are legally required to stay within budget.¹⁰⁰ NICE is caught in a political impasse: on one hand it shields Parliament from making difficult budget decisions not to recommend some treatments, but on the other when it

⁹⁷ Jones and Irvine, 2003.

⁹⁸ Newdick, "Accountability for Rationing - Theory into Practice", 2005, 208.

⁹⁹ Summerhayes and Catchpole, 2006.

¹⁰⁰ Checkland et al., "Accountable to whom, for what? An exploration of the early development of Clinical Commissioning Groups in the English NHS", 2013.

does recommend them it puts strains on resources, putting pressure on the government to increase NHS funding.¹⁰¹ Despite recommendations that NICE include a program of disinvestment appraisals in its work, it has yet to adopt such measures.¹⁰² CCGs are not legally shielded from the decisions of where to cut services in order to provide for the new ones in the way that they are when NICE does not recommend a treatment. This will inevitably cause tensions between them and NICE and postcode variation amongst CCGs.¹⁰³ CCGs must re-evaluate their priorities in light of the priorities handed down from NICE. The problems for CCGs are two-fold. The first is that postcode prescribing will persist since each CCG will make its own determinations of how to manage its budget. Second is that CCGs must be able to justify the local priority-setting they do—returning to the earlier argument of whether the system ought to be national or left to local decision-making. Currently, it sits uneasily between the two.

Although NICE was established to reduce variation in access to services and ration care, it has only been partially successful at these aims, and it has introduced new challenges. Rawlins, the first chair of NICE, along with his colleague Pearson, optimistically argued that NICE had effectively ended postcode prescribing and fostered innovation because by securing access to treatments, manufacturers were assured a market.¹⁰⁴ While it is true that NICE secures a market with its technology appraisals, it has not eliminated postcode prescribing. Yes, the appraised treatments will be available across NHS England, but managing the opportunity-costs of providing these new treatments is left up to CCGs. Furthermore, NICE's appraisals

¹⁰¹ Gutmann and Thompson, *Why Deliberative Democracy?*, 2004, 113.

¹⁰² Pearson and Littlejohns, "Reallocating resources: how should the National Institute for Health and Clinical Excellence guide disinvestment efforts in the National Health Service?", 2007.

¹⁰³ Newdick, 2005, 48-9, 93, 206; Drummond, "NICE: A nightmare worth having?", 2007.

¹⁰⁴ Pearson and Rawlins, 2005.

introduce a two-tier priority system in which the interventions NICE has appraised are prioritised over others because of the statutory requirement to provide them.

Against this backdrop of postcode prescribing, local and national tensions, and the inherent problems of prioritising some treatments via technology appraisals, NICE has high demands to meet in order to show that its work should be accepted. What this chapter has aimed to show is that the process of setting priorities is a politically complex and high-stakes one for NICE and for CCGs. The procedure that NICE uses must address the concerns about limit-setting and legitimacy, both normative and descriptive, that the Institute faces. It is with this sort of practice in mind that I turn now to AFR, which is designed to be a fair and legitimate process for making these kinds of difficult limit-setting decisions.

4 Accountability for reasonableness: a fair and legitimate procedural approach

So far Part I has considered the general trend towards procedural approaches to limit-setting and then the specific problem faced in the UK. In this chapter, I introduce Daniels and Sabin's account of their theory "accountability for reasonableness" (AFR). In my discussion of AFR here, I focus on the themes I have raised so far: AFR as a procedural approach and how AFR positions itself as a procedure for legitimate decision-making. I present Daniels and Sabin's account of AFR, but I focus on those elements of it related to procedural approaches and legitimacy.

Daniels and Sabin first published on AFR in 1997 as a response to the trend towards procedural approaches in international priority-setting. Daniels and Sabin's view is that in light of the disagreement over how to use principles—even when there is agreement on what those principles ought to be—requires a fair process. Their proposed process for these decisions is AFR.¹⁰⁵ Since 1997, AFR has been widely cited and considered a model for procedural decision-making.

Daniels and Sabin's account of AFR begins with two problems for limit-setting that AFR is meant to address: the legitimacy and fairness problems. I will briefly discuss Daniels and Sabin's account of AFR, and then give consideration to how AFR has been used in the literature. I will give detailed attention to each condition throughout the subsequent chapters of the dissertation as each one becomes relevant to the particular discussion rather than discussing them in depth here. The following chapter (5), takes up Daniels and Sabin's account, its underpinning in

¹⁰⁵ Daniels and Sabin, *Setting Limits Fairly*, 2008.

democratic deliberation, and discusses how AFR resolves the legitimacy problem in greater detail.

4.1 The fairness and legitimacy problems

Daniels and Sabin recognise the problem that there are limits to the available resources for healthcare, so not all needs can be met. They ask how, given the limited resources, healthcare limits can be set in a fair and legitimate way. This is an important question for justice since, as I discussed above (2.1), meeting healthcare needs is a way of protecting fair equality of opportunity, so the setting of limits on healthcare is an issue of social obligation and justice. They approach the question by breaking it down into two problems:

The legitimacy problem asks, “Why or when should a patient or clinician who thinks an uncovered service is appropriate or even “medically necessary” accept as legitimate the limit-setting decisions of a MCO?”¹⁰⁶

And the fairness problem, “When does a patient or clinician who thinks an uncovered service appropriate or even medically necessary have sufficient reason to accept as fair the limit-setting decisions of a managed care organization?”¹⁰⁷

These two problems are distinct and tease out different concerns about healthcare limits. The fairness problem is concerned more with the substantive content of the reasons given for the decision and what constitutes a fair distribution of

¹⁰⁶ "Limits to health care", 1997,304.

¹⁰⁷ Ibid., 305.

MCO is a “managed care organisation”, a kind of health insurer in the US. In later restatements of these problems, Daniels and Sabin change out MCO for a health plan or public authority in order to make the problems inclusive of all healthcare rationing, such as that in a national system, like the NHS, rather than limiting it to the American MCO insurance model. See *Setting Limits Fairly* (2008) p. 26 for one such restatement.

resources. According to Daniels and Sabin, the legitimacy problem is concerned with who decides and how the decision is made.

Legitimacy in the decision-making concerns the moral authority of how the decisions are made. Legitimacy encompasses the moral authority of who makes the decision and also how it is made, so for a decision to be legitimate it must not only be made by the appropriate people but also in the appropriate way.¹⁰⁸ The legitimacy problem asks under what circumstances the public and the population affected by the decisions take the process and the decision-makers to be legitimate, i.e. under what conditions should they trust their decision-making?¹⁰⁹ In the introduction, I distinguished two types of legitimacy, normative and descriptive. The legitimacy problem is phrased in terms of descriptive legitimacy: how the individual patient views the decision and what conditions mean she will view it as legitimate. Daniels and Sabin do not make this distinction in their discussion though, and they move between normative and descriptive legitimacy as they construct their account of AFR.

Daniels and Sabin's response to the fairness and legitimacy problems is to turn to fair procedures for decision-making and to establish the accountability of the decision-makers. They argue that not only will procedures best answer the legitimacy and fairness problems but that principles will fail to do so. Their turn to procedures reflects the discussion above about how national systems have handled priority-setting. Daniels and Sabin begin from a position of assuming that there will be disagreement about principles for how to set limits; in a modern, pluralistic, democratic society it seems implausible that there will ever be agreement on moral

¹⁰⁸ Daniels, "Accountability for reasonableness: Establishing a fair process for priority setting is easier than agreeing on principles", 2000; "Reasonable Disagreement about Identified vs. Statistical Victims", 2012.

¹⁰⁹ Daniels and Sabin, "Last Chance Therapies and Managed Care Pluralism, Fair Procedures, and Legitimacy", 1998; "Closure, Fair Procedures, and Setting Limits Within Managed Care Organizations", 1998.

positions, principles, and how to apply principles for rationing.¹¹⁰ The lack of agreement is consistent with both modern political philosophy that assumes pluralistic societies and with observed experience.¹¹¹ Daniels and Sabin know of no democratic society that has a consensus agreement on moral issues and principles for priority-setting.¹¹² Given the lack of agreement over principles, Daniels and Sabin focus on fair procedures and what about a procedure makes it legitimate.

4.2 AFR: four conditions for a procedural framework

The procedure Daniels and Sabin propose is called “accountability for reasonableness” (AFR). Their aim with it is to establish a procedure that can be agreed on and will hold the decision makers accountable. The public should view the decision as legitimate because of its parameters and agreed on procedure.¹¹³ Accountability for reasonableness is as it says: it holds decision-makers accountable to the public and stakeholders for the reasonableness of their decisions. As a fair and legitimate process the attributes of the procedure translate to the outcomes, which will be fair and legitimate and should be accepted as such.

In order for a decision to be fair and legitimate, AFR requires procedures to follow four conditions:

1. **Publicity Condition:** Decisions regarding both direct and indirect limits to care and their rationales must be publicly accessible.
2. **Relevance Condition:** The rationales for limit-setting decisions should aim to provide a *reasonable* explanation of how the organization seeks to provide “value for money” in meeting the varied health needs of a defined population

¹¹⁰ "Limits to health care", 1997; Daniels, "Accountability for reasonableness: Establishing a fair process for priority setting is easier than agreeing on principles", 2000.

¹¹¹ See, for example, Rawls, *Political Liberalism*, 1993; Gutmann and Thompson, *Democracy and Disagreement*, 1996.

¹¹² Daniels and Sabin, *Setting Limits Fairly*, 2008, 3.

¹¹³ "The ethics of accountability in managed care reform", 1998; Daniels, "Justice, Health, and Healthcare", 2001.

under reasonable resource constraints. Specifically, a rationale will be reasonable if it appeals to evidence, reasons, and principles that are accepted as relevant by fair-minded people who are disposed to finding mutually justifiable terms of cooperation.

3. Revision and Appeals Condition: There must be mechanisms for challenge and dispute resolution regarding limit-setting decisions, and, more broadly, opportunities for revision and improvement of policies in the light of new evidence or arguments.

4. Regulative Condition: There is either voluntary or public regulation of the process to ensure that conditions 1-3 are met.¹¹⁴

Taken together, these four conditions require decision-makers to be held accountable for their decisions and achieve this through transparency and substantive limitations on rationales.

AFR responds to the trends I discussed above since it is an explicit and procedural approach to rationing. AFR requires explicit limit-setting rather than implicit or obscured decisions. The Publicity Condition requires that the decisions as well as their justifications be shared. Daniels and Sabin claim that by sharing the justifications for limit setting, patients and the public will learn about the need for setting limits and what sorts of reasons are appropriate for meeting needs.¹¹⁵ Publicity also changes the terms on which someone understands the limit setting and how she might appeal it—if she understands the justification for the decision, then she knows whether it was based on interpretation of evidence or a value-based decision like whether the treatment is considered enhancement, for example.¹¹⁶ The requirement to publicise decisions and rationales is something Daniels considers crucial to justice since the outcomes and process can only be evaluated if publicised,

¹¹⁴ Daniels and Sabin, *Setting Limits Fairly*, 2008, 45. Emphasis theirs. These four conditions are repeated, with minor variations, in many of Daniels's published works on AFR.

¹¹⁵ Daniels, "Decisions About Access to Health Care and Accountability for Reasonableness", 1999; Daniels and Sabin, "What Are Fairness and Consistency in a National Pharmacy Benefit?", 2001.

¹¹⁶ Daniels, "Accountability for reasonableness in private and public insurance," 2000.

and it breaks with a tradition of preferring implicit rationing because of the moral distress of the matter.¹¹⁷

There are procedural and substantive components to AFR, although Daniels and Sabin describe it as a procedure and focus on its procedural elements. The Relevance Condition constrains the substantive principles that are acceptable in the framework. Daniels and Sabin phrase AFR in procedural terms and refer to it as a procedural account, but embedded in it is the Relevance Condition, which precludes certain considerations. My reading of Daniels and Sabin's inclusion of the Relevance Condition is that they consider it to address the fairness problem. Because reasons must be acceptable and relevant to the decision (a standard I discuss in detail in section 5.3), the Relevance Condition rules out manifestly unjust principles.

Finally, AFR should be put into practice. Daniels and Sabin propose AFR as a theory-based pragmatic solution to concerns about health insurance companies' rationing decisions. Though a theory, their aim is for decision-makers to use AFR in practice to strengthen the fairness and legitimacy of their decisions and also to allow for a public discussion of priority-setting. In evaluating AFR, we must regard it both as a theory that should be coherent and also as a pragmatic framework for implementation.

AFR will be at the centre of the upcoming discussion, so with this brief introduction, my aim is to show how it fits in to the problems for healthcare rationing in this chapter. AFR is an explicit and procedural approach that focuses on the elements of the process of making a decision in order to answer the legitimacy and fairness problems.

¹¹⁷ *Seeking Fair Treatment*, 1995. For arguments in favour of implicit rationing, see Calabresi and Bobbitt, 1978.

4.3 AFR in the literature

In this section, I give an overview of how AFR has been adopted in the literature and the response to it. My aim is not to do an exhaustive literature review, but rather suggest how AFR is being used. Looking at the literature will also serve to distinguish the critique of AFR that I make in Chapters 5 & 6 and NICE's use of AFR in its guidance development process.

One area of literature on AFR compares current practices against the framework, generally with an aim of recommending revisions to practice. Numerous studies examine priority-setting practices, either with a review of published processes, observing practice, or qualitative interviews to discern how decision-makers on priority-setting make decisions. Some of these are large scale, like pharmaceutical reimbursement schemes for a whole country, and others look at micro-level decisions, like prioritising patients for kidney transplantation at a particular hospital.¹¹⁸ These studies take extant practices and compare them to the framework of AFR to consider which conditions are met and use this as the basis of evaluating the current process.¹¹⁹

However, I believe that comparing current practice against AFR, while it may be internally useful for a system to evaluate itself, is not a good way to evaluate AFR. Few of these systems meet all the conditions and satisfy them to varying degrees. These sorts of evaluations are useful for demonstrating potential weaknesses in health systems and their procedures. These sorts of studies are not an appropriate reflection

¹¹⁸ Cho, Park, and Kang, "Pitfalls in Reimbursement Decisions for Oncology Drugs in South Korea: Need for Addressing the Ethical Dimensions in Technology Assessment", 2013; Omar et al., "Priority setting in kidney transplantation: A qualitative study evaluating Swedish practices", 2013.

¹¹⁹ For example, the above two and: Bukachi et al., "Healthcare priority setting in Kenya: a gap analysis applying the accountability for reasonableness framework", 2013; Mielke, Martin, and Singer, "Priority setting in a hospital critical care unit: Qualitative case study", 2003; Mori and Kaale, "Priority setting for the implementation of artemisinin-based combination therapy policy in Tanzania: evaluation against the accountability for reasonableness framework", 2012; Romero and Quental, "Research for better health: the Panamanian priority-setting experience and the need for a new process", 2014; Tromp et al., "Priority setting in HIV/AIDS control in West Java Indonesia: an evaluation based on the accountability for reasonableness framework", 2014.

on the intentional implementation of AFR because the priority-setting practices involved never made a claim to be using AFR, yet are being held to its standard. Such studies are of limited usefulness when we want to understand AFR in practice.

Concerning the practice of AFR is a smaller body of literature that focuses on priority-setting programs designed with AFR as a procedural framework. These sorts of studies draw attention to the challenges faced by priority-setting bodies when they implement AFR in practice.¹²⁰ They also reveal how each body interprets the requirements of the conditions. For example, a Tanzanian study focused on involving stakeholders and communities in developing reasons and principles for priority-setting and tensions between national and local priorities.¹²¹ Their view of stakeholder involvement is much more inclusive and extensive than what Daniels and Sabin's account of AFR requires. In contrast, Ibrahim presents an example of a neurosurgery unit in Toronto where surgeons decided to use AFR to prioritise elective operations each day in case some had to be cancelled. The example shows a good process of AFR except that it is not public at all and is done within the closed group of the surgeons.¹²² Daniels and Sabin view AFR as a process that allows for public discussion and debate, which this sort of private and internal priority setting does not include. These sorts of case studies are useful for drawing out successes and obstacles to the implementation of AFR.

¹²⁰ For examples, see: Winquist et al., "An Evaluation Framework for Funding Drugs for Rare Diseases", 2012; Browman et al., "6-STEPs: A modular tool to facilitate clinician participation in fair decisions for funding new cancer drugs", 2008; Urquhart, Mitton, and Peacock, "Introducing priority setting and resource allocation in home and community care programs", 2008; Lindström and Waldau, "Ethically acceptable prioritisation of childless couples and treatment rationing: "Accountability for reasonableness"", 2008.

¹²¹ Byskov, "Accountable priority setting for trust in health systems--the need for research into a new approach for strengthening sustainable health action in developing countries", 2009; Maluka S, "Improving district level health planning and priority setting in Tanzania through implementing accountability for reasonableness framework: Perceptions of stakeholders", 2010; Maluka, "Strengthening fairness, transparency and accountability in health care priority setting at district level in Tanzania", 2011; Maluka S, "Implementing accountability for reasonableness framework at district level in Tanzania: a realist evaluation", 2011.

¹²² Ibrahim, Tymianski, and Bernstein, 2013. Priority lists were not published so as not to distress patients.

In Part III, I will use NICE as a case example for the implementation of AFR. Unlike the first set of literature I raised concerns about, NICE is explicitly committed to using AFR in designing and running its procedures.¹²³ NICE's use of AFR is a claim the Institute makes to legitimacy, but in my discussion of it, it also reveals weaknesses with AFR as a theory fit for practice.

4.4 Part I: adopting procedures for priority-setting

This first part to the dissertation has focused on a shift to procedural approaches for healthcare limit-setting and AFR as a procedure that aims to produce fair and legitimate decisions. Resource limitations are inevitable, and we are unlikely to ever be able to meet all the need for healthcare. Recognising the potential strains on healthcare budgets, countries began establishing priority-commissions in the 1980s and early 1990s in order to make decisions about how to ration healthcare. Most of these commissions began with sets of principles, but these substantive approaches proved to have little effect on rationing in practice, and there was continued disagreement over using principles in practice to make concrete decisions. The 1990s saw a shift to procedural approaches to priority-setting.

Procedural approaches draw their normative justification for outcomes from the process of arriving at them rather than the substantive values at stake. AFR exemplifies the trend through the 1990s of turning to procedural approaches, and it has stuck, becoming the dominant model for priority-setting.

In Part One, I also introduced NICE as a national priority-setting body for the UK. NICE plays an important role in England and internationally as a role-model in

¹²³ NICE, Social Value Judgements, 2008; Cookson, "Justice and the NICE approach", 2015.

making process-based decisions about access to healthcare services and interventions. Part Three will take up the issue of how NICE uses its procedures, specifically AFR, to develop its legitimacy claims.

While AFR has been successful in establishing itself as an exemplar process, in the next part of the dissertation, I challenge whether AFR can result in legitimate outcomes. In addition to challenging the legitimacy of AFR, I will raise two concerns about the Relevance Condition, which will become particularly important when AFR is translated into practice. These chapters have shown the high stakes of having legitimate priority-setting, so I aim to offer an account that will strengthen both the theory and practice of AFR.

II. Relevance and Fair Consideration: Legitimacy Problems for AFR

The previous chapter introduced the procedure AFR, a process for fair and legitimate decision-making about limits in healthcare. In the following two chapters, I delve into the requirements of AFR, focussing on the Relevance Condition and AFR's claim to normative legitimacy. Despite the claim that AFR results in fair and legitimate decisions, in these next two chapters, I argue that the four conditions of AFR are not sufficient for normative legitimacy.

Chapter 5 begins with an examination of the state of reasonable disagreement and Daniels and Sabin's claim that reasonable disagreement and the kind of positions that disagreement concerns require a procedural, rather than substantive, resolution. The kind of procedure matters too: it must be democratic but the simplest of democratic devices, aggregation, fails to take into account the particular moral significance of reasonable disagreement. That is why Daniels and Sabin turn to deliberative democracy, which they then adapt for non-democratic settings as AFR.

The move to AFR is motivated by the special importance of reasonable disagreement and the moral positions it involves, which grounds the chapter's arguments. Daniels and Sabin do not give a clear indication of how we are to identify these kinds of positions. "Reasonable" is defined in the Relevance Condition along with relevance. However, the Relevance Condition bases this definition on what fair-minded people consider relevant, which merely shifts what must be defined to the concept of "fair-mindedness". Daniels and Sabin use an inexact analogy to explain

fair-minded people, so we are left still with the problem of how to positively determine reasonableness.

Daniels and Sabin's definition of relevance leaves us with two problems for discerning what is relevant. The first is what sorts of reasons are included or excluded from the AFR process. I address their exclusion of religious reasons, offering a new argument that what Daniels and Sabin actually intend is to reinforce the requirement that relevant reasons must be mutually justifiable rather than what their critics suppose them to mean. The account I offer of Daniels and Sabin's criteria for relevance has implications for practice since it affects how we should evaluate reasons. It also strengthens the theory of AFR against a particular criticism that arises about the exclusion of reasons.

The second problem is what sort of agreement is necessary for relevance, whether it must be empirical or normatively objective. This is a problem that has been overlooked in the literature on AFR despite the scrutiny of the Relevance Condition and relevant reasons. The kind of agreement that is necessary is important since whether reasons are drawn from an idealised range or not has implications for the feasibility of implementing AFR. A requirement for empirically justified reasons would have implications for what normative legitimacy requires.

While I do not conclusively resolve either dilemma, I suggest solutions and raise these as problems that we will see play out in practice when institutions implement AFR, as I show in Part III. A third concern is the kind of substantive commitments Daniels and Sabin make in their theory, particularly their commitment to value for money, which will recur as a concern in Chapter 9 on NICE's practice of AFR. Identifying relevant rationales is important for knowing when there is reasonable disagreement and for making decisions in accordance with AFR and on

acceptable grounds. Chapter 5 addresses reasonable disagreement, relevance, and the challenges to pinning down these concepts in a practicable way for users of AFR.

In Chapter 6, I argue that AFR fails to answer the legitimacy problem. I set aside the problem of relevance and instead focus on how the process treats relevant rationales and reasonable disagreement. The procedure, as it is defined by the four conditions, fails to treat reasonable disagreement in the right way. Given the moral importance of reasonable disagreement and relevant rationales, this gap in AFR poses a challenge to claiming that the results of the process are legitimate. I will show this with an example and then argue that the answer to this problem is an additional AFR condition requiring “fair consideration” of reasons. Fair consideration, the idea of taking reasons seriously, is necessary for both the normative legitimacy of AFR’s procedure and for the perception of its legitimacy, which is important for the buy-in of stakeholders to the procedure and its outcomes.

I will argue that AFR and its four conditions as they stand cannot answer the legitimacy problem Daniels and Sabin pose, and I offer a new account of AFR that includes the condition of fair consideration. Fair consideration is necessary, though not sufficient, for legitimacy in the AFR procedure. This part is a theory-based critique of AFR. In Part III, I will look at how an institution, NICE, adapts AFR into its process in order to make decisions it can justify as fair and both normatively and descriptively legitimate.

Throughout this part, I orient my examination of Daniels and Sabin around how they address legitimacy and fairness. I present their account as it relates to the legitimacy and fairness problems. My aim with this is to refine their account of legitimacy and relevance.

The last chapter traced the shift to procedures for making difficult decisions about healthcare limit-setting and the emergence of AFR as an exemplar of process. My aim with these two chapters and arguments about AFR is not to demonstrate the overall inadequacy of the theory. Instead, I hope to make AFR more coherent as a theory, pointing out theoretical weaknesses, responding to critics, and delineating what the theory is and is not designed to accomplish. The criticism of its normative legitimacy concludes with a recommendation of how to enhance the legitimacy of the AFR procedure with fair consideration. Fair consideration is not merely another smoothing out of the theory but also a contribution to how AFR circumscribes procedures and may feasibly be implemented in order to make a decision on healthcare limits. My attention then is to AFR both as a procedural theory but also to one that is translated into practice and how it can best achieve that translation.

5 Reasonable disagreement and two problems for relevance

This chapter addresses the Relevance Condition of AFR, and unanswered problems from Daniels and Sabin's definition of relevance. The purpose of this chapter is to point to gaps in the theory, suggesting new ways to understand it and also what challenges these gaps pose when AFR is translated into practice. I am not setting out to solve the substantive problems the Relevance Condition raises but rather to show how the substantive problems that arise with the Relevance Condition will be implicated in the procedure of AFR and its translation into practice.

The chapter begins with an examination of reasonable disagreement and the important point that reasonable disagreement is a particular kind of disagreement that is morally significant. It is this significance that leads Daniels and Sabin to turn to deliberative democracy. However, they do not fully embrace an account of deliberative democracy. My explanation of their relationship to deliberative democracy is different from the most common in the literature on AFR, which assumes that AFR is meant to enable deliberative democracy and be an extension of that concept.¹²⁴ Instead, I argue that the relationship between the two theories is not so clear, and AFR is not an example of deliberative democracy, which will affect the justification of its normative legitimacy and how we ought to evaluate AFR.

I then take up an examination of the Relevance Condition and make three arguments about problems it raises for AFR both as a theory and pragmatic framework. Two concern substantive commitments Daniels and Sabin make with regard to religious reasons and value for money. The third is the question of how

¹²⁴ Lauridsen and Lippert-Rasmussen, "Legitimate allocation of public healthcare: beyond accountability for reasonableness", 2009.

Daniels and Sabin determine relevance and whether it is a normative or empirical standard. I discuss these substantive issues because how they are settled becomes a procedural problem, which ties in with my focus on procedural accounts.

The first substantive issue addressed is Daniels and Sabin's apparent exclusion of religious reasons. I reframe this exclusion as one that requires a closer look at mutual justifiability in reasons rather than excluding them based on their origins. This argument is in contrast to the prevailing literature since I offer a more charitable reading and one that will provide a better translation of AFR theory into practice.

The second argument concerns the problem of whether AFR requires real or objective agreement about what reasons are relevant. Daniels and Sabin use the concept of ideal fair-minded people to define relevance, but they leave unresolved the question of whether these fair-minded people must carry out the process. Is relevance determined by an objective standard of what fair-minded people would agree to or what people actually do agree about? I frame this problem as one of what is justifiable vs. justified. Again, this problem for relevance is one that will affect its implementation since we must know whether we will need a normative concept of relevant reasons or a process for empirically confirming them.

The final section of the chapter ties together the discussion of relevant reasons with an examination of what reasons Daniels and Sabin themselves consider relevant. I begin this with a critique of the inclusion of "value for money" as a condition of relevance since it commits the process to a particular kind of justificatory reason. Broadening the discussion of their reasons, formal fairness is one of the strongest reasons they claim will be relevant, and it has repercussions for how consistency will be valued in decision-making.

This chapter focuses on relevance, Daniels and Sabin's approach to substantive principles. The Relevance Condition has received considerable attention since it is the only substantive constraint in AFR which is otherwise process oriented. In this chapter, I offer new arguments and perspectives on relevance, drawing attention to problems in the definition and understanding of the concept that will have repercussions for those who aim to implement AFR.

5.1 The significance of reasonable disagreement

Daniels and Sabin's account of AFR begins from the problem of reasonable disagreement. "Reasonable disagreement" is when there are conflicting substantive moral positions about a policy or how to answer one of the rationing problems, for example, but each position is reasonable. Each of the positions in reasonable disagreement is an appropriate, justifiable, and reasonable principle, so none can be ruled out on the grounds of substantive unfairness (like discrimination) or collapsed into each other. What exactly Daniels and Sabin mean by "reasonable" is a discussion I will flesh out below. For now, it is enough to note that in the case of reasonable disagreement, the debate is not between a fair position and an unfair one but rather between two positions, each of which looks like it is a fair and reasonable response. Reasonable disagreement is a well-discussed problem in the political philosophy literature, where it signifies a particular and special case of disagreement over well thought out positions that cannot be reconciled.¹²⁵

¹²⁵ Caney, "Liberal legitimacy, reasonable disagreement and justice", 1998; McMahon, *Reasonable Disagreement: A Theory of Political Morality*, 2009.

In this chapter I borrow the phrase "moral position" from Gutmann and Thompson in order to indicate those positions that are of a particular kind of significance and part of reasonable disagreement. I do not intend to take on board Gutmann and Thompson's definition of a moral position nor their account of deliberative democracy in doing so. "Position" seemed an appropriate term to convey the significance of these views.

Daniels and Sabin do not refer to these discussions though, and their take on reasonable disagreement has a particularly empirical bent: it is the fact that there is not agreement on principles of distributive justice. They know of no society that has achieved this agreement, and they predict it is unlikely there will ever be consensus.¹²⁶ This means that it is possible there could be agreement so no procedure would be necessary, but even in such cases, Daniels urges that we use a procedure in case we are convinced by a new reason or our society's values shift over time.¹²⁷

Reasonable disagreement is a substantive problem, but Daniels and Sabin argue it requires a procedural solution. There will not be agreement on principles and moral positions, so a process is necessary for determining a fair outcome. They back this with an agnostic view on the rightness of the substantive principles: it is possible there are morally right answers to distributive problems, but we have no way to know the right answer. Therefore, a procedure is the best recourse for resolving the disagreement. If there are principled solutions—correct moral answers—then the democratic procedure for rationing should aim to reach the right solution. If there are not principled solutions, then the outcome of the democratic process will be considered right, since it is the process that makes the outcome just rather than a claim that the outcome itself is the right answer.¹²⁸ A democratic process is the ultimate authority for decision-making when there is reasonable disagreement.¹²⁹ Lack of agreement on principles requires a procedure to make a decision.

Before continuing the discussion of procedures, I want to highlight the point that reasonable disagreement entails two or more reasonable, substantive moral positions that conflict, so in order to make a decision when there is this disagreement,

¹²⁶ Daniels and Sabin, *Setting Limits Fairly*, 2008, 4.

¹²⁷ Daniels, Porteny, and Urritia, "Expanded HTA: Enhancing Fairness and Legitimacy", 2016.

¹²⁸ Daniels, *Seeking Fair Treatment*, 1995, 123.

¹²⁹ Daniels and Sabin, *Setting Limits Fairly*, 2008, 34.

a fair process is necessary. This assumption about reasonable disagreement and the positions it involves grounds much of the upcoming discussion. There is something specific to reasonable disagreement and the kinds of positions in the disagreement that is morally significant and warrants a special kind of treatment, in this case procedural decision-making. The significance of reasonable disagreement is demonstrated in Daniels and Sabin's argument in support of deliberative rather than aggregative democracy.

5.2 Daniels and Sabin's account of deliberative democracy

Daniels and Sabin claim that democratic procedures bestow the proper authority when there is disagreement, but aggregative, democratic procedures are unacceptable in the case of reasonable disagreement. Aggregative democracies give each person one vote, so everyone's interests are counted equally, and the majority position determines the outcome. While this is a successful means of preference satisfaction, since whatever the majority prefers will be chosen, it is not the right way to make policy decisions when there are moral positions involved.¹³⁰ Daniels and Sabin argue that majorities may be wrong, and when it comes to moral positions in policy, the aim is not mere preference satisfaction.¹³¹ This is known as "the democracy problem", and Daniels and Sabin make no claim to solve it. Their hope is that a process, like AFR, will lead us to better, more coherent outcomes.¹³²

¹³⁰ "Closure, Fair Procedures, and Setting Limits", 1998.

¹³¹ "Limits to health care", 1997; Daniels, "Symposium on the Rationing of Health Care", 1998.

This concern over aggregative democracy traces back to John Stuart Mill who formulated the 'harm principle' to set limits on government in response to the threat of the 'tyranny of the majority'. Part of his concern is that those in the majority will vote based on their feelings and preferences, which may undermine more important political values. (Mill, *On Liberty*, 2003, 76-83.)

¹³² Daniels and Sabin, *Setting Limits Fairly*, 2008, 64.

I will focus on the second part of their claim: Daniels and Sabin believe that moral disagreement on policies, like healthcare limit-setting, significantly differs from preference satisfaction. Because of the difference, there should be limits on what the majority may choose to enact. The majority may have a preference for something that is not a reasonable position, and the minority should not be subjected to this preference when it overrides reasonable moral positions. In practice, we restrict majority rule, for example with a constitution that protects rights.¹³³ Regardless of whether the majority gets the morally right answer, there are some things, like the moral positions at stake in reasonable disagreement, that should not be treated as preferences and subject to mere aggregation (a qualified claim since in Daniels and Sabin's account they may eventually be voted on).¹³⁴ This goes back to the claim that there is something significant about reasonable disagreement, and it deserves special treatment.

Daniels and Sabin turn to deliberative democracy as an alternative to aggregation because it takes into account reasonable disagreement and the significance of moral positions. Deliberative democracy requires that the basis of policy be moral positions everyone can agree are acceptable grounds for the policy and that rather than simply voting there is deliberation about the positions and the policies they entail. These are two large claims, which Daniels and Sabin do not directly address, so let's take them in succession.

The first claim about deliberative democracy is that there are certain kinds of moral positions that are acceptable, and these will form the basis of policy. Daniels and Sabin do not identify how they discern between preferences and moral positions, instead referring to "moral views" and distinguishing them from those things that are

¹³³ Daniels, *Seeking Fair Treatment*, 1995.

¹³⁴ Daniels and Sabin, "Limits to health care", 1997; Daniels, "Justice, Health, and Healthcare", 2001.

mere preferences, which seem to be decisions that are not matters of justice.¹³⁵ How to define and recognise these moral views is a problem that I will return to in the discussion of relevant reasons, and it is one of the unresolved problems of AFR. Broadly, moral views permitted in deliberative democracy are the positions that are justifiable to all who “seek mutually justifiable terms of cooperation”, which we can take to mean cooperative, engaged citizens, implying that they buy into the process. Daniels and Sabin repeat this definition in AFR as an articulation of relevant rationales.¹³⁶ This constraint means the minority can at least recognise that the reasons of the majority are appropriate and reasonable for informing policy even if the minority does not agree with them and would not chose those reasons themselves.¹³⁷ Because only some kinds of reasons are appropriate for decision-making, deliberative democracy respects the pluralism of moral views and the reasonable disagreement they engender.

Daniels and Sabin’s second, implicit, claim about deliberative democracy is that its procedures require deliberation rather than straightforward aggregative voting. Rather than an aggregative approach, people should argue and deliberate on their moral views. People may be persuaded of other views, or maybe their own succumb to more convincing arguments. All these exchanges are good; Daniels and Sabin claim that it is more important for people to do what is right, and what they have been

¹³⁵ Daniels and Sabin, "Limits to health care", 1997; *Setting Limits Fairly*, 2008.

When it comes to preferences, they use the example of voting on what flavour ice cream the group should get and distinguish this kind of aggregation, which is acceptable, from aggregation about health policy when there is reasonable disagreement. A relevant difference between these two examples is that one concerns an issue of justice, the provision of healthcare, whereas ice cream is not a matter of justice. Expanding on this distinction, we would expect policies about education, like providing free primary school, to be an issue of justice but policies on traffic design, like whether to install traffic lights at one intersection or the next, to not be a matter of justice. The distinction is not always clear as things that look simple may become more complex—closing a bus route may disadvantage those who are already badly off by keeping them from getting to an area where there are many jobs. This would start to look like an issue of justice and fair equality of opportunity rather than mere preference over transportation planning.

¹³⁶ *Setting Limits Fairly*, 2008, 36.

¹³⁷ "Limits to health care", 1997,339; *Setting Limits Fairly*, 2008, 36.

convinced is right, than to hold onto their own views.¹³⁸ Implicit in their description of offering reasons and arguments is a deliberation that is free of coercion and in which people are able to engage with each other on equal footing and cooperate to arrive at the truth or best possible answer to the rationing problem. Despite the deliberation, a consensus may not be reached in which case a vote will be necessary. Even with a vote, though disagreement persists because reasons are constrained and there is deliberation, Daniels and Sabin claim that the minority will at least be satisfied that the right kinds of reasons are used and the outcome is just.¹³⁹ Deliberative democracy constrains the kinds of moral views that may inform voting and policy, so it respects the moral significance of reasonable disagreement.

Although Daniels and Sabin draw on deliberative democracy and its concepts to develop AFR, they do not subscribe to any particular account of it and their own is meagre. They claim their account of AFR is compatible with deliberative democracy, but AFR is different from deliberative democracy and the commitments it may entail. For example, deliberative democracy is focused on public deliberation and citizens participating to make a decision, which is what makes it democratic.¹⁴⁰ AFR is a pragmatic account designed to be used by exclusive groups of decision-makers, like insurance company boards, rather than a public and inclusive decision-making process.

The account of deliberative democracy that most closely resembles Daniels and Sabin's is Gutmann and Thompson's, but from this too they distance themselves. Daniels notes that there are similarities, and the two theories developed contemporaneously. However, he also claims that although AFR works well with

¹³⁸ "Limits to health care", 1997; *Setting Limits Fairly*, 2008.

¹³⁹ "Limits to health care", 1997, 339; "Last Chance Therapies", 1998, 37; Daniels, "Justice, Health, and Healthcare", 2001, 13.

¹⁴⁰ Gutmann and Thompson, *Why Deliberative Democracy?*, 2004, 9.

Gutmann and Thompson's theory, it was developed independently and does not draw its justification from their theory.¹⁴¹

Daniels and Sabin write "We hope to make the rationale for our account plausible independently of appeal to a more general theory, however, and we make no attempt to derive our account from that theory or justify its more controversial features."¹⁴² Simultaneously, they also argue that AFR is a way to extend the elements of deliberative democracy to non-public institutions, and it is consistent with deliberative democracy.¹⁴³ The relationship of AFR to deliberative democracy is one area where Daniels and Sabin's theory is unclear. The reason I highlight this is that it means we cannot evaluate AFR as an embodiment of a particular parent theory. I will argue below, however, that there are elements of deliberative democracy, like the process and substantive constraints described above, that intuitively strengthen the legitimacy of the theory, yet Daniels and Sabin fail to translate some of these elements into AFR.

Daniels and Sabin consider AFR to be compatible with deliberative democracy and claim it contributes to a broader, public deliberation about healthcare limits. The Publicity Condition ensures that the decisions and rationales are available to the public for discussion. However, AFR is not itself a method of deliberative democracy and cannot replace democratic decision-making.¹⁴⁴ It takes the ethos of deliberative democracy and applies it to private institutions where decision-making

¹⁴¹ Daniels, "Justice, Health, and Healthcare", 2001.

Daniels has also criticised Gutmann and Thompson's account since it is not grounded in constitutional principles, which he thinks means their substantive commitments lack necessary justification. ("Enabling Democratic Deliberation: How Managed Care Organizations Ought to Make Decisions about Coverage for New Technologies," 1999.) I will not give a full account of Gutmann and Thompson's theory here, but rather will draw on its elements and point out similarities as we go along in order to show how a comprehensive account of deliberative democracy, which Daniels and Sabin's decidedly is not, addresses some of the concerns that I will raise with AFR.

¹⁴² Daniels and Sabin, "Limits to health care", 1997,307.

¹⁴³ Ibid.

¹⁴⁴ Ibid.

need not be a democratic procedure. Indeed, institutions will have different forms and variations of decision-making.¹⁴⁵ There are two important points here: the first is that AFR is designed for private deliberation, so it is not necessarily a mode of inclusive or public, democratic deliberation. Second, AFR allows for process variation, so institutions may design their own procedures that suit their needs so long as the four conditions are met. I will pick up on both these points again in the discussion.

Although not itself a deliberative democratic practice, deliberative democracy informs AFR's four conditions. As a theory that is meant to be applied, AFR needs to develop the elements of deliberative democracy into a practicable form. However, having distanced itself from deliberative democracy, which provides its own accounts about reasonableness, and with its four conditions, AFR leaves us with two lacunae about relevance that pose challenges to the theory and its practice.

5.3 The Relevance Condition

I introduced AFR and its four conditions in Chapter Four, and I will revisit them before moving on to a discussion of AFR and the Relevance Condition in particular. With the background in deliberative democracy and other political philosophy theories (as we'll see), AFR is a pragmatic rendering of Daniels and Sabin's arguments supporting deliberative democracy and their concept of public accountability.

However, in this section I will argue that their definition of relevance, as given in the Relevance Condition, leaves the concept underdetermined, which poses problems both for the theory and its implementation. As with deliberative

¹⁴⁵ Ibid.; "The ethics of accountability in managed care reform", 1998; Daniels, "Symposium on the Rationing of Health Care", 1998; Daniels and Sabin, "Last Chance Therapies", 1998; Daniels, "Decisions About Access to Health Care and Accountability for Reasonableness", 1999; "Justice, Health, and Healthcare", 2001.

democracy, Daniels and Sabin invoke a conception from political philosophy, public reason, but also distance themselves from it in order not to take on the commitments and criticisms of the parent theory. Despite this, the Relevance Condition of AFR has garnered strong scrutiny and criticism. I look at some of these criticisms, mostly around the kinds of reasons that are included or excluded, and I offer a new reading of AFR that is more inclusive of different types of reasons. Pinning down the Relevance Condition is important because it is what defines “reasonable”, which we need for knowing that there is reasonable disagreement and thus a need for a fair procedure. It also will inform us which reasons may be included or excluded from the decision-making. In addition to strengthening the theory, identifying reasonable and relevant rationales is important for putting AFR into practice. The chapter concludes with the argument that Daniels and Sabin are wrong to emphasise “value for money” in the Relevance Condition as this compromises the respect for reasonable disagreement that is so important to them initially and motivates the turn to deliberative democracy and its translation into AFR.

Recall the four conditions of AFR:

1. *Publicity Condition*: Decisions regarding both direct and indirect limits to care and their rationales must be publicly accessible.
2. *Relevance Condition*: The rationales for limit-setting decisions should aim to provide a *reasonable* explanation of how the organization seeks to provide “value for money” in meeting the varied health needs of a defined population under reasonable resource constraints. Specifically, a rationale will be reasonable if it appeals to evidence, reasons, and principles that are accepted as relevant by fair-minded people who are disposed to finding mutually justifiable terms of cooperation.
3. *Revision and Appeals Condition*: There must be mechanisms for challenge and dispute resolution regarding limit-setting decisions, and, more broadly, opportunities for revision and improvement of policies in the light of new evidence or arguments.
4. *Regulative Condition*: There is either voluntary or public regulation of the process to ensure that conditions 1-3 are met.¹⁴⁶

¹⁴⁶ Daniels and Sabin, *Setting Limits Fairly*, 2008, 45. Emphasis theirs.

The Relevance Condition limits the kinds of reasons that may be used to inform policy and decision-making, like the constraints of deliberative democracy. Daniels and Sabin use a concept of mutual justification amongst cooperating decision-makers to define relevance. The Publicity Condition recalls deliberative democracy as a public process and also speaks to the need for public accountability. Daniels and Sabin use the background of deliberative democracy and what they consider good practice in insurance companies to inform the conditions and construct a framework for decision-making across institutions.¹⁴⁷

For now, I will focus on the Relevance Condition. The other three I will discuss in greater detail in Part III, when I examine how NICE has applied these conditions in its decision procedures.

The Relevance Condition addresses the substantive content of the reasons that will justify decisions, but it lacks clarity on how we may distinguish which rationales are reasonable and relevant. (I use “reasons” and “rationales” interchangeably.) I will draw attention to some of the criticisms raised about the Relevance Condition and indicate how these will cause problems for translating it into practice. Daniels and Sabin leave their concept of a relevant rationale fairly vague, and it excludes only the most clear cut discrimination.¹⁴⁸

¹⁴⁷ "Limits to health care", 1997.

¹⁴⁸ Daniels and Sabin never define what they mean by “rationale” or “reason”, two terms I will use interchangeably. I take them to use these words in the sense of justificatory reasons, i.e. normative judgements about the rightness of an action and the belief guiding the agent to act. A person’s beliefs, including moral views and interpretations of evidence, give her reasons to act in certain ways. See Baier, *The Moral Point of View: A Rational Basis of Ethics*, 1958; Finlay and Schroeder, "Reasons for Action: Internal vs External," 2008; Lenman, "Reasons for Action: Justification vs. Explanation," 2009.

5.4 Public reason and fair-minded people

Daniels and Sabin use the concept of “fair-minded people” to define relevant reasons. The concept of relevant reasons looks to be derived from Rawls’s public reason. Rawls uses a similar approach and defines his concept of public reason through that of reasonable people and what sorts of rationales they offer each other in public deliberation. Daniels and Sabin’s “fair-minded people” are those who seek cooperation and mutual justification, but a problem that will arise and recur in the dissertation is whether we are meant to understand fair-minded people as ideal deliberators who justify the process and what it means to have relevant reasons, or whether we are meant to understand them as instantiating the process, and AFR requires actual fair-minded people to deliberate. In this section and the following two, I focus on how Daniels and Sabin’s definition of relevance leaves us with two gaps that will cause problems for the theory and its implementation.

Daniels and Sabin derive their account from Rawls’s concept of public reason, following in a tradition of modern, liberal political theory. Rawls considers public reasons to be the kinds of reasons that are appropriate for fair and equal citizens in a just society to offer to each other. For Rawls, reasonable persons are willing to propose fair terms of cooperation and be bound by them, knowing that other reasonable persons reciprocate and will be bound by the terms they propose too. Rawls purposefully keeps the definition of “reasonable” loose in order to be inclusive and avoid arbitrary exclusions.¹⁴⁹

Rawls’s definition of a reasonable person looks much like Daniels and Sabin’s approach to relevance as judged by fair-minded people, “who are disposed to finding

¹⁴⁹ Rawls, *Political Liberalism*, 1993, 59.

mutually justifiable terms of cooperation”.¹⁵⁰ Reasonable persons, as citizens, will hold irreconcilable views, a state Rawls calls “reasonable pluralism” and that gives rise to “reasonable disagreement”. On issues of policy, Rawls’s answer is to propose that the citizens must use public reasons to reach agreement. Because they are the reasons citizens give to each other in public forums, they must be ones that the proposing citizen can reasonably expect all the others to endorse, so they cannot be based on privately held views. A further constraint: public reasons must be consistent with the society’s constitution.¹⁵¹ The citizens recognise others’ reasons as public reasons even if they are not their preferred reason or the one they believe best. Daniels picks up on this, writing “Rawls develops the view that ‘public reason’ must constrain the content of public deliberations and decisions about fundamental matters of justice, avoiding special considerations that might be elements of the comprehensive moral views that people hold.”¹⁵² Rawls’s concept of public reason is consistent with Daniels and Sabin’s concept of relevant reasons and mutual justifiability.

Daniels and Sabin’s concept of relevant reasons is founded on what “fair-minded people” find mutually justifiable. Therefore we need an understanding or criteria for fair-mindedness in order to be able to define relevance. But, what it means to be fair-minded is never fully explained. Daniels and Sabin elaborate on the concept of being “fair-minded” with an analogy to sportsmen. Sportsmen agree to play by the rules of the game, and they respect that the rules are meant to bring out the game’s exciting elements rather than confer advantage to one side.¹⁵³ In rugby, the players agree to what is an appropriate tackle and would rule out eye gouging in order

¹⁵⁰ Daniels and Sabin, *Setting Limits Fairly*, 2008, 45.

¹⁵¹ Rawls, "The Idea of Public Reason Revisited", 1997.

¹⁵² Daniels, "Justice, Health, and Healthcare", 2001, 14. In his earlier discussions of AFR, Daniels did not explicitly reference Rawls’s public reason, although he clearly drew on it.

¹⁵³ "Decisions About Access to Health Care and Accountability for Reasonableness", 1999.

to bring out the best in the game. They also would not agree to rules that give one team the advantage, like having an extra player on the field. (Daniels and Sabin use a similar example with American football.) There may be disagreement about how to apply the rules—was that really a foul? —but the scope of disagreement is narrowed to the application of the rules rather than the drafting of the rules themselves.¹⁵⁴

Similarly, in the case of relevant reasons, the scope of disagreement is limited to those reasons so it becomes a question of how to apply them. The players also arrive committed to playing the game, and we may expect fair-minded people to be committed to the decision process and following it through.

The sports analogy is inexact to AFR and relevant reasons, but it does help to inform us about the nature of mutual justifiability and fairness that fair-minded people seek out. One glaring difference is that players do not make the rules of the game themselves, whereas the decision process may be constructed,¹⁵⁵ but then the decision-makers follow it like the players. The analogy holds up in describing fair-minded people as those “who in principle seek to cooperate with others on terms they can justify to each other”, much like the sportsmen who will not agree to play by rules that unfairly advantage one team.¹⁵⁶ The concept of reasonable and relevant that Daniels and Sabin use is based on the fair-minded person as someone who offers rationales that will be mutually justifiable.

Mutual justification rests on the belief that there are rationales that people can agree are acceptable ways to make the decision, despite their different moral convictions, and these can be distinguished from rationales that are not acceptable and cannot be justified to others. Rationales that “have no publicly recognizable,

¹⁵⁴ "Reflective Equilibrium."; "Decisions About Access to Health Care and Accountability for Reasonableness", 1999; Daniels and Sabin, *Setting Limits Fairly*, 2008, 44.

¹⁵⁵ Ford, "Accountability for reasonableness: the relevance, or not, of exceptionality in resource allocation", 2014.

¹⁵⁶ Daniels and Sabin, *Setting Limits Fairly*, 2008, 44.

reasonable grounds for persuading most people in a pluralist culture to accept their view” are excluded.¹⁵⁷ Relevant rationales are those that recognise the fact of reasonable disagreement and engage the diversity of moral views:

the giving of reasons must itself respect the moral diversity of those affected by the decisions. Not just any kind of moral reason, compelling as it might be to the decision-maker (or the patient), will command recognition of its appropriateness or relevance from those affected by the decision. The reasons offered by decision-makers must be the types of reasons those affected by the decisions can recognize as relevant and appropriate for the purpose of justifying decisions to all who are affected by them.¹⁵⁸

What Daniels and Sabin mean by reasons that all can recognise as relevant focuses on this idea of mutual justification and acceptance. However, what they believe is mutually justifiable and what this definition precludes is subject to debate.

5.5 Mutual justifiability and an argument for the inclusion of religious reasons

Daniels and Sabin offer little insight into what they take to be relevant rationales and mutually justifiable with the exception of excluding rationales based on religious beliefs. In this section, I will argue that the requirement for mutually justifiable reasons is the primary characteristic of relevant reasons and make the case for the inclusion of some religious reasons as an illustration of this. The aim of this argument is to clarify the concept of mutual justifiability although I do not provide a definitive or comprehensive answer to what it requires. The argument that mutual justifiability will allow for the inclusion of religiously based reasons responds to criticisms levelled at AFR. A consistent valuation of mutual justifiability that does

¹⁵⁷ Daniels, *Seeking Fair Treatment*, 1995, 148. This particular quote comes from a passage in which he argues that abstinence only sex education in schools fails to meet standards of reasonableness. This argument, and its topic, is particularly reminiscent of Guttmann and Thompson’s view of moral positions.

¹⁵⁸ Daniels and Sabin, "Limits to health care", 1997, 330.

not depend on the origin of reasons should improve the prospects of translating AFR into practice.

Religious reasons are a challenge to mutual justifiability because Daniels and Sabin exclude them from being relevant reasons. They write:

“Where their well-being or fundamental liberties or other matters of fundamental value are involved and at risk, people should not be expected to accept binding terms of cooperation that rest on reasons they cannot view as acceptable types of reasons. For example, reasons that rest on matters of religious faith will not meet this condition. Reasonable people differ in their religious, philosophical, and moral views, and yet we must seek terms of fair cooperation that rest on justifications acceptable to all.”¹⁵⁹

The first part of their statement reiterates the concept behind relevant reasons and the moral significance of reasonable disagreement, disagreement that the last part recognises. However, their exclusion of reasons that are grounded in religion is problematic without further explanation of the reason and its justifiability. They give an example to illustrate this exclusion: there is a woman who wants a last chance therapy with little proven effectiveness for an advanced terminal illness. She claims her religious belief requires her to do everything possible to stay alive, and this treatment may yet provide a miraculous cure. Although the patient holds this reason, it is not relevant to anyone outside her faith, and she should not expect others to agree to consider this kind of reason:

Compelling though this reasoning might be to the patient, it has no relevance at all for those who lack the appropriate faith. The patient (or clinician) advancing it must recognize that she cannot expect those who do not share her faith to give weight to this type of reason or to consider it relevant to the deliberation.¹⁶⁰

Daniels and Sabin’s exclusion of religious reasons, which are significant to many people, raises sharp criticism. If they accept reasonable disagreement and the

¹⁵⁹ Ibid., 338-39.

¹⁶⁰ Ibid., 331.

pluralism of views that people hold, then religious reasons do not seem like they should be singled out as unacceptable.

One problem with excluding religious reasons is that it is not clear that they are any less accessible than reasons justified by other ethical and moral theories. Alex Friedman argues that a religious reason is no more acceptable to the utilitarian than the utilitarian's reason is to the religious person. Any criterion that bases relevance and reasonableness on the origin of the reason is a commitment to values about the sources of acceptable rationales. What should matter, Friedman argues, is not the origin but the mutual justifiability and explanatory power of reasons. His response is to abandon the Relevance Condition altogether.¹⁶¹

However, on the terms of the Relevance Condition, I argue we should keep the Condition but include some religious reasons under the rubric of mutual justifiability. Whether a reason is mutually justifiable would permit religiously grounded reasons since the requirement refers not to the origins of the reason but to its acceptability to others. There will be religious and secular reasons that fail to be mutually justifiable.

For example, a relevant rationale grounded in the Christian virtue of charity could still be acceptable to others. Someone might argue that a public health plan addressing social inequalities and health disparities was the most appropriate way to spend public health funds and back her argument with an appeal to the principle of

¹⁶¹ Friedman, "Beyond Accountability for Reasonableness", 2008.

Many of the criticisms that apply to Rawls's concept of public reason and Gutmann and Thompson's view of moral positions in deliberative democracies could also be considered in relation to relevant rationales. For example, John Finnis attacks Rawls's exclusion of religiously based reasons from public reason. One of his arguments is that these fundamental views cannot be separated out from a person's public reasoning because they are fundamental beliefs shaping policy views. On Gutmann and Thompson's moral positions, Stanley Fish argues that reciprocity and their requirements for acceptable reasons are based on substantive commitments that they hold to certain kinds of reasons, which are consistent with the liberal academy, rather than being open to the full range of reasons in a pluralist society. I will not respond to these criticisms, but I point them out here to show that within Daniels and Sabin's circle of political thought, they are not alone in facing these criticisms nor are they prepared with robust responses that the critics would find satisfactory (Finnis, "Political Neutrality and Religious Arguments," 2011; "Public Reason' and Moral Debate," 2011; Fish, "Mutual Respect as a Device of Exclusion," 1999.)

charity and a God given obligation to benefit the poor.¹⁶² Yet the argument to reduce health inequalities and help the worst off is something that others, who do not share her value of Christian charity, can agree to, and there are real instances of support for such a principle that do not have a religious justification.¹⁶³ A rationale that has its origin in religious beliefs may still function as a relevant rationale because it is mutually justifiable.

In contrast, it is possible for secular or philosophical theories to prove to be not relevant and not reasonable. Take for instance the solipsist who holds that there are only her thoughts and experiences, so she cannot give meaning to the fact of anyone else having thoughts and experience.¹⁶⁴ The solipsist is incapable of considering others' reasons and the (presumably) egocentric rationales and limit-setting plans she offers will not be acceptable to anyone else. Therefore, even though the solipsist holds a secular view, it is not mutually justifiable and cannot be a relevant rationale.

The case of the solipsist and Daniels and Sabin's example of the woman who hopes for a miracle cure, are both instances of reasons that are not mutually justifiable and take the form of individual preference and expectation. The solipsist's view is focused on her own needs and desires and how she will satisfy them. For the woman who hopes for a miracle, her reason could be reframed and reduced not as a religiously founded reason, but as a belief that the treatment will work for her (despite evidence to the contrary). These kinds of "I want" reasons are likely to arise in

¹⁶² Edwards, "Christian Charity or The Duty of Charity to the Poor, Explained and Enforced", 1732; Pellegrino, "Agape and Ethics: Some Reflections on Medical Morals from a Catholic Christian Perspective," 1989, 289, 92.

¹⁶³ NICE's Citizens Council, a group of lay members that I will discuss in Chapter 8.3, has expressed similar views, for example. Helping the worst off to reduce inequalities also looks to be consistent with Rawls's difference principle, yet neither of these positions are motivated by charity. Rawls, *A Theory of Justice*, 1999; NICE Citizens Council, Report on NICE Citizens Council Meeting: Inequalities in Health, 2006.

¹⁶⁴ I am grateful to Stuart Ramsay for suggesting this example to me. see Thornton, "Solipsism and the Problem of Other Minds."

practice too: consider the person who gives as his reason for funding a treatment for leukaemia, “my father died of this condition, so we should fund this treatment for it.” Such a reason cannot be taken to be mutually justifiable and relevant since it rests on his individual preference. As important as it is to him to support those with a condition affecting his own family, such will be the case for every patient and his family members, and this personal view will not be mutually justifiable to them. It may motivate him to act privately though: it will be a good thing if he decides to donate to leukaemia research, for example, but that is in the domain of his private activity rather than public life.

The charity example shows a religious reason that is mutually justifiable, and the miracle example one that is arguably not religious. An example of a religious reason that would be excluded is, perhaps, if those religions that value and praise acts of self-sacrifice were to consider them a duty rather than supererogatory acts.¹⁶⁵ Someone may hold the view that faith requires self-sacrifice on the part of all, like putting others’ needs before your own, and that is not something that others will agree is mutually justifiable. Self-sacrifice could be likened to the problem of separateness of persons that utilitarianism faces, in that the burdens (sacrifices) on individuals do not necessarily involve benefits to the same individuals. While it may be valued for someone to be self-sacrificing, it is unlikely to be accepted as a mutually justifiable reason.

These examples are meant to highlight the way in which mutual justifiability works and address criticism about the exclusion of religious reasons. On my reading of Daniels and Sabin’s account it is not the fact of a reason being religious, per say, but that it is one that no one else can agree is acceptable and mutually justifiable that

¹⁶⁵ I draw this example from comments in Coady, *Messy Morality*, 2008.

means it is not relevant. Ford offers a compelling argument in support of including religious reasons: even if we don't share the substantive view, we do share the view that a person's beliefs should be respected.¹⁶⁶ (Though there may be limits to the extent to which we think this.) Daniels and Sabin exclude religious reasons, but based on their claims about mutual justifiability and relevance there is good reason to include them.

It matters that AFR does not a priori exclude reasons because this recognises the reasonable disagreement that exists about principles and even about what is relevant. Excluding religious reasons would be inconsistent with Daniels and Sabin's recognition of reasonable disagreement since it is possible, as I have shown above, that there may be religious reasons that are mutually justifiable and non-religious ones that are not. (The more inclusive reading of what relevance allows for is also in keeping with Rawls's inclusive account of public reason, which would admit religious reasons, making it consistent with the public reason origins of relevant reasons.¹⁶⁷) Second, the broader account will be better when it comes to implementing AFR. People care deeply about their religious views, and it is hard to divorce these views from their political ones. If we take Daniels and Sabin to require mutual justifiability rather than a substantive limitation on the origins of reasons, then this should improve the practical use of AFR and the recognition of its decisions as descriptively legitimate and fair by those affected.

Mutual justifiability answers criticisms of AFR's exclusion of religious reasons, but it is itself problematic. One criticism is that people with strongly held views will not find other ones mutually justifiable. As Lauridsen and Lippert-Rasmussen put it, the true utilitarian will not find a reason prioritising the worst off at

¹⁶⁶ Ford, 2014.

¹⁶⁷ Rawls, *Political Liberalism*, 1993, 247-48.

a loss to welfare justifiable, and the prioritarian will not find ignoring the worst off in favour of greater welfare justifiable. Even these two basic positions will end up not being mutually justifiable.¹⁶⁸ These concerns about what people do take to be or are likely to find mutually justifiable lead to a larger problem with the concept and with it as a requirement: how do we determine mutual justifiability and to whom must reasons be justifiable? Determining which rationales are relevant starts to look like its own procedure of testing reasons against a standard of mutual justification.

5.6 Mutual justifiability—conceptual or actual acceptability?

If mutual justifiability is the standard for relevant reasons, then we need a way to determine if reasons meet it. There are two questions mutual justifiability raises: does it require actual justifiability, i.e. reasons that are justified, or is it normative? and to whom are reasons justified? Daniels and Sabin do not answer these questions, and they are both problems for the theory to address and ones that arise in the practice of AFR.

Daniels and Sabin couch mutual justifiability in terms of agreement and acceptability as another way to consider the concept of justifiability. The Relevance Condition defines relevant reasons as ones that are mutually justifiable, but elsewhere they describe them as reasons all can agree are relevant to making fair decisions.¹⁶⁹ Phrasing mutual justifiability in terms of agreement and reasons all can agree to makes more evident the questions of whose agreement is necessary and whether actual agreement or conceptual agreement is necessary.

¹⁶⁸ Lauridsen and Lippert-Rasmussen, 2009.

¹⁶⁹ Daniels and Sabin, "Limits to health care", 1997; "The ethics of accountability in managed care reform", 1998; "Last Chance Therapies", 1998; Daniels, "Accountability for reasonableness: Establishing a fair process for priority setting is easier than agreeing on principles", 2000; "Accountability for reasonableness in private and public insurance," 2000.

The first question for AFR is whether reasons may be mutually justifiable conceptually or actually. An empirical standard would mean reasons must be justified, i.e. people actually agree on them. If reasons must be actually justified, then the sort of procedure that is necessary for decision-making would probably look quite different: rather than deliberating on decision-making and reasons, we would be out conducting surveys and attempting to discern what those relevant reasons are. However, conceptual agreement poses its own challenges about how we determine what reasons are normatively justifiable. To claim that a reason is mutually justifiable and therefore relevant means there is a standard of what is justifiable that is assumed.

A related problem to determining conceptual justifiability is the question of to whom reasons must be justified. Daniels and Sabin write that reasons must be ones that all can agree are relevant, which is both a question of the scope of all and whether this rests on actual or conceptual agreement. If reasons must be actually justifiable to every person, then we face a problem when one person objects to a reason, giving individuals veto power over reasons and principles.¹⁷⁰ If reasons are not empirically justified, then it will not be the case that they must be justified to each person, and instead the problem becomes one of whose agreement on reasons is necessary.

Daniels and Sabin define relevance via the concept of fair-minded people, and using the fair-minded people standard suggests a normative and conceptual approach to justifiability and agreement. As we've seen above though (5.4), the concept of fair-mindedness is not easy to articulate. In practice, this definition also means either determining who is or acts fair-mindedly or deciding on a list of reasons that idealised fair-minded people would agree to, an iterative problem of who decides that list on

¹⁷⁰ Hasman and Holm, "Accountability for Reasonableness: Opening the Black Box of Process", 2005.

behalf of fair-minded people. Daniels and Sabin use the concept of fair-minded people to define relevance and shape the decision procedure without giving an account of whether it is fair-minded people who must also instantiate the procedure. In comments they make, they suggest that decision-makers should act like fair-minded people, but they never make it a clear requirement on decision-makers, and it is something that will be challenging to affect in practice.

Although Daniels and Sabin's account does not appear to require empirical, actual justification or agreement, they encourage it and stakeholder participation for determining relevant reasons. AFR does not require stakeholder or public participation, but especially as Daniels has worked more on the right to health, he has adopted the idea from rights theory that relevant rationales are those reasons that the stakeholders in the decision hold, a more empirical view of justification. The strongest statement of this view suggests that stakeholders should vet reasons while weaker versions claim that there should be attempts to determine the stakeholders' views and thus what is relevant.¹⁷¹ Although he looks to involvement to develop the set of relevant rationales, he does not think that participation is necessary for accountability since following the conditions of AFR should establish that decisions are reasonable and relevant.¹⁷² Alternative positions develop from this: the Relevance

¹⁷¹ Gruskin and Daniels, "Process is the point: justice and human rights: priority setting and fair deliberative process", 2008; Daniels, "Reasonableness and its definition in the provision of health care," 2010; Daniels, Porteny, and Urritia, 2016; Daniels, "Fair process in patient selection for antiretroviral treatment in WHO's goal of 3 by 5", 2005.

A view worth noting here is Hasman and Holm's argument that relevant rationales will vary based on a society's values. They give the example of solidarity, a principle that has much traction in Scandinavian countries but holds little weight in some others, like the USA where autonomy might be more highly valued. As a result, relevant reasons are relative to the society's view of what is acceptable and mutually justifiable. (Hasman and Holm, 2005.) If we accept their view, then the notion of stakeholders generating reasons makes more sense since there is not an obviously objective list, even though Daniels and Sabin claim there is a limited range of reasons (Daniels and Sabin, *Setting Limits Fairly*, 2008, 65.) This is yet one other place where Daniels and Sabin may diverge from Gutmann and Thompson who consider that moral positions will be socially sensitive and so may evolve over time reflecting new views or awareness. (Gutmann and Thompson, "Moral conflict and political consensus", 1990.)

¹⁷² Daniels and Sabin, "The ethics of accountability in managed care reform", 1998.

Condition must be met, but we do not have clarity on whose agreement matters, and AFR does not require participation yet encourages involving stakeholders to determine relevant reasons. In Chapter 8, I will argue, using the case of NICE, that in practice relevant reasons can be developed with a combination of approaches: stakeholder involvement is beneficial for uncovering new reasons or emphasising particular facets of reasons, but a process will still be required to determine relevance. A purely conceptual approach will focus on developing a list of the right kinds of reasons, but a more empirical one will involve determining which reasons people value. As we will see with NICE it has undertaken a bit of both, with notable examples of attempts to consider reasons that people value.

The legitimacy problem itself calls up this difference between mutually justifiable and justified. The legitimacy problem asks: “Why or when should a patient or clinician who thinks an uncovered service is appropriate or even “medically necessary” accept as legitimate the limit-setting decisions of a MCO?”¹⁷³ As discussed above (4.1), the problem is couched in terms of an empirical question; what would or does satisfy a patient with regards to legitimacy, but we can also consider it as asking a question of a conceptual patient. The question is not what a specific person would accept but what a non-specific rational person would consider legitimate. This recalls Rawls’s approach of a person deciding about what a just society would look like; the question is not one that is resolved empirically but through the consideration of what is justifiable.

These ways of developing a range or list of relevant rationales suggest procedures for determining what is relevant and mutually justifiable, but Daniels and Sabin do not explain what this might entail. The form of the agreement has

¹⁷³ “Limits to health care”, 1997,304.

implications for AFR in practice: must an institution exhaustively survey its stakeholders and anyone affected? Is it enough for a committee to justify the reasons it considers reasonable or use some common sense standard? If mutual justifiability is normative and conceptual and so too are fair-minded people, then we need some means to break into the concepts of relevance and mutual justifiability.

A similar problem arises for reasonable disagreement and whether it is supposed or actual. Daniels and Sabin assume there will always be disagreement, but we could have circumstances where none is expressed, or there is apparent agreement. Daniels argues that in such circumstances we still need a procedure since there may be new force to arguments or a shift in social views.¹⁷⁴ This raises a good problem though: must disagreement be actual, something that is present and so prompts a procedure, or should it be assumed if there is reason to think that the kinds of reasons fair-minded people would think relevant and disagree about will be involved? Based on Daniels' view about using procedures even when there is the appearance of agreement and the argument I make in the next chapter about fair consideration, we will see that there is a need for procedures lest a single position come to dominate the discourse without the opportunity to recognise alternate principles.

In this section, I have laid out two questions for Daniels and Sabin's account of AFR: does mutual justifiability require conceptual, normative agreement or must reasons be actually justified, and whose agreement matters? The account of AFR looks to be using normative approaches to both rather than requiring actual agreement, but Daniels and Sabin also encourage stakeholders' actual acceptance of reasons. Using a normative approach leaves the problem of how to decide on reasons, and referring to real stakeholders the problem of whose agreement and views matter.

¹⁷⁴ Daniels, Porteny, and Urritia, 2016.

Daniels and Sabin do not answer this with their account, and we will see these questions arise again as challenges in the practice of AFR when real people must make normative decisions.

5.7 Daniels and Sabin's relevant reasons and "value for money"

In the last section, I showed that when it comes to picking out relevant rationales, the basis of inclusion and exclusion is ill-defined. In this section, I will look at what substantive reasons Daniels and Sabin suggest and also pose a criticism that they show themselves to hold prior commitments to particular views that they build into AFR. Their commitment to "value for money" sets the scene for the next chapter, an argument about the normative legitimacy of AFR, since it shows they fail to treat reasonable disagreement in the right way when they commit to certain rationales.

So far, I have focused on the second half of the Relevance Condition, which addresses fair-minded people and mutual justification. Now let's turn to the first part of the Relevance Condition:

The rationales for limit-setting decisions should aim to provide a *reasonable* explanation of how the organization seeks to provide "value for money" in meeting the varied health needs of a defined population under reasonable resource constraints.¹⁷⁵

What stands out is that rationales aim to provide accounts of "value for money".

Value for money presupposes a utilitarian rationale that justifies the benefits given their cost. Despite AFR seeming like a process open to deliberation and allowing decision-makers to determine what is best, the very definition of the process

¹⁷⁵ Daniels and Sabin, *Setting Limits Fairly*, 2008, 45. Emphasis theirs.

conditions presupposes consequentialist reasoning about value for money.¹⁷⁶ In their discussion of the merits of deliberative democracy, Daniels and Sabin describe a process in which people give arguments for their reasons and try to convince each other of the merits of their positions. This view of deliberation suggests an open starting point for decision-making, which respects reasonable disagreement and in which we expect the most convincing arguments to win out. However, the presupposition of value for money vitiates this possibility since it assumes rationales will be pinned to consequentialism and certain justifications. This rules out, for example, more deontically focused arguments about need and how we ought to treat people who have a healthcare need.

Daniels and Sabin may defend “value for money” with an appeal to the context and its resources in which they developed AFR. They constructed AFR as a response to concerns about limit-setting practices in the US healthcare system, which is scattered across profit and not-for-profit insurance companies. They constructed AFR from a combination of observed good practices and philosophical theory. Since their context was one of an insurance market and health system guided by money, they could argue that it is the financial trade-offs that limit healthcare and must be justified.¹⁷⁷ However, this limits the scope of AFR from being a more widespread theory for decision-making. It also seems to rule out non-financial resource problems or require other resources to be reduced to financial terms, like hospital beds or organs for transplantation, both of which face their own rationing stresses. Given the disagreement present in these and other cases of rationing, AFR should be a fair procedure available for use here too.

¹⁷⁶ Syrett, *Law, Legitimacy and the Rationing of Health Care*, 2007, 104.

¹⁷⁷ Similarly in the UK context, Ford claims that value for money is not controversial because the NHS is tasked with providing free healthcare funded by taxation, so value for money is a necessary aim for the system. (Ford, 2014.) In the next chapters, I will explore this further and the challenge it poses to the fairness and legitimacy of NICE.

The “value for money” rationale will arise again as a problem when we look at the translation of AFR into practice in the next part (III). It also relates closely to the criticism I will make of AFR in the next chapter and how it fails to treat rationales and reasonable disagreement appropriately. The argument about fair consideration I will give further demonstrates why it is inappropriate for AFR, if it wishes to claim normative legitimacy, to include a commitment to value for money in its very definition of relevant rationales since in doing so it ignores the special consideration due to reasonable disagreement by excluding reasonable positions. Before moving on to these arguments, let's briefly look at what sorts of rationales Daniels and Sabin do think will meet the Relevance Condition.

5.7.1 Daniels and Sabin's relevant reasons

Daniels and Sabin do not give a list of reasons they consider to be in the range of relevant reasons, but throughout their work they suggest several reasons as relevant and the kind that would be considered in the decision-making. They posit a few substantive rationales and also a formal principle. They claim that some rationales will be straightforward considerations, like safety and clinical effectiveness, which would give people reasons to provide a treatment or not.¹⁷⁸ In contrast, arguments like not providing a treatment in order to offer higher CEO salaries, increase profitability, or pay for marketing are not mutually justifiable and will not be accepted by those affected.¹⁷⁹

¹⁷⁸ Daniels and Sabin, *Setting Limits Fairly*, 2008, 58.

¹⁷⁹ These reasons could be relevant if they can be shown to make healthcare better and not disadvantage patients, but Daniels and Sabin think this unlikely. These reasons are not mutually justifiable because they disadvantage one group (patients) for the advantage of another (businessmen). Such reasons are not categorically ruled out, but they would require robust empirical support, like accounting information, to justify them. (Daniels, "Reflective Equilibrium."; Daniels and Sabin, "Limits to health care", 1997; "The ethics of accountability in managed care reform", 1998.)

Daniels and Sabin's discussions of the conflict between cost-effectiveness and meeting needs suggests that they take both of these to be relevant rationales and the considerations that motivate the very problem of resources and limit-setting.¹⁸⁰ Fair equality of opportunity, the grounding principle for Daniels's account of healthcare justice, is too indeterminate to answer rationing problems, but it is also unclear to what extent Daniels believes relevant rationales and limit-setting decisions must support and promote fair equality of opportunity.¹⁸¹ Fair equality of opportunity, though, will rule out discriminatory rationales, like those that single out groups of people for reasons that are not relevant in the healthcare setting.¹⁸² Looking to Daniels and Sabin's examples of relevant rationales (safety, efficacy, cost-effectiveness, need) leaves the concept fairly open to possible reasons so long as they are not unfairly discriminatory.

Daniels and Sabin do insist on formal fairness, which we may take as a procedural requirement for relevant rationales. Formal fairness is the principle that cases that are alike in relevant respects ought to be treated alike. It also reinforces non-discrimination: two patients who are clinically similar should be offered the same treatment. If they are not, the justifications for different treatment should rest on clinical features, like different risk, not on non-relevant ones, employment status, for example. As will be raised again in NICE's guidance, some features sit between these two zones, sometimes relevant and sometimes not. Gender, ethnicity, age may indicate different clinical risks and effectiveness and so be relevant, or they may be used to unfairly violate formal fairness and distinguish patients on non-relevant

¹⁸⁰ "Limits to health care", 1997; Daniels, "Justice, Health, and Healthcare", 2001; Daniels and Sabin, *Setting Limits Fairly*, 2008.

¹⁸¹ Hasman and Holm, 2005.

¹⁸² Daniels, "Just health: replies and further thoughts", 2009.

grounds. This shows too that relevance is a concept of what is morally significant in the circumstances.

Formal fairness plays out in a principle about disadvantage and is reinforced by the case-law component of the Publicity Condition. The nature of limit-setting is that the decision will disadvantage someone. Therefore the fact of disadvantage is not a justifiable argument against a decision. But, if someone or a group is disadvantaged more than it needs be given alternate possibilities, then the decision is unfair. Along similar lines, someone should not be disadvantaged when other patients who are like her in relevant respects are not—this is an instance of formal fairness.¹⁸³ Formal fairness is reinforced with the case law component of the Publicity Condition, which asserts the value of precedent. Precedent will set the standard of how cases have been treated in the past, so there must be an argument, drawing on a relevant rationale, why the new case is different if it is to be treated differently. Daniels and Sabin predict that these precedents will develop over time to show a society or institution's value commitments and will facilitate future decision-making.¹⁸⁴ The value given to precedent will come up in the discussion of NICE's threshold (9), and is suggested in the next chapter's discussion about how we ought to approach reasons.

To conclude, Daniels and Sabin's concept of relevant rationales fits in with modern, liberal social-contract theory derived political philosophy, but it is not clear what its requirements are for determining relevance and how a decision-making committee may go about affirming that it is using relevant rationales. Although I

¹⁸³The problem of being disadvantaged more than someone needs be recalls Rawls's difference principle—lest we forget Rawls's strong influence on Daniels. ("Symposium on the Rationing of Health Care", 1998; "Justice, Health, and Healthcare", 2001..

Determining when someone is disadvantaged more than she needs be will involve analysing a near impossible number of permutations (Ford, 2014.).

¹⁸⁴ Daniels and Sabin, "Limits to health care", 1997; *Setting Limits Fairly*, 2008.

have not given an answer to this problem, I have shown how it has been subject to scrutiny around what sorts of substantive values inform relevance. I have also raised concerns about how we arrive at these rationales, whether they are objective, require empirical testing, or can be process generated, a thought I will return to in the next chapter. Finally, a problem to pay attention to is Daniels and Sabin's use of "value for money" in defining relevance, a problem that will return in the later discussion of cost-effectiveness (9.4). Value for money presupposes particular value commitments, and with this sort of condition AFR cannot treat reasonable disagreement appropriately. In the next chapter, I will build on this theme of what it means to act appropriately in the face of reasonable disagreement and argue that AFR's failure to do so jeopardises the procedure's normative legitimacy. Even though I have raised the problem that it is difficult to determine what is meant by relevance in AFR, in the following discussion, I will assume that there is a sense of what it means for a rationale to be relevant, and argue with this assumption in place.

6 Fair consideration and problems for AFR's legitimacy

In the last chapter, we saw how the Relevance Condition means the definition of relevant rationales is underdetermined in potentially problematic ways. In this chapter, I will take the concept of reasonable disagreement and relevant rationales and argue that the special nature of these kinds of reasons requires certain kinds of treatment. Daniels and Sabin make clear that reasonable disagreement, and by extension relevant rationales, is a special instance of disagreement because of the kind of moral views involved. In this chapter, I will argue that the move to deliberative democracy recognises the special value of moral views, but the procedure of AFR does not. Daniels and Sabin claim that AFR is a fair and legitimate procedure for decision-making and that the resulting decisions are also fair and legitimate. (Daniels and Sabin do not distinguish between normative and descriptive legitimacy.) However, AFR is not sufficient for normative legitimacy because it does not ensure that reasons are treated rightly. Lack of specification about the decision-making procedure AFR requires means procedures can meet the four conditions but fail to respect reasonable disagreement. I propose an answer to this problem in the form of “fair consideration”, a concept of taking reasons seriously. Fair consideration does not tell us how to make the decision, so it does not make the process more determined than AFR's original conditions, but it does constrain the process, and the new parameters resolve a problem for normative legitimacy. In this section, I will argue that AFR is not sufficient for legitimacy and then give an account of “fair consideration” as a necessary condition for AFR.

The criticism I make of AFR's legitimacy and the need for fair consideration is a new approach. The literature on AFR has focused on the fairness of the

procedure and the Relevance Condition or on the legitimacy of institutions that use it, like NICE.¹⁸⁵ There is limited discussion of the decision procedures of AFR and their legitimacy, with Lauridsen and Lippert-Rasmussen giving it the most attention. Their argument focuses on the premise that AFR is legitimate because it enables deliberative democracy, and deliberative democracy is sufficient for legitimacy. Therefore, AFR is a necessary condition of legitimacy, but they then show why AFR fails to meet the requirements of deliberative democracy since it does not require deliberation or assure citizens equal influence in the process.¹⁸⁶ Their argument has some similarities to mine, but also some important differences. As I argued in Chapter (5.2), AFR was never powered to be a part of deliberative democracy both because Daniels and Sabin do not accept an account of deliberative democracy and specifically design AFR for non-democratic settings. Therefore, AFR's claim to normative legitimacy does not depend on its being a process of deliberative democracy. The existing literature on AFR takes up the issue of substantive fairness, assumed legitimacy from deliberative democracy, and legitimacy from enhancing the role of citizens in decision-making. I will argue none of these points and instead put forward an argument for fair consideration as a requirement that will address the normative legitimacy problem for AFR I raise. The legitimacy problem and fair

¹⁸⁵ Syrett, 2002; Syrett, "Deconstructing Deliberation in the Appraisal of Medical Technologies", 2006; Hasman and Holm, 2005; Friedman, 2008; Rid, "Justice and procedure: how does 'accountability for reasonableness' result in fair limit-setting decisions?", 2009; Ford, 2014.

Syrett's work draws on a public law account to analyse NICE and its legitimacy. Rid's criticism of AFR shows how despite making claims at procedural justice, it does not fit the Rawlsian models of procedural justice (pure, imperfect, and perfect), and is instead what she calls a form of 'constrained pure procedural justice', which is a procedure without an independent criterion of fairness but a constrained set of possible fair reasons to use. The Relevance Condition constrains AFR in this way, and Daniels agrees with her assessment of AFR as a process of 'constrained pure procedural justice'. (Daniels, "Just health: replies and further thoughts", 2009.)

Hasman and Holm, Friedman, and Ford each focus on the Relevance Condition and the kinds of reasons it allows for.

¹⁸⁶ Lauridsen and Lippert-Rasmussen, 2009.

consideration entails a revision to the four conditions and has implications for the implementation of AFR, which we will see in the following chapters.

6.1 Unspecified decision procedures

At the start of the previous chapter (5), I pointed out Daniels and Sabin's claim that there is a difference between the kinds of views that are involved in reasonable disagreement and preferences, and reasonable disagreement necessitates a fair process. Reasonable disagreement involves positions that are thought out, mutually justifiable, and cannot be resolved substantively. Since a procedure is necessary, it should take into account the fact that there is reasonable disagreement; these are not reasons that may simply be set aside since there is not a substantive basis on which to make such decisions. This is what I have referred to as the moral significance of reasonable disagreement and relevant rationales. Relevant reasons are a certain kind of reason with value to the people who hold them, and the purpose of having a fair process, like AFR, to make a decision is in order to respect that value and the way in which it matters.

A problem for AFR is that the decision procedure remains unspecified, and the constraints of the AFR procedure cannot ensure that reasonable disagreement is treated appropriately. I will use the "decision procedure" to indicate the actual process of making a decision. For example, a decision procedure may be a closed committee meeting and its rules about how evidence is presented, debated, and decisions negotiated, or it could be a procedure that involves a stakeholder referendum on a decision. Both these types of decision procedures could be done as part of a process that works within the procedural requirements of AFR. Despite the

focus on deliberative democracy and public deliberation, AFR does not actually require deliberation for decision-making. I will not argue for a more determinate decision procedure, but I will argue that fair consideration circumscribes a given procedure such that it avoids the legitimacy problems that may still arise with the four conditions of AFR.

Daniels and Sabin claim that AFR will make decision-making transparent and take it out of a “mysterious black box”.¹⁸⁷ Although decision-making may be more transparent due to the Publicity Condition, the decision procedure is still a black box. The four conditions of AFR are a structural framework around a decision procedure and do not explain what the decision procedure should be.¹⁸⁸ Above, I argued that this was a benefit of AFR since it allows for institutions to design their own process to fit their needs and circumstances. However, it means that the AFR conditions work around the decision procedure: the Publicity Condition, for example, calls for the decision itself to be publicised not for a fully transparent and publicly accessible process. What kind of appeal process the Appeals Condition requires is never made clear. Significantly, although the Relevance Condition constrains the kinds of reasons that are acceptable, it does not indicate how decision-makers are meant to choose between or balance reasons. These are points about what AFR requires that pose problems to those attempting to apply the theory; as we’ll see in the next part of the dissertation, NICE has faced criticisms about how it applies the conditions. What it means for the theory of AFR is that the decision procedure applied within the framework may not be normatively legitimate.

¹⁸⁷ Daniels and Sabin, *Setting Limits Fairly*, 2008, 46.

¹⁸⁸ Hasman and Holm also make this point in their critique of AFR with particular focus on the problem of determining what is or is not relevant. (Hasman and Holm, 2005.)

6.2 Fair consideration

For this argument, I will focus on normative legitimacy rather than fairness. Although I raised concerns about the Relevance Condition, if we assume it appropriately constrains rationales, then we can also assume that at stake is not a problem of substantive unfairness or injustice. Because the reason will be one that is mutually justifiable, the problem becomes how to choose between these reasons and principles rather than their appropriateness or fairness. Therefore, I will focus my discussion on a problem of legitimacy and the acceptability of the procedure rather than on fairness.

Reasonable disagreement requires that reasons be treated in a certain way, and the decision procedure should reflect that. In AFR, the decision procedure is a black box and of the many possible decision procedures, it is essential for normative legitimacy that no matter the form the procedure takes, the reasons are treated appropriately. The appropriate way to treat reasons, I argue, is with fair consideration.

Fair consideration is the idea of “taking seriously” reasons. This means giving them the right kind of consideration in the deliberation. It does not require that reasons are given equal weight in decision-making; rather it requires that reasons are taken into account and consciously given an appropriate weight.¹⁸⁹ Some reasons should be taken more seriously than others even though both are relevant to the decision.

¹⁸⁹ Gutmann and Thompson use the idea of “taking seriously” others’ moral positions to make the case that in deliberation, a person should not just be respectful of the other’s positions but promote institutions that allow challenges to laws and their justifications. Their idea of “taking seriously” is different from mine, though using the same language, since it is about challenging reasons and decisions. (Gutmann and Thompson, “Deliberative democracy beyond process”, 2002, 165.)

Fair consideration looks similar to respect, but it requires a different approach to someone's reasons. Uniacke's concept of consideration respect addresses how fair consideration operates within a closed committee, and it is useful towards developing an idea of what fair consideration requires. Her account of "consideration respect" is the idea that when I deliberate how to act, I take seriously the thing that I respect, like someone else's wishes about how I should act.¹⁹⁰ If my neighbour asks me not to tear up the rosebush in my front garden that she enjoys too, then I show her consideration respect when I take that into account while making my landscaping decisions. In the cases we are interested in, the decision-makers show consideration respect to others' positions when they weigh up those reasons alongside their own. We would expect that sometimes the other people's reasons will prevail and sometimes their own will. Consideration respect is not the same as fair consideration, but it is a useful way to build up the idea of fair consideration and taking seriously others' reasons.

One way we might conceive of fair consideration is to imagine the kinds of arguments the person who held a particular reason would give and to incorporate those into the deliberation and decision-making. This is similar to respect in that we can think of fair consideration as requiring us to imagine the person who holds the position is actually present—respecting her and her position and giving it fair consideration would require more than merely acknowledging its existence. She would want to be respected yes, but she would also want her position to be taken

¹⁹⁰ Uniacke, "Respect for autonomy in medical ethics," 2013.

Her account of consideration respect, part of an account of autonomy, is derived from Stephen Darwall's work. Respect is an attitude that someone feels or expresses towards an object, whether it is another person, an institution, or a thing/object. Darwall drew a distinction between "appraisal respect" and "recognition respect". Appraisal respect concerns how we evaluate characteristics of people, like whether they are good cooks or trustworthy. In contrast, recognition respect is what a person shows when she considers features of an object and deliberates how to act. For example, I have recognition respect for the mountain, as a mountaineer, or recognition respect for the law when I take into account before deciding whether to do an illegal action (Darwall, "Two Kinds of Respect", 1977.) Uniacke further divides recognition respect into compliance respect—the thing I respect determines my actions; I act in accordance with the law, say—and consideration respect.

seriously and to see the other decision-makers weigh it up and consider it against the other positions. Fair consideration requires this same level of consideration, respect, and taking seriously reasons even though the person who holds them is not present. The account I offer of fair consideration is focused on valuing reasons in the right kind of way and giving them the appropriate strength of consideration in the decision-making.

6.3 Why we need fair consideration

With reasonable disagreement there will be disagreement on how much weight a reason should be given—some people will want it to be the deciding reason, and others will want to minimise its effect. It is impossible to satisfy both these demands, and since fair consideration does not require equal weight to be given either, we would instead want decision-makers to justify their evaluations of reasons, something which Daniels and Sabin's account of AFR does not require.

In order to illustrate why fair consideration is essential for legitimacy, consider the following example:

A committee meets to make a limit-setting decision, like whether to fund a new drug treatment for multiple sclerosis. The members of the committee hear from different stakeholders, they arrive at a decision not to provide the new treatment, and they support their decision with a justificatory reason, R. However, when the committee convened, the members were already convinced that providing the treatment was not the right decision because of the value of R. Although the members heard other arguments founded on relevant reasons, they did not take them into account because they were already convinced by R. The committee was pre-decided.

In this case, we should challenge the legitimacy of the committee even though it has followed and can meet the requirements of AFR. To meet the conditions of AFR the committee may publicise its decision and its justificatory reason, R, which is relevant and reasonable. The committee may have an appeals procedure in place, and will review its decision in a few years time, and there is enforcement from a regulatory agency to make sure that it has followed its decision procedure and AFR, which it has. So the conditions of AFR are met, yet we should not accept the normative legitimacy of the decision. Because the committee was pre-decided it failed to acknowledge reasonable disagreement and treat the relevant reasons put forward with fair consideration. If anything, it seems to negate the need for a committee at all if a principle is going to be applied without taking into consideration any others.

The case of the pre-decided committee is an extreme one, but it shows us that it matters that reasons are given consideration and fair consideration too. It is not enough for the reasons to be voiced and shared. The pre-decided committee was not open to new reasons—although even being open to reasons does not resolve the concern; a person must be open but also appropriately consider all the relevant reasons (not be open to some reasons, or the first reason). The decision-makers must seriously consider the reasons and what sort of force they have on the decision. They should be open to being convinced by the reasons. The concern about decision-makers is raised in Emanuel's review of *Setting Limits Fairly*, where he worries that to keep powerful insurers in check, a principle of fair consideration is necessary for AFR. He does not elaborate much on what this requires, suggesting merely that there should be a mechanism to "assess and incorporate every person's interests and

preferences” in the limit-setting.¹⁹¹ His sense of fair consideration is different from mine since it is aimed more at including the public voice than the significance of reasonable disagreement and the necessary consideration it should entail. Fair consideration, as I will show below is necessary for and strengthens both normative and descriptive legitimacy.

Fair consideration is about recognising the fact of reasonable disagreement and accounting for it in the process by treating reasons appropriately, which makes it necessary for legitimacy. When there is reasonable disagreement, a procedural solution relies on a process to resolve it, and we expect people to accept the result of the process as fair and legitimate. The process should positively take into account the reasonable disagreement that motivates procedural approaches in the first place. Legitimacy is about making the decision in the right way, and fair consideration demonstrates that reasonable disagreement and relevant reasons matter; if the decision is to be normatively legitimate and be accepted as descriptively legitimate by those affected, then it needs to recognise that people will reasonably disagree and hold different principles of what should be done.

AFR developed out of deliberative democracy, and deliberative democracy’s values of reciprocity or respect resemble fair consideration. Gutmann and Thompson’s account of deliberative democracy requires mutual respect and reciprocity. Respect requires citizens to recognise the moral nature of their opponents’ views and calls for a certain standard and openness of interaction. Mutual respect also requires that citizens take each others’ reasons into account and are open to being convinced by them, something that will promote legitimacy.¹⁹² Gutmann and

¹⁹¹ Emanuel, "Book Review of Setting Limits Fairly: Can We Learn to Share Medical Resources", 2002, 954.

¹⁹² Gutmann and Thompson, "Moral conflict and political consensus", 1990; *Why Deliberative Democracy?*, 2004, 10-11.

Thompson's account of mutual respect seems to encompass something similar to fair consideration, but this kind of requirement is not translated into AFR. Gutmann and Thompson's account of deliberative democracy is one that involves all citizens, so mutual respect is about the interactions of citizens, whereas with AFR, we are considering a closed committee that is not required to deliberate or involve the public and which makes decisions with reasons its members may not even hold, but must recognise as relevant and so fairly consider. An advantage of fair consideration as an addition to AFR and comment on it is that it fits within the model of decision-making that AFR is designed for. Rather than require public participation or input from all stakeholders, fair consideration concerns how a closed group of decision makers must act in order to render the process and decision normatively legitimate.

6.4 Fair consideration and legitimacy

So far, I have argued that because AFR does not specify the decision procedure, it leaves open the possibility that decision procedures may meet its conditions but lack normative legitimacy. In response to this concern, I have proposed that giving fair consideration to reasons is necessary. In this section, I tackle the issue of how fair consideration contributes to legitimacy taking into account both normative legitimacy and the value of the descriptive legitimacy of decisions.

Fair consideration contributes to legitimacy because in the face of reasonable disagreement, while we can agree that the outcome is substantively fair, the right kind of procedure is meant to assure us that it is also legitimate. AFR's claim to legitimacy in part rests on its appeal to elements of deliberative democracy although it is distinct from it. But, AFR misses out on this legitimacy since it does not require deliberation, is not democratic, and the decision procedures that satisfy its requirements may still

fail to treat reasons in the right way, like with the pre-decided committee. Treating reasons in the right way matters because these are all relevant, reasonable reasons; the very problem of requiring a procedure is that we do not have the substantive tools to pick between them. Fair consideration is not the same as deliberation and it is not democratic, but it does require serious regard for other reasons and, as I will discuss below, while not involving the public it recognises other interests and views. My claim is limited, and I do not attempt to make a claim about fair consideration's role in deliberative democracy. Instead I claim that fair consideration is necessary for the normative legitimacy of decisions made with the AFR procedure.

The publicity condition does not suffice to meet the demands of fair consideration and resolve the legitimacy problem. Daniels and Sabin argue that the Publicity Condition will mean that decision-makers are careful in their reasoning and pay attention to other reasons.¹⁹³ While it is true that in practice, publicity is likely to mean that decision-makers are careful about how they respond to reasons, it does not require them to do so, and it misses the point of fair consideration. Similarly, Daniels and Sabin could argue that the Appeals Condition means that decision-makers must be able to explain their reasons and reconsider their decision in light of other arguments. Again, this does not preclude the case of the pre-determined committee or address the concern that fair consideration must happen in the first instance of decision-making. Appeals are limited in their scope: because something like mere disadvantage or disagreement with the outcome is inevitable, these cannot be reasonable grounds of appeal. Therefore, fair consideration in the initial decision is essential if those affected by the decision are to be satisfied with its legitimacy. Furthermore, anything hinging on appeals moves the burden of legitimacy onto

¹⁹³ Daniels and Sabin, *Setting Limits Fairly*, 2008.

stakeholders who must be savvy and involved enough to appeal. To truly claim fairness and normative legitimacy, decision-makers should themselves take seriously the positions rather than testing publicity or who appeals.

Daniels and Sabin may defend that fair consideration is implicit in AFR and lurks behind the conditions. Something like fair consideration is suggested when Daniels comments that AFR includes “a fair, deliberative process in which conflicting views are considered”.¹⁹⁴ Statements like this appeal to the deliberative democracy background of AFR, but that background is lost when AFR is codified into a procedure. The conditions do not themselves call for a deliberative process! Considering conflicting views is also a weaker requirement whereas fair consideration is a stronger one specifying the duty of the decision-makers to take each position seriously and give it its due weight in the decision.

Daniels and Sabin come close to a statement about fair consideration when they write that fair-minded people do not need to themselves hold and represent every view in society. They do think it is beneficial for a broad range of stakeholders to be consulted in order to include a wide range of views.¹⁹⁵ This gets back to the issue of justifiable vs. justified reasons discussed above (5.6). Decision-makers should take into account the reasons that society holds, but they are not beholden to these reasons and the numbers of people who do hold them. Daniels and Sabin, though, do not go into greater detail about the relationship between fair-minded people and their representativeness.

Fair consideration requires that each relevant reason be considered, but it does not require that someone be present to represent each reason or that the decision-makers act as representatives. As I pointed out above (5.6), fair-minded people

¹⁹⁴ Daniels, "Reasonable Disagreement about Identified vs. Statistical Victims", 2012,42.

¹⁹⁵ Daniels and Sabin, *Setting Limits Fairly*, 2008, 63.

determine what reasons are mutually justifiable rather than attempting to determine which reasons are justified, and this stance is similar to the Rawlsian tradition of the conceptualised rational agent who considers the broad interests of society making a decision.

Fair consideration does not require direct representation of reasons or persons, but that does not diminish the requirement to take reasons into account in decision-making. The decision-makers are not representatives of any particular group of people or interests, and they are obliged to consider each reason. The distinction here is that fair consideration requires the decision-makers to consider each reason but not to actually hold those reasons themselves or hear directly from a representative of the reason. Similarly, the decision-makers are not present as representatives of their social group and should not view themselves as such.¹⁹⁶ (The role of the committee member as non-representative is something that we will see again with NICE's committee members in section 7.2.) A central feature of fair consideration is that a person does not need to be present in order for her reason to be given fair consideration. This is important for the normative legitimacy and descriptive legitimacy of the process since it does not mean someone must be sought out who is a representative for each position (and we do not then struggle with the problem of better and worse advocates) to participate in the decision-making. I will expand on this view in the next section (6.4.1) and in particular how it relates to descriptive legitimacy. The relationship of fair consideration to representativeness of reasons is important for normative legitimacy; fair consideration ensures the consideration of reasons but not the direct representation of the people who hold the reasons.

¹⁹⁶ Sheehan, "Should research ethics committees meet in public?", 2008.

A final point about fair consideration: it implies that committees making decisions must use their judgement. Because fair consideration is not the same as equal consideration or giving equal weight to each reason, it means the decision-makers must use their judgement about how to value reasons and what weight is appropriate for each reason—something that may vary from case to case. This sort of judgement is not democratic. Whereas deliberative democracy would highlight the decision-making by citizens, fair consideration draws out the process of judgement that a small group of people make. Although it means that this exclusive group has authority and power in the decision, fair consideration should reassure us of the decision's legitimacy. Daniels and Sabin's account of AFR does not preclude a significant role for judgement; it is just that fair consideration makes it more explicitly present. In the next chapters, we will see judgement in practice with the autonomy given to NICE's Appraisal Committees to exercise their judgement.

AFR is different from deliberative democracy and is designed for settings that may not even be democratic, so rather than pick up the elements of deliberative democracy and directly transfer them over, I have proposed a new condition for AFR. AFR is not a deliberative democratic procedure, so rather than try to make it one, fair consideration reflects some of the intuitions about legitimacy and respect in deliberative democracy and applies them to AFR.

In this section, I have argued that AFR has a legitimacy problem and the conditions are not sufficient for legitimacy. I have supplemented AFR with an account of fair consideration, which is necessary for legitimacy. In the next section, I will look at how my account of AFR, which includes fair consideration, enhances the perception of legitimacy for decision-making.

6.4.1 Fair consideration and the public: enhancing descriptive legitimacy

I've just argued that fair consideration is necessary for the normative legitimacy of decision-making with AFR. In this section, I will argue that fair consideration also enhances descriptive legitimacy, i.e., the perception of legitimacy. One connection I make is between the issue of representativeness, discussed above, and public involvement. I do not mean to suggest that fair consideration requires public involvement; on the contrary, fair consideration addresses some of the reasons that public involvement is valued while not requiring the involvement itself.

One challenge for the requirement of fair consideration will be knowing when decision-makers have given fair consideration to reasons. The Relevance Condition and fair consideration are normative requirements about how decision-makers ought to act. Fair consideration is not a part of the process that can be stated and easily checked the way publicity or appeals can be. We would expect to see recognition of other positions, like arguments specific to each one and responses to arguments in favour of other positions, whether actual or conjectured. Ultimately, we cannot know that a person has acted appropriately and truly given fair consideration to reasons. We can expect that individuals will act in accordance with the requirement of fair consideration, but we only have the outward manifestations of such integrity.

AFR will likely be used by small groups of decision makers, such as a panel within an insurance company or a committee of a public body that must make decisions on service provision. I assume and believe it likely that the members of the committee do not themselves hold all the relevant reasons pertaining to the decision. They are not representatives of the relevant reasons. Stakeholders in the decision, who do not get to be a part of the decision procedure, care that their reasons are considered. It matters to them that their reasons are given fair consideration, and the

decision procedure will need to demonstrate that it has done so in order for the outcome to be acceptable to stakeholders. Fair consideration means the decision-makers have shown respect to their reasons and taken them seriously, even in their absence. Fair consideration should matter to stakeholders and so too does their perception of it. Because views are not necessarily personally represented in the decision-making, stakeholders need to see that their reasons have been given fair consideration in order to trust the normative legitimacy of the procedure, a step towards descriptive legitimacy.

Looking at Daniels and Sabin's examples of good practice, some of them fail to take fair consideration into account. If these are good models of decision-making, according to Daniels and Sabin, then it is not clear that their account of AFR does require fair consideration. One patient-centred deliberation approach they praise is the case of lung volume reduction surgery, an unproven treatment for emphysema in the 1990s. Several insurance companies made decisions that satisfied patients who demanded the operation, and Daniels and Sabin admire that they did so without comparing trade-offs and opportunity costs.¹⁹⁷ Though they praise the insurers for their detachment from opportunity costs, we should not be so quick to do so. Just as it is important to give consideration to the need of the emphysema patients, so too should the patients who lost out on operating room time, hospital beds, or premium changes and coverage of services have their concerns about opportunity costs considered. It does not mean that a different decision would be reached, but we should not be content that ignoring a principle in order to seem more caring to one group was a legitimate way to make the decision.

¹⁹⁷ Daniels and Sabin, *Setting Limits Fairly*, 2008, 86, 90.

Fair consideration is not a substitute for public participation, but in a process that does not include the public, it provides an assurance that each view is considered, and so contributes to the perception of legitimacy. Daniels and Sabin are explicit that AFR does not require public participation, yet stakeholder engagement is of concern to Daniels and certainly to commentators on AFR. Especially as Daniels's work has included more focus on the right to health, he has incorporated the view that stakeholder input is important for identifying relevant reasons, but he does not justify such involvement as democratic.¹⁹⁸ We should not confuse stakeholder involvement of this sort with an enhancement of democratic legitimacy since the involved stakeholders are not proper representatives of the affected population nor are they democratically selected. Rather than focus on whether public participation is democratic or necessary, I want to show how given the limited role for it, fair consideration enhances descriptive legitimacy.

For those proponents of participation or empowerment of stakeholders in AFR, fair consideration addresses some of their concerns. Commentators on AFR have called for an additional condition of 'empowerment' or more explicit participation as a way for people to influence decision-makers, to level out influence, or to be involved in the process.¹⁹⁹ Daniels's response to these suggestions about empowerment has been concern that everyone needs to be equally empowered or else another inequality is introduced.²⁰⁰ Since fair consideration requires that each reason be given its due weight, people's positions will not be overlooked just because they

¹⁹⁸ Daniels, "Capabilities, opportunity, and health," 2010; "Reasonableness and Its Definition," 2010; "Reasonable Disagreement about Identified vs. Statistical Victims", 2012.

In contrast, other arguments criticising AFR include that it is not representative enough because of the lack of participation, so it cannot be truly accountable. (Williams-Jones and Burgess, "Social Contract Theory and Just Decision Making: Lessons from Genetic Testing for the BRCA Mutations", 2004.) I am not going to take up the problem of whether participation is necessary for accountability.

¹⁹⁹ Emanuel, "Book Review of Setting Limits Fairly: Can We Learn to Share Medical Resources", 2002; Maluka, 2011.

²⁰⁰ Daniels, "Legitimacy and fairness in priority setting in Tanzania", 2011.

are not present and cannot participate in the decision. Rather than empower people, we might say that it empowers reasons, demanding that they be taken seriously and considered. What it does not do is require that they be equally weighted, so it does not equally empower reasons. We might think of fair consideration as providing for the fair equality of opportunity of reasons. While this response will not satisfy those who believe that participation is intrinsically valuable, it should promote descriptive legitimacy since it rules out the possibility of the pre-decided committee. In decision procedures that lack public participation, fair consideration is an assurance that those who are not present have their positions taken seriously.

6.4.2 Objections to fair consideration: sufficiency and descriptive legitimacy

As with empowerment, there have been other suggestions of conditions to add to AFR, and there is the risk that we will overburden the theory in an effort to make it fair and legitimate. At some point a decision must be made; there cannot be an endless recourse to procedure. Indeed, a pragmatic appeal of AFR is its simplicity and that its conditions are not too numerous. I have argued why fair consideration is necessary and addresses a real problem for normative legitimacy. My account of AFR plus fair consideration preserves advantages of the original framework, like allowing for institutional design flexibility, since it is still open to different decision procedures. Fair consideration though retains more of the intuitions about the legitimacy of deliberative democracy and brings them to bear in AFR. Yet it does not convolute the process such that making a decision becomes impracticable and unfeasible.

Fair consideration is necessary for normative legitimacy, but it implies decision procedures that would be unlikely to be descriptively legitimate. We can see

this intuitively in the example of the one-person committee. Suppose that the committee that meets to make a decision about the provision of healthcare services turns out to be just one person. This single person is able to meet the conditions of AFR (publicising decisions, etc) and what's more she is able to fairly consider each relevant rationale and the reasons at play in the decision.

The account of AFR and fair consideration of reasons that I have given includes the one person committee as normatively legitimate. However, we can see that empirical concerns will likely arise from this case, which is a problem for descriptive legitimacy. This case draws out some of the differences between normative and descriptive legitimacy, and points to how actual practices will need to address both.

Intuitively, a one-person committee seems like it cannot have descriptive legitimacy for decision-making. But it also is not clear how scaling up affects this problem and at what point the number of people becomes sufficient: two people are just as capable of fair consideration as four, as ten, as fifty, and so on. Empirically, a one-person committee will struggle to achieve fairness and legitimacy since it is hard for one person to do all the things of considering each reason fairly, evaluating relevant evidence, deliberating on the interactions between reasons and evidence and how values fit in, and so on. In principle it is possible that a modern-day philosopher king could make the decisions, but in practice, we are more likely to take a conservative view that a single person or even very small committee will struggle to do everything the decision procedure and AFR, including fair consideration, requires.

The one-person committee does show us how the requirements of normative and descriptive legitimacy may differ. Daniels and Sabin do not address this distinction, but it is this need for procedural precision that can address both that

becomes a challenge for the implementation of AFR. In Part III, I will show how NICE implements AFR yet is not able to satisfy the descriptive legitimacy demands on it with AFR alone.

In this chapter, I have argued that the conditions of AFR are not sufficient for normative legitimacy and that fair consideration is a necessary addition. I levelled two criticisms at Daniels and Sabin: the first concerned uncertainty over how to determine a relevant rationale, and the second that AFR is not enough for normative legitimacy because it fails to treat reasonable disagreement properly.

In this chapter, I have also offered a revised account of AFR that includes a requirement for fair consideration. This requirement fits best as an addendum to the Relevance Condition:

Relevance Condition, part 2: The decision-makers must give fair consideration to the relevant rationales and should demonstrate they have done so.

My account of AFR better captures the intuitive legitimacy of deliberative democracy as a decision-making process while still recognising that AFR is not a procedure of a deliberative democracy and will be applied in non-democratic settings.

Fair consideration is necessary for the normative legitimacy of the decision procedure, and it also contributes to the descriptive legitimacy of the procedure although it does not secure it. Since fair consideration requires that reasons be treated appropriately, it is essential to the process of decision-making and thus its legitimacy. I have argued fair consideration is necessary for legitimacy within the context of AFR, and I do not attempt to extend the claim more broadly. Although fair consideration is a valuable procedural concept, I confine my argument for it AFR and applications of its framework.

Throughout Part II, a theme that has run through the discussion is that of normative vs. empirical requirements for legitimacy and decision-makers. In chapter 5, I raised the question of whether AFR requires mutually justifiable or justified reasons, and if the former how those might be determined. Fair consideration picks up on this theme since it does not require representation but rather decision-makers who are open to reasons and take them seriously. Through this part, I have built up an account of AFR and fair consideration that addresses normative legitimacy. However, when it comes time to putting that account into practice, it will face different challenges to its descriptive legitimacy.

Fair consideration and my account of AFR have implications for how institutions adopt and apply AFR. Fair consideration emphasises the reliance on decision-makers' judgement when they balance or consider reasons to make a decision. As an additional condition of AFR, it further circumscribes the acceptable procedures and addresses a gap in the normative legitimacy of the procedures. It does not dictate how a decision should be made or what the decision procedure will look like, but it is another element that we should evaluate in procedures. In the next chapter, I take on precisely this task. In it, I will examine NICE, which claims to put AFR into practice. The case example of NICE will show how AFR must be further developed by institutions to meet their particular legitimacy needs. However, NICE does not meet the requirement of my account since it fails to fairly consider reasons. This means that in the conclusion, I will evaluate the feasibility of fair consideration and the implications for its implementation.

III. NICE and its Procedures: AFR in Practice

“NICE may prove to be one of Britain’s greatest cultural exports, along with Shakespeare, Newtonian physics, the Beatles, Harry Potter, and the Teletubbies.”²⁰¹

The National Institute for Health and Care Excellence (NICE) makes priority-setting decisions for NHS England in its role as an explicit rationer and centralised decision-maker. Responding to concerns about regional variation due to local priority-setting, NICE runs a technology appraisal programme that evaluates new interventions and makes recommendations on whether the NHS should adopt them. Though these technology appraisals are only one part of NICE’s activities, and indeed only a small part of the total NHS budget, they have received a great deal of attention, and I too focus on them. The technology appraisals bring out issues of fairness and legitimacy since they are an explicit process in which NICE makes judgements about evidence and social values. Technology appraisals are a matter of justice since they concern the availability of and access to healthcare, so it is essential that NICE’s decisions are fair and normatively legitimate.

NICE is a public body making decisions for another, NHS England, and both NICE’s normative and descriptive legitimacy are essential to its success. In order to secure its claim to normative legitimacy, NICE has adopted AFR as a procedural framework for its decision-making. Approaches to decision-making that draw on deliberative democracy are gaining ground in institutions that wish to demonstrate that they take into account the voices of more people and respect citizens with their

²⁰¹ Smith, "Editor's Choice: The triumph of NICE", 2004.

decisions.²⁰² NICE's adoption of AFR is a demonstration of a commitment to a procedural approach to decision-making and the elements of deliberative democracy that it translates into practice. NICE still faces criticism as well as public discontent with its decisions and process, showing that its adoption of AFR does not meet the need for descriptive legitimacy.

In Part II, I examined the framework of AFR and its claims to normative legitimacy. I argued that AFR requires an additional condition of fair consideration for normative legitimacy. I also argued that the Relevance Condition calls for a standard of mutual justifiability. Both of these are normative commitments that shape the procedure, and in this part, we will see how NICE works towards instantiating these concepts as an example of AFR in practice.

Part III is broken up into three chapters that build a picture of NICE's technology appraisal process, the normative framework it uses to justify its legitimacy, and how that process translates into practice. Chapter 7 takes a critical eye to the legitimacy problem that NICE faces and its process-based decision-making. NICE is one of a few institutions that explicitly uses AFR. Critics of NICE claim it has not met the requirements of AFR, but I argue that NICE has met each condition of AFR in Daniels and Sabin's account. NICE uses AFR as a framework of procedural justice, and it has added to it with procedural principles its appraisals must follow. Implicit in NICE's addition of procedural principles is a criticism of AFR: it is not specific enough to meet the demands of an institution actually making decisions and must be supplemented to account for the legitimacy problems of real-world decision-making.

²⁰² Syrett, "Deconstructing Deliberation in the Appraisal of Medical Technologies", 2006.

Chapter 8 takes up a particular weakness of AFR in practice: the determination of relevant reasons. Mirroring the arguments of Chapter 5, I consider how NICE develops its relevant reasons, drawing a distinction between those it consistently considers relevant and reasons that arise in the appraisal process. In order for reasons to be relevant, NICE must show that they are mutually justifiable, but it does not have a clear means to do so and whose agreement matters is unclear. This problem is instantiated in the Citizens Council, a citizens jury NICE convenes to deliberate on issues and values of priority-setting. The Citizens Council is meant to develop social value judgements and provide NICE with insight into the views of the British public. However, the Council's views are not necessarily adopted by NICE, which still relies on the expert views of its advisory bodies to form its substantive values. Greater transparency about the process of developing relevant reasons would enhance NICE's normative legitimacy.

Chapter 9 returns to my revised account of AFR that requires fair consideration. In Chapter 6, I argued that fair consideration is necessary for AFR's normative legitimacy, so if NICE claims legitimacy from using AFR then it will need to demonstrate that it gives fair consideration to reasons. Although NICE has the framework in place for fair consideration, it uses a cost-effectiveness threshold, a range of cost-effectiveness values that should not be exceeded by new interventions. The threshold means that there is a presumption in favour of a particular reason, and this fails to account for reasonable disagreement or take seriously other relevant reasons. Fair consideration is a requirement for the procedure rather than a substantive commitment to certain reasons or outcomes, and given NICE's concerns about legitimacy, the lack of fair consideration is a flaw in its process that should be addressed in order to enhance its normative legitimacy.

I use NICE's normative guidance documents to inform the discussion. I will primarily refer to the *Social Value Judgements* guidance, *Guide to the processes of technology appraisal*, and *Guide to the methods of technology appraisal*.²⁰³ These documents are guides for the Appraisal Committees, who undertake technology appraisals, directing them as to the process of the appraisal, how evidence should be analysed, and what principles and reasons should be considered in the process. Referring to these documents does not tell us what NICE actually does when it undertakes an appraisal. Rather, these are normative guides about how NICE should operate and expects to operate. These expectations and ought to's show how NICE has designed its procedures in order to implement AFR and make fair, legitimate, and reasonable decisions.

Part III covers the ground of NICE's normative guidelines to its Appraisal Committees and its approach to procedural justice and then onto how these procedures are realised and the legitimacy concerns they raise. The same themes and problems recur both in developing the processes and putting them into practice: questions of which reasons are relevant, whose agreement determines relevance, and whether presumptions in favour of one reason challenge legitimacy. NICE is the exemplar institution for using AFR and healthcare priority-setting. Its claims to legitimacy and its procedures reflect back on AFR and can serve as a model to guide other institutions seeking to implement theories of procedural justice.

²⁰³ NICE, *Social Value Judgements*, 2008; *Guide to the methods of technology appraisal*, 2013; *Guide to the processes of technology appraisal*, 2014.

7 NICE's implementation of AFR as a claim to legitimacy

As a public body it benefits NICE to demonstrate its descriptive legitimacy, and NICE has a duty to the public on whose behalf it makes decisions to be fair and normatively legitimate. Fitting into the trend in countries to adopt procedural approaches to healthcare limit-setting, NICE is procedurally focused. Its technology appraisals are the result of a lengthy and thorough process designed to examine evidence and values and include a wide range of stakeholders' voices. Despite these processes, NICE's legitimacy is challenged both in public discussions, like the media, and academic critiques of its procedures.

NICE grounds its claim to normative legitimacy in procedural justice, and it has adopted AFR as a framework for procedural decision-making. In this chapter, I go against the prevailing view and argue that NICE fulfils each condition of AFR. However, NICE's introduction of additional procedural principles shows us that AFR alone is not enough for descriptively legitimate decision-making in real-world institutions.

7.1 NICE's legitimacy problem

NICE's expertise and process aim to legitimate the priorities of NHS England. NICE's transparency and due process, stakeholder involvement, and procedural consistency ought to affirm its legitimacy. Even the very existence of NICE is a demonstrable commitment to consistency in NHS decision-making rather than the postcode lotteries.²⁰⁴ Despite this, it has not shaken off criticism that its procedures are opaque and complex, its appeals process is not impartial, and that NICE fails to

²⁰⁴ Syrett, 2002.

meet requirements of AFR. Criticisms of NICE's legitimacy are founded on either the problem of public perception or the procedures that NICE uses for technology appraisals. NICE has a legitimacy problem.

NICE is a public body, making decisions for the NHS, another public body, so one challenge to its legitimacy comes from the public perception of its activities. Such criticisms are levelled at problems of descriptive legitimacy. NICE's public perception is a very real problem for it since a negative view would undermine trust in its decisions. Although rationing occurs at all levels of the NHS, NICE receives a great deal of public scrutiny and media attention for its decisions.²⁰⁵ When NICE does not recommend an intervention, patient groups and pharmaceutical manufacturers lobby politicians to exert pressure on NICE. Trust in NICE's decisions is essential to its functioning and to its ability to carry out appraisals without being undermined or pressured either by court cases or the government stepping in to respond to lobbying and public concerns; media and public relations are essential to NICE's success.²⁰⁶ Media attention and public sympathies lie with patients, so assertions that NICE makes efficient and fair decisions do not necessarily align with public values. In particular, media focus on individual patients and the inaccessibility of treatments to them garners public sympathy while neglecting the interchange between individuals and population health NICE considers.²⁰⁷ If the values expressed in NICE decisions and public discussion, like the media, are not the same, then there will be less trust in NICE and its procedures.²⁰⁸ This is particularly clear when NICE does not recommend a new treatment and aggrieved patients express their

²⁰⁵ Hasman, "The Accountability Problem of the National Institute for Health and Clinical Excellence", 2008.

²⁰⁶ Brown and Calnan, "Political accountability of explicit rationing: legitimacy problems faced by NICE", 2010.

²⁰⁷ Wilmot, "Evidence, ethics and inclusion: a broader base for NICE", 2010.

²⁰⁸ Syrett, 2002.

disappointment in any number of news sources.²⁰⁹ These public perceptions of NICE and its work underscore the main tension of priority-setting between meeting individuals' health needs and considering the overall population health.

Beyond its public perception, there are criticisms that NICE itself and its procedures lack normative legitimacy, founded on claims about the transparency of its procedures and who may participate. For example, a criticism of NICE's procedures is that they are too complex, so the process cannot be well understood and evaluated from the outside.²¹⁰ Transparency, i.e. understanding and knowing both the procedures and how NICE makes its decisions, is important to NICE's accountability and descriptive and normative legitimacy since people outside the institution criticise it when they do not have access to its process and reasoning.

Perhaps the biggest legitimacy problem for NICE is that its Appraisal Committees make decisions about which there is reasonable disagreement. Such conflicts are inherent to the kind of decision they are tasked with making, but it does put them under greater scrutiny, and there are objections to the degree of freedom they have to make judgements. NICE's Appraisal Committees are meant to have expertise in order to make judgements about evidence, but they must also make moral judgements, and it is difficult to support any claim to authority and expertise in this realm. Even though NICE appears to be making scientific, evidence-based decisions, it is also making political, moral judgements when it decides what is the best use of NHS resources.²¹¹ The remainder of this chapter will address how NICE seeks to establish its legitimacy for making these kinds of decisions.

²⁰⁹ The rhetoric often focuses on putting a price on life and denying people months of life, for example, "NICE rejects kidney cancer drug everolimus," 2011; Abernethy, "Parents fear little Anna Turner will die if wonder drug taken away," 2015; "Cystic fibrosis drug 'too pricey for the NHS': Almost 3,000 patient set to miss out on 'breakthrough' treatment," 2016.

²¹⁰ Hasman, 2008.

²¹¹ Ibid.

NICE's response to the criticisms of its legitimacy has centred on demonstrating that its procedures for decision-making are robust, meet requirements for fairness and normative legitimacy, and take moral considerations into account. I'm going to focus on NICE's claims to legitimacy via its procedures. NICE fits the trend of procedural rather than principle based priority-setting in countries' national health systems, and the normative legitimacy of its decisions derives from the process of the appraisal rather than claims about the rightness of the outcome. It matters that the process is legitimate and viewed as such, but I focus on NICE's normative rather than descriptive legitimacy. First, I'll briefly give an overview of the technology appraisal process, and then consider what sorts of claims to procedural justice NICE makes and justifies. It should come as no surprise that this is where AFR comes back: NICE supports its claim to procedural justice with AFR.

7.2 NICE's technology appraisal process

In order to be able to reflect on NICE's procedures and whether they are normatively legitimate, I will briefly outline the procedure for a technology appraisal here. What I want to draw attention to is that the process includes a series of exchanges about evidence and reasons between the NICE Appraisal Committee, who deliberate and make the decision, and stakeholders, like the manufacturer, patients, and clinical professionals.

Technology appraisals are conducted by Appraisal Committees who review evidence and make a recommendation, which NICE publishes as official guidance. There are four Appraisal Committees, and each one has twenty-four members, including two lay members. The members are drawn from the NHS, academia, CCGs, and industry, so they have professional backgrounds that give them insight

into limit-setting. The lay members also have relevant experience with the NHS or patient care. Importantly, the members are asked to draw on their perspectives and expertise when making decisions, but they are not there to represent any particular body or view.²¹² Like the hypothetical decision-makers in Chapter 6 (see 6.4), NICE's Committee members are not representatives but rather people who are meant to make good judgements.

The steps of technology appraisal are as follows:

1. Topic Selection: as discussed in Chapter 3, the appraisal process begins with the selection of health technologies. The Department of Health refers these to NICE for appraisal. Topic selection is a first step in limit-setting decision-making since only some technologies can be appraised.

2. Scoping and consultee lists: The Appraisal Committee drafts and responds to comments on the draft scope. The scope details what issues the appraisal will cover, including the technology and condition it treats, the clinical evidence under review and other considerations, like equality concerns, that will need to be taken into account. Scoping entails judgements about defining the issues that will be examined in the appraisal.²¹³

At this stage, the Appraisal Committee also confirms the list of consultees and commentators, i.e. those parties with a vested interest in the appraisal and who will have a role in the process. Consultees are groups with strong interests in the technology, like the manufacturer, patient and professional groups, NHS England (as a commissioner), a few CCGs, which are randomly selected to represent them all, and the Welsh government. Consultees may submit evidence, nominate experts to give oral evidence, and have the right of appeal. Commentators are other stakeholders

²¹² NICE, Technology Appraisals Committee Terms of Reference and Standing Orders, 2015; "Appointment of lay committee members: Information pack for applicants," 2015.

²¹³ Culyer, "NICE's use of cost effectiveness as an exemplar of a deliberative process", 2006.

who have the opportunity to review evidence and comment on the procedure but may not recommend experts or appeal.

3. Evidence submissions and review: The manufacturer submits its evidence to an Assessment Group or Evidence Review Group (AG/ERG).²¹⁴ The AG/ERG will also review all published evidence, in order to present on the clinical effectiveness, cost of the technology, and models of cost-effectiveness. The report on the evidence is sent to the Appraisal Committee, consultees and commentators, and shared on NICE's website.

In addition, consultees may submit evidence at this stage. This could take the form of qualitative evidence on effects on patients and carers, unpublished evidence, or clinical expert evidence. Written evidence submissions are also published on NICE's website.

4. Appraisal Committee meeting: at the first meeting of the Appraisal Committee it reviews the evidence reports and submissions it has received. It also hears from clinical experts and patients who give their own evidence as well as helping to clarify how trial evidence aligns with actual practice and experience. The meeting is an opportunity to clarify the evidence, methods, and conclusions with the AG/ERG and manufacturer present.

The Appraisal Committee then privately deliberates to make a decision about its recommendation. Even though consultees and members of the public are present for the first part of the meeting, the Appraisal Committee alone makes the decision, and it carries out its deliberations in private.

²¹⁴ These two kinds of review groups serve the same function—when only one technology is being appraised, a “single technology appraisal” (STA) the review group is called an ERG. When multiple technologies are appraised (multiple technology appraisal or MTA), it is called an AG. The review groups are based at nine independent academic centres.

5. Appraisal Consultation Document (ACD) published: The ACD is the initial recommendation and includes an overview of the evidence and reasons for the decision. Once it is published, consultees, commentators, and the public have four weeks in which to respond to the ACD.

6. Appraisal Committee meeting two: The Appraisal Committee responds to the comments it receives, and at this meeting it may re-consider evidence in light of the comments. The Committee then privately meets to deliberate and review its decision.

7. Final Appraisal Document (FAD) published: The Appraisal Committee publishes the FAD, which contains its recommendation, evidence summary, and consideration of the evidence. The FAD may be appealed (8) or published (9).

8. Appeals process: a consultee may appeal the FAD recommendation within 15 days of its publication. An Appeal Panel is convened who hears the appeal. If the appeal is upheld, the Appraisal Committee is directed to reconsider the appraisal in line with the Appeal Panel's directives. If it is not upheld, then the FAD is published, as per step 9.

9. Executive review and publication: The NICE Guidance Executive reviews the FAD, and may choose to clarify or ask the Appraisal Committee to reconsider its decision. Once the Executive is satisfied that the process has been followed and the evidence accounted for, the FAD is published as official NICE guidance.²¹⁵

With this overview of what NICE's technology appraisal process requires, the question remains of whether it is a legitimate process and one that can result in fair outcomes. There are two matters to consider: whether the process itself is designed so

²¹⁵ NICE, Guide to the processes of technology appraisal, 2014.

as to be able to provide the legitimacy NICE needs and what substantive issues NICE considers and how it incorporates those into its decision-making process. It is to these questions that we now turn our attention.

7.3 NICE's deliberation

A legitimacy question for NICE concerns whether it can deliberate, in the sense of democratic deliberation, since its Appraisal Committee's make their decisions in private. If it does not do democratic deliberation, then NICE needs an account of its process to justify its legitimacy, which is why it turns to AFR.

On some accounts of democratic deliberation, it is a process that must be public and should be open to all citizens.²¹⁶ Deliberation cannot merely take into account perspectives; it must include all perspectives in the process, according to Syrett's account. On such an account, NICE cannot do deliberation since deliberation requires citizens to participate.²¹⁷ If deliberation requires public participation in the decision-making itself, then NICE cannot and does not do (democratic) deliberation.

NICE's Appraisal Committees make their decisions in private, so it is a significant component of the process that is kept confidential. At each meeting, the first part is open to the public and invited experts—patients, clinicians, manufacturer representatives, and the AG/ERG. However, the second part is closed and private, with only the members of the Appraisal Committee present. The advantage to a private deliberation in this case is that the Committee members can speak freely without fear of personal recrimination.²¹⁸ Even though the individual members of each Committee are identified on NICE's website and in the guidance, when the

²¹⁶ Schauer, "Talking as a Decision Procedure," 1999; Syrett, *Law, Legitimacy and the Rationing of Health Care*, 2007, 147; Cohen, "Deliberation and Democratic Legitimacy," 2009.

²¹⁷ Syrett, "Deconstructing Deliberation in the Appraisal of Medical Technologies", 2006.

²¹⁸ Sheehan, "Should research ethics committees meet in public?", 2008.

Appraisal Committee does make its decision, it aims to reach a consensus and the members take collective responsibility for the outcome.²¹⁹ The transparency principle does not open up this portion of the process, but it does mean the outcome and its reasons are published.

Rather than aiming to enact an idealised form of democratic deliberation, NICE engages in deliberative decision-making within an exclusive and expert committee. This is not so dissimilar from what Daniels and Sabin's account of AFR would expect; it enables the public discussion of principles and decisions not through public involvement and participation but because the decisions are accessible and published, i.e. because they are published, they may be discussed. Indeed, Gutmann and Thompson have praised NICE's deliberative process: "the creation of NICE supported the value of reciprocity by providing citizens with an example of deliberation in action in which they could assess the justifications their representatives give for policies that will affect their wellbeing in important ways."²²⁰ If we adopt a different view of deliberation, one that focuses on what the discussion requires with elements like fair consideration, rather than on who is involved in it, then NICE holds up a good account of deliberation.

Indeed, Anthony Culyer, the founding Vice Chair and economics lead at NICE, argues that NICE is a good model of deliberation, which he defines by the kinds of evidence and reasons that must be considered in the circumstances rather than democratic deliberation. NICE must make decisions when there is uncertainty, disagreement about values and evidence, and issues of fairness. NICE uses a combination of reasons and evidence to produce guidance that is determined by the Committee's judgement. In particular, for the kinds of decisions NICE makes, it is

²¹⁹ NICE, Technology Appraisals Committee Terms of Reference and Standing Orders, 2015.

²²⁰ Gutmann and Thompson, 2002, 158.

important that there is a sense of either public or professional ‘ownership’.²²¹

Balancing between these needs and kinds of evidence using judgement is what marks out deliberation for Culyer, and under his account of deliberation, NICE is a model institution.

Whether NICE can do deliberation, and so how it fits in with theories of democratic deliberation and public deliberation, depends on the account of deliberation that one adopts. NICE does not have an open deliberative process, but instead one that is closed and relies on the judgement of an expert group. While this does not fit with most accounts of deliberation, democratic deliberation is not necessarily essential for normative legitimacy.²²² The account it does fit with is Daniels and Sabin’s since they address decision-making by closed groups, like boards of health insurers. With good procedural practices and transparency about the decision outcomes and reasons, NICE can still demonstrate a commitment to fair and legitimate decision-making despite not involving the public in the actual decision-making.

7.4 NICE’s procedural justice design: a commitment to AFR and process

NICE’s *SVJ* makes the explicit commitment that NICE will follow the procedure of AFR in all its guidance, and it is AFR that gives its guidance normative legitimacy. In this section, I will make two arguments about NICE’s use of AFR. The first is that NICE meets the conditions of Daniels and Sabin’s account of AFR. (I set aside my own account and return to it later in the chapter.) This claim is in contrast to criticism in the literature that NICE does not do AFR and misses out on

²²¹ Culyer, 2006.

²²² Syrett, "Deconstructing Deliberation in the Appraisal of Medical Technologies", 2006.

key components of the conditions. NICE's account of procedural justice for its decision-making consists of AFR as a procedural framework and a set of principles for procedural justice. Alongside the argument that the design of NICE's procedures meets the requirements of AFR, I will argue that the procedural principles of NICE are how it constructs a decision procedure specific to its needs. The procedural principles demonstrate that even though NICE claims AFR is necessary for legitimacy, it must further elaborate on AFR's procedural approach and introduce additional principles to meet the specific descriptive legitimacy concerns it faces as an institution. In this section, I will examine these two arguments alongside each other, working through the AFR framework and NICE's principles and responding to the criticisms levelled at NICE's implementation of AFR.

NICE's account of procedural justice is outlined in *Social Value Judgements: Principles for the development of NICE guidance (SVJ)*.²²³ The *SVJ* is a normative document that outlines the values NICE should take into account when making decisions and issuing guidance, though I focus on technology appraisals. The aim of the *SVJ* is to address social value judgements, which are moral and ethical principles, and social preferences. While NICE can claim that its Appraisal Committee members are expert in scientific value judgements, i.e. analysing and interpreting clinical, cost, and scientific evidence, it cannot make the same claim about their ethical expertise. The *SVJ* is an ethical framework for the Appraisal Committees to work with. The *SVJ* was developed from the ethics literature, the Citizens Council, a citizens' jury I will discuss below (8.3), and a national survey on values.²²⁴ It has since been revised following a review by NICE's advisory bodies of the further meetings of the Citizens

²²³ NICE, *Social Value Judgements*, 2008.

²²⁴ *Social Value Judgements*, 2005.

Council and the literature on the *SVJ* and priority-setting.²²⁵ Combining ethics literature and expert review (insofar as there is such) with the views expressed by members of the public in the Citizens Council, the *SVJ* captures general ethical norms that should guide Appraisal Committees. It includes nine principles as well as other considerations that Appraisal Committees must take into account or exclude, which I will return to in Chapter 8.1. The *SVJ* seems to serve two roles: it lays out the background procedural commitments of NICE, which I discuss here, and second states substantive commitments the Appraisal Committees must abide by, addressed below. The *SVJ* begins by setting the ethical scene and stating NICE's claim to legitimacy because of its careful use of procedural justice.

The *SVJ* claims procedural justice is the appropriate way to make decisions because it is the most legitimate means, and there is disagreement about principled approaches. It implicitly cites the sorts of arguments about procedural and substantive approaches from the experiences of the UK and other countries in developing their priority-setting approaches. The *SVJ* cites utilitarian and egalitarian distributive justice as both significant to informing NICE's work but also insufficient for the problems that NICE faces when it must make appraisal decisions about value. Neither approach satisfactorily addresses the real rationing problems NICE faces of balancing individual benefits with overall health and benefits. With principles that cannot be easily resolved and about which there is reasonable disagreement, NICE, like Daniels and Sabin, turns to procedures for legitimate decision-making.

The *SVJ*'s description of procedural justice is that it is valuable because it "provides for 'accountability for reasonableness'".²²⁶ It uses the phrase in the sense of requiring decision-makers to be held to account for the reasonableness of their

²²⁵ Littlejohns and Rawlins, "Social value judgements: implementing the Citizens Council reports," 2009.

²²⁶ NICE, Social Value Judgements, 2008, 2.3.

decisions, much like Daniels and Sabin intend to indicate with the name for their procedural framework. The *SVJ* articulates:

“Procedural justice provides for ‘accountability for reasonableness’. For decision-makers to be ‘accountable for their reasonableness,’ the processes they use to make their decisions must have four characteristics: publicity, relevance, challenge and revision, and regulation.”²²⁷

In the *SVJ* procedural justice means AFR, and it is by using this framework that NICE claims legitimacy for its decisions that it would otherwise lack.²²⁸ NICE’s decisions are normatively legitimate because of the process, and the process is legitimate because it meets the conditions of AFR. Using AFR as a foothold for legitimacy is also cited in the literature on NICE, and Rawlins, the chairman of NICE, believes AFR gives NICE greater acceptance amongst professionals, the public, and politicians.²²⁹ This claim rests on an assumption that AFR does indeed structure a normatively legitimate process and that NICE follows the conditions of AFR in its own procedures. In the previous chapter (6), I challenged AFR’s claim to legitimacy because it does not include any provision for fair consideration and the appropriate treatment of reasonable disagreement. Rather than focus on fair consideration in this section, I will de-construct how NICE does meet the conditions of AFR and what sort of legitimacy they confer on its procedures. In particular, we will see that NICE has to supplement AFR with its own procedural principles that respond to its specific descriptive legitimacy concerns. While AFR provides an important framework for NICE’s legitimacy, NICE has also developed its own robust account of its procedural and descriptive legitimacy.

²²⁷ Ibid.

²²⁸ Social Value Judgements, 2005, 3.3.8..

Interestingly, the first edition *SVJ* (2005) is a much denser document. It goes into greater detail about the principles and ethical background it uses and is more citation heavy. In contrast, the second edition (2008) must have around half the word count and is much more sparse in its explanations and citations.

²²⁹ Syrett, 2002; Rawlins, "Pharmacopolitics and deliberative democracy", 2005.

As with the last chapter, the focus here is on legitimacy rather than fairness. In part, this focus on legitimacy is a reflection of NICE's concerns in its guidance documents. The question of fairness and substantive fairness is dealt with primarily in the principles of the *SVJ*, which rule out discrimination, discussed below.

Prior to the publication of the first edition of the *SVJ* in 2005, NICE's procedures mapped onto AFR and implicitly followed its procedural requirements. NICE "unconsciously" followed the "precepts of Daniels and Sabin with a commitment to transparency and accountability in decision-making on the funding of new technologies."²³⁰ NICE has since moved to an explicit commitment to AFR. There are two possibilities: NICE's invocation of AFR is lip service to the framework in order to try to strengthen its legitimacy claims, so the procedures will reflect AFR but not always line up with it, or NICE's procedures have developed so as to be consistent with AFR. I will argue the latter point, that NICE's procedures are consistent with AFR, and it is likely that even without an explicit commitment to that framework they were designed with AFR in mind. Therefore NICE does not happen to follow the procedural framework but intentionally supports it as the means of legitimate, procedural justice and decisions.

AFR is the procedural justice framework that NICE appeals to, but NICE has further fleshed it out with eight procedural principles. Some of these principles, like challenge, are very similar to AFR's, but others, like inclusiveness, are notably distinct. AFR is meant to ensure a fair and legitimate procedure, yet NICE feels the need to add to the procedural framework of AFR with its own procedural principles. These principles are part of the institutional design of NICE, and they respond to the descriptive legitimacy challenges NICE faces. NICE's need to include a second

²³⁰ Ham and Coulter, 2001, 167.

commitment to procedural justice in the form of its principles, which are what it cites in its discussions of its guidance rather than AFR, does however demonstrate that AFR is not fully fit for the legitimacy needs of NICE.

In the table below, I give AFR's four conditions alongside NICE's procedural principles. Principles in the third column (H, I) are not included in but are consistent with AFR and are what some believe it does or should require. While those below (F, G) do not match up with AFR since they address the real-world legitimacy problems NICE faces. While some of the principles elaborate on AFR's conditions, others do not match up at all, and NICE does not have a principle for each of AFR's conditions although that does not mean that the process fails to meet the conditions.

AFR Conditions	NICE Principles	
1. <i>Publicity</i>	A. <i>Transparency</i> (a more exacting form of publicity)	H. <i>Inclusiveness</i> (public involvement)
2. <i>Relevance</i>	B. <i>Scientific rigour</i> (a specific focus for relevance)	I. <i>Independence</i> (fair-mindedness)
3a. <i>Appeals</i>	D. <i>Challenge</i>	
3b. <i>Revisions</i>	E. <i>Review</i>	
4. <i>Regulation</i>	--	
	F. <i>Support for Implementation</i>	
	G. <i>Timeliness</i>	

Table 1: AFR conditions and NICE principles

In the following sections, I will examine these principles alongside the conditions. In doing so, there are two arguments I will address: the first is to show how NICE meets the conditions of AFR, which critics claim it does not do. Second is to show how NICE's procedural principles enhance procedural legitimacy and address NICE's legitimacy problem.

7.4.1 Publicity and transparency

NICE's transparency principle is a more detailed requirement than the Publicity Condition, and it specifies the need for publicity throughout the decision process. Given the limited requirements of AFR's Publicity Condition, NICE meets those, yet it has still faced criticism that it fails to do so and is not transparent enough. The transparency principle is targeted at increasing NICE's legitimacy as a public body that requires a higher level of transparency and publicity than AFR does in order gain support and be perceived as legitimate.

First, recall the Publicity Condition: "Decisions regarding coverage for new technologies (and other limit-setting decisions) and their rationales must be publicly accessible."²³¹ The Publicity Condition requires that the final decision and its justification be publicly accessible, but it does not require that the proceedings of the decision procedure be publicised. It also does not require the criteria for the decision to be published or agreed on in advance.²³² What I want to draw attention to is that the Publicity Condition is not a requirement for open decision-making, public hearings and involvement, or institutional transparency.

NICE meets the terms of AFR's Publicity Condition given its extensive publication of its decisions, guidance, and the evidence in support of its guidance. NICE's guidance is available on its website in multiple forms and even as a mobile app. The technology appraisal guidance includes the final recommendation and the reasons for it, which are explained under the headings of clinical need and practice, an overview of the technology, clinical and cost-effectiveness evidence and its interpretation, and consideration of the evidence, which is where in the guidance the Appraisal Committee explains its weighting of reasons and judgement. The

²³¹ Daniels and Sabin, "Limits to health care", 1997,323.

²³² *Setting Limits Fairly*, 2008, 12.

availability of the guidance means that NICE meets the criteria of the Publicity Condition.

Although NICE meets the Publicity Condition's requirements, it cannot ensure everyone reads and understands the guidance and reasoning. The sections on clinical and cost-effectiveness are technical, requiring an understanding of trials and analysis methods to fully grasp. Even though the guidance is available, the public may not understand the reasons, and its view of the guidance will often be shaped by media descriptions. The public's perception of NICE is a very real problem for it, and a poor perception that it is opaque, political, or fails to take into account public concerns will undermine its legitimacy and trust in its authority and recommendations.²³³ Even amongst those in the healthcare profession, NICE's guidance was greeted with the suspicion that it was political rather than being evidence-based.²³⁴ In addition, as a public body making decisions for the NHS, there is a greater expectation of publicity than what AFR requires.

Some critics of NICE argue that its use of scientific evidence and role as a public body means that it should be more transparent, and it therefore fails to meet the Publicity Condition.²³⁵ While we may support the argument that NICE could do better with its transparency, for example, making its reasoning more intelligibly accessible, NICE successfully meets the requirements of the Publicity Condition of AFR. Therefore a claim that NICE requires greater transparency is a comment on what sort of transparency is necessary for its descriptive legitimacy as a public body rather than NICE's use of AFR.

²³³ Brown and Calnan, 2010.

²³⁴ Smith, "The failings of NICE", 2000.

²³⁵ Hasman, 2008; Schlender, "The use of cost-effectiveness by the National Institute for Health and Clinical Excellence (NICE): no(t yet an) exemplar of a deliberative process", 2008.

NICE has recognised the need to be more transparent about its procedures in order to secure its perception of public accountability and legitimacy, which is what its transparency principle is aimed at. The transparency principle requires NICE to share its guidance development process, publish the evidence for its decisions, share draft as well as final versions of the guidance, and try to explain the reasoning of the decision.²³⁶ NICE is publicly criticised for its decisions and comes under particular scrutiny as a public institution making decisions on behalf of another. Therefore, it expands on the requirements of the Publicity Condition, which are not so rigorous, in order to open up its process and judgements to greater scrutiny and public discussion.

However, in two instances NICE is not consistent with transparency: the use of confidential evidence and in its sharing of economic models, and the latter has been addressed by the courts. When the AG/ERG evaluates evidence and presents it, NICE asks for the evidence to be shared and published. However, in ‘exceptional circumstances’ when the evidence is commercial or academic in confidence, meaning it would affect commercial interests or the ability to publish, the owner of the evidence may ask for it to be kept confidential.²³⁷ The most common case of this seems to be manufacturers asking to keep pricing information confidential. The evidence will be shared with the Appraisal Committee for use in its deliberations but is not published, which means the public does not have access to the real reasons of the decision, if that evidence affected the outcome. The burden of proof is on the owner of the evidence to argue why it is that the evidence must be kept confidential since NICE, in keeping with transparency, is expected to publish it.²³⁸ NICE is in a difficult position since it needs the data owners’ cooperation in order to use all the available evidence, but confidential information impinges on its ability to be

²³⁶ NICE, Social Value Judgements, 2008, 3.2.

²³⁷ Hasman, 2008; NICE, Social Value Judgements, 2008, 3.2.

²³⁸ Guide to the methods of technology appraisal, 2013, 3.1.24.

transparent and to fully explain its reasoning for decisions, which will come into conflict with the Relevance Condition.

NICE's procedures have not always required it to share its economic models, and this too limits its transparency and the understanding of its recommendations. The economic models NICE uses to determine the cost-effectiveness of a new technology may not be shared except with consultees and commentators, who sometimes do not even have access to a workable model. Since cost-effectiveness is a significant consideration in the recommendation decision, not sharing the models damages NICE's public accountability.²³⁹ It is a failure of transparency and has repercussions for NICE's claims to Publicity insofar as the model explains the reason for the decision.

The first time NICE was taken to court was over the issue of sharing economic models. Eisai, the manufacturer of donepezil for the treatment of Alzheimer's, sued that NICE had failed to follow its own procedure and be sufficiently transparent since it did not share a fully executable model of its cost-effectiveness evaluation.²⁴⁰ The Court of Appeal upheld that it was unfair of NICE to have not disclosed its model since this did not allow Eisai sufficient opportunity to respond to NICE's interpretation of its evidence.²⁴¹ The case set a precedent requiring NICE to share models with, at minimum, consultees during the appraisal. The judgement also highlights that NICE must consistently follow its own procedures, which the courts have enforced.

The criticisms of NICE and whether it meets the Publicity Condition concern, to a greater extent, its transparency rather than the strict requirements of Publicity.

²³⁹ Schlender, 2008.

²⁴⁰ Eisai Ltd., Appeal by Eisai Limited against the final appraisal determination by the National Institute for Health and Clinical Excellence, 2006.

²⁴¹ Syrett, "Health technology appraisal and the courts: accountability for reasonableness and the judicial model of procedural justice", 2011. See *R (on the application of Eisai Ltd v NICE)* [2008]

The Publicity Condition only requires the decision and its rationale to be shared, which NICE does. When NICE cannot share information, it substitutes publicly available information in for the confidential and explains the effect on its decision. For example, in the appraisal of eculizumab, publicly available prices are used in the published guidance because of a confidential discount agreed with the manufacturer. NICE's transparency may be the very thing that gives rise to greater criticism of it: Drummond believes NICE "is probably the most transparent public decision-making body in the world", which is what allows for the level of scrutiny and discussion it has been subject to.²⁴² NICE faces particular pressures as a public body, and the Publicity Condition is not enough to ensure its descriptive legitimacy, as the criticisms of it show. NICE's principle of transparency targets this descriptive legitimacy concern by requiring much of the process to be shared and made accessible in order to enhance its public accountability and legitimacy.

7.4.2 Relevance, rigour, and independence

The Relevance Condition of AFR limits what sorts of reasons are acceptable to use in decision-making, and NICE has principles and guidance documents that give its normative views on reasons and evidence. The Relevance Condition, I argued, poses problems for practice because it is not clear how decision-makers are meant to determine relevant reasons or how Daniels and Sabin's account distinguishes what is or is not relevant. In Chapter 8, I will discuss several of NICE's relevant reasons and how it has developed them, but in this section, I keep the focus on NICE's procedural principles—scientific rigour and independence.

²⁴² Drummond, 2007,207.

Given the concern about how to distinguish relevant reasons, NICE has put in place both substantive requirements and procedural principles, scientific rigour and independence, that relate to the reasons its Appraisal Committees may use. Ford claims that since the Relevance Condition is problematic, no institution has implemented it.²⁴³ I believe this is a mistaken claim; it is certainly the case that the Relevance Condition is problematic to implement, but NICE has constructed normative rules and procedures about relevance. What Appraisal Committees ought to take into account has the effect of constraining the kinds of reasons that may be used and limiting them to those that are clinically relevant and fit its preferred standards of evidence or reasons reflecting social values and ethical principles.

The principle of scientific rigour calls for a “scientifically rigorous” guidance development process that uses a systematic review of all available, i.e. published and unpublished, evidence.²⁴⁴ NICE expects manufacturers to submit their evidence and for the AG/ERG to conduct an extensive review of it all. NICE draws on several sources of evidence, and the quality and kind of evidence varies between appraisals, so it has standardised its preferred analysis. The *Guide to the methods of technology appraisal* sets the standard “reference case” as the parameters of what sorts of issues should be addressed in the evidence review, such as the time horizon considered, cost-utility, health related quality of life, and costs. There is disagreement over the reference case and its methods, reflecting that there are value judgements even in how scientific evidence is understood. Because of this disagreement, non-reference case analysis is also accepted with a justification.²⁴⁵ Even at the level of scientific, quantitative evidence, there is disagreement about how to assess and interpret it. The principle of scientific rigour is a procedural principle calling for a certain standard of

²⁴³ Ford, 2014.

²⁴⁴ NICE, Social Value Judgements, 2008, 3.2.

²⁴⁵ Guide to the methods of technology appraisal, 2013, 3.3.6-3.3.7, 5.1.1-5.1.2, Table 5.1.

evidence analysis. It is made substantive with the reference case that sets out specific issues that should be addressed in the analysis and interpretation of clinical and cost evidence.

A second principle that relates to the Relevance Condition is NICE's procedural principle of independence. One criticism of Daniels and Sabin's account of AFR is that they do not emphasize the impartiality of the decision makers, leaving the field open to special interests in the deliberation.²⁴⁶ If this were the case, and the public viewed NICE as allowing special interests, whether pharmaceutical companies or patient groups, to have greater sway over the decision, NICE would undermine its legitimacy.²⁴⁷ The independence principle reinforces both that NICE's Appraisal Committees act independently, and the members must declare any conflict of interest.²⁴⁸

NICE reinforces its position as distinct from the NHS and non-political. Once the Secretary of State for Health refers a technology to NICE for appraisal, there is no further involvement from the Department of Health or the NHS, except in exceptional circumstances, which have yet to be invoked. Indeed, the Department of Health and National Assembly of Wales are consultees on each appraisal with no greater rights

²⁴⁶ Rid, 2009; Emanuel, "Book Review of Setting Limits Fairly: Can We Learn to Share Medical Resources", 2002.

²⁴⁷ I noted in an Appraisal Committee meeting I attended that the representatives of pharmaceutical manufacturers had limited contact with the Committee members (the public are allowed none). The manufacturer representatives are not invited for lunch or tea, which would provide opportunities to informally talk with the Committee members. In contrast, patient representatives and clinical experts are invited to lunch and tea, so if anything the concern may be that they have greater opportunity to informally exert influence. This has also been noted as a (minor) sore point by members of the pharmaceutical industry in their relationship with NICE. (Timmins, Rawlins, and Appleby, 2016.)

Despite best efforts, there has been news coverage raising concerns about conflicts of interest and possible breaches of independence. (Brimelow, "NICE conflicts of interest: Call for MPs to investigate," 2014; Malhotra, "Is the failure of health regulation damaging our well-being?," 2015.).

²⁴⁸ Internally, NICE considers itself to be doing well on declaring conflicts of interest and developing transparent and independent guidance. However, there have been concerns raised about the trust-based system this entails and that the guidance on conflicts of interest is not comprehensive enough and should be supplemented with clearer guidelines. (Graham, Alderson, and Stokes, "Managing Conflicts of Interest in the UK National Institute for Health and Care Excellence (NICE) Clinical Guidelines Programme: Qualitative Study", 2015.)

than any other consultee, including patient groups and the manufacturer. NICE has also been independent to design its procedures and methods.²⁴⁹ NICE considers itself able to conduct reviews on its own terms and evidence without political influence.

The members of the Appraisal Committee and their rules of conduct are similar to elements of Daniels and Sabin's concept of fair-minded people. Fair-minded people are those who seek to cooperate and agree to rules of the process. Appraisal Committee members have their own rules around respect and upholding the "Seven Principles of Public Life", which apply across the civil service and emphasise the impartiality and accountability of those making decisions.²⁵⁰ The Appraisal Committee members are drawn from the NHS, academia, and related industries like patient care and pharmaceuticals. There are also two lay members who have experience with the NHS or patient care. Even though the members have backgrounds that give them specific perspectives on the NHS and healthcare spending, they are directed not to bring these to bear on their decision-making. No one is chosen as a representative, rather they are chosen because they have expertise in the relevant fields.²⁵¹ With rules about declaring conflicts of interest, potential clashes and lack of independence should be avoided. In Chapter 6, I argued that fair consideration means decision-makers give fair consideration to reasons rather than acting as representatives. This requirement is consistent with NICE's position of its Appraisal Committees as reasonable individuals rather than individuals who represent particular reasonable views.

²⁴⁹ Department of Health, 2002.

²⁵⁰ NICE, "Appointment of lay committee members: Information pack for applicants," 2015; Technology Appraisals Committee Terms of Reference and Standing Orders, 2015.

The principles, developed by the Nolan Committee are: selflessness, integrity, objectivity, accountability, openness, honesty, and leadership.

²⁵¹ "Appointment of lay committee members: Information pack for applicants," 2015; Technology Appraisals Committee Terms of Reference and Standing Orders, 2015.

These rules around how Appraisal Committee members are expected to act are similar to the idea of fair-minded people as sportsmen who respect the game.

Independence also addresses concerns that AFR should insist on the impartiality of decision-makers because the principle requires procedural safeguards against self-interest in decision-making. Self-policing both of oneself and others in the group will be necessary to truly make the decisions independent and impartial. NICE's independence principle is aimed at establishing the fairness of Appraisal Committees and their members as adjudicators of evidence and values. It responds to concerns about NICE's role within the government and also picks up on proposals for additions to AFR.

In later sections I will discuss NICE's substantive relevant reasons, but here I have shown how NICE has specified two further procedural requirements that associate with the Relevance Condition. Scientific rigour is a requirement for the standard of evidence that may serve as a reason. Independence addresses criticisms raised of AFR and NICE that decision-makers should be impartial when making their judgments.

7.4.3 Appeals and challenge

The AFR Appeals and Revisions Condition requires that there be an appeals mechanism in place, and NICE's challenge principle supports this condition and specifies the appeal opportunities. However, NICE's appeals process has been criticised for limiting who may appeal and relying on internal appeal panels. I argue that NICE meets AFR's Appeals Condition (I will address revisions in the next section) but leave open the problems of the appeals process, which could be changed given the concern over legitimacy they present.

Following the release of the final appraisal document (FAD), consultees on the appraisal have fifteen days to appeal the decision. Appellants may not repeat arguments or present new evidence that was not initially submitted. There are two specific grounds for appeals: (1) NICE has acted unfairly or exceeded its powers and (2) NICE has arrived at an unreasonable conclusion from the submitted evidence.²⁵²

The first ground of appeal is striking since it defines NICE's sense of what it means for the Appraisal Committees to act fairly. Fairness in this case is procedural: that NICE has acted fairly towards the parties in the appraisal process rather than a colloquial being "unfair" to patients who do not have their treatment approved. The grounds of appeal also exclude claims that the appellant disagrees with the recommendation. An appeal may also be made that NICE has exceeded its powers as a public body by either exceeding its remit or acting unlawfully.²⁵³ These grounds of appeal concern the process and how NICE has treated the parties involved in it. It also highlights a meaning of "fair" NICE uses in this instance as fair treatment in the process rather than substantive fairness—of particular interest in this procedural account of NICE.

The second ground of appeal is that NICE's recommendation is unreasonable given the evidence that was submitted. This means that the conclusion reached is illogical, irrational, absurd, or unarguably wrong, and any reasonable committee would not have reached the same conclusion based on the evidence available to it. What's of note here is that the guideline points out that different committees may arrive at different conclusions without being unreasonable.²⁵⁴ This is an illustration of reasonable disagreement: reasonable people will disagree and may arrive at different conclusions. This element of the appeals process also shows that NICE allows and

²⁵² Guide to the processes of technology appraisal, 2014, 4.1, 4.3.

²⁵³ Guide to the technology appraisal and highly specialised technologies appeal process, 2014, 4.4.

²⁵⁴ Ibid.

even expects that its Appraisal Committees may arrive at different decisions from one another. Appraisal Committees must be consistent about the procedure they use, which is why there is such focus on the reference case and kinds of evidence.²⁵⁵ The procedure is fair, and each Appraisal Committee follows the same procedure, but since each one may use its judgement to make a decision and weigh up the relevant considerations, different outcomes are possible.

Schlender criticises NICE's appeals procedure as more restrictive than AFR's requirement, but this is a mischaracterisation of AFR. AFR does not specify what sort of appeals process should be in place, only that there must be one. Schlender argues that NICE's appeals process is too limited since there are only certain grounds on which appeals can be made, new evidence may not be submitted, and only consultees may appeal.²⁵⁶ He may think this is not how NICE should be handling appeals or that it is inconsistent with the democratic aims of AFR, but NICE's appeal process meets AFR's condition because Daniels and Sabin do not specify an appeals process. NICE has publicised procedures in place that meet the condition. There is a mix here of procedural and substantive concerns, some of which are pragmatic for NICE, like only allowing consultees to appeal and having a fixed time period in which they may do so. The grounds of appeal recognise the problem of reasonable disagreement and the nature of tough decision-making that will always leave someone disagreeing with the result.

More worrying is the concern that NICE's appeal process is not impartial. Hasman argues that because the Appeal Panel is made up of members of NICE, even though they were not on the initial Appraisal Committee, NICE dominates the appeal

²⁵⁵ Culyer, 2006.

²⁵⁶ Schlender, 2008.

process and even concerns about who is on the panel will be internally managed.²⁵⁷

While this does not contradict AFR's Appeals Condition, it looks like a credible threat to NICE's normative legitimacy, and it must convince us that an internal process is fair and unbiased. The challenge principle does recognise that there is an independent option available, which is to challenge NICE in the courts. However, given the expense, this is not an option that is readily accessible to all consultees. The courts have generally supported NICE and do not weigh in on the substantive content of the decisions.²⁵⁸ However, they do enforce NICE's procedure, as with the *Eisai* case, so it is on the first ground of fair treatment that NICE has had to revisit its process and decisions.

NICE elaborates on the Appeals Condition with its challenge principle, stating what options are available to consultees who wish to appeal and making clear that guidance may be appealed. In addition, the challenge principle notes that draft guidance is available for comment, so that consultees, commentators, and the public are able to weigh in on it, in a sense pre-empting appeals. The appeals process also points to the grounds of appeal that are acceptable and how NICE handles unfairness and inevitable substantive disagreement.

7.4.4 Revisions and review

AFR's Revisions Condition (the second part of Appeals and Revisions) requires for there to be available the opportunity to revise decisions, either because of

²⁵⁷ Hasman, 2008.

²⁵⁸ Syrett, "Health technology appraisal and the courts: accountability for reasonableness and the judicial model of procedural justice", 2011.

The courts have generally recognised the need for rationing and so they have weighed in on the procedures used for decision-making, at NICE and for PCTs/CCGs, but they have not (or very rarely) given substantive directives about the outcomes of the decisions. (Newdick, *Who Should We Treat? Rights, Rationing, and Resources in the NHS*, 2005.)

challenge from appeals or because of new evidence or arguments. NICE's review condition builds on this specifying the time scale of regular review, normally three to four years. The review process has not raised any significant criticism or legitimacy concerns, and it is one instance where NICE clearly fulfils AFR's condition. NICE conducts reviews of its guidance three to four years after its publication or if there is significant new evidence, assessing the newly available evidence in order to revise its decision.²⁵⁹ NICE's review condition does not significantly vary from AFR except in specifying the process of review that NICE will use, and like it both are of little interest here.

7.4.5 Regulation

AFR's Regulation Condition, or Enforcement Condition, requires the first three conditions to be enforced and followed. NICE has no corresponding procedural principle, but its processes do include a regulatory step. In addition, it is subject to Department of Health oversight, although the Department has not yet exercised this power.²⁶⁰ However, a critical concern is that here too NICE uses an internal process of enforcement and review. The quality of the guidance and its adherence to process do not necessarily need their own procedural principle and independent oversight if NICE can demonstrate its internal regulation means it consistently follows its procedure.

Before guidance is finalised, the Guidance Executive reviews it in order to ensure that it has met the standards of the appraisal process. The Guidance Executive may return the guidance to the Appraisal Committee and ask it to reconsider its

²⁵⁹ NICE, Guide to the processes of technology appraisal, 2014, 6.1-6.2.

²⁶⁰ Timmins, Rawlins, and Appleby, 2016.

recommendations.²⁶¹ The Guidance Executive is an internal enforcement group that checks each appraisal is carried out to standard and does not come to unreasonable conclusions or exceed NICE's powers. AFR's Regulation Condition is not specific about what form regulation should take, only that there should be either public or private regulation. Therefore, NICE can show that it has met the condition.

The concern about the Regulation Condition and the Guidance Executive is similar to the concern about appeals and their independence. Since enforcement is carried out in-house, its legitimacy may be questioned. For example, the only quality check on the evidence and analysis is what comments stakeholders make contesting it in the draft guidance. It is not clear that NICE in anyway falls short with its enforcement of the procedure, but this is an example where descriptive legitimacy (the perception of it) is threatened. Transparency ought to assure stakeholders that the procedures are followed. However, if concerns persist about internal enforcement, then an effort at independent, external review, perhaps on select appraisals, may help bolster the perception of legitimacy that NICE strives for.

7.4.6 Timeliness and support for implementation—NICE's pragmatic procedural principles

Two of NICE's principles, timeliness and support for implementation, have no correlate in AFR, but they are important for NICE's legitimacy and practical operations. Implementation of NICE guidance remains a challenge. CCGs do not uniformly adopt clinical guidelines and may even be slow to pick up technology appraisals. Implementation particularly affects the pharmaceutical industry's view of

²⁶¹ NICE, Guide to the processes of technology appraisal, 2014, 3.7.38.

For example, in the appraisal of donepezil, rivastigmine, galantamine, and memantine for Alzheimer's, the Guidance Executive sent the FAD back to the Appraisal Committee to resolve concerns about how subgroups were treated in the analysis. (Dillon, "Health Technology Appraisal: Donepezil, rivastigmine, galantamine and memantine for the treatment of Alzheimer's Disease," 2005.)

NICE since after submitting evidence, negotiating discounts, and going through guidance development, the industry is frustrated when there is a slow adoption of its new, recommended technology.²⁶² Implementation puts the recommendations into practice, one more test of their legitimacy, and by implementing them, NICE demonstrates that they are guidelines that should be taken seriously and put to use.

Timeliness requires that NICE publish its guidance in a “timely manner”, but it must balance this need for speed with its other principles that ensure a good process and proper review of the evidence.²⁶³ When new technologies receive market authorisation, there is considerable pressure from patient groups to make them available. When NICE conducts its appraisal, it may face a build up of political and patient pressures around a new technology and its availability. In addition to these pressures, NICE’s process means that access to the technologies is delayed while it conducts its appraisal—the so-called “NICE blight”. Speeding up appraisals became a focus for NICE, and it now begins topic selection for new technologies that will receive market authorisation in order to appraise them sooner, although this does limit the evidence base.²⁶⁴ Because of the political pressures and the need to appraise technologies quickly in order to make them available, timeliness is an important principle for NICE’s perceived legitimacy.

AFR does not include provisions for timeliness and support for implementation, nor are they conditions Daniels and Sabin discuss. However, for NICE both these procedural principles are important for its pragmatic, descriptive legitimacy problems. AFR is a procedural framework, but NICE’s procedural principles are specific to its legitimacy needs—the needs of a public body that must

²⁶² Timmins, Rawlins, and Appleby, 2016.

²⁶³ NICE, Social Value Judgements, 2008, 3.2.

²⁶⁴ Syrett, "Deconstructing Deliberation in the Appraisal of Medical Technologies", 2006; Timmins, Rawlins, and Appleby, 2016.

make actionable decisions promptly while under political pressure and media scrutiny. Timeliness recognises the need for NICE to act quickly while meeting its obligations of procedural fairness and evidence review.

7.4.7 Inclusiveness: participation and responsiveness

AFR does not require public participation, but stakeholder involvement is important to NICE and promotes its legitimacy and perception of legitimacy. The AFR conditions do not require that the public be involved, and Daniels and Sabin have been explicit that public participation will not enhance the legitimacy or fairness of AFR. However, this is one area that has perhaps received the most comment, and many argue that the procedure would be better with public involvement.²⁶⁵ These arguments also extend to its implementation: legitimacy, deliberation, and agreement would be better achieved with public participation.²⁶⁶ NICE's inclusiveness principle calls for the inclusion of "all parties with a legitimate interest in the guidance" to be involved in the decision process.²⁶⁷ Although inclusiveness responds to concerns about participation, it does not give any role to stakeholders in the decision-making itself. It does, however, go beyond the requirements of AFR which do not stipulate any public involvement. The Publicity Condition does not require public participation nor does the Relevance Condition, although discussions of AFR sometimes assume otherwise or argue for its addition.

²⁶⁵ Biron, Rumbold, and Faden, 2012; Emanuel, "Justice and Managed Care", 2000; Rid, 2009; Sabik and Lie, "Principles Versus Procedures in Making Health Care Coverage Decisions", 2008; Shah et al., NICE's Social Value Judgements about Equity in Health and Health Care, 2011; "NICE's social value judgements about equity in health and health care", 2012.

²⁶⁶ Gibson, Martin, and Singer, "Priority setting for new technologies in medicine: A transdisciplinary study", 2002; Syrett, 2002.

²⁶⁷ NICE, Social Value Judgements, 2008, 3.2.

Inclusiveness requires that stakeholders have the opportunity to be involved in the guidance during the process of developing it. Stakeholders have the opportunity to comment on the draft scope, the document that outlines what issues will be looked at in the appraisal, and so shapes what evidence must be considered and what it should be examined for.²⁶⁸ During the appraisal process, drafts of the appraisal consultation document (ACD) are available for consultees, commentators, and the public to comment on.²⁶⁹ The inclusiveness principle encompasses these activities, ensuring that in the process stakeholders may be involved in the scope and ACD.²⁷⁰ When someone comments on the ACD, she may challenge the interpretation of evidence, comment on patient quality of life and need that should be considered, present new evidence if there is a source that has not been considered, or otherwise comment. The Appraisal Committee responds to each comment.

The value of inclusiveness is that it means the recommendations do not come out of a black box, and it strengthens the perception of legitimacy because NICE takes into account other views during its process. Inclusiveness also pre-empts appeals in that consultees have the chance to raise concerns before the final decision is made, whether these concerns are about the interpretation of evidence or unfair treatment. Since the public have an opportunity to comment too, inclusiveness is a way to engage with the whole population who will be affected either directly or indirectly.

Whether people actually do comment is another matter; given the technical focus of the ACD, it is difficult to weigh in on it.²⁷¹ The expertise or at least ability to

²⁶⁸ Guide to the processes of technology appraisal, 2014, 2.5.4.

²⁶⁹ Ibid., 1.12. Consultees include the relevant patient and professional groups, the manufacturer(s), the NHS and CCGs, and others.

²⁷⁰ Social Value Judgements, 2008, 3.2.

²⁷¹ Individual comments often seem to follow a form that look like they may be recommended by patient groups. For example, see the comments on the Mifamurtide ACD: the patients and carers often repeat sentences, suggesting a form letter that was recommended by a patient group. (Mifamurtide for the treatment of osteosarcoma: Response to consultee, commentator and public comments on the Appraisal Consultation Document (ACD), 2010.)

understand the evidence and its analysis poses a barrier to full public participation in the process.

Inclusiveness goes beyond what AFR requires, though it is similar to Daniels's idea of involving stakeholders in determining what the range of relevant reasons for a decision is. Daniels's work increasingly claims that stakeholders should inform the scope of relevant reasons though he does not specify what form the inclusion should take.²⁷² Inclusiveness works towards that since it allows stakeholders a say on the reasons involved in the guidance recommendation. The benefit of inclusiveness then is not the stakeholder as a decision-maker, since it does not give stakeholders an opportunity to participate in the decision-making. The benefit is that stakeholders' reasons are included in the process and can be given fair consideration. Inclusiveness allows NICE to develop its principles and reasons for decision-making, as I will elaborate on below (8.2).

Although not a condition of AFR, inclusiveness builds on the conditions and procedure. For the proponents of greater participation, those who think that it is a good in itself or good for those involved, inclusiveness will not satisfy the need for greater participation and involvement. However, it addresses some of the concerns about NICE's legitimacy by inviting greater involvement, public openness about the process, and the ability for all to engage in the process.

7.4.8 What NICE's procedural principles tell us about AFR

I've made the argument that NICE meets the AFR conditions and supplements them with procedural principles that address its particular legitimacy problems.

²⁷² Daniels, "Capabilities, opportunity, and health," 2010; Daniels, Porteny, and Urritia, 2016.

Concluding this discussion now, I point to the implications of these procedural principles for AFR and for institutions putting AFR into practice.

NICE meets the requirements of AFR with its process of technology appraisal. The process, which is detailed in the *Guide to the processes of technology appraisal*, addresses each condition of AFR, although it does not do so explicitly. NICE only explicitly commits itself to AFR in the *SVJ*, but we can see that it meets the conditions in the construction of its technology appraisal procedure. NICE meets the conditions of AFR as they stand in Daniels and Sabin's account. Claims that NICE fails to meet the conditions take a much more expansive view of them, drawing on elements that are not actually present in AFR. While these are valuable comments on the legitimacy of NICE and its perception, they should not be taken to constitute valid arguments of NICE's failure to implement AFR.

To meet these other descriptive legitimacy concerns, in this case the empirical question of how people view NICE, and those specific to NICE's position as a public body, NICE has its own set of eight procedural principles that its guidance development process must follow. These principles elaborate on the conditions of AFR, which shows us that while AFR provides a framework of procedural justice, it cannot resolve all of the procedural legitimacy concerns NICE faces. NICE must enhance its legitimacy with its own process principles.

NICE is one of the few institutions to explicitly use AFR—it is certainly the most prominent—so its additional principles indicate a challenge to the adequacy of AFR for other institutions. If an institution wishes to use AFR to support its decision-making, it will find that the conditions are inadequate to specify a decision procedure, and it will, like NICE, face criticism about the legitimacy of the decision procedure or reasons it uses. NICE's additional procedural principles provide a starting point that

other institutions may wish to adopt of how the AFR framework can be strengthened and meet the legitimacy problems faced by public decision-makers. Despite raising criticisms of AFR and critiquing the process, I do believe it is the best process framework available for fair and legitimate decision-making, and it is with examples of institutes like NICE that we can strengthen the procedure in order for it to be adopted more widely.

These procedural principles and the framework of AFR are NICE's claim to legitimacy because of its process. NICE uses a process for its decision-making rather than a substantive approach, and so it requires a procedure it can justify as fair and legitimate, which it believes it achieves with AFR and its procedural principles. The next chapters will consider the substantive issues and social value judgements that play a role in NICE's decisions and legitimacy. It is in developing the substantive values that problems for the theory of AFR become apparent in its translation into practice.

8 NICE's relevant reasons

The previous chapter considered the relationship between NICE's technology appraisal procedures and AFR as the basis for the normative legitimacy of priority-setting decisions. I showed how NICE builds on the conditions of AFR with its own procedural principles, which is an implicit criticism of the AFR framework as a pragmatic approach to priority-setting. In this chapter, I turn to the Relevance Condition and how NICE develops the relevant reasons it uses in its technology appraisals.

Daniels and Sabin's fairly thin account of relevant reasons means the requirements of the Relevance Condition are not clear and will pose difficulties for decision-makers who attempt to use them. Given this thin account, it is straightforward for NICE to claim that it uses relevant reasons, but it must provide a more substantial account of how it determines which reasons are relevant and its authority to make these distinctions in order to secure a claim to the normative legitimacy of the reasons it uses. In the previous chapter, I discussed how scientific evidence and rigour contribute to the reasons NICE uses to make decision in the form of evidence about clinical effectiveness and cost-effectiveness. In this chapter, I set aside the discussion of how evidence is analysed and instead focus on the values that inform the decision-making and how those values are adopted as relevant reasons.

In this chapter, I discuss two ways that NICE's Appraisal Committees consider relevant reasons in the process of technology appraisal. The first is what we might call prior relevant reasons; these are the reasons that are included in the *Social Value Judgements (SVJ)* guidance and the *Guide to the methods of technology appraisal*. The *SVJ* includes broad principles and rules about what Appraisal

Committees may and may not take into account when making their decisions. These reasons are “prior” in that they apply and are considered relevant independently of and prior to the specific appraisal. The *Guide* includes specific rules about analysing evidence that will affect important reasons included in the decision, like clinical and cost-effectiveness. The Appraisal Committees consider the relevant reasons included in the *SVJ* and the *Guide*, and because of their enumeration in these guidance documents we can expect that the Committees will take them into account in each appraisal.

I call the second form relevant reasons take in the appraisal “contextualised” relevant reasons. These reasons are considerations specific to the appraisal in question and arise in the process of the appraisal, most notably through the comments and responses on the draft guidance. The Appraisal Committees determine the relevance or not of these reasons, so it is possible that there will be variation between Committees in how they approach and decide on the relevance of such reasons. This distinction between prior and contextual relevant reasons does not mean there is a different standard, rather I wish to draw attention to the two points in the appraisal process where relevant reasons enter into explicit consideration and how this effects the affirmation and legitimisation of the reasons.

How NICE determines relevant reasons falls back to the challenge for AFR I raised in Chapter 5.6. I posed the question: should reasons be mutually justifiable or mutually justified, i.e. is conceptual normative agreement or empirical agreement necessary? Tying into this question is the Citizens Council at NICE. The role of the Citizens Council is unclear. The literature on NICE tends towards viewing the Citizens Council as a way to demonstrate that reasons are mutually justified, but I will argue that the Council fails to provide the necessary legitimacy to claim reasons are

mutually justified. Furthermore, it is not clear how NICE makes use of the Council's recommendations, but it is certain that the Council does not directly determine NICE's relevant reasons as they are in the guidance documents.

I end the chapter with two cases that illustrate the development of relevant reasons in technology appraisals. The appraisal of mifamurtide demonstrates an example of a reason that arose in the appraisal process, like a contextual relevant reason, and was then taken up as a prior relevant reason. This case shows that there is a process NICE uses for incorporating new relevant reasons into its guidance to Appraisal Committees. The second case, the appraisal of acetylcholinesterase (AChE) inhibitors and memantine for Alzheimer's, shows how a reason that is suggested in the *Guide* was interpreted by an Appraisal Committee based on contextual features of the appraisal. However, this case raises concerns about variability since it is not clear when the reason applies and is considered relevant. The cases illustrate that, as with its other areas of decision-making, NICE should use processes to incorporate new relevant reasons into its decision-making if it wants to ensure consistency between Appraisal Committees.

8.1 Prior relevant reasons: the *SVJ* and *Guide to the methods*

NICE contrasts two kinds of value-based decisions it makes. "Scientific value judgements" are judgements about evidence and its analysis. NICE's Appraisal Committees are expert at these. The Committees cannot claim expertise in the second kind, "social value judgements."²⁷³ Social value judgements are judgements about the moral, ethical, and cultural views of society. The claim from NICE that its

²⁷³ NICE Citizens Council, Report on NICE Citizens Council meeting: Quality Adjusted Life Years (QALYs) and the severity of illness, 2008, 3. This forward is repeated in several its reports.

Committees are not expert in social value judgements implies that these values are beyond the epistemological grasp of any one individual. Instead, social value judgements are meant to reflect the general views of society of both what matters morally and also how different considerations ought to be weighed up or balanced against each other. For now, I will set aside the problem of how to make decisions between these values and instead focus on how NICE determines what these social values are that the Appraisal Committees ought to be taking into account. Continuing with my examination of NICE's application of AFR, I consider social value judgements to be relevant reasons because they are the reasons and principles that are acceptable and appropriate to the decision.

NICE commits itself to procedural decision-making, but it must inform its decision-making with substantive principles. The *SVJ* and the principles in it were developed from a national survey on values, expert input, the Citizens Council (discussed further below), and the ethics literature.²⁷⁴ Originally published in 2005, it was revised in 2008. The *SVJ* begins with a framework procedural justice and principles, which I discussed in Chapter 7.4. It then lays out NICE's substantive commitments, which are effectively a set of relevant reasons the Appraisal Committees should consider in their decision-making. I summarise and paraphrase these substantive principles:

I. Secretary of State's Directions to NICE²⁷⁵

When making decisions, appraisals must have regard to

- The balance of clinical benefits and costs
- Patients' clinical need
- Any special directive the Secretary of State issues
- The long-term benefits of innovation to the NHS

II. Principles (as numbered in the *SVJ*)

²⁷⁴ NICE, Social Value Judgements, 2005.

²⁷⁵ Social Value Judgements, 2008, 3.1.

1. There must be sufficient evidence to make a recommendation.²⁷⁶
2. Appraisals will take into account the relative costs and benefits of interventions.²⁷⁷
3. Recommendation decisions should not be based on costs and benefits evidence alone; NICE must consider “other factors”, like “the need to distribute health resources in the fairest way within society as a whole.”²⁷⁸
4. NICE will usually express cost effectiveness as cost per quality-adjusted life year (QALY) gained. “NICE should explain its reasons when it decides that an intervention with an ICER below £20,000 per QALY gained is not cost effective; and when an intervention with an ICER of more than £20,000 to £30,000 per QALY gained is cost effective.”²⁷⁹ (This is the “threshold” I will discuss in chapter 9.4)
5. NICE recognises that individuals will expect to receive treatments that affect their condition, but this does not obligate NICE to recommend interventions that are not effective or are not cost-effective enough.²⁸⁰
6. NICE should respond to and consider comments it receives on its draft guidance, but Appraisal Committees use their own judgment to decide that a treatment is cost-effective, bearing in mind the need to fairly distribute health resources.²⁸¹
7. NICE may only recommend a restriction on an intervention limiting it to a specific group within the approved patient population if there is clear evidence of better efficacy, a legal requirement to do so, or other reasons that relate to fairness. Groups that NICE suggests to protect are based on: race/ethnicity, disability, age, gender/sex and sexual orientation, conditions associated with stigma, behaviour-dependent conditions, and socioeconomic status.²⁸²
8. When choosing guidance topics, developing guidance, and implementing it, NICE should consider reducing health inequalities, including inequalities associated with sex, age, race, disability, and socioeconomic status.²⁸³

III. Other constraints in the *SVJ*

- NICE will strive to respect individual choice and respect for individual’s values, but it may have to limit individual choice in the interests of the whole population at times.²⁸⁴
- NICE will evaluate rare conditions in the same way as other conditions.²⁸⁵

²⁷⁶ Ibid., 4.1.

²⁷⁷ Ibid., 4.2.

²⁷⁸ Ibid., 4.2, p.18.

²⁷⁹ Ibid., 4.2, p.19.

²⁸⁰ Ibid., 4.3.

²⁸¹ Ibid., 5.

²⁸² Ibid., 6.1-6.7, Principle 7.

²⁸³ Ibid., 8.

²⁸⁴ Ibid., 4.3.

²⁸⁵ Ibid., 4.4. Ultra-orphan drugs have their own appraisal process, called the Highly Specialised Technologies Programme, which takes into account the circumstances of extreme rarity that contribute to high pharmaceutical costs and a poor evidence base. (Interim Process and Methods of the Highly Specialised Technologies Programme, 2013.)

- NICE will not use a rule of rescue in its decisions.²⁸⁶

Some of these principles concern the process of appraisal and some of the substantive limitations that may arise, for example requiring sufficient evidence for a decision when the Appraisal Committee makes its recommendation. (Committees may request more evidence from the manufacturer and shelve the appraisal until they are satisfied.) The Secretary of State's directives, that the Appraisal Committees must take into account patient need and the balance of benefits and costs broadly summarises the very problem of priority-setting, which is how to decide between need and the trade-offs of benefits and burdens.

The substantive principles are fairly broad and cover the general considerations the Appraisal Committees should take into account. The Committees must consider cost-effectiveness (and the particular limits of cost-effectiveness, which I discuss in Chapter 9). But in addition, other considerations must be taken into account, though these are not so clearly specified. Fitting into concerns about equality of opportunity, the *SVJ* rules out what we might consider broad unfairness based on arbitrary patient characteristics. NICE may only single out groups in its considerations for clinical reasons related to the effectiveness of an intervention or risks, though even this is not straightforward. The inclusion of age in this category is subject to debate. Proponents of fair-innings style arguments consider age an appropriate consideration for justly distributing resources while others argue its inclusion treats people unfairly and fails to respect individuals.²⁸⁷ (I will further discuss the tensions in NICE over ageism at 9.4). What this shows about these values

²⁸⁶ Social Value Judgements, 2008, 4.5.

²⁸⁷ Harris, "It's not NICE to discriminate", 2005; Bognar and Kerstein, "Saving lives and respecting persons", 2010; Bognar, "Fair Innings", 2014; Dolan, Edlin, and Tsuchiya, The relative societal value of health gains to different beneficiaries, 2008.

Daniels's own views on justice would distribute based on age in his prudential lifespan account (Daniels, *Am I My Parents' Keeper?*, 1988; "Justice between Adjacent Generations: Further Thoughts*", 2008; "Global Aging and the Allocation of Health Care Across the Life Span", 2013.)

in the *SVJ* is that while they are not universally uncontroversial, they are still a broad set. The principles do not, for instance, indicate a hierarchy of principles the decisions should follow.

What I want to draw attention to with the principles in the *SVJ* is that they are what I term ‘prior relevant reasons’. Because they are included in the *SVJ*, they are a set of reasons that all the Appraisal Committees must consider, and they are determined to be relevant prior to the appraisal. (Indeed, the *SVJ* applies to all of NICE’s activities, not just the technology appraisals.) The Appraisal Committees make judgements about new technologies, and they are given leeway to do so. NICE anticipates that its Appraisal Committees will vary in their decisions.²⁸⁸ Procedural justice, on AFR’s and NICE’s account, means that as long as the Committees use relevant reasons and follow the process, they may arrive at different decisions that are reasonable and normatively legitimate. What is important about these prior relevant reasons is that they are relevant reasons each Committee must consider for each appraisal. Unlike a reason that the Committee may decide is relevant in a particular case, these reasons are always relevant and should always be accounted for.

Similarly, the *Guide to the methods* contributes to the prior relevant reasons since its specifications of what evidence should be included and how to analyse the scientific evidence are value-based judgements about evidence that influence how it functions as a reason. For example, QALYs, a tool for evaluating cost-effectiveness, are considered independently of other patient characteristics, reinforcing the *SVJ*’s non-discrimination principles. QALYs may not be weighted to take into account patients’ productivity costs, so the tool does not reflect it and Appraisal Committees

²⁸⁸ NICE, *Guide to the technology appraisal and highly specialised technologies appeal process*, 2014, 4.4.

should not take it into account.²⁸⁹ These sorts of commitments to how evidence is interpreted play out in direct implications for cost-effectiveness and how that evidence informs reasons for deciding to recommend a technology. Because the *Guide to the methods* applies to all technology appraisals, each Appraisal Committee follows its guidelines for appraising technologies. Although these guidelines do not take the form of principles, as with the *SVJ*, they are another form of relevant reason that will be consistently accounted for in each appraisal.

The challenge of legitimately determining what should be in this list of relevant reasons may be one reason they are few and broad. NICE claims normative legitimacy from its procedures, yet the process of developing and amending the relevant reasons in the *SVJ* and the *Guide* is not transparent. Several sources inform the development of the *SVJ*, but how the different principles are decided on and in what form is not shared. As I will illustrate with the example of the mifamurtide appraisal (see below, 8.4), there is a process by which new relevant reasons are incorporated into the list of prior relevant reasons, which implies a process of vetting reasons and deciding which to include. However since this is not shared, it is difficult to judge the legitimacy of this process. This contributes to a tension between public values and expert values, which we will see play out in Chapter 9 with the cost-effectiveness threshold and exceptions to it. Having a process to decide on relevant reasons is consistent with the concept of mutually justifiable reasons as well as mutually justified reasons.

²⁸⁹ *Guide to the methods of technology appraisal*, 2013, 5.4.2, 5.5.12.

8.2 Contextual relevant reasons and the principle of inclusiveness

In the previous section, I argued that the principles and guidelines in the *SVJ* and *Guide* serve as prior relevant reasons because of the role they have in each appraisal. The Appraisal Committees also evaluate reasons and evidence themselves, making determinations of what is relevant. I label the reasons that arise in the technology appraisal process and are specific to the particular appraisal contextual relevant reasons.

Unlike with the prior relevant reasons, we know the source of contextual relevant reasons since they are ones that the Appraisal Committee considers during the appraisal process. It may be the case that the Appraisal Committee takes into account the evidence and decides that a particular element is a relevant reason for its decision. Also likely is that a stakeholder proposes a reason that the Appraisal Committee agrees is a relevant reason. The latter source of reasons stems from NICE's inclusiveness principle.

The *SVJ* and the *Guide to the processes of technology appraisal* require Appraisal Committees to publish draft guidance (the ACD) so that stakeholders can comment on it and then to respond to the comments, as I discussed above (7.4.7). ("Inclusiveness" indicates the inclusion of stakeholders in this drafting process; it is procedural and not a substantive feature of principles.) As a procedural principle, inclusiveness contributes to legitimacy. In this instance, I examine it for its role in developing relevant reasons.

Stakeholder comments on draft guidance are an additional source of relevant reasons. The comments may draw attention to a reason that the Appraisal Committee would otherwise have overlooked, offer arguments for a reason to be considered, and provide alternative interpretations and analysis of evidence. The fair opportunity to

submit relevant reasons as part of a transparent process contributes to the normative (and descriptive) legitimacy of the decision-making.²⁹⁰ With more perspectives weighing in, involving stakeholders is a way to identify the full range of relevant reasons.²⁹¹ Inclusiveness highlights the role of stakeholders in reason gathering rather than decision-making. Comments on the drafts do not give stakeholders a voice in the decision-making itself, but it does give them and the public the opportunity to raise concerns and argue for reasons they consider relevant.

Stakeholder and public comments are a way for Appraisal Committees to expand the scope of the reasons that are considered, but inclusiveness does not mean stakeholders serve any direct role in decision-making. The gathering of reasons is consistent with Daniels's concept of public involvement in AFR, in which stakeholders do not participate in decision-making but may inform the range of relevant reasons.²⁹² This is a distinct condition from publicity and concerns the substantive elements that go into the decision-making.

The Appraisal Committee must respond to these comments and decide whether the reasons are indeed relevant. The reasons may fit into the list of prior relevant reasons, or they may be reasons that the Appraisal Committee considers relevant to the specific appraisal. As the case of mifamurtide illustrates (see Mifamurtide and new relevant reasons), stakeholders may also propose reasons the Appraisal Committee decides should be added to the list of prior relevant reasons.

Unlike with prior relevant reasons, Appraisal Committees themselves determine whether a reason is relevant, and this process is open to variation between Committees. There is no set process by which a Committee decides a reason is

²⁹⁰ Kreis and Schmidt, "Public Engagement in Health Technology Assessment and Coverage Decisions: A Study of Experiences in France, Germany, and the United Kingdom", 2013.

²⁹¹ Clark and Weale, "Social values in health priority setting: a conceptual framework", 2012.

²⁹² Gruskin and Daniels, 2008; Daniels, "Reasonableness and Its Definition," 2010.

relevant, but in providing responses to the comments, they must offer reasonable and defensible comments on the proposed reasons. (It is useful to note that the Committees are bound to be consistent between each other once a decision has been made. For example, in the appraisal of lapatinib, an appeals panel upheld the complaint that the Appraisal Committee had differed from another Committee on defining a “small” patient population, which was relevant to the appraisal under the end of life premium (see 9.6). The Appeal Panel responded that although the Appraisal Committee was reasonable with its definition, it needed to be consistent with the definitions of the other Committee.²⁹³)

Contextual relevant reasons are specific to the decision, so it would be contradictory to specify them all in advance. Because they are not specified prior to the appraisal, the Appraisal Committee determines in the process of appraisal which of the reasons are relevant, in addition to considering the prior relevant reasons. This too is consistent with Daniels and Sabin’s account of AFR, which does not require that the relevant reasons and criteria for decisions be published in advance.²⁹⁴ The inclusion of stakeholder views in the process though allows the Appraisal Committee to be flexible and take in contextual variation of the cases.

Prior and contextual relevant reasons are two different approaches to defining and determining relevance in the process of technology appraisals. Prior relevant reasons rely on determinations of relevance that happens independently of any particular appraisal and applies across all the appraisals. As a result, these principles are fairly broad since they apply in all of NICE’s technology appraisals. Contextual relevant reasons are specific to particular appraisals. It is important to note that prior

²⁹³ Appeal Panel et al., Lapatinib and trastuzumab in combination with an aromatase inhibitor for the first-line treatment of metastatic hormone receptor positive breast cancer which over-expresses HER2, 2011.

²⁹⁴ Daniels and Sabin, *Setting Limits Fairly*, 2008, 12.

and contextual relevant reasons are not different kinds of relevant reasons—I draw the distinction of when they arise in the process, how likely they are to be broad or specific, and the process of defining them.

Relevant reasons are an important feature of AFR and the technology appraisal process, defining what substantive considerations may be used to make a recommendation. I have drawn a distinction between processes of defining those reasons and when reasons enter the procedure. I’ve pointed two sources of reasons—official guidance and stakeholder comments. In the next section, I consider a third source, the Citizens Council, and the role it plays in shaping relevant reasons.

8.3 The Citizens Council

In the previous two sections, I argued there are two sources of relevant reasons for Appraisal Committees, prior and contextual reasons. The Citizens Council, a citizens jury that meets to deliberate on values, is yet another source of reasons. However, the role of the Citizens Council in informing relevant reasons is unclear, and I will argue that it plays less of a determinative role than much of the literature gives it credit for. The Citizens Council does not fit comfortably into NICE’s process as either a means of descriptive or normative legitimacy. It also fails to show that reasons are mutually justified, returning us to the problem of what sort of agreement is necessary for relevance.

NICE justified the establishment of the Citizens Council on two counts: one, since NICE and the NHS are taxpayer funded services, it was important to consider the values and views of taxpayers in making decisions. Two, NICE’s Appraisal Committees are expert at scientific value judgements but not social value judgements, so the Council would provide a reflection of general social values and what values

should inform guidance.²⁹⁵ In order to be informed of social values, NICE turned to citizens' juries as a method for including citizens in decision-making and deliberative democratic practices.

The Citizens Council was in the works early on at NICE with rough plans for it taking shape in a 2000 government report, and it first met in 2002.²⁹⁶ The Council is a group of thirty volunteers who are chosen to represent the public of England and Wales. The members are selected with the aim of representing the demographic and social diversity of England and Wales—age, employment, class, race, gender, and disability are all taken into account—(the very characteristics that are normally excluded from consideration in appraisals!) The Council meets once or twice a year and deliberates on questions set to it by NICE. These questions generally reflect issues NICE currently faces in its appraisals.²⁹⁷ (Appendix 2 gives a table of the topics the Citizens Council has addressed.)

The Citizens Council developed from positive work on citizens' juries as a method of informing policy and determining public views, which NICE wished to incorporate, recognising reasonable disagreement. Methods like polling reveal only superficial preferences, and there is evidence that people's views change when they deliberate.²⁹⁸ In-depth survey methods, like discrete choice experiments, have their own methodological concerns, and responses vary based on the questions and whether people make decisions about their own or group values.²⁹⁹ Citizens' juries bring

²⁹⁵ NICE Citizens Council, Report on NICE Citizens Council meeting: Quality Adjusted Life Years (QALYs) and the severity of illness, 2008.

²⁹⁶ Timmins, Rawlins, and Appleby, 2016.

Timmins also notes that the government report was very vague about the Citizens Council, something he takes credit for as a deliberate plan to allow NICE to design it to suit its institutional needs.

²⁹⁷ NICE Citizens Council, Determining "Clinical Need", 2002.

²⁹⁸ Abelson et al., "Does deliberation make a difference? Results from a citizens panel study of health goals priority setting", 2003.

²⁹⁹ Whitty et al., "Harnessing the Potential to Quantify Public Preferences for Healthcare Priorities through Citizens' Juries", 2014; Hasman, "Eliciting reasons: Empirical methods in priority setting", 2003.

together small groups to discuss a specific issue, like two alternatives for a new policy, and they were gaining traction through the 1990s as a successful way to engage people and produce recommendations for policy-makers.³⁰⁰ The priority-setting literature generally supports the inclusion of the public and public input into decision-making about healthcare services and limits.³⁰¹

The Citizens Council appears to be an exercise in descriptive legitimacy and a process for developing relevant reasons. While there is critical discussion of it, a general trend amongst commentators on NICE is to assume that the Citizens Council directly informs NICE's social values and reasons and is a method of representing the public.³⁰² I will argue that contrary to such views, the Citizens Council does not satisfy any claim to legitimacy and does not appear to have much direct influence on the *SVJ*.

Taken at face value as a means of involving the public in decision-making and reason gathering, the Citizens Council's role would be to show which reasons are mutually justified. In this capacity, it would be a means of testing reasons in order to see which ones people actually do find acceptable, i.e. whether the reason satisfies an empirical standard of what counts as relevant. If that were the case, then we would expect that NICE would adopt those values that the Citizens Council recommended since they would be shown to be mutually justified reasons.

However, the role of the Citizens Council in informing reasons is unclear and certainly limited since NICE does not adopt all of the Council's recommendations.

The *SVJ* and its principles are the moral backbone of NICE, and it is the values and

³⁰⁰ Lenaghan, "Involving the public in rationing decisions. The experience of citizens juries", 1999.

³⁰¹ Kieslich et al., "Public participation in decision-making on the coverage of new antivirals for hepatitis C", 2016.

³⁰² see for example: Soares, "Is the QALY blind, deaf and dumb to equity? NICE's considerations over equity", 2012; Loader, "Is it NICE? The appeal, limits and promise of translating a health innovation into criminal justice", 2010; Taylor, "NICE, Alzheimer's and the QALY", 2007.

principles in this guidance that are most frequently referenced. Although the Appraisal Committees may take the Citizens Council's reports into account, there is not evidence, i.e. reference in the recommendations, indicating that they do, so.

The *SVJ* also does not always incorporate the recommendations of the Citizens Council. Some of the Citizens Council's views are the same or incorporated into NICE's guidance: the *SVJ* principle about age takes the same view as the Council's about when it is an appropriate consideration; the *Guide to the methods* leaves judgements about severity to the Appraisal Committees, which is consistent with the Council's view that it should be considered but not included in the quantitative QALY scores.³⁰³ However, NICE does not adopt all of the Citizens Council's recommendations into the *SVJ* or its guidance to the Appraisal Committees. The Council supported some adoption of the rule of rescue, which they took to mean exceptional cases where there was an imminent threat to life.³⁰⁴ The *SVJ* guidance states that NICE will not adopt a rule of rescue since it must balance commitments to present and future patients.³⁰⁵ What's more, the *SVJ* is infrequently revised, and despite discussion of a 2014 revision programme, no new *SVJ* has been released. There have been at least seven Council reports since the 2008 *SVJ* was published. The Council has also been asked to consider issues after NICE has already made a decision on them, which makes the Council look more like a justificatory strategy to support NICE's decisions rather than the originator of values. It is not clear how NICE would respond if the Citizens Council outright disagreed with its principles.

In addition to its ambiguous role in informing NICE's principles, the Citizens Council lacks legitimacy as a representative of public views, so at best it is another

³⁰³ NICE Citizens Council, NICE Citizens Council Report on Age, 2003; Report on NICE Citizens Council meeting: Quality Adjusted Life Years (QALYs) and the severity of illness, 2008; NICE, Social Value Judgements, 2008; Guide to the methods of technology appraisal, 2013.

³⁰⁴ NICE Citizens Council, NICE Citizens Council Report: Rule of Rescue, 2006.

³⁰⁵ NICE, Social Value Judgements, 2008.

means of gathering potential relevant reasons. The Citizens Council has no formal mandate from the public to represent it, and as a small, self-selecting sample of demographics it is hardly representational.³⁰⁶ Although the members of the Citizens Council report that they benefit from the experience and feel empowered to join in public discourse, the empowerment of thirty people hardly equates to a wider public conversation or increasing the involvement of society in decisions.³⁰⁷ Since the Citizens Council is not representative of the public, it does not legitimately represent the public's views and social values. Therefore it does not provide empirical support for relevant reasons by proving them to be mutually justified.

The Citizens Council is not representative and NICE does not necessarily adopt its recommendations, so the role of the Council is reason gathering. Like the principle of inclusiveness that allows for stakeholders to comment on the draft guidance and offer reasons, the Citizens Council is a way for a small group of citizens to deliberate and propose reasons. Whether these reasons are relevant and should be adopted into the guidance to Appraisal Committees is then determined by NICE's board and advisory bodies. The split between the Council as a source of potential reasons and NICE's experts as determiners of relevant reasons relates back to the discussion in Chapter 5.6: relevance does not require that reasons are mutually justified, which would mean proving that people do indeed agree to their relevance and acceptability. Instead, relevance requires that reasons are mutually justifiable, a conceptual threshold of what ought to be reasonable and acceptable.

³⁰⁶ Kreis and Schmidt, 2013; Barham, "Public and Patient Involvement at the UK National Institute for Health and Clinical Excellence", 2011.

³⁰⁷ Davies et al., *Opening the Box: evaluating the Citizens Council of NICE. Report prepared for the National Coordinating Centre for Research Methodology, NHS ...*, 2005.

Davies also points out that given the expense of running each meeting of the Citizens Council, the public would be right to question the benefit of the project. (I do not mean to suggest that Davies claims the Council is not worth the cost, but he does point out that it is expensive deliberation.)

If relevant reasons are mutually justifiable, the challenge for NICE shifts from implementing the Citizens Council to demonstrating the normative legitimacy of the process by which its board and Appraisal Committees determine which reasons are relevant. In contrast to NICE's usual commitment to transparency about its procedures, it has not stated how it determines relevant reasons. NICE would have a stronger claim to legitimacy if it were to share its deliberations on determining reasons and the recommendations of the Citizens Council.

8.4 Mifamurtide and new relevant reasons

In the previous three sections, I have argued that NICE develops its relevant reasons in two ways as either prior or contextual relevant reasons. Contributing to prior relevant reasons is the Citizens Council, which is credited with shaping NICE's values but actually plays a more ambiguous role in informing relevance. To conclude the chapter, I return to this distinction between prior and contextual reasons and turn to two cases that illustrate their development.

My discussion of these cases is based on NICE's published appraisal documents. I refer to the documents that NICE publishes throughout the appraisal process, like the scope, evidence submissions, comments and responses, and draft and final guidance, to inform this section and the next. It is true that these are cleaned up, public ready documents. The value in them is that they are NICE's own account of what it does.

NICE's appraisal of mifamurtide for osteosarcoma illustrates some of the features of NICE's use of relevant reasons I described in the previous sections. Stakeholder comments on the ACD highlighted features of the appraisal that challenged the relevance of a prior relevant reason in this case. The Appraisal

Committee accepted this alternative relevant reason and initiated a process to change the guidance in the *Guide to the methods* before adopting the new relevant reason in the appraisal.

Mifamurtide, brand name Mepact and manufactured by Takeda, was the first new therapy for osteosarcoma in twenty years. Osteosarcoma is a rare bone cancer that affects children and young adults. Treatment aims at cancer remission and limb salvage, and what is striking about it is that patients who are successfully treated and recover with no five-year recurrence go on to live full, healthy lives at normal life-expectancy.³⁰⁸ Mifamurtide increases survival rates, reducing the risk of death, meaning that more patients are likely to be effectively cured.³⁰⁹

I will discuss the details of QALYs and ICERs in Chapter 9. For now, it suffices to say that QALYs are a measure of clinical effectiveness and the ICER is the ratio of the effectiveness to its cost. A treatment that has a greater increase in QALYs for the same cost will have a lower ICER. For calculating QALYs, NICE uses a future benefits discount rate. The discount rate is based on Treasury guidance to government agencies to use a 3.5% discount rate on future costs, and NICE also applies this to benefits, meaning each subsequent year of benefits is counted as 3.5% less than the preceding year.³¹⁰ The justification for the discount rate is both economic and value driven: it predicts anticipated economic growth and reflects a general social preference for having benefits now rather than at a future point.³¹¹ The

³⁰⁸ NICE, Single Technology Appraisal: Mifamurtide for osteosarcoma, 2008; Mifamurtide for the treatment of osteosarcoma: Response to consultee, commentator and public comments on the Appraisal Consultation Document (ACD), 2010; Mifamurtide for the treatment of osteosarcoma, 2011.

³⁰⁹ Mifamurtide for the treatment of osteosarcoma: Response to consultee, commentator and public comments on the Appraisal Consultation Document (ACD), 2010; Final appraisal determination: Mifamurtide for the treatment of osteosarcoma, 2010.

³¹⁰ Guide to the methods of technology appraisal, 2013, 5.6.

³¹¹ NICE Citizens Council, How should NICE assess future costs and health benefits?, 2011; Williams, "The value of QALYs," 2012.

discount is included in the *Guide to the methods*, which means it acts as a prior relevant reason shaping the evidence analysis.

The principle of inclusiveness gives stakeholders and the public the opportunity to comment on the ACD, and their comments on the mifamurtide appraisal focused on the discount rate. Stakeholders wrote to argue that the future benefits discount was not relevant in the mifamurtide appraisal because it was an unreasonable way to assess the benefit of the treatment. Compared to other cancers that use measures of five-year survival rate, five-years was the baseline for successful treatment in this case and the main benefit of treatment was that patients would go on to live normal lives.³¹² Because of the future benefits discount, the value of these future QALYs was decreased, and so the initial economic evaluation concluded mifamurtide was not cost-effective and should not be recommended.³¹³

Responding to the reasons the stakeholders proposed, the Appraisal Committee was consistent with the prior relevant reasons in NICE guidance. The *SVJ* does not allow distinctions to be made between patient groups based on the age of the patients unless it directly affects clinical effectiveness or risk. Even though osteosarcoma affects people aged 2-30, the Appraisal Committee did not seek to revise its relevant reasons based on the age of the patients. In keeping with the *SVJ* no special consideration was given to the rarity of the condition, even though Takeda, the manufacturer, argued that it should be because of the smaller evidence base and higher market price due to a small patient population. The Appraisal Committee responded that the *SVJ* requires appraisals to be treated the same regardless of

³¹² NICE, Mifamurtide for the treatment of osteosarcoma: Response to consultee, commentator and public comments on the Appraisal Consultation Document (ACD), 2010; BCRT Trustees, Bone Cancer Research Trust and Sarcoma UK submission, 2010; Hurst, Osteosarcoma-mifamurtide: expert written personal statements-Hurst, 2010; Francis, "Osteosarcoma-mifamurtide: expert written personal statements-Francis", 2010.

³¹³ NICE, Osteosarcoma-mifamurtide: appraisal consultation document, 2010; Final appraisal determination: Mifamurtide for the treatment of osteosarcoma, 2010.

rarity.³¹⁴ This is a demonstration of formal fairness and also the consideration of prior relevant reasons; age and rarity are not reasons about which the Appraisal Committee may vary its judgements of relevance.

The future benefits discount rate is also a prior relevant reason, so the Appraisal Committee did not use its judgement to override or alter the reason, instead taking it to NICE's advisory body for revision. As a prior relevant reason, one in the *Guide to the methods*, the future benefits discount rate applies to all appraisals. This is different from a contextual relevant reason, which would be relevant in the specific case. Between the release of an initial FAD (October 2010) and a second one (August 2011), NICE revised its methods. In July 2011, NICE published a clarification to the *Guide to the methods of technology appraisal* that addressed the discount rate. The Treasury rate of 3.5% was still generally applicable, but:

Where the Appraisal Committee has considered it appropriate to undertake sensitivity analysis on the effects of discounting because treatment effects are both substantial in restoring health and sustained over a very long period (normally at least 30 years), the Committee should apply a rate of 1.5% for health effects and 3.5% for costs.³¹⁵

The mifamurtide appraisal introduced contextual features that challenged the broad relevance of the future benefits discount rate. The revision to the *Guide* recognises that there will be circumstances in which the discount is not relevant because of the long-term benefits of treatment compared to others that offer mostly short term benefit.

Although NICE includes the alternate discount rate in its prior relevant reasons, there is reasonable disagreement about whether discount rates should be

³¹⁴ Mifamurtide for the treatment of osteosarcoma: Response to consultee, commentator and public comments on the Appraisal Consultation Document (ACD), 2010.

There is a separate process, the Highly Specialised Technologies Programme (HST) for ultra-orphan conditions and their treatments. As several stakeholders voiced, including Takeda, it is not clear why mifamurtide was referred to NICE for a standard appraisal rather than as an ultra-orphan condition to be considered under the HST process.

³¹⁵ Discounting of health benefits in special circumstances, 2011.

varied. Discount rates appear to be a different sort of reason than non-discrimination principles, but I include them here as relevant reasons because the discount affects the evaluation of cost-effectiveness, a reason NICE heavily considers in its appraisal process. Therefore, deciding whether or not to use a discount and how much it should be is a decision about how to value the benefits of a treatment and the reasons for recommending it or not. A lower discount rate means that a treatment may meet a lower threshold of cost-effectiveness (I will discuss the explicit threshold in Chapter 9). The concern here is that using the different discount rates means that some people's QALYs are counted for more than others'.³¹⁶ Opponents of different discounting argue that it is effectively age discrimination since the conditions for using the lower rate require a thirty-year survival benefit.³¹⁷ There is reasonable disagreement over whether different thresholds, achieved via different discount rates, should be used.

Deciding what counts as relevant reveals more layers of reasonable disagreement within a priority-setting decision. When there is reasonable disagreement about the decisions, Daniels and Sabin argue we need a fair and legitimate procedure to make a decision. But, within that procedure new areas of reasonable disagreement arise. Clearly, there cannot be an endless regression of procedures. However, given the disagreement that exists, NICE should publicise how it decided on new relevant reasons. Since the process of deciding on the new discount rate was not publicised, greater transparency and sharing of reasons motivating the different rates would strengthen NICE's normative legitimacy here.

After introducing the lower future benefits discount, NICE turned to the Citizens Council, which provided a justification for it after the fact. As I argued

³¹⁶ Paulden et al., "Some Inconsistencies in NICE's Consideration of Social Values", 2014.

³¹⁷ O'Mahony and Paulden, "NICE's Selective Application of Differential Discounting: Ambiguous, Inconsistent, and Unjustified", 2014.

above (8.3), the Citizens Council's role in relation to NICE's values is unclear, and this case illustrates that. The Citizens Council consulted on the discount rate several months after the addendum and FAD were published.³¹⁸ The Council agreed that future benefits should be discounted and that there were conditions when a different rate should be used, including preventive treatment, upfront costs for long-term gains, and the treatment of children. (The Council did not feel qualified to state what the rates should be.)³¹⁹ I have argued that the Council does not serve to demonstrate that reasons are mutually justified. In this instance, the Council affirmed the reasons proposed in the ACD comments, so we can view it as a further illustration of reason gathering and arguments for the relevance of certain reasons in specific cases.

The technology appraisal of mifamurtide illustrates the role of prior relevant reasons in technology appraisals and the revision of one of these reasons based on contextual features of an appraisal. Because of NICE's principle of inclusiveness, the Appraisal Committee heard proposals for reasons that should be relevant in the case based on the specific features of the condition and technology compared to other appraisals. The Appraisal Committee decided that these were relevant and used an internal process at NICE to amend the guidance on evidence analysis, which affects the reasons for making a recommendation or not. The mifamurtide appraisal highlights the role of prior relevant reasons and the process of revising them. The appraisal case in the next section, considers how contextual relevant reasons are specified.

³¹⁸ NICE Citizens Council, How should NICE assess future costs and health benefits?, 2011.

It may be that one part of the NICE process moved faster than the other; since the Citizens Council meetings are prepared well in advance, it may have been intended to precede or coincide with the addendum and FAD, although even though it would look like a weak justification.

³¹⁹ Ibid.

8.5 Appraising Alzheimer's

In the previous section, I examined a case of prior relevant reasons, i.e. reasons that apply across all appraisals. In this section, I turn to contextual relevant reasons, the reasons that arise in specific cases. NICE gives clear guidance to Appraisal Committees about how they should evaluate future benefits, but when it comes to evaluating benefits to people other than the patient, there is not clear guidance, so it is left to the Appraisal Committee. NICE initially appraised treatments for Alzheimer's in 2006, with updates in 2007, 2009, and 2011. (In 7.4.1, I briefly touched on the court case related to this appraisal, but I set it aside in the discussion here.) In the appraisal of the treatments for Alzheimer's the Appraisal Committee took into account the benefit to carers that results from treatment. Including these benefits is an instance of the Appraisal Committee determining that the benefits were relevant to the appraisal and should be included in the relevant reasons considered in the deliberation. This is a contextual relevant reason, but it also raises questions about the inclusion of others' benefits in other appraisals and how these should be evaluated.

In the UK, dementia is the most expensive mental health condition for the NHS; there are around 800,000 people living with dementia, of which Alzheimer's accounts for half the cases.³²⁰ As the disease progresses, a person loses her cognitive ability (memory and reasoning) and functional abilities, i.e. being able to do daily activities of living—hygiene, mobility, etc. Other symptoms are changes in behaviour and mood.³²¹ Management of dementia involves treating cognitive, behavioural, and psychological symptoms and supporting the affected person with

³²⁰ McCrone et al., *Paying the Price*, 2008; Kane and Cook, *Dementia 2013: The hidden voice of loneliness*, 2013; NICE, *Health Technology Appraisal: Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease (Review of TA 111)*, Final Scope, 2009.

³²¹ *Health Technology Appraisal: Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease (Review of TA 111)*, Final Scope, 2009.

increased assistance with daily activities, home nursing and personal care, community services, day centres, respite care, and care homes.³²² Alzheimer's is a costly and demanding illness, and as it progresses, patients become increasingly dependent on the care and services of others.

The NICE technology appraisal considered four pharmaceutical treatments for Alzheimer's, which reduce the symptoms of the disease. Three acetylcholinesterase (AChE) inhibitors: donepezil (brand name Aricept, manufacturer Eisai), rivastigmine (Exelon, Novartis), and galantamine (Reminyl, Shire) and a fourth drug memantine (Ebixa, Lundbeck).³²³ The 2011 guidance recommends the AChE inhibitors for mild to moderate Alzheimer's and memantine for severe Alzheimer's or those who cannot tolerate the side effects of the AChE inhibitors.³²⁴ The drugs do not cure the disease, but they may slow its progression, and they help mitigate the symptoms like decline in cognition, function, and behaviour.³²⁵ The primary benefit of these drugs is that they delay the symptoms of Alzheimer's, making a person more lucid and with higher functioning and better behaviour for a longer period of time while the disease progresses.

The Alzheimer's treatments benefit patients by delaying their symptoms, and this in turn benefits the people who care for the patients. Alzheimer's dementia is a care intense condition, and patients require increasing amounts of support from carers as it progresses. Much of the care for Alzheimer's patients comes from 'informal carers', usually family members. The estimate is that there are 670,000 informal

³²² Ibid.

³²³ Ibid.

³²⁴ NICE technology appraisal guidance 217: Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer, 2011.

This was the second appraisal for this group of drugs and replaced earlier, revised guidance that had already been amended twice.

³²⁵ Priaulx and Donegan, Overview: Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease, 2010.

carers who save the state £8 billion a year in costs.³²⁶ When middle-aged children take care of their older parents, some are forced to give up working in order to care for the person with Alzheimer's.³²⁷ Informal carers contribute significantly to the care of patients and also to the NHS since they relieve it of providing care.

Since there are apparent and quantifiable benefits to carers, this appraisal raises the question whether those should be included in the evaluation of the technology. The reference case for technology appraisals generally looks at health-related quality of life and benefits not captured in the QALY for the patient who is being treated, but in the Alzheimer's appraisal health-related quality of life for carers was included too. Carers of Alzheimer's patients have increased rates of depression, anxiety, illness, social isolation, and use more prescriptions and GP visits, indicating an emotional and social burden as well as one that affects the health of the carers.³²⁸ Treatment of people with Alzheimer's improves carers' quality of life by reducing the demands on them. (One study cited that carers gained up to two hours a day when they did not have to actively be helping someone, a significant reduction in their caring time.³²⁹) There is no set rate of how much carer utility should count for or even when it should be included in an appraisal. The manufacturer model for donepezil, for example, included carer utility as 10% of the overall utility, i.e. total

³²⁶ Kane and Cook, 2013.

³²⁷ Iliffe, "The National Institute for Health and Clinical Excellence (NICE) and drug treatment for Alzheimer's disease", 2007.

³²⁸ NICE, Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease (review of TA111): Response to consultee and commentator comments on the draft scope, 2009; Ballard, Sorensen, and Sharp, "Pharmacological therapy for people with Alzheimer's disease: The balance of clinical effectiveness, ethical issues and social and healthcare costs", 2007.

One estimate put carer utility at 0.87 QALYs for a carer of someone with moderate dementia and 0.86 QALYs for a carer of someone with severe dementia. Another showed QALY benefit difference of treatment with donepezil from an increase of 0.109 to 0.121 QALYs when carer utility was included (Priault and Donegan, 2010, 3.2.6; NICE, 2011.).

³²⁹ Ballard, Sorensen, and Sharp, 2007.

QALYs, which the AG/ERG accepted into its analysis.³³⁰ In the FAD, the Appraisal Committee states that it did take into account carer utility.³³¹

NICE does not have clear guidance on when to consider carer utility.³³² The reason it is important to determine whether carers are relevant is that including their utility makes the technology more cost-effective since there are more QALYs gained for the same cost. The Appraisal Committee recognised that including carers affected the evaluation of cost-effectiveness, i.e. the ICER.³³³ Whether to include carers was a decision left to the Appraisal Committee, so the Committee had to determine whether carer benefit is relevant.

The Appraisal Committee decided that including carer benefits was relevant in the appraisal, and this is an example of a contextual relevant reason. Carer benefits are not always included in appraisals, but in this circumstance and given the large burden on carers, the Appraisal Committee judged it was relevant.

One concern about a contextual relevant reason like carer utility is how to account for it across conditions. Those conditions that have a higher carer burden will be given more weight if benefits to multiple people are counted. Caring is a socially dependent feature of a condition and will apply only in cases where patient groups are likely to have informal carers or may be more reliant on them, like the elderly and children.

Another question that will arise is what sort of carer burden should be considered relevant. Unusually, in the FAD for mifamurtide, discussed above, the Appraisal Committee took into account the effect on the patient's family due to illness

³³⁰ Priaux and Donegan, 2010, 3.2.3; NICE, 2011.

³³¹ 2011.

³³² I am grateful to G. J. Melendez-Torres for drawing my attention to this and discussing the point with me.

³³³ Priaux and Donegan, 2010.

and the death of a young family member.³³⁴ In that appraisal the Committee included considerations of the family's welfare without specifying health-related quality of life benefits. In contrast, the Alzheimer's appraisal focused on quality-of-life benefits to carers. This highlights the judgement exercised by the Appraisal Committee's in determining how to value burdens on third parties. It also calls into question formal fairness between appraisals, especially as these benefits may not be readily comparable.

The challenge for contextual relevant reasons is when they may be excluded from consideration without violating formal fairness. In this case, we would want to see the Appraisal Committee justify why carers should be considered in this particular appraisal even if their benefit is not included in other appraisals. The appraisal leaves us asking who should be counted and when. The articulation of the reason in this particular appraisal does not determine it for all appraisals, as a contextual relevant reason, it addresses particular features of this decision.

Contextual relevant reasons will require careful scrutiny of the particular circumstances and a justification of the appropriateness of the reason in that instance in order to respect formal fairness. Committees should be prepared to justify why they consider a reason relevant when it may not have applied elsewhere or be a deviation from other decisions. When the Appraisal Committee's use their judgement to determine what is a relevant reason based on the features of the appraisal case, they need to provide a robust justification of the relevance of the reason in order to secure the normative legitimacy of their decision-making.

³³⁴ NICE, Mifamurtide for the treatment of osteosarcoma, 2011, 4.14.

In this chapter, I have examined how NICE determines relevant reasons and the ways in which Appraisal Committees adopt relevant reasons and define new ones. I began with a distinction between prior and contextual relevant reasons that signals not a difference in their content or force but in what part of the process they arise and whether they are reasons that are general to all technology appraisals or specific to some.

As I argued in Chapter 5, Daniels and Sabin leave the question of how to determine relevant reasons open in their account of AFR. NICE can demonstrate that it meets the conditions of AFR, yet it still must develop a robust process for vetting and justifying the reasons it uses. While the Citizens Council may appear to be one such process for developing reasons, it has an ambiguous relationship to NICE's statements of principles and reasons in the *SVJ* and *Guide to the methods of technology appraisal* and serves more as a resource to gather potential reasons than to determine which reasons are relevant. This leaves open the problem of how NICE secures the normative legitimacy of its relevant reasons. There are two points at which relevant reasons enter the appraisal process, either prior to it with the reasons outlined in the guidance or during the process. NICE should be more transparent, in keeping with its procedural principles, about how it determines relevance.

In Chapter 6, I argued that normative legitimacy requires that decision-makers give fair consideration to relevant reasons. So far, I have discussed how NICE determines the content of those reasons, and in the next chapter I take up the issue of the consideration NICE gives to the reasons in its appraisal process.

9 Fair consideration and the cost-effectiveness threshold

In this chapter I bring together the arguments of chapters 6 and 8. In the previous chapter, I discussed how NICE develops its range of relevant reasons and allows the Appraisal Committees to determine which reasons are relevant in the context of a particular appraisal. A central focus of NICE's relevant reasons is the *SVJ* and *Guide to the methods of technology appraisal*, guidance documents that list specific reasons that should be taken into consideration in technology appraisals. Taking NICE's relevant reasons, I now look at how these fit into the account of AFR plus fair consideration that I gave in Chapter 6. There, I argued that normative legitimacy requires decision-makers to give fair consideration to all relevant reasons.

In this chapter, I will argue that although NICE is set up for its Appraisal Committees to be able to practice fair consideration of reasons, the inclusion of a cost-effectiveness threshold in the *SVJ* and *Guide* means that NICE cannot properly engage in fair consideration in the appraisal process. I begin with an overview of the structure in place that looks like it should promote fair consideration. I will then explain how NICE uses QALYs and the ICER, and how these contribute to a cost-effectiveness threshold, i.e. an upper limit defining what is considered cost-effective. The threshold means that NICE privileges cost-effectiveness over other considerations, and it begins each appraisal with a presumption in favour of cost-effectiveness. An additional concern is that since some relevant reasons are in the *SVJ* there seems to be an implicit emphasis given to them rather than contextual relevant reasons.

I conclude the chapter with an illustration of the debate about the threshold as it has been extended for the "end-of-life premium". If certain conditions are met, then there is a higher threshold in place. While this looks initially like fair consideration, it

is a problematic exception to the threshold that raises questions about formal fairness and fair consideration in NICE's appraisals.

I start by bracketing the issue of the cost-effectiveness threshold, and will argue as if it is consistent with fair consideration in order to focus on the procedure NICE uses and what about it is conducive to fair consideration. In the next section, I will first explain the origins of the threshold and then take it up as a serious problem for fair consideration.

9.1 The potential for fair consideration in the appraisal process

The substantive commitments of NICE and its procedural principles show the elements necessary for fair consideration are present in its principles and the appraisal process. The *Guide to the methods of technology appraisal* and the *SVJ* both include principles and directions to the Appraisal Committee that would indicate fair consideration in the appraisal process. Requirements to consider a range of relevant reasons and not give any particular reason sole consideration in a decision support the process of fair consideration.

As discussed in chapter 7.4.2, the Appraisal Committee members do not serve as representatives of a particular view or of society generally. Rather, the member's role is to consider principles and evidence, like those in the *SVJ*, and evaluate them for each decision. The remit of the committee members is consistent with what fair consideration requires of decision-makers with regard to their (non) representativeness. As reasonable decision makers who give fair consideration to reasons, they take seriously each reason, but they do not from the outset serve as representatives or advocates of particular reasonable views.

The *Guide to the methods* and principle 3 of the *SVJ* direct Appraisal Committees not to rely solely on cost-effectiveness and to take other considerations into account when making a recommendation. (For the list of principles, see 8.1) This is stated in the *SVJ*, and the *Guide to the methods* requires the Appraisal Committees to consider the social value principles from the *SVJ* as well as those expressed by the Citizens Council and human rights legislation.³³⁵ Though, as I argued in Chapter 8.3, the Citizens Council appears to have little direct effect. The *Guide* recognises that there are many kinds of benefits to healthcare, and these are not all captured in QALY calculations. QALYs are meant to be a starting point of consideration and assist in thinking through the problems of allocation rather than making thinking redundant with a rule based system.³³⁶ Other considerations that are not included in the QALY must also be accounted for and are usually not quantitatively measured. Indeed, NICE has repeatedly decided not to numerically weight other values and considerations, like need, severity, and non-health benefits.³³⁷ Without numerical weightings how these other considerations are to be valued is unclear.³³⁸ Instead, the Appraisal Committees are required to take these other considerations into account alongside cost-effectiveness. Because not every reason is quantified, the Appraisal Committee must use its judgement about the reasons—the values and evidence. Practically this poses a challenge for the decision-makers who must compare quantitative and qualitative entities. The Appraisal Committee is expected to consider a range of reasons, like those in the *SVJ* and the Secretary of

³³⁵ Guide to the methods of technology appraisal, 2013, 1.4.4, 6.1.8, 6.2.20.

I have yet to find an instance in which an Appraisal Committee cites a Citizens Council report to justify a decision. I welcome an example.

³³⁶ Culyer, 2006.

³³⁷ Shah et al., NICE's Social Value Judgements about Equity in Health and Health Care, 2011; NICE, Guide to the methods of technology appraisal, 2013; NICE Citizens Council, Report on NICE Citizens Council meeting: Quality Adjusted Life Years (QALYs) and the severity of illness, 2008.

³³⁸ Shah et al., NICE's Social Value Judgements about Equity in Health and Health Care, 2011.

State's directives, demonstrating a commitment on the part of NICE to give consideration to its full range of relevant reasons.

Principle 6 of the *SVJ*, which requires the Committees to consider and respond to comments, and the procedural principle inclusiveness both provide opportunities for the Appraisal Committees to practice fair consideration. The process of appraisal gives stakeholders and the public the opportunity to comment on the appraisal. I suggested above that this provides an increased range of potential relevant reasons. Inclusiveness also allows stakeholders to challenge interpretations of evidence and the conclusions drawn from it. The public comments and Committee's responses are an exchange of reasons reinforcing the idea of fair consideration because of the Committee's duty to respond. The Committee must give an explanation of how it has considered each comment, either incorporating it into its considerations or arguing why it is not the appropriate reason or way to interpret the evidence. Principle 6 highlights the consideration given to reasons expressed in the comments since NICE not only must respond to them, as inclusiveness requires, but also "consider" the comments, though the nature of that consideration is not specified.

While the requirement to use other considerations and respond to comments cannot assure us that the Appraisal Committees will give fair consideration to reasons, the framework is there for them to do so. We know that they must take into account the principles in the *SVJ* with its set of prior relevant reasons NICE regularly draws on. In addition, they must take into account the comments on the draft guidance, which means that they must give consideration to the reasons proposed by stakeholders and members of the public that will be specific to the appraisal. In published guidance, the Committee shares its reasoning about the decision, which provides an opportunity to account for how it used the reasons and balanced them

against one another. The framework for fair consideration is there—relevant reasons, a means of demonstrating consideration both in responses and the final guidance. The Appraisal Committees ought to be able to give fair consideration to relevant reasons.

However, cost-effectiveness remains the primary focus for NICE’s appraisals, and the cost-effectiveness threshold embodies the primacy of this reason. Indeed, even when taking into account other considerations, these are always weighed up against cost-effectiveness in what looks like an adversarial approach to decision-making. Therefore, in the next section I will consider the threshold and how it means fair consideration cannot be achieved. We will look at positions in support of the threshold, and then the argument why having a threshold at all and the presumption of cost-effectiveness limits NICE’s claim to normative legitimacy and fairness. First though, I will briefly explain NICE’s approach to cost-effectiveness and the threshold.

9.2 QALYs are a tool for cost-effectiveness

The quality-adjusted life year (QALY) is the measure NICE uses to assess health benefits, but the QALY as a measure is a source of disagreement. There is disagreement about both using QALYs and the methodology to calculate them.

QALYs are a measure of health-related quality of life, developed during the 1960s and 70s, as a means to compare different health states. QALYs assess the “utility” of health states: an idea of how good the health state is judged by the quality of life of that state.³³⁹ One year of healthy life expectancy is worth 1.0, a year of unhealthy life expectancy is worth less than 1.0, death is worth 0.0, and the value in between is adjusted based on health -related quality of life.³⁴⁰

³³⁹ Nord, *Cost-Value Analysis in Health Care: Making Sense out of QALYs*, 1999.

³⁴⁰ Williams, 2012.

The adjustments based on quality of life are calculated using several methods that require surveying people about their preferences. Because of how people make these judgements and who is asked, there is methodological concern around what QALYs measure and how they do so. QALYs aggregate and average out individual preferences and apply them to groups, so they do not reflect specific individual's preferences or even community values.³⁴¹ Standard gamble and time trade-off approaches ask respondents about their willingness to sacrifice length of life for quality of life based on specific conditions. A third approach uses rankings of various health states to classify them.³⁴² Yet another approach tries to objectively score health states based on a questionnaire, the EQ-5D, and scoring these results requires a value judgement about quality of life and its worth.³⁴³ Who is asked will give different results too; it is well known that people rank disabilities, like loss of mobility, at a greater disutility before they have experienced them than after, so using scoring from people before they have experienced an event will result in different outcomes than post-event scores.³⁴⁴ Who is asked becomes an important methodological issue for QALYs.

QALYs have built in assumptions; by valuing time, for example, they will tend to favour health gains to the young who have a greater life expectancy. QALYs also do not take into account the initial severity of an illness. These are value choices about what QALYs should include that were made by the originators of the QALY in the 1960s and 1970s, and they do not reflect societal value preferences.³⁴⁵ These comments are to point out that although the QALY is used as an 'objective' measure

For example, five years of life lived at full quality, would give 5 QALYs: $5 \times 1.0 = 5$ QALYs. Ten years of life lived at an adjusted quality of 0.5 also gives 5 QALYs: $10 \times 0.5 = 5$ QALYs.

³⁴¹ Ubel, *Pricing Life: Why It's Time for Health Care Rationing*, 2000.

³⁴² Nord, 1999.

³⁴³ Cookson and Culyer, "Measuring overall population health: the use and abuse of QALYs," 2009.

³⁴⁴ Wolff, "Measures of health and the value of healthcare" 2016.

³⁴⁵ Nord, 1999.

of health benefit and utility, it is a construct that has built in value assumptions and methodological disagreement.

QALYs are not themselves a distributional measure, but they tend to be used as the basis for cost-effectiveness analysis since they quantify health states and benefits and can be used across health conditions. Here, I want to briefly touch on some of the arguments concerning QALYs in order to illustrate the kind of reasonable disagreement there is about them.

Proponents of QALYs argue that they are egalitarian since they only look at health states and treat all health gains the same no matter who they benefit. The opponents of the QALY argue this is misleading and raises problems for fairness. For example, QALY benefits may be aggregated, which leads to some counterintuitive outcomes and the objection that they fail to treat people with equal respect. Curing many people of a sore throat or adding one month to the life of many people could outweigh saving someone's life or adding ten years of life for just a few people. These aggregations strike many as wrong since they allow discomfort of the many to outweigh significant benefits to a few.³⁴⁶ But where the distinction between these falls is unclear; some people consider that extra month of life significant and worth such trade-offs while others do not. The other argument against aggregation is that it fails to treat people equally since aggregating the time they have left to them and the quality of that time ignores their equal interest in being alive.³⁴⁷

An argument against QALYs of particular relevance to NICE is that they discriminate against the elderly and the disabled. Because QALYs add up time, they

³⁴⁶ Kamm, 1999; McKie and Richardson, 2003.

³⁴⁷ Harris, "Life: quality, value and justice", 1988; "More and Better Justice," 1988.

A variation on this argument is that QALYs fail to recognise the 'separateness of persons', the argument Rawls uses against utilitarianism. Daniels makes this Rawlsian argument against cost-effectiveness analysis as a form of decision-making (Daniels, "Distributive Justice and the Use of Summary Measures of Population Health Status," 1998. See too Rawls, *A Theory of Justice*, 1999.)

will favour people with more years of life to be gained from treatment and so will be inherently ageist. If NICE uses QALYs then it looks like it has accepted a discriminatory tool at its core.³⁴⁸ Similarly, someone who is disabled cannot achieve as high a QALY score from the same treatment as someone who is not disabled, for example from a treatment that will additionally restore the person's mobility that the disabled person never had. QALYs risk discriminating against the disabled.³⁴⁹ Both these claims would be contrary to NICE's substantive commitments in the *SVJ* not to discriminate by age or disability.

NICE's defence of its use of QALYs is that it has taken account of the weaknesses of the QALY in order to avoid discrimination. Appraisal Committees use their judgement and discretion in cases where there is the risk of discrimination and do not rely on QALY calculations alone.³⁵⁰ QALYs are not a distributive principle themselves, and we only care about them because they help us to achieve our ends, like maximising health benefits or comparing interventions.³⁵¹ QALYs are a practical tool, and since NICE must make decisions its chairman has defended the use of measures like the QALY. Committees do not have the luxury of extended philosophical debate.³⁵² NICE therefore relies on QALYs as a comparative tool.

NICE uses QALYs in its cost-effectiveness calculations, a considerable piece of evidence in its decision-making even though there is reasonable disagreement about QALYs. The QALY is rarely considered on its own; instead it is used as the basis for determining cost-effectiveness.

³⁴⁸ Harris and Regmi, "Ageism and equality", 2012; Harris, "QALYfying the value of life," 2012.

³⁴⁹ Brock, 1995.

³⁵⁰ Stevens et al., "National Institute for Health and Clinical Excellence appraisal and ageism", 2012.

³⁵¹ Edlin et al., "Understanding Harris' understanding of CEA: is cost effective resource allocation undone?", 2013.

³⁵² Rawlins and Dillon, "NICE discrimination", 2005.

9.3 Understanding NICE's cost-effectiveness threshold

NICE uses comparative cost-effectiveness, expressed as additional cost per QALY gained, in its decision-making.³⁵³ The incremental cost-effectiveness ratio (ICER) is a comparative measure of how much it costs to produce one additional QALY. The ICER is the difference in costs between the new and old treatments, i.e. the technology under appraisal and current practice, divided by the difference in their effectiveness, or the QALY gain of each.

$$\text{ICER} = (\text{Cost}_{\text{new}} - \text{Cost}_{\text{old}}) / (\text{Effectiveness}_{\text{new}} - \text{Effectiveness}_{\text{old}})$$

The ICER does not tell us the cost per QALY of the new treatment rather it is *how much more* it costs to buy 1 QALY with the new treatment. It is important to note here that cost-effectiveness is always comparative, even if the comparison is between the new treatment and doing nothing. The ICER takes the comparison further to see how much more the additional benefit costs rather than the current benefits in the system.³⁵⁴

NICE uses a threshold where an ICER in the range of £20,000-£30,000 per QALY is considered cost-effective. The threshold range indicates where NICE has determined the probability of reasonable cost-effectiveness is achieved. The threshold range is a value judgement about opportunity-costs: recommending a treatment at the upper end of the threshold or above it means that costs will have to be shifted from other services. It may be that the new recommendation supplants the old

³⁵³ Using QALYs is actually an example of “cost-utility,” but NICE and the literature generally use the concept and wording of “cost-effectiveness”, so I will too.

³⁵⁴ I am grateful to G.J. Melendez-Torres for clarifying QALYs and ICERs for me.

because the intervention is more effective, but as NICE is neither a budget holder nor the clinician making treatment choices, that is not necessarily the case.³⁵⁵

As with QALYs, there is reasonable disagreement about the threshold. Those who object to using cost-effectiveness will reject the use of a threshold as unfair, but even supporters of cost-effectiveness object to NICE's threshold as inaccurate. The threshold's origins are somewhat vague; economists who reviewed the first few years of NICE's appraisals, found that the recommended interventions clustered around certain ICER values. These values formed the basis of an initial threshold, and NICE's advisory bodies adopted the concept and formalised the threshold in 2004.³⁵⁶ The basis for the threshold is not the result of an analysis of actual opportunity costs; it developed from precedent and an advisory body that made a judgement about what it ought to be.³⁵⁷ The origins of the threshold combine precedent and NICE's value judgement.

The threshold should reflect opportunity costs, and that is a problem for the budget holder, NHS England and the Department of Health, rather than NICE. The NHS budget is outside of NICE's jurisdiction. It should not be for NICE to determine

³⁵⁵ When NICE does a technology appraisal, the comparator technologies are not affected by the resulting recommendations, i.e. a recommendation in favour of a new technology does not displace the old or recommend disinvestment from current practices.

³⁵⁶ Devlin and Parkin, "Does NICE have a cost-effectiveness threshold and what other factors influence its decisions? A binary choice analysis", 2004; Dakin et al., "The Influence of Cost-Effectiveness and Other Factors on Nice Decisions", 2014.

The threshold does have curious origins—Devlin reports that one appraisal stated a threshold of £20,000, another report £30,000 and meanwhile the chairman denied that NICE had any threshold at all. (Devlin and Parkin, 2004; Rawlins and Culyer, "National Institute For Clinical Excellence And Its Value Judgments", 2004.) The lower threshold of £20,000 was first confirmed in April 2004 (Culyer, 2006.) The 2004 *Guide to the methods of technology appraisal* includes the £20,000-£30,000 range beyond which decisions will need to be more strongly justified on other terms. (NICE, *Guide to the Methods of Technology Appraisal*, 2004.)

³⁵⁷ Appleby et al., "Searching for cost effectiveness thresholds in the NHS", 2009.

Thresholds are a problem for any priority-setting institution, and Australia's Pharmaceutical Benefits Advisory Committee has faced a similar problem and also has precedents that reveal a certain range in which interventions are likely to be considered cost-effective. (Buxton, "How much are health-care systems prepared to pay to produce a QALY?", 2005.)

the point of affordability for the NHS—that should be something that the ministers decide, so the threshold should be set as a political and budgetary matter.³⁵⁸

The argument against the current threshold, from those who accept cost-effectiveness, does not oppose its existence and use but that £20,000-£30,000 is not appropriate and fails to recognise the value—economic and political—of an accurate threshold. The threshold should either reflect society's willingness to pay, i.e. how much a QALY is valued, or it should reflect the actual affordability of marginal QALYs and purchasing additional QALYs.³⁵⁹ The latter represents what is known as the “shadow price” of a QALY, which is the additional cost of a QALY up to the point that it displaces 1 QALY elsewhere in the system. Determining this is an empirical question. A 2013 study estimated that the best actual threshold estimate is an ICER of £12,936 per QALY or below.³⁶⁰ This threshold is the opportunity cost of introducing new technologies into the NHS. Assuming a fixed budget and that the NHS uses its full budget, any new technology introduced will displace some service elsewhere as costs shift. However, if the new technology surpasses NICE's current threshold, then it displaces more QALYs than it provides, arguably introducing more harms than benefits.³⁶¹ But in the following, I set aside these questions and consider the threshold as NICE uses it.

³⁵⁸ Williams, *What Could be Nicer Than NICE?*, 2004; Culyer et al., "Searching for a threshold, not setting one: the role of the National Institute for Health and Clinical Excellence", 2007.

³⁵⁹ Williams, *What Could be Nicer Than NICE?*, 2004; Baker et al., "Searchers vs surveyors in estimating the monetary value of a QALY: resolving a nasty dilemma for NICE", 2011; Appleby, "Crossing the line: NICE's value for money threshold", 2016.

³⁶⁰ Claxton et al., *Methods for the Estimation of the NICE Cost Effectiveness Threshold*, 2013.

An alternative view is that the ICER is methodologically insufficient because it does not consider total costs of a new intervention, and therefore cannot inform the actual trade-off of benefits and disinvestment that will occur. (Gafni and Birch, "NICE Methodological Guidelines and Decision Making in the National Health Service in England and Wales", 2003.)

³⁶¹ Claxton et al., "Causes for Concern: Is NICE Failing to Uphold Its Responsibilities to All NHS Patients?", 2014.

For example, according to Claxton et al. introducing ranibizumab for a subgroup of diabetic macular oedema patients at its market price would have displaced 4,367 QALYs elsewhere in the system, which likely includes 295 deaths and 1,337 life years gone. There is a strong correlation with decreased quality of life in diseases in respiratory, neurological, and mental health categories as the

The argument in favour of a threshold is based on this problem of opportunity costs. The threshold is an attempt to make explicit the opportunity costs inherent in priority-setting, and it is this problem of trying to consider both individual and population costs and benefits that lies at the heart of NICE's decision-making.

9.4 The threshold in the appraisal process

Appraisal Committees use the threshold in the appraisal process and decision-making as a benchmark of cost-effectiveness, and if it is to be exceeded, the burden lies on other reasons to outweigh the threshold. Because the Appraisal Committees take into account other reasons, the threshold is not a rule for decision-making, and it does not act as an algorithm that determines yes or no whether something ought to be recommended or even help us predict that accurately whether an Appraisal Committee will recommend an intervention.³⁶² The fact that interventions with an ICER over the threshold are recommended demonstrates that it is not a rule and the Committees do use their judgement.

NICE relies on the Appraisal Committee's judgement, and it is difficult to isolate the effects of any single other consideration. The *Guide to the methods* stipulates that above a plausible ICER of £20,000 per QALY the following conditions must be taken into account, and if the plausible ICER is over £30,000 per QALY, an even stronger case must be made for recommending the technology as an effective use of resources:

effect of deprived investment resulting from the costs of introducing new technologies. (Claxton et al., Methods for the Estimation of the NICE Cost Effectiveness Threshold, 2012.)

³⁶² Dakin et al., 2014.

Their review of NICE's decisions found that the likelihood of a technology being recommended or rejected actually changes in an ICER range of £39,000-£44,000 per QALY.

- The degree of certainty around the ICER. In particular, the Committee will be more cautious about recommending a technology when they are less certain about the ICERs presented.
- Whether there are strong reasons to indicate that the assessment of the change in health-related quality of life has been inadequately captured, and may therefore misrepresent the health utility gained.
- The innovative nature of the technology, specifically if the innovation adds demonstrable and distinctive benefits of a substantial nature which may not have been adequately captured in the reference case QALY measure.
- The technology meets the criteria for special consideration as a 'life-extending treatment at the end of life' (discussed below at 9.6).
- Aspects that relate to non-health objectives of the NHS.³⁶³

Even though the Committees may use their judgement when arriving at a decision, they must also use one of the above reasons to justify recommending interventions that fall in the threshold range or above it. The reasons to exceed the threshold reflect many of the relevant reasons expressed in the *SVJ*, but they are not necessarily consistent with the Citizens Council, who tend to be more favourable towards exceptions for life-saving treatments, for example.³⁶⁴ Despite the requirement for increasingly strong reasons close to and above the threshold, in practice the threshold has become the upper limit of £30,000.³⁶⁵ Treatments with ICERs below £10,000 are usually recommended.³⁶⁶ The Appraisal Committees are given freedom to make judgements and consider reasons, but at the same time they are constrained to certain reasons if they decide to challenge the threshold and recommend a technology above it.

³⁶³ NICE, Guide to the methods of technology appraisal, 2013, 6.3.3.

³⁶⁴ NICE Citizens Council, Report on NICE Citizens Council meeting: Departing from the threshold, 2008; NICE Citizens Council Report: Rule of Rescue, 2006.

³⁶⁵ Claxton et al., 2014.

³⁶⁶ NICE and NHS England, Proposals for changes to the arrangements for evaluating and funding drugs and other health technologies appraised through NICE's technology appraisal and highly specialised technologies programmes, 2016.

9.5 The threshold as a failure of fair consideration

Recalling the arguments of Chapter 6, I argue that the priority given to the threshold means the Appraisal Committees do not give fair consideration to reasons. Even though the threshold is not a rule for decision-making, it is the assumed starting point, and the reasons must line up against it in a sort of adversarial system. Beginning with this assumption of cost-effectiveness means that reasonable disagreement is not taken seriously and it poses a challenge to the normative legitimacy of the decision. I will argue that NICE needs to change its process, not its outcomes, to give fair consideration to reasons and enhance the normative legitimacy of the decisions and the way it uses the threshold and stakeholders' relevant reasons.

Fair consideration is the idea of taking seriously relevant reasons and the relevant positions that people hold in the deliberation and decision-making. When we go into a decision and fairly consider reasons, there is an expectation that no reason has already been chosen as the one that is the most important and will determine the outcome. This is the problem of the pre-decided committee I posed (6.1). When we start with a presumption in favour of one reason, there is not a level playing field for the other reasons; something the fair-minded people would not agree to as mutually justifiable.

Fair consideration is essential for normative legitimacy, and the threshold is a challenge to it. Certainly cost-effectiveness and considering opportunity costs are relevant reasons for consideration (even though there is disagreement over how these are analysed). However, so too are the clinical need of patients, the severity of the condition, and social aims and values achieved by treating conditions. The patients whose intervention is under consideration will challenge the legitimacy of the

decision if their reasons never had a chance or were not seriously considered by the Appraisal Committee.

The argument against NICE's use of the threshold and the need for fair consideration is focused on the process of the decision-making rather than the outcome. The Appraisal Committee has a set of relevant reasons it ought to take into consideration and weigh up in the decision, and it will need to judge which ought to take priority in the particular case. Using cost-effectiveness makes sense for NICE. It is comparing interventions against each other, and it does have a duty to the population of England and Wales to make recommendations about how to provide the best service on the NHS, so it should consider opportunity costs. However, the importance of cost-effectiveness and opportunity costs does not prevent the Appraisal Committee from taking into account other reasons and fairly considering them.

NICE might respond that the threshold is an important consideration of opportunity costs and its obligations to the whole NHS population. Weighing up costs and benefits is at the core of NICE's establishment and work as an institution. NICE's Establishment Order states that it will perform "such functions in connection with the promotion of clinical excellence, and the effective use of available resources in the health service".³⁶⁷ NICE is a rationing body for the NHS, and it has an obligation to the population the NHS serves to determine the best use of limited resources for meeting the population's health needs. The best use of resources does not necessarily mean the most effective and efficient use of resources, but it is often framed as such. Each time NICE approves an intervention above the threshold it does so at the cost of health elsewhere in the system. The *Guide to the methods* states, "the Committee will take non-health objectives of the NHS into account by considering

³⁶⁷ NICE, Social Value Judgements, 2008, 3.1.

the extent to which society may be prepared to forego health gain in order to achieve other benefits that are not health related.”³⁶⁸ This statement from the *Guide* illustrates NICE’s defence of cost-effectiveness: it must take it into account to fulfil its obligation as a decision-maker on value for the NHS. Other values are given priority when they are worth more than the health loss. For NICE a fair distribution is one that protects the interests of society as a whole rather than the interests of individuals.³⁶⁹ Even though NICE frames this in empirical terms, it relies on normative legitimacy and the concept of what is mutually justifiable to determine what additional benefits people would accept burdens for. The value of the threshold (setting aside the problem that the threshold does not reflect actual opportunity costs) is that it provides a voice to the patients whose services are not being appraised and may suffer as a result of introducing a new intervention.

Cost-effectiveness and opportunity costs are important considerations, so we would expect them to be taken seriously by the Appraisal Committee and given a strong weighting in the decision-making. However, this does not mean that they must be the presumed reason for making a decision in each appraisal.

It may be the case that fair consideration will not affect the outcome of the decision, i.e. the recommendations will be the same whether the Committee fairly considered reasons or not. Given the importance of cost-effectiveness as a reason, it will probably be given important weight in the decision. However, AFR and NICE rest their normative legitimacy on the process by which they arrive at decisions not the outcome of those decisions; that is what it means for them to use procedural justice. Fair consideration is a necessary element of AFR for a normatively legitimate decision procedure. Even if the outcome is the same, giving fair consideration to

³⁶⁸ Guide to the methods of technology appraisal, 2013, 6.2.21.

³⁶⁹ Chang, "Cost-effectiveness and fairness in health care: NICE appraisals", 2012.

reasons makes the process by which the outcome is arrived at and thus the outcome itself normatively legitimate.

A final consideration is to relate the threshold back to Daniels and Sabin's account of AFR, which is complicated by its commitment to "value for money" and case law. In chapter 5.7, I argued that "value for money" is a problematic commitment in the Relevance Condition, and in NICE's use of the threshold we can see an example of how it plays out in practice. I argued that value for money means that Daniels and Sabin's account of AFR precludes any serious possibility of giving fair consideration to reasons, a further problem for the normative legitimacy of decision procedures and the AFR framework.

Using the threshold looks like the use of case law from Daniels and Sabin's account of AFR. Daniels and Sabin argue that because decisions are published this means a case law will build up over time of precedents from past decisions. Daniels writes, "The earlier decision reflects a *commitment* to continue to act on the cited reasons and rationales in future similar cases."³⁷⁰ They also claim that as society makes decisions over time and asserts the same values, it will make new decision-making easier, a claim that Gutmann and Thompson echo in their account of deliberative democracy.³⁷¹ The extension would be that NICE has made decisions based on cost-effectiveness that clusters around a certain ICER value, and so it should continue to do so. The idea of a threshold then would be consistent with this development over time of case law. Indeed, that is more or less how the threshold was arrived at—by looking at precedent.

However, case law is yet one more reason that should be considered in the decision-making from the level starting point of fair consideration. I use "case law"

³⁷⁰ Daniels, "Capabilities, opportunity, and health," 2010 146. Emphasis in the original

³⁷¹ Daniels and Sabin, "Limits to health care", 1997; *Setting Limits Fairly*, 2008; Gutmann and Thompson, *Why Deliberative Democracy?*, 2004, 101.

and “precedent” in an everyday sense, as do Daniels and Sabin. In order for the precedent to apply, it must first be established that the case bears similarities to previous ones, which is a different condition from a starting presumption of the cost-effectiveness threshold. The value of consistency between appraisals, when there are features that pick them out to be relevantly similar, is something that can be considered and addressed through argument and reasoning in a process that gives fair consideration to it as a reason for making a particular decision.

This use of precedent should not be confused with a strict precedent, which would be contrary to fair consideration. In this everyday sense of precedent, over time certain reasons will be relevant in appraisals, so a part of the appraisal will be considering whether those reasons apply in the present case too. However, if a decision is made on the grounds of precedent, then the decision-makers fail to give fair consideration to the reasons that pertain in the decision instead deferring to one set of reasons. Precedents undermine fair consideration because they fail to acknowledge reasonable disagreement instead assuming agreement.

It is important for NICE to take into account cost-effectiveness and opportunity costs, but these are substantive principles that should not determine the outcome but rather contribute to a legitimate and fair process. NICE’s claims to normative legitimacy rest on procedural justice and the appraisal process as a fair and appropriate process. However, when Appraisal Committees begin with a presumption about the threshold, they do not give fair consideration to reasons, and fair consideration is necessary for normative legitimacy.

In order to give fair consideration to reasons, NICE would need to change its directions to Appraisal Committees and establish the threshold as one of many reasons important in the appraisal and that should be taken seriously. A shift to a

legitimate process may not change the outcomes of that process, but it would enhance NICE's legitimacy and respond to challenges it faces to the legitimacy of its decision-making.

Despite the framework of technology appraisals that should allow for fair-consideration, the cost-effectiveness threshold means that NICE's Appraisal Committees always begin the appraisal with a presumption in favour of cost-effectiveness as the determining reason. The other considerations then must stack up against cost-effectiveness. If there were fair consideration, we would expect that another reason, like meeting need or reducing inequalities, might begin on equal footing with cost-effectiveness, and then as the deliberation preceded, the judgement would be made in favour of one or the other as the overriding reason in the case. Instead, by always presuming cost-effectiveness, NICE has assumed away an area of reasonable disagreement and assumed that everyone agrees the threshold is the most important reason with which to evaluate a new technology.

In the following section, I turn to the end-of-life premium as an example of how reasons may push on the threshold and extend it. I will argue that the end-of-life premium raises new contentious reasonable disagreements and while it looks like other considerations override the threshold, that is a misinterpretation of what the premium achieves.

9.6 The end-of-life premium

In this chapter, I have so far argued that NICE is structured to be able to give fair considerations to reasons but it systematically fails to do so because of the cost-effectiveness threshold. In this section, I use additional guidance that NICE introduced in 2009, the end-of-life premium, to illustrate how the threshold was

extended for certain conditions. While this looks like an example of other considerations outweighing the threshold, closer examination shows that the threshold is as strong as ever. Rather than be an example of fair consideration, the end-of-life premium highlights an instance where particular reasons are privileged in the appraisals. Bringing in the discussion of chapter 8, the end-of-life premium is also an instance of reasonable disagreement, and it is not clear how NICE justifies the distinctions it draws between the conditions that satisfy the end-of-life premium and others.

In 2009, NICE introduced this “end-of-life premium” in response to public criticism of NICE, which was repeatedly not recommending new cancer treatments. New cancer treatments increasingly target specific patient groups and offer small benefits to survival or quality of life. Through the 2000s, NICE was not recommending many new cancer treatments because they were not cost-effective. Media and patient pressure focused in on NICE and the cost-effectiveness threshold, which many new treatments well exceeded. At the same time, debates over “top-up” payments in the NHS brought to light patients who were able to buy these medicines privately and the potential of a two-tiered NHS, which left many uncomfortable.³⁷² New generations of cancer therapies tend to focus on patient sub-groups, those with a particular tumour type or genetic mutation, for example, resulting in a smaller market and higher costs. (An alternative explanation is that given the demand for them, they may also be priced based on what manufacturers believe the market will bear.³⁷³) Many new cancer treatments offer small survival benefits at high prices, but they also

³⁷² Jackson, 2010.

³⁷³ Kolata and Pollack, 2008.

The point is also made that the major pharmaceutical manufacturers no longer gain income from “block buster” drugs, on patent drugs taken by many people, like blood pressure lowering medication. Cancer is the most profitable area to develop and must make up lost revenue as high prevalence treatments go off patent. (Timmins, Rawlins, and Appleby, 2016.)

offer hope to patients and innovation. Public criticism of NICE was (and is) high, and when NICE rejects new treatments it faces a problem of being perceived as unfair.³⁷⁴

In 2009, NICE introduced new guidelines into the *Guide to the methods of technology appraisal* on “appraising life-extending, end-of-life treatments”. The aim of the additional guidance is to allow the Appraisal Committee to “fully consider all the benefits which it is appropriate to take into account” when it appraises end-of-life and life-extending treatments.³⁷⁵ If certain criteria are met, the Appraisal Committee should consider what the QALY benefit would have to be to make the intervention’s ICER fall in the cost-effectiveness threshold, if it took the health utilities to be the same as those for a healthy individual. The criteria require that

- (1) The treatment is for patients with a short life expectancy, less than 24 months.
- (2) Compared to NHS current treatment standards, the treatment extends life by at least three months.
- (3) The treatment is licensed or indicated for a small patient population.³⁷⁶

In addition, the Appraisal Committee should make sure that there is a good standard of evidence to support the claim that a treatment meets these criteria.

Although the guidance does not stipulate a new threshold, it has been effectively interpreted as a higher threshold, judged to be around an ICER of £50,000 per QALY, although there is a range of ICERs for approved treatments. This higher threshold is not formally stipulated but rather is what past decisions indicate.³⁷⁷

³⁷⁴ See for example: "Thompsons Solicitors Condemn Delay in Provision of Breast Cancer Drug Herceptin," Thompsons Solicitors, <http://www.thompsons.law.co.uk/ntext/breast-cancer-drug-herceptin.htm>; "A life-or-death scrap with Nice 'barbarians'," 2008; Jack, "Blow for GSK's breast cancer drug," 2008; Harris, "British Balance Benefit vs. Cost of Latest Drugs," 2008.

³⁷⁵ NICE, Appraising life-extending, end of life treatments, 2009, 1.4.

³⁷⁶ Appraising end of life 2.1.

³⁷⁷ Stewart et al., "The Impact of NICE's End-of-Life Threshold on Patient Access to New Cancer Therapies in England and Wales", 2014. The ICERs for the 13 treatments considered and recommended under this criteria range from £31,800 to £51,800 per QALY. However, since 2009, the

Interestingly, although the guideline is framed so as to ask the Appraisal Committees to consider what health utility scores would make the treatment cost-effective and then presumably whether weighting the QALYs this way is reasonable, the criteria seem to have been treated instead as an increased threshold. (Consider that one of the first drugs appraised under the guidance, sunitinib, would require its QALYs to be valued at 70% higher than normal for its ICER to fall in the threshold.³⁷⁸)

Furthermore, even though the end-of-life premium does not limit the kinds of conditions and treatments that may be considered, the criteria mean that it applies to cancer treatments almost exclusively.³⁷⁹ The end-of-life premium is the subject of reasonable disagreement and debate between those who care about treating cancer patients at the end of life a certain way and those concerned about opportunity-costs. In this debate we can also see that the end-of-life premium is not an instance of giving fair consideration to relevant reasons resulting in a raised threshold but rather another formulation of the threshold.

9.6.1 Higher thresholds and reasonable disagreement

People may reasonably disagree about the end-of-life premium and what sort of value should be given to small gains in life expectancy for people who have little time left. There are several points of disagreement—whether everyone's benefits count the same or the value of helping known, sick patients. Arguments in support focus on how much it matters to give someone who is terminally ill hope, that life when you have little left matters more, that to deny treatment would be putting an explicit price on the value of someone's life. On the other side are arguments that the

ICER range of interventions in submitted appraisals has been steadily increasing, and fewer have been recommended.

³⁷⁸ Shah et al., NICE's Social Value Judgements about Equity in Health and Health Care, 2011.

³⁷⁹ Chalkidou, "Evidence and values: paying for end-of-life drugs in the British NHS", 2012.

end-of-life premium fails to take seriously opportunity costs and so causes harm to those patients who are not identified, and it does not treat everyone's health benefits equally.

The arguments in favour of the higher threshold reflect a desire to support innovation and treat the worst off, defined as those facing imminent death. Prioritarian accounts of justice argue that we should distribute resources so as to help the worst off. The case of cancer patients with terminal illness who have the possibility to live longer is compelling. The Citizens Council identified circumstances when a majority of members thought NICE should recommend a treatment with an ICER over the threshold, which included if it is life-saving, treats children, has a significant effect on family members, treats a severe illness, or there are no other treatments available.³⁸⁰ Similarly, they supported the possible application of the rule of rescue, understood by them as exceptional cases above the threshold, if NICE considered and weighed up whether treatment would prevent immediate loss of life, increase life expectancy, and improve quality of life.³⁸¹ An argument often appealed to is that saving people, such as providing them with the best treatment available, is an important part of being a humane and caring society even though it may not make the most economical sense. It may be better to live in a society where we have important moral imperatives to treat the severely ill.³⁸²

However, the threshold's conditions mean that in practice it is applicable to cancer, and NICE does not defend why terminal cancer is different from other terminal conditions. The arguments in favour of the premium can be extended to other conditions. The premium gives special consideration to cancer patients rather

³⁸⁰ NICE Citizens Council, Report on NICE Citizens Council meeting: Departing from the threshold, 2008.

³⁸¹ NICE Citizens Council Report: Rule of Rescue, 2006.

³⁸² Jonsen, "3. Bentham in a box: Technology assessment and health care allocation", 1986. Note that this is not Jonsen's position, but he raises this as an argument supporting such a position.

than to others who face terminal illness but may not have treatments meeting the other criteria. For example, palliative care or a treatment that improved quality of life for someone with a motor neurone disease are important at the end of life but would not meet the criteria since they are not life-extending.³⁸³ Arguments in support of the higher threshold, like the marginal value of life when you have little left of it, apply in other conditions too.³⁸⁴

The criteria also appear arbitrary, and NICE has not justified their relevance. It is not clear, for example, why the life-extension should be for conditions that have a life expectancy of 24 months. Someone who has a 26-month life expectancy would surely wish to have her condition included. The small patient size criterion also seems tailored to cancer, with its new treatments targeted at subgroups. The small patient size is economically rather than morally motivated in order to keep the costs of expensive treatments contained, but given the structure of NICE's decision-making, ideally, the economic reason would not need to be conflated with other conditions.³⁸⁵ Indeed, there has been disagreement within NICE of what size constitutes a "small population" with different Appraisal Committees arriving at different conclusions.³⁸⁶ Because the conditions have not been justified in light of these concerns, the relevance of the reasons is challenged. As a point of clarification,

³⁸³ Hughes, "Palliative Care and the QALY Problem", 2005; Jackson, 2010.

Palliative care, as Hughes points out, generally struggles with QALYs because while it may improve health related quality of life, it does not extend it, and so does not produce many QALYs.

³⁸⁴ Cookson, "Can the NICE "End-of-Life Premium" Be Given a Coherent Ethical Justification?", 2013.

³⁸⁵ Health Committee, "Top-up fees: Fourth Report of Session 2008-09," 2009; Health Economics Strategic Pricing Director, Notice of Appeal, 2011; Jackson, 2010.

³⁸⁶ Appeal Panel et al., 2011.

In its appeal decision, the Appeal Panel stated that the Appraisal Committee for trastuzumab and lapatinib (Technology Appraisal 257) had been wrong not to take into account a previous Committee's definition of a small patient size. This Committee could not use a different definition based on what they believed reasonable unless they justified it with reference to the previous decision, otherwise it would be unfair to this group of patients. In the FAD, the Appraisal Committee acknowledges that although it disagrees with 7,000 people being a small patient size, it uses this definition for reasons of fairness. (NICE, Lapatinib or trastuzumab in combination with an aromatase inhibitor for the first-line treatment of metastatic hormone- receptor-positive breast cancer that overexpresses HER2, 2012.)

I do not intend to contest that the basis of either side's reasons is reasonable—the problem is in the justification of the conditions of the premium as relevant given the objections raised.

When introducing the higher threshold, NICE argued that it was supported by the value of innovation and again turned to the Citizens Council for reason gathering. If NICE were to rigidly stick with a lower threshold, the NHS may be left behind as new drugs become available. In its core considerations, as per the Secretary of State's directive to NICE, the Institute should aim to promote innovation. It is telling that in 2009, the same year the end-of-life premium was introduced, the Citizens Council was asked to consider the value of innovation, something NICE was accused of failing to properly take into account.³⁸⁷ New treatments, reflecting high research costs, come with a high price tag, and so using a fixed threshold will fail to support the market for innovation and leave England's population lagging behind as these drugs become available.

One way of framing this disagreement, which is an example of the general problem NICE faces with its appraisals, is as the 'identified individuals vs. statistical lives' problem.³⁸⁸ In this instance identified individuals are the cancer patients with new treatments—we know who is gaining those extra QALYs and benefitting from a few months more of life. The statistical lives are the patients elsewhere in the system who have less money spent on their healthcare services because the resources have been shifted to cancer care. The statistical patients may also be receiving life-

³⁸⁷ NICE Citizens Council, *Health Innovation and Value*, 2009.

³⁸⁸ Daniels, "Reasonable Disagreement about Identified vs. Statistical Victims", 2012.

This is also framed as the "rule of rescue". The phrase describes how despite the logic of effectiveness, efficiency, and costs, there is a powerful desire to help those in dire circumstances whose lives we might be able to save. Jonsen describes this as an impulse to save lives: that the few individuals whose cases are being assessed (artificial hearts in his 1986 paper) win out over the many—people whose lives would have been better with more resources for nutrition, immunization, and early treatment of conditions (Jonsen, 1986.)

extending treatments, like those for coronary disease or preventive treatments that will result in life-extending health gains. The identified lives are compelling since we can identify who and how we are helping, but these must be balanced against the statistical, population health benefits. This kind of problem of deciding between the two is a reason why these rationing decisions are difficult.

Critics of the end-of-life premium argue that we should not give greater value to the identified individuals. One argument against is that by raising the threshold for some patient groups we fail to treat people's health benefits equally. There is not a reason why the identified patients should be treated differently and matter more. The strength of the QALY is that it counts the same for everyone, but when we give one group a higher threshold, then their QALYs are of greater value.³⁸⁹ (This argument also holds for the future benefits discount rate, discussed above.) Higher thresholds also mean bigger trade-offs; when NICE recommends new treatments over the threshold, someone else in the NHS loses out.

The end-of-life premium displaces more QALYs than it introduces. Based on the appraisals carried out between 2009-2011, the treatments approved under the end-of-life premium resulted in a loss of 5,933 QALYs, if we take the higher threshold of £30,000 per QALY, or 15,098 QALYs lost using the lower threshold of £20,000.³⁹⁰ These displaced QALYs are the opportunity costs of introducing new treatments. The argument against is that even if we care about helping people at the end-of-life, we should not do so to the detriment of others, who we can predict will lose healthcare treatments and benefits but cannot identify.

³⁸⁹ McKie and Richardson, 2003; Paulden et al., 2014.

The House of Commons Health Committee disagreed with the introduction of the end-of-life premium on the grounds of the opportunity costs it entails. The disagreement of the MPs reinforces that NICE is indeed politically independent (Health Committee, 2009.)

³⁹⁰ Collins and Latimer, "NICE's end of life decision making scheme: impact on population health", 2013.

There is reasonable disagreement over whether it is right for NICE to extend a higher threshold for patients with certain conditions and treatments compared to others. It is compelling and important for society to help those who face terrible illness. Simultaneously, the opportunity costs of doing so place others at disadvantage and deprive them of healthcare. Resolving such disagreement is why we turn to fair and legitimate process for making decisions, and NICE must show that it uses such a process. However, NICE's use of the premium indicates that the Appraisal Committees do not give fair consideration to reasons.

In the previous section (9.5), I argued that the use of the cost-effectiveness threshold indicated a failure of fair consideration. With the end-of-life premium, we see another example of a failure to fairly consider reasons compromising normative legitimacy. The cost-effectiveness threshold is still used, and technologies considered under the special conditions have been not recommended because they exceed the new, implicit threshold. However, the higher threshold and the special conditions for it to apply assume that certain kinds of reasons are relevant and matter more than others; small gains in life for cancer patients are valued over the opportunity costs of those gains, as the identified individuals vs. statistical lives problem illustrates. This claim does not contradict my earlier argument against the cost-effectiveness threshold; my argument is that both the cost-effectiveness threshold and the conditions of the premium presume certain reasons as the basis for decisions which means fair consideration is not given to the relevant reasons and reasonable disagreement is ignored.

9.6.2 Who disagrees? Expert vs. public views

As a concluding point about the end-of-life premium, I return to the question I posed in Chapter 5 of how we decide what is a relevant reason. Chapter 8 explored ways that NICE establishes relevant reasons. One striking issue about the end-of-life premium is the disagreement over whether or not it is relevant. Roughly, the end-of-life premium received support from the public but not from experts. In either case this means not everyone finds it mutually justified, but this split also illustrates an instance where the people who would claim a reason is justifiable (the experts) are at odds with what the public considers justified.

The public, i.e. the general population not involved in healthcare or government priorities, are supportive of providing new cancer therapies even though they cost more and are not cost-effective based to the threshold. Patient groups and manufacturers also support the higher threshold. In contrast, experts, those people who work in academia, the NHS, CCG priority-setting, and the government, oppose the higher threshold because of the opportunity-costs it entails.³⁹¹

NICE claimed that the end of life premium reflected social values for providing new cancer treatments even at a higher cost. According to NICE, it responded to the public when it introduced the new, higher threshold for end of life.³⁹² However, the empirical support for this was not well established—surveys after the premium was introduced show that there is a majority trend in support of it, but it is

³⁹¹ Chalkidou, 2012; Health Committee, 2009.

³⁹² Baker, Mason, and McHugh, "Paying more for less: is there public support for making 'end of life' a special case?," 2016.

NICE did carry out some public consultations before introducing the premium. For example, the public consultations showed that a proposed fourth criteria that required there be no alternative treatment with comparable benefit available on the NHS ended up being excluded because of concerns about what 'alternative' could mean (Shah et al., NICE's Social Value Judgements about Equity in Health and Health Care, 2011.).

by no means a large margin majority or a clear-cut view.³⁹³ Certainly, as discussed at above, there was significant media and patient pressure to support the provision of these new treatments.

The Citizens Council falls between the two views. It trends towards supporting something like the end-of-life premium, and its members tend not to be strict observers of cost-effectiveness. But they are also cautious about the circumstances in which the threshold should be surpassed since they discuss the opportunity-costs in depth.³⁹⁴ So it cannot be said the members would outright recommend the raised threshold although they certainly express sympathy with it.

In contrast, on the professional side of NICE, there is much greater concern for opportunity-costs and how the introduction of new technologies will affect existing services. Their arguments frame the issue around equality and making exceptions for some people's QALY benefits. Opportunity-costs, though, seem to be the realm of the health economists and those involved in the policy of the NHS. While public groups acknowledge it, there is often also a sense that more money could be found or a reluctance to consider explicit trade-offs.³⁹⁵

The disagreement over the end-of-life premium highlights the question of who should be deciding what is relevant. If NICE is determined to move to a model where it intends to satisfy public demand, then in order to do this in a descriptively

³⁹³ Baker, Mason, and McHugh, 2016; Shah, Tsuchiya, and Wailoo, "Valuing health at the end of life: an empirical study of public preferences", 2013; "Valuing health at the end of life: A stated preference discrete choice experiment", 2015.

³⁹⁴ NICE Citizens Council, Report on NICE Citizens Council meeting: Departing from the threshold, 2008.

³⁹⁵ Consider, for example, some of the patient group campaigners who spoke with the Citizens Council and insisted that the money could be managed so that such trade-offs would not be necessary, see *ibid*.

However, it is not always the case that only the public want to make exceptions: in the appraisal of lapatinib, the Appraisal Committee considered that even though its survival benefit was 1.9 months, there was a strong and compelling case for providing it. The Committee did not recommend it though because of cost-effectiveness, but on appeal, the Appeal Panel noted that a compelling case was not grounds for decision-making at NICE since its role is to consider compelling and difficult cases for patients who are gravely ill (Clark, Social Values and Health Priority Setting Case Study: Lapatinib for the treatment of advanced or metastatic breast cancer, 2012.)

legitimate way, it must conduct thorough empirical research to determine the public's views; the Citizens Council will not suffice for the reasons discussed above (8.3). The tensions over the end-of-life premium illustrate the problem of how to decide what is relevant as it plays out in practice for institutions seeking normative legitimacy.

On the basis of the normative legitimacy argument I have been making, empirically justified reasons are not necessary for normative legitimacy. Rather NICE must present coherent arguments in support of why the reasons are justified. In the end-of-life premium case, NICE has failed to argue for the relevance of the premium and its conditions. If NICE were to offer a justification, it would still need to consider the premium amongst the other relevant reasons as part of fair consideration when making a decision in order to give all the reasons fair consideration and so establish the normative legitimacy of its decisions.

9.7 NICE and AFR: implications for practice

In Part III, I have argued that NICE successfully meets the conditions of Daniels and Sabin's account of AFR, despite criticism that it does not, but that it fails to meet my expanded account of AFR, which requires fair consideration for normative legitimacy. There are two points I wish to draw out from Part III, the first concerning what NICE shows us about implementing AFR and the second about fair consideration.

NICE uses AFR to strengthen its claim to normative legitimacy, something it needs as a public body making prominent decisions. NICE needs both normative and descriptive legitimacy, and it is through the use of AFR that it aims to establish this. However, alongside AFR, NICE has introduced its own procedural principles that

supplement the framework of AFR. What this shows us is that the conditions of AFR as they stand are not sufficient to be translated into practice. The Relevance and Publicity Conditions in particular are too thin to meet the descriptive and normative legitimacy concerns of an actual institution under intense scrutiny. NICE's procedural principles address its legitimacy problem, but they are not so specific that other institutions cannot adopt them. Therefore, they provide a model of how institutions may seek to implement AFR.

The Relevance Condition, which leaves wanting much direction on how to determine relevant reasons, has been supplanted at NICE with prior relevant reasons in the *SVJ* and *Guide to the methods* and contextual relevant reasons that the Appraisal Committees determine are relevant in specific appraisals. Looking at examples of appraisals shows the challenge of justifying relevant reasons and their application in one case, as with the inclusion of carer benefits as a contextual relevant reason in the appraisal of treatments for Alzheimer's. NICE could improve on its determination of relevant reasons by sharing the process it uses to decide relevant reasons. The Citizens Council, which it often cites, is insufficient for this role. From the appraisal process and revisions to the *SVJ* and *Guide* it appears that NICE has a process for confirming relevant reasons, and in keeping with its procedural principles, this process should also be subject to transparency in order to enhance normative legitimacy.

However, NICE's presumption in favour of cost-effectiveness with its threshold undermines the effect of these efforts at normative legitimacy since it fails to take into account reasonable disagreement. The moral significance of reasonable disagreement means that it is not normatively legitimate to use a decision process that ignores it or assumes away disagreement. NICE's use of a threshold does just that,

and its jump to assuming cost-effectiveness is a challenge for NICE's normative legitimacy. Given NICE's concern about descriptive legitimacy, it is also pragmatically unwise for it to presume one reason over others. The failure to give fair consideration does not mean that NICE's decisions are illegitimate; as Daniels and Sabin understand legitimacy, it is a range and an institution can have more or less. NICE's decisions are an important matter of justice about which people feel passionately, so greater legitimacy is desirable.

The other option for NICE would be to ground its process in the use of the threshold as its primary consideration as it does, but then it must justify the normative legitimacy of that procedure through a different framework from AFR. I do not venture to propose what the alternative argument for legitimacy may be. NICE currently grounds its procedure in AFR, a widely accepted framework for procedural justice, so I limit my discussion to how NICE may best instantiate it.

My aim here is not to reject cost-effectiveness as a relevant reason or claim that NICE cannot ever be normatively legitimate. Rather, I point to ways that NICE could strengthen its legitimacy, like a commitment to fair consideration, even if this will be difficult to judge in practice, and the transparent justification of its relevant reasons in order to be normatively legitimate under the expanded account of AFR. NICE could improve its normative legitimacy and procedures, setting an example for other institutions that look to it, if it respected reasonable disagreement and found a way to use cost-effectiveness consistent with giving fair consideration to relevant reasons.

10 In conclusion: AFR and NICE, new directions for legitimacy

NICE and AFR both stand out as leaders in their respective areas of priority-setting. AFR is the exemplar model procedure for making limit-setting decisions. NICE leads the way in technology appraisals and the methodologies it has developed for assessing interventions. I have examined each in turn and how NICE instantiates the procedure and theory of AFR in order to enhance its normative legitimacy. I criticised the theory of AFR pointing to the gaps it leaves and drawing attention to how these translate into problems for the procedures NICE designs and how these problems play out when the procedures are applied in technology appraisals.

AFR is the prevailing theory for procedural approaches to limit-setting, and my aim has been to challenge its weaknesses and propose solutions that will help to strengthen the theory. Daniels and Sabin develop AFR with a background of deliberative democracy in mind. The elements of deliberative democracy do not translate into the procedural requirements of AFR, so the very reason for looking to deliberative democracy—its respect for reasonable disagreement—is lost. I first identified two problems for the Relevance Condition: (1) the problem of determining what is or is not precluded from the category of relevant reasons, exemplified with whether religious reasons should be included, and (2) that it is unclear whether relevance must be determined conceptually by fair-minded people in an objective list of reasons or whether it requires empirical agreement. Based on Daniels and Sabin's framework, I proposed that AFR requires a conceptual standard of mutual justifiability rather than empirical agreement on reasons.

The questions about relevance arise again in NICE's procedures for technology appraisals. NICE uses stakeholder input and the Citizens Council to

gather reasons, but its process for deciding which reasons are relevant is unclear. “Prior” relevant reasons in the *SVJ* and *Guide to the methods* are broad reasons that apply in all appraisal cases. Because they are written into NICE’s guidance, the Appraisal Committees consistently consider these reasons and include them in their thinking about the appraisal case. Contextual relevant reasons are those reasons that the Appraisal Committee identifies and agrees are relevant but are specific to the appraisal case. The question of which reasons to include or exclude is borne out in the appraisal of AChE inhibitors in which the reasons for including carer health utility were not clearly articulated, leaving open a question of when these considerations are or are not relevant. Proposals for strengthening NICE’s process include carefully documenting problematic cases, like the ones picked out here, in order to assess the decision-making criteria.³⁹⁶ In addition, NICE should use the same procedural principle of transparency it applies to its appraisals to the process by which it determines its principles and reasons.

A second question about relevance is who decides on relevance and whose agreement matters? The Relevance Condition stipulates that reasons are relevant if they are the sort fair-minded people would accept, and Daniels and Sabin also describe reasons as needing to be ones that all can agree to. The question of whether there is an objective list of reasons, of what we can assume fair-minded people would accept or whether we should seek out empirical agreement strikes at a classic problem for democracy and whether we take into account expert views. Daniels and Sabin give no indication of how they would answer this problem, and it is a problem that persists in NICE’s development of relevant reasons. Although NICE has the Citizens Council deliberate on issues and report on its values in order to give a “snapshot” of

³⁹⁶ Weale et al., *Cost-Effectiveness and Social Values: Recommendations for Revising NICE's Social Value Judgements*, 2014.

the public's view,³⁹⁷ its advisory bodies review these reasons before incorporating them into the *SVJ*, and the Citizens Council does not have the legitimacy to determine relevance. The question of who decides on reasons carries over into the appraisals. NICE's end-of-life premium is rejected as unfair by experts in priority-setting who argue that a higher threshold should not be given to life-extending, end-of-life treatments. To defend the premium, NICE has argued that the public support the higher threshold. In this case, moving from AFR to process design to the process itself, the problem of who decides on reasons and which ones should determine the recommendation persists and affects actual policy decisions and outcomes.

These problems and questions of relevance will not be easily solved, so NICE must look to strengthening and justifying the procedures it uses. For example, rather than stating that NICE relies on the Citizens Council for developing the social values it takes into account, a fuller explanation of who reviews the Council's reports and how these are integrated into NICE's institutional values should be given. Disagreement may persist over whether NICE should rely on the Citizens Council or its own expert review, but at least, as with its other areas of decision-making, a transparent explanation of its review process will provide some answers and responses to the criticisms.

The second significant argument I made is that AFR's four conditions are not sufficient for normative legitimacy because they do not require fair consideration of reasons. I argued that fair consideration is necessary for normative legitimacy since when there is reasonable disagreement it is necessary to consider each relevant

³⁹⁷ NICE, "NICE group publishes final report on which values influence decisions on how health and social care resources are shared out," 2014, <https://www.nice.org.uk/news/press-and-media/nice-group-publishes-final-report-on-which-values-influence-decisions-on-how-health-and-social-care-resources-are-shared-out>.

reason. I proposed a revised account of AFR, which requires fair consideration of reasons as an addition to the Relevance Condition.

While NICE meets the requirements of Daniels and Sabin's account of AFR and introduces its own procedural principles, it fails to give fair consideration to reasons, and we can see this as a normative legitimacy problem illustrated by the cost-effectiveness threshold. When Appraisal Committees go into the appraisal process, there is a presumption in favour of cost-effectiveness, which means they do not give fair consideration to reasons. Fair consideration is a legitimacy concern since the normative and descriptive legitimacy of the process requires taking seriously stakeholders' relevant reasons. A failure to fairly consider reasons is also evident in NICE's end-of-life premium that extends the threshold if certain conditions are met.

In order for NICE to strengthen its normative legitimacy, it needs to demonstrate that it gives fair consideration to relevant reasons. Fair consideration does not require a radical reworking of NICE's procedures. Starting from a position of fair consideration is a change to how the procedure of appraisal is carried out and means no reason is presumed to dominate the process. Indeed, it may be the case that there is no change to the outcomes of the appraisals. Making the procedural change will enhance the legitimacy of the process and therefore its outcome. What matters about fair consideration is that it is necessary for normative legitimacy, and if NICE implements fair consideration, it can demonstrate to its diverse stakeholders that it has taken their reasons seriously rather than presuming some reasons (like cost-effectiveness) are more important. Since normative legitimacy treats stakeholders and their reasons appropriately, we may also expect that it will increase descriptive legitimacy.

When it comes to implementing AFR and the revised account of AFR, greater clarity about procedures and revising the procedure in the case of fair consideration will contribute to NICE's normative legitimacy, likely enhancing its descriptive legitimacy too. The aim of these arguments is not to overhaul NICE's processes or undermine the work NICE does since it is largely a good example of procedural decision-making that is backed by well-developed reasons and deliberation. Rather the aim of these arguments is to support AFR and NICE to achieve the best possible legitimacy in the design and implementation of their procedures.

10.1 NICE's future

NICE considers the cost-effectiveness of new technologies to ask whether they are a good use of NHS resources, and we might ask the same question of NICE: is it a good use of public resources? NICE has grown substantially since its founding in 1999 when it had a staff of only ten and a turnover of £600,000. In 2014/15 NICE employed 600, had a government grant of £65 million and a turnover of £71 million (NICE spends £4.0 million on technology appraisals compared with £13 million on clinical guidelines).³⁹⁸ NICE is a considerable financial and resource investment for determining better uses of resources, and it faces limit-setting pressures itself with new budget-reduction goals. Its deliberation and procedures, including the Citizens Council, do not come cheaply, so it raises the question of whether NICE is a good use of resources. I do not attempt to answer this question—NICE's activities encompass a wide range of areas, of which technology appraisals are a small part.

It appears that the technology appraisals have increased NHS spending, with positive recommendations adding £890 million (10%) to NHS pharmaceutical

³⁹⁸ Timmins, Rawlins, and Appleby, 2016.

spending. The increase in spending coincided with growth in the NHS budget, but this is likely to plateau.³⁹⁹ These numbers do not account for NICE's negative recommendations against using new interventions, which may yet have saved the NHS more in spending if CCGs would otherwise have chosen to provide the treatments. Certainly, NICE's activities and how they contribute to financial aims may raise questions about the value for money of NICE itself.

The fair and legitimate procedures that NICE has developed have so far only been applied to recommendations either introducing new interventions or not recommending them (although its *SVJ* guidance applies to all its guidance programmes). NICE was established to address the postcode lottery—the variation between commissioning groups in their provision of healthcare services, but the current program of technology appraisals cannot accomplish that. The technology appraisals are statutory guidance that CCGs must implement, but the recommendations add new costs to CCGs without offering insight into how the CCGs should balance their budgets and realign priorities. The addition of new interventions that should be provided adds strain to CCG budgets and infrastructure. It also privileges patients whose interventions have been appraised by NICE since their interventions must be provided for whereas other patients have no statutory requirements in force. As NICE continues to develop its activities and appraisals, one area it should develop is a programme of appraisals for disinvestment from current services.⁴⁰⁰

Just as NICE uses AFR's procedural justice framework and its own procedural principles to guide its appraisal of new technologies, this same process, including fair

³⁹⁹ Ibid.

⁴⁰⁰ Gold and Stirling, "A response to Birch and Gafni – some reasons to be cheerful about NICE", 2007; Newdick, *Who Should We Treat?*, 2005.

I have not touched on other controversial areas of NICE's guidance development, particularly the Cancer Drugs Fund.

consideration, could be established to determine what interventions should no longer be provided by the NHS. Taking into account similar reasons and arguments as are currently used to support the appraisals of new interventions, NICE could develop a process and programme for disinvestment. Recommendations on disinvestment would help to manage a balanced budget and reduce variation of available services at the commissioning level, furthering NICE's aims.⁴⁰¹ The problem so far is that NICE is not responsible for the NHS budget, and so it does not consider the affects of its recommendations on the overall budget or the individual budgets of commissioning groups. Just as NICE makes positive recommendations about new interventions, which are taken up across NHS England, it could review extant interventions. If NICE takes more responsibility for the budget, its decisions will have greater legitimacy and credibility for those who must implement them. Appraisals of currently used interventions would also recognise the interests of patients who are not in the groups whose treatments are considered in technology appraisals, and this too could enhance NICE's legitimacy.

NICE has continued to change and add guidance programs to its remit since its establishment and address some of the concerns raised about its operations. In the fall of 2016, NICE opened a consultation on its technology appraisal process to address issues with appraisal costs, speed, and the budget effects of its recommendations. The proposed changes include adding a 'fast track' appraisal process for technologies with ICERs below £10,000 per QALY and explicit budget-impact thresholds.⁴⁰² The process of consultation and revision shows that NICE is a dynamic organisation responding to perceived problems with its procedures. Changing the procedures is a

⁴⁰¹ Drummond, 2007.

⁴⁰² NICE and NHS England, 2016.

matter of public consultation and internal review, so NICE is able to effect changes in response to its shortcomings.

NICE is an international model in priority-setting, and for all that it does well, there are still programs its activities could include that would further its legitimacy and support for its guidance. The strained relationship between NICE and commissioning groups illustrates one area where NICE's activities neglect to take into account the realities of their implementation at the local level. Expanding NICE's role in commissioning would bring the same rigorous process to more of the difficult decisions faced in healthcare priority-setting.

10.2 Not just health

This dissertation has focused exclusively on healthcare as the subject for AFR and procedural justice, but the procedures discussed could be applied to other areas of decision-making. Daniels and Sabin's work on AFR has exclusively concerned healthcare. The procedure of AFR though need not be specific to healthcare decision-making nor is my revised account of AFR. Reasonable disagreement arises in many areas of public life, something theories of deliberative democracy recognise, and where there is reasonable disagreement, a fair procedure is the appropriate means of decision-making, to extend the argument for AFR.⁴⁰³

Daniels and Sabin proposed AFR as a procedure for legitimate decision-making when there is reasonable disagreement about an issue of a justice. At the start of the dissertation (2.1), I gave Daniels account of justice and health, which is based on its importance of maintaining and returning people to a normal opportunity range. Other social goods fall under this definition of justice too: education and availability

⁴⁰³ Gutmann and Thompson, *Democracy and Disagreement*, 1996.

of clean air and water, for example. There is reasonable disagreement on these issues, like debates over the best way to resource and support education, questions about what even counts as a good education and ought to be made available, and disagreements over trade-offs between environmental protection and economic gains. Procedural approaches address reasonable disagreement on policy issues by legitimising the process since there will not be consensus on outcomes.

AFR is a procedure for making legitimate decisions when there is disagreement, and with the addition of fair consideration and the procedures NICE has introduced, it offers a robust framework for public and private bodies to follow. In the dissertation, I have discussed Daniels and Sabin's account of AFR and argued for the need for fair consideration. These conditions are necessary for the legitimacy of decision-making, and that legitimacy is important when the decisions concern issues of justice. Reasonable disagreement over issues of justice is not limited to health, and the procedures of AFR are not particularly specified to health; they ought to be translatable into other areas of disagreement and issues of justice. On other policy issues then, we would expect to see decision-makers follow a procedure of publicity, appeals, determining relevant reasons, and giving fair consideration to those reasons. Indeed, NICE's process and in particular its political independence has already led one writer to argue that the criminal justice system should look to it as a model.⁴⁰⁴

In the private sector, there is still an important role for AFR and procedural approaches on matters of justice. The private provision of healthcare matters, as Daniels and Sabin argue, because it addresses a concern of justice, which means

⁴⁰⁴ Loader, 2010.

private providers have a social obligation to meet.⁴⁰⁵ Because of this obligation, they need to justify their decisions and policies as fair and legitimate beyond a normal consumer relationship. AFR is a procedure designed for affirming the legitimacy of the decisions of private institutions. This is not specific to health: a private corporation faced with decisions over an issue of justice needs to make fair and legitimate decisions and demonstrate that it does so. In the private sector, the justification of relevant reasons will be particularly scrutinised since the most pressing reasons for a private corporation are likely to vary from those of a public or government body and an independence principle like NICE's may not be feasible. Sharing relevant reasons and the process of defining them will be an important step in affirming legitimacy.

Beyond policy issues that concern issues of justice, anytime an exclusive group makes a decision over an issue people feel passionately about, a procedure like AFR assists in making the outcomes legitimate and acceptable. AFR provides a framework for how a committee may go about its decision-making, structure its reasoning, and share with the public. A commitment to a principle of inclusiveness, like NICE's, is a means of engaging stakeholders in the decision process in order to elicit relevant reasons and a broad range of views. Even when a decision is not an issue of justice, disagreement may warrant particular consideration.

The process specified in AFR and NICE's procedural principles requires transparency and publicity, relevant reasons and rigorous evidence, appeals and inclusiveness. To this I have added fair consideration and better transparency about how relevance is determined. These elements of decision-making contribute to the legitimacy of the process, translating into legitimate outcomes. The content of the

⁴⁰⁵ Daniels, "Accountability for reasonableness in private and public insurance," 2000.

procedures is not specified, so they may be used in any area that gives rise to reasonable disagreement in order to enhance the normative legitimacy of decisions.

AFR stands as a feasible, pragmatic approach to procedural decision-making. I have raised concerns about its procedure and substantive constraints and propose fair consideration as a necessary condition for normatively legitimate decision-making with AFR. Rather than condemn AFR, I hope that these criticisms have drawn out the challenges of implementing it, and what must be added to it to enhance the legitimacy of the procedure and the outcomes. NICE gives us an example of how to implement AFR, what problems arise, and what additional principles are necessary for an institution that grounds its legitimacy in theory but must also meet the legitimacy demands of real-world practice. With this example in mind and with the inclusion of fair consideration, AFR may serve as a framework for procedures in areas beyond healthcare where fair and legitimate decision-making is needed.

11 Appendix 1: Acronyms used

ACD	Appraisal Consultation Document
AChE	acetylcholinesterase (inhibitors)
AFR	accountability for reasonableness
AG/ERG	Assessment Group and/or Evidence Review Group
CCG	Clinical Commissioning Group
FAD	Final Appraisal Determination
ICER	incremental cost-effectiveness ratio
MCO	managed care organisation
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PCT	Primary Care Trust
QALY	quality adjusted life year
SVJ	<i>Social Value Judgements guidance</i> (NICE, 2008)

12 Appendix 2: Citizens Council topics

Table 2 Citizens Council topics by year⁴⁰⁶

<i>Year</i>	<i>Citizens Council Topic</i>
2002	Clinical need What factors should be taken into account regarding need?
2003	Age Are there circumstances when age should be taken into account and if so, what are they?
2004	Confidential enquiries What does the Council think of NICE using patient medical records in research to identify causes of death?
2004	Ultra orphan drugs Should special consideration be given to ultra orphan drugs and should the NHS pay higher prices for them?
2005	Mandatory public health measures What is the role of the state vs. the individual in taking responsibility for health, and to what extent should the state promote interventions that promote overall health but may harm or inconvenience a minority? What principles should be used when introducing mandatory public health measures?
2006	Rule of rescue Should NICE take into account a rule of rescue, i.e. saving people in imminent danger of death?
2006	Health inequalities Should resources improve the health of the whole population, possibly widening socio-economic gaps, or should resources be focused on improving the health of the most disadvantaged members of society, possibly leaving others with fewer health benefits?
2007	Only in research What circumstances should determine whether NICE recommends an intervention for use in a research programme only
2007	Patient safety Should NICE consider the cost of patient safety solutions, and if so what principles of cost-effectiveness should it use, and if not what criteria should it apply to recommend patient safety solutions to the NHS?

⁴⁰⁶ <https://www.nice.org.uk/Get-Involved/Citizens-Council>

- 2008 Quality adjusted life years (QALYs) and severity of illness
Should QALYs include a measure of severity and/or should Appraisal Committees take severity into account?
- 2008 Departing from the threshold
Under what circumstances should NICE recommend interventions with a cost-effectiveness outside the threshold of £20,000-£30,000 per QALY?
- 2009 Innovation and value
What features should be considered when assessing the value of innovation?
- 2009 Smoking and harm reduction
Should NICE be promoting a switch to safer products for individuals in order to reduce harm while also encouraging smokers to quit?
- 2010 Incentives
In what circumstances are incentives an acceptable means to change individual behaviour as a way to promote better public health overall?
- 2011 Future costs and benefits discounts
Should NICE discount future costs and benefits and are there features that should be taken into account for using different discount rates?
- 2013 Social care values
- 2014 Trade-offs between equity and efficiency
What values should be considered when NICE makes trade-offs between equity and efficiency in its guidance?
- 2015 Using anonymised data
What principles should be considered when patient data is used and analysed?

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