



Medicine and Social Justice: Essays on the Distribution of Health Care

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Allocating Health Care Resources in the UK

Putting Principles into Practice

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Abstract and Keywords

This chapter examines the **ethical principles** behind just **allocation of health care resources in the UK**, with particular emphasis on the National Health Service (NHS). These ethical considerations include equality of outcome and equality of persons or equity; the latter can be considered through the principles of fair process, need, and rescue. The chapter analyzes how these ethical principles work in practice on the national, regional, and local levels. The national level is governed by the National Institute for Health and Clinical Excellence, and uses the principles of **cost effectiveness and equity** in order to make fiscal and clinical recommendations to the lower levels. The chapter also looks at the Oxfordshire Primary Care Trust and how it uses the South Central Ethical Framework to make decisions about why an individual patient should receive a treatment that is not usually covered by the NHS. Finally, it discusses the issue of rescue and Individual Funding Request (IFR) panels.

Keywords: resource allocation, health care resources, UK, National Health Service, National Institute for Health and Clinical Excellence, cost effectiveness, equity, Oxfordshire Primary Care Trust, South Central Ethical Framework, rescue

The Importance and the Unavoidability of Rationing

The British **National Health Service (NHS)** is one of the world's four largest **direct employers**; half the size of the Chinese People's Army but on a par with Wal-Mart and the Indian National Railways.¹ It has around 1.7 million employees. Just under half of the NHS workforce are clinicians, including about

400,000 nurses, 120,000 hospital doctors, 40,000 primary care doctors, and 25,000 ambulance personnel. Three quarters of the British population visit their primary care doctor at least once each year. Five million consultations between patients and doctors take place within the NHS each week. The NHS, in short, is the largest provider of health care in the world.

The NHS has an annual budget of £100 billion: about £2,000 per person. Around 20% of the budget is spent on medicines and supplies. The funding comes from general taxation. The purpose of the NHS is to provide health care, free at the point of delivery, to the entire UK population. The NHS therefore has a rather pure problem of resource allocation: how should the funds collected through taxation be best distributed? Until 20 years ago this question was difficult to ask because no government would admit that the resources were insufficient to provide the very best health care for everyone. A few brave people used the “R-word”—rationing—but not in political circles. This changed around the mid-1990s. The government’s desire to keep public spending under control highlighted the fact that there were expensive new treatments with some benefits and that not all could be afforded all of the time. Rationing, or to use its softer soubriquet resource allocation, had to be tackled explicitly within the NHS.

Rationing has to be faced by all health systems whether private, public, or mixed. Medical advances mean that no health system can afford the very best management for all patients all of the time. A purely libertarian system based on patients bearing the entire cost of private treatment might avoid explicit discussion of rationing but only at the expense of excluding large parts of the population from the ability to afford much of the care. Rationing in such a system is on the basis of socioeconomic status. An insurance system has to ration because no contract can foresee the medical advances. Insurers, like the NHS, are faced with a budget that cannot provide the very best care for all their clients all of the time. In the US there has been interest in the process of rationing decisions precisely because it is recognized that rationing has to take place (Daniels & Sabin 1997, Daniels 2000, Daniels & Sabin 2002).

The NHS experience should be of interest to anyone concerned with how rationing should be tackled in practice. Whatever its weaknesses, the NHS is an enormous health care provider that has grasped the nettle of rationing and has made serious attempts to develop proper processes and principles within the practical and political constraints that health care providers have to face. How health care resources are distributed makes an enormous difference to people’s health and affects who will live and who will die. It is therefore one of the most important issues in bioethics.

In this chapter we examine the way in which resource-allocation decisions are made in the NHS. We sketch the processes, principles, and decisions that are made. First, we articulate a range of principles and assumptions that are generally in play in the context of UK resource-allocation decision-making. To some extent these are aspirational—not all decisions are grounded (p.220) in these principles alone, and in some cases they are not explicitly adopted. Then we examine the decision-making processes at both national and local levels. The focus at the national level is on the operation of the National Institute for Health and Clinical Excellence (NICE). The focus at the local level is primarily on the working of local or regional Priorities Forums and Individual Funding Request (IFR) panels.

Ethical Principles

In this section we articulate the main ethical principles that inform the processes of decision-making in the NHS. These principles, we believe, need to be considered in any context of health care resources allocation. In part, they define the ethical and distributive justice problems. We use the term *principle* very broadly to capture a range of considerations that are normatively involved in the decisions in question. We understand “principle” not to mean a prescriptive precept or rule but a *prima facie* consideration that partly proscribes the spectrum of relevant ethical issues. The section is divided into three parts, each of which deals with a specific set of issues and their constitutive principles.

Background Conditions

Background conditions are constraints on any system of fair distribution of resources with a given budget. They are conditions that either contribute to defining the problem or are features of the situation that any account must acknowledge.

At root, a problem in distributive justice arises when the size of the “cake” of resources is less than the potential demand. If we can add pieces to the cake whenever needed, the distribution problem goes away (Broome 1988, 1990). In practice there are a number of levels at which the cake analogy might operate within a health care system. It might be that the cake represents the health care budget, or it might represent a higher-level resource decision, say between government departments such as education, roads, transport, and military. In cases where the given budget is dependent on levels of taxation, the distribution problem might be mediated by questions about taxation levels—so the tradeoff might be between reasons for keeping taxes lower and the value in increasing the size of a given budget. These variations in how we understand the nature of the cake shift the scope and context of the problem without solving it. For our purposes the fixed budget in question is the health care budget given to the

NHS. The problem of distributive justice is how to allocate these resources justly.

The first background condition is **cost**: the cost of an individual treatment matters. If cost is ignored this is tantamount to adopting a strategy for distribution that privileges temporal order—that is, resources are distributed on a first-come, first-served basis. Those demands on resources that arise earlier in the financial year are funded at the expense of those that arise later. This is an unjust strategy because there is nothing morally distinctive about being diagnosed (for example) earlier in the financial year rather than later. In a libertarian system cost affects distribution because it affects the ability of individuals to pay.

The second background condition is the idea of **opportunity costs**. At its most general the idea is that if money is spent on *this*, it is not available to be spent on something else. The *opportunity costs* are those opportunities for spending that are lost as a result of using the money for *this*. Opportunity costs are particularly salient in the setting of a fixed budget. Perhaps the most straightforward way to understand the ethical force of opportunity costs is as a requirement that resource-allocation decisions be made in the context of a budget where the relative value of various courses of action can be effectively compared. Any justification for funding treatment A must take into account the fact that funding A will mean not funding B, C, or D, just as the justification for funding B must take into account what will not be funded as a result.

The third background condition is **effectiveness**. A system of health care resource allocation should take into consideration the extent, probability, and duration of the effect of any of the treatments. This is because the central aim of a health system is to affect the health of those it cares for. One implication of this is that resources should not be used to fund treatments that do not work.

Equality of Outcome

How do we distribute the available health care resources justly? Aristotle's thought that we should treat equals equally and unequals unequally is often taken to give us a formal answer to this question and to provide an important link between the idea of a just distribution and equality. That is, it suggests that distributing resources justly requires deciding the respects in which people are equal and unequal. So, for example, insofar as X and Y are citizens of a country they ought to be treated equally with regard to citizenship issues. **(p.221)** However, insofar as X and Y are different with respect to health (X being healthy and Y not), they should be treated differently with respect to health. What is missing from Aristotle's dictum is any account of the various relevant respects in which we are equal and unequal. For our purposes there are two general approaches: equality of outcome and equality of persons.

An approach that focuses on equality of outcome places value in the outcomes. Equal treatment is determined with reference to those outcomes. Two treatments that have the same outcome ought to be resourced to the same extent. If treatment A has a better outcome than treatment B, then (other things being equal) A should be prioritized over B.

The central way in which equality of outcome is usually fleshed out is in terms of **cost-effectiveness**. That is, the overriding principle of justice is one that maximizes the outcome per resource unit—"value for money." This counts as a principle of justice because it takes it that it is fair for everyone if the resources available are used to bring the most overall benefit to the relevant population. Moreover, by focusing on overall value for money, a cost-effectiveness strategy is well placed to be impartial between people and between types of condition.

There are various ways of measuring cost-effectiveness in the context of health care. The measure that has received the most attention and use in the UK is **cost per quality-adjusted life-year (QALY)**. The essence of a QALY is that it takes a year of healthy life expectancy to be worth 1, but regards a year of unhealthy life expectancy as worth less than 1. Its precise value is lower the worse the quality of life of the unhealthy person (which is what the quality-adjusted bit is all about) (Williams 1988). The general idea behind the QALY approach is that a beneficial health care activity is one that generates a positive number of QALYs, and that an efficient health care activity is one where the cost per QALY is as low as it can be. A high-priority health care activity is one where the cost per QALY is low, and a low-priority activity is one where the cost per QALY is high.

Equality of Persons

An alternative approach to justice focuses on the equality of persons rather than the equality of outcome. Attempts to articulate this approach often involve reference to some kind of moral rights. Part of the idea involved in attributing rights to people is that it is with respect to those rights that we are considered equal. On this view, it is the person, or a morally significant property of the person, who should be treated equally with others. Each individual person is to be treated as being distinct and of value. The value here lies intrinsically with the person rather than extrinsically with the person as a bearer of "good outcomes." In the context of resource allocation in the UK the claim that the equality of persons is an important aspect of justice is often referred to as a claim about the importance of **equity**.

The three principles below represent different ways in which a conception of justice based on equality of persons might be developed.

Fair Process

One important way of treating persons equally is by giving them a chance to a fair hearing or a decision procedure that enables the full and equal

consideration of the range of reasons that each stakeholder might see as relevant. This approach takes distributive justice to rest on the idea, familiar in legal contexts, of a **fair process**. To a large extent the resource-allocation decision-making system in the NHS is shaped around the idea of a fair process, with striking resonances with Daniels and Sabin's "accountability for reasonableness" model (Daniels & Sabin 1997). In this respect the system strives to be accountable not just in the decisions that it makes but, crucially, in the reasons for making those decisions.

One important element of this idea is that although it is based on an account of justice that privileges equality of persons, it does give significant hearing to the kinds of cost-effectiveness measures that make up the equality-of-outcome approach. In this way considerations of cost-effectiveness are able to be important determinants in decisions alongside other ethical considerations. Indeed, arguably when economic constraints are more severe the system is able to adjust by allowing, in an appropriate way, for cost-effectiveness to be a more pressing concern.

As a "principle" the idea of a fair process functions in a different way from the others. The operation of this principle governs *the way* in which decisions are made rather than guiding the content of those decisions. In practice it means that part of the attention of the decision-makers should be directed to the functioning of the process of decision-making in addition to the decisions themselves. On its own, fair process is insufficient because it tells us little about what reasons are relevant, and gives no decision-making guidance to those involved in the process.

(p.222) Need

Ethical discussions of resource allocation often highlight the importance of **need**. The idea is that those who are in a worse state should be given higher priority for an intervention: people should get what they need and resources should be distributed so that needs are met. This principle falls under the heading of equality of persons primarily because the respect in which people are judged to be equal is based on a morally relevant feature of the person (the extent to which she is in need) rather than on the outcome of particular interventions.

The three major problems associated with taking needs as the only principle of allocation are: (1) how to define and rank needs, (2) what do we do when needs outrun resources, and (3) a very large proportion of the resources is likely to be spent on marginally effective interventions for the most needy. With regard to the first issue a patient with end-stage renal failure, for example, needs dialysis, whereas patients with a fully healed but extensive burns scar many not *need* cosmetic surgery, or at least not to the same extent (Scanlon 1975, Lockwood 1988). This is not to deny that there may be benefits associated with the latter—

not all things that are of benefit are needed. The main problem here involves the specification of the goal that the fulfilled need makes possible. That is, needs are *for something*—we need F in order to G. The problem is how to characterize G in such a way as to be able to rank needs, and distinguish needs from “mere” desires. One suggestion is that the lack of what we need compromises our capacity to flourish as a human being (Wiggins 1998). This may well be the right account, but until we have an account of what it is to flourish as a human being and what it means for that capacity to be compromised, we are not much closer to a practical solution.

The second difficulty involves the concern that the resources required to satisfy all needs will outrun the resources available. Arguably the resource-allocation problem in the NHS is precisely to decide *between* needs rather than between needs and mere desires—by and large, coronary artery bypass grafting is a more pressing need than knee reconstruction surgery. Accordingly, we might allocate more resources to the former than to the latter. The problem is that by the time all of the most pressing needs have been fully dealt with, those with “lesser” needs are likely to miss out. If we have a satisfactory way of ranking needs it may look as though we have gone a good way towards satisfying the ethical claim of needs. Thus it may be right not to fund knee surgery if we do not have sufficient resources to save all lives. But there are further difficulties associated with the third major problem. For example, how would we rank a very expensive intervention with a low, but non-zero, probability of extending life by a short period, against a knee operation? It would seem that cost and effectiveness must also be taken into account alongside need. A metric that does just that has been proposed (Hope et al. 2009).

Rescue

Although it might be seen as a particular example of giving priority to need, the *rule of rescue* merits separate discussion as it has taken on a life of its own in discussions of resource allocation. Broadly speaking, the *rule of rescue* involves spending large amounts of resources “rescuing” identifiable individuals who are in imminent danger (Jonsen 1986). This “rule” was invoked in Ontario to overturn a decision not to fund treatment for Gaucher’s disease, and it has also been used to justify resource decisions in Israel concerning the same condition (Gross 2002).

It seems reasonable to understand the rule of rescue as a general empirical tendency—that is, as an empirical fact of human psychology perhaps more aptly named the “Identifiable Victim Effect” (Jenni & Loewenstein 1997). It does seem true that we are prepared to spend significant resources rescuing seriously endangered identifiable individuals. But if the rule of rescue is taken to be an empirical fact, there remains a serious question about how it should feature in

decisions about the distribution of resources. Is it morally right, or is it a psychological tendency that should be resisted on moral grounds?

It might be suggested that people's willingness to go to great lengths to save a few is indicative of an agent-relative obligation. Agent-relative obligations are obligations that we have because of a particular relationship or set of circumstances. They are to be contrasted with agent-neutral obligations—obligations that apply to all, independent of a particular circumstance or relationship. On this suggestion, we have agent-relative obligations to someone with whom we have a relationship, or to someone who is identifiable, or to someone in serious need of help who is nearby. Do those involved in health care policy and resource allocation have such agent-relative obligations to individual patients? The answer depends on how we see their role. We might suggest that **(p.223)** health care is not simply a business. On one view those making policy decisions in health care can be taken to have obligations both to the population as a whole and to particular patients—they have agent-neutral and agent-relative obligations. This is not to say that one always trumps the other; nor is it to say that the decision between them is always straightforward. But it is to claim that an account of policymaking in health care that omits agent-relative obligations is an impoverished one (Sheehan 2007).

One practical approach to the problem of whether the rule of rescue should be used in prioritization is to specify policy (i.e., in agent-neutral terms) but to have an additional process for examining individual cases that are considered exceptional (see below). The process for examining individual cases asks the question: how do we handle those whom we think should be “rescued” by a health care system but who are overlooked by the earlier decisions?

The Structure of NHS Resource-Allocation Decisions

Having given a brief overview of the principles of resource allocation we now consider its practice as exemplified by the NHS. As the US attempts to provide more universal health care coverage of the population it will need to grapple with many of the same issues. To understand allocation decisions, some knowledge of the structure of the NHS is required.

Very broadly, commissioning decisions (resource-allocation decisions about what to fund) are made at three levels across the NHS: national, regional, and local. In spite of this the central focus of the decision-making comes at the local level, with the higher-level processes representing an attempt to cover issues that are difficult for the lower levels or that are particularly politically sensitive. The system is thus driven from the bottom level up. Primary Care Trusts (PCTs) are the main local budgetary units at the time of writing, although there are plans to make primary care *practices* the main local unit. There are 151 PCTs (and over 8,000 primary care practices) in England. PCTs are grouped together into 10 regions as Strategic Health Authorities (SHAs). So, for example, Oxfordshire

PCT is a part of South Central SHA. In terms of commissioning the SHA organizes and commissions treatments, as “specialised services,” that are more efficiently provided at the regional level. Although a small amount of commissioning is carried out at the national level, the principal body at this level that affects resource allocation is the National Institute for Health and Clinical Excellence (NICE). In the next section we will explain how NICE works and give examples of the issues it has considered and the ways it has tackled them. In the section after that we will focus on regional and local levels.

Principles in Practice: NICE

The Nature of NICE

NICE was created in 1999 in part to solve a political embarrassment. Since NHS budgets are devolved to local areas, and since there are drug treatments that provide only slight extra benefit for great extra cost, it was not surprising that in one area a patient might receive, for example, an expensive cancer drug free under the NHS whereas in another area the decision had been made not to fund that particular drug and to use the money saved for other types of health care. The result was that a patient in one part of the country might be denied a treatment, under the NHS, that another patient in an identical clinical state, but who lives in a different part of the country, obtains free of charge. In a *national* health service that is unfair, and the unfairness is easy to see. No wonder the media worked hard to identify such inequities: they made good copy. “Post-code rationing,” as it is called, became a national scandal.

NICE was set up by the Secretary of State for Health as an independent body to provide national advice on promoting good health and preventing and treating ill health. It aimed to offer NHS professionals advice on how to provide their patients with the highest available standards of care. The Secretary of State directed NICE that in appraising health care interventions it should consider “the broad balance of clinical benefits and costs.” Although NICE formally provides advice only, if NICE recommends that a particular drug should be provided on the NHS it is a brave local decision-maker who will go against the advice: both politically and legally this could be problematic. Conversely, if NICE advises that a particular drug is too expensive, given its small benefits, to be provided under the NHS, the local decision-maker is likely to sigh with relief: there will be more money available for meeting some of the other demands on the limited NHS purse. At one stroke NICE removed two causes of headache **(p. 224)** for politicians. First, it could eliminate any post-code rationing that was proving politically problematic. NICE could be directed to report on whether the relevant intervention should or should not be available within the NHS and all local funders would then step into line. Second, it distanced government from decisions to limit treatment availability.

NICE effectively makes resource-allocation decisions affecting an enormous budget and in the full glare of media scrutiny. It tackles real issues that arise in modern health care and it cannot equivocate. It uses a careful process that must be seen to be defensible in a modern democracy and it has to justify its decisions in terms of reasons. Over its 10 years NICE has built up a considerable body of work and its decisions form a kind of case law for its future decisions. NICE explicitly recognizes that its decisions involve a combination of scientific and ethical judgments, which NICE calls “social value judgements” (SVJ). These social values as well as all its reports are readily available on the website and provide an almost unique example of practical decision-making.²

The Values of NICE

In 2002 NICE set up a Citizens Council to advise the NICE board on the public’s views about some of the difficult issues which it faced. This Council consists of 30 people at any one time chosen to be representative of ordinary people across the UK. This Council produces reports about these issues, and in addition its views are taken into account by the board in producing its SVJ, in effect its ethical framework, now in its second edition (NICE 2008). This framework is also informed by the law (for example by the Human Rights Act), government policies, consultations, and the experience of advisory board members.

According to the board these ethical principles must be taken into account by the various advisory committees in giving their advice. Philosophers may be disappointed, however, by how thin the ethical discussion is that is contained in most of the reports compared with the thoroughness of the scientific and economic analyses.

The explicit values of NICE are a combination of procedural values and substantive values. The procedural values highlight that decisions should be made on the basis of rigorous scientific analyses, that they should be transparent, and that reasons for the decisions should be explicit. The decisions are reviewed internally and there is an appeals procedure.

With regard to the substantive values the approach is pluralistic and pragmatic. NICE tries to make sure that its decisions can be carried out in practice by the NHS and it aims to take into account the specific circumstances of each case as they impinge on the NHS, and of the perspectives of the various groups affected by the decision.

The SVJ considers explicitly most of the principles adumbrated above. We will consider these under similar headings but also reflecting the discussion in the SVJ.

Cost-Effectiveness

Central to the working of NICE is what is technically called the incremental cost-effectiveness ratio (ICER). Consider a new drug, let's say for cancer, that gives a slightly better survival rate than the drug currently used (and funded under the NHS). The new drug is considerably more expensive. For the sake of exposition, suppose that this new drug gives a 2% better chance of cure—that is of normal lifespan—than the current drug and that the current drug gives a 50% better chance of cure than no treatment. The total cost of the course of this drug treatment, let us say, is £10,000 *more* than the current treatment. On these figures, if we pay for the new drug rather than continue with the current treatment then we will pay £10,000 times 50 (because there is an increase in cure rate of 1/50), which is £500,000 per life saved. If the average life expectancy (if cured) of patients in the relevant group is 20 years, then the cost per life-year saved of using the new drug, compared with using the old drug, is £25,000. The incremental cost-effectiveness ratio for this new drug is therefore £25,000 per life-year saved. We say it is *incremental* because it is the cost-effectiveness of our increasing the treatment option compared with current, or best alternative, treatment (not compared with no treatment). Effectively this is cost per QALY interpreted in the setting of evolving treatments. In this example we have considered only the effect on life-years. A quality adjustment can be added as described above.

The SVJ states, in essence, that there would need to be good reasons to fund an intervention that has an ICER above £30,000 per QALY, and good reasons not to fund an intervention with an ICER below £20,000. There can be good reasons, such as considerations of *equity* and *need* (see below), and NICE has recommended treatments that cost more than £30,000 per QALY. But the cost-effectiveness is generally the starting point in **(p.225)** considering whether to fund an intervention. These figures are based on experience and are thought to represent what the NHS on average can afford.

The experience of NICE is that even if cost-effectiveness is accepted as a key consideration in allocating resources, there are a number of further issues that raise ethical questions and that need to be tackled. Three issues in particular have been highlighted, each raised in our discussion of principles above.

Equity

Equity is at the heart of the NHS, and concern about inequity—post-code rationing—was a key reason for establishing NICE. The SVJ has a number of things to say about equity: “The NHS aims to provide free, necessary and appropriate treatment to the whole UK population. Legislation on human rights, discrimination and equality requires that patients are not denied access, or have different or restricted access, to NHS care because of their race, disability, age, sex/gender, sexual orientation, religion, beliefs, or socioeconomic or other status. The board of NICE expects everyone working for or with NICE to be

particularly vigilant in avoiding discrimination and promoting equality” (NICE 2008, 23). With regard to situations relating to disability the SVJ states: “NICE should take special account of the needs of disabled people, which includes considering whether there are obstacles that might prevent them from benefiting from NICE guidance. Where necessary and appropriate it should take positive steps to take account of these needs” (NICE 2008, 23).

The Citizens Council was asked to consider whether NICE should focus its work on improving health for the whole population even at the risk of widening the gap between socioeconomic groups, or should concentrate on trying to improve the health of the most disadvantaged members of society. The Citizens Council response was that “under most circumstances the process of allocating resources should be first and foremost by the identification of a health condition worth tackling; only then should we consider who suffers from it, and whether resources need to be targeted disproportionately to particular sections of the community. If those individuals happen to belong to a particular ethnic or socio-economic group—so be it. Target them. By contrast, to launch a process with the primary and expressed aim of helping out this or that ethnic or economic group will, we suspect, invite complaints of unfair discrimination, and generate avoidable controversy” (NICE 2006b, 15). It is noteworthy that the reasoning in the final part of this statement relates more to political expediency than to ethical principle.

Need

The SVJ says very little about need. What it does say appears to reject using need as an additional consideration once cost-effectiveness and equity have been taken into account (NICE 2008, 20–21). Considerations of need, however, do seem to have been taken into account in NICE’s decision about riluzole (NICE 2001).

At the time of the assessment riluzole was the only licensed drug available for the treatment of motor neurone disease (amyotrophic lateral sclerosis). Riluzole could delay the time when the patient needed ventilation (needed because the muscle weakness eventually makes unassisted breathing impossible). The data showed that the cost-effectiveness (ICER) was around £38,000, which is above the normal threshold for NICE to recommend treatment. NICE, however, approved riluzole for treatment under the NHS because the committee took account of the severity and relatively short lifespan of people with the condition. In essence it looks as though NICE considered that people with the condition were so badly off that it was justified to pay more than the usual cost-effectiveness threshold.

Rescue

The NICE Citizens Council Report on the Rule of Rescue states that “a majority [of the Citizens panel] (21 out of 27) said that it [the rule of rescue] should not be rejected completely and it should be applied in certain exceptional cases” (NICE 2006a, 6). Indeed, the Citizens Council preferred to use the term “exceptional case” in preference to “rule of rescue.” The second edition of SVJ is more definitive: “NICE considers that the principles provided in this document are appropriate to resolve the tension between the needs of an individual patient and the needs of present and future users of the NHS. The Institute has not therefore adopted an additional ‘rule of rescue’” (NICE 2008, 20–21).

Comment on NICE

The value of NICE to those interested in resource allocation in the real world is that it provides **(p.226)** publicly available documents not only about its stated values but also about how it has tackled specific issues. We will pick out some of these specific issues for comment.

Effectiveness

NICE generally uses a standardized, self-completion questionnaire of health outcomes, the EQ-5D, to assess the quality adjustment needed to estimate QALYs (Shaw et al. 2005). This measure, however, is not appropriate for all types of intervention because it does not adequately measure some kinds of outcomes, such as hearing loss. One example, therefore, where NICE had to use a different measure of health outcome to generate QALYs was when considering cochlear implants to enable people with profound hearing impairment to hear better. NICE used the Health Utilities Index version 3, which includes hearing, in order to calculate cost-effectiveness (Feeny et al. 2002). This enables interventions for hearing impairment to be compared, but its use raises the problem of how one can compare QALYs calculated using different measures for quality of life.

A second problem that NICE has had to confront is how benefits that are not health benefits should be taken into account. This arose in the assessment of parent training, and other educational programs, in the management of children with conduct disorders (NICE 2006c). Effective treatment is likely not only to improve a child’s health but also his educational achievement and employment, and reduce the chance of his committing crime. The question arises as to whether, in considering the cost-effectiveness of the intervention, the non-health benefits should be put into the equation. NICE decided to take the effects on education into account.

Costs

It is not only the measurement of the effectiveness that can be problematic, but also what is included in the costs. This issue arose in the context of drugs for Alzheimer’s disease. To the extent that such drugs might delay the need for nursing or residential care, they can reduce costs both for informal caregivers

and for the public purse because in many cases part of the cost of such care is borne by the state. NICE decided that the reduction in costs for the public purse should be taken into account in the overall cost of treatment, even though most of this reduction benefited the social services budget rather than the health budget, but that the costs to family and caregivers should not be taken into account (NICE 2009).

Opportunity Costs

NICE effectively makes resource-allocation decisions but it does not have responsibility for a budget. The NHS budgets are devolved locally. It is these local bodies, principally the PCTs, that have the responsibility to see that the NHS budget is used wisely for the health of its local population. The scientific evidence, including cost-effectiveness analyses, collected and summarized by NICE can be very helpful to the PCTs in managing their resources. But NICE goes further: NICE tells the PCTs that they must use their limited resources in certain ways, but NICE does not have to face the opportunity costs. In other words, NICE has neither the responsibility for nor knowledge of the health care that cannot be carried out because resources are being spent on what NICE decides must be carried out. This is power without the relevant responsibility (McMillan et al. 2006). Locally managed funding is seen as crucial so that each locality can best address the health needs of its population, recognizing that different populations are different. But if each locality is to make its own decisions, then it is inevitable that different decisions will be made.

Principles in Practice: Local Decision-Making

The Process of Local Decision-Making

Oxfordshire PCT receives a budget from the government—as part of the NHS—and has the responsibility of using this money to purchase the health care for the population it serves (roughly the 600,000 inhabitants of Oxfordshire). The PCT pays for all the primary care, and most of the hospital care, that is provided on the NHS. The government also provides some money directly to SHAs to pay for highly specialized regional services.

PCTs are under statutory duties both to promote the health of the local community and not to exceed their annual financial allocation. The Oxfordshire Priorities Forum is a body established to advise the PCT's Clinical Executive (which has ultimate responsibility for decisions) on particular resource priorities for health care interventions to be provided to the Trust's population. The Forum provides advice on which interventions and treatments are to be considered a "low priority" for funding and are therefore not normally commissioned by the Oxfordshire PCT. The Forum publishes its advice as policy statements.³ These statements occasionally outline eligibility criteria for treatment.

(p.227) In addition to the Priorities Forum, the Trust also has in place a mechanism for considering the claims of individual patients who, with the

support of their clinician, feel that their situation warrants special attention. This mechanism involves the IFR panel and is the route through which the PCT considers exceptions to its adopted funding policies. The IFR process does not make policy on behalf of the PCT but begins with the policy position and examines exceptionality from there. The key part of the PCT's policy for considering exceptional circumstances is as follows:

Central to our consideration of individual requests for funding, is the question:

"Why should this treatment be provided for this patient when the treatment in question is not normally funded?"

...If funding is to be agreed, there must be some unusual or unique factor about the patient's clinical circumstances, which suggests that:

- The presentation/effect of the condition in the patient differs significantly from that found in the general population of patients with the condition

And

- The patient is likely to gain significantly more benefit from the proposed treatment than might be expected from the average patient with the condition." (NHS Oxfordshire 2010, 22)

Principles

In Oxfordshire, the South Central Ethical Framework (NHS Oxfordshire 2008) is the key document governing the way in which the principles are applied. This framework helps to ensure that the relevant considerations are raised in the discussions about priority-setting decisions in the region. The ethical framework presents the range of *prima facie* principles to be considered in making the judgement about the funding of a treatment—they do not have prescriptive weight or a particular ranking. It also provides the basis of reasons for decisions reached through the priority-setting process.

There are seven principles that make up the Ethical Framework:

1. Evidence of clinical and cost-effectiveness
2. Equity
3. Health care need and capacity to benefit
4. Cost of treatment and opportunity costs
5. Needs of the community
6. Policy drivers
7. Exceptional need

With the exception of numbers 5 and 6 these are straightforward instances of the principles previously discussed. In principle 3, “need” is included alongside the concept of capacity to benefit. That is, it is not enough that a group of patients has a certain health need; the health care intervention in question, to address this need, should be one from which that group of patients can benefit. As such, “capacity to benefit” combines an element of effectiveness with patient’s needs and in doing so moderates the way in which the need is addressed. Principle 7 picks up the issue of rescue—this principle functions as a marker for the idea of fair process and should not explicitly feature in the deliberations of the Priorities Forum. Instead, it is instantiated in the IFR process.

Principles 5 and 6 register the importance of the policymaking context of the PCT. On the one hand it is required to take into consideration initiatives, policy, and guidance that are made at the regional and national level. These include “National Service Frameworks, NICE technology appraisal guidance, Secretary of State Directions to the NHS and performance and planning guidance” (NHS Oxfordshire 2008, 4). Principle 5 is primarily directed at the local level, registering the importance for the PCT of serving the local community through preventive medicine and addressing the specific range of needs of that community.

Comment on Local Decision-Making

As in the previous section, the local decision-making structures and their application of the ethical principles outlined above throw up a number of interesting ethical issues that are worthy of discussion.

Effectiveness

Several questions arise about the status of the evidence of effectiveness. A significant amount of research is done in gathering the relevant evidence of effectiveness of the interventions that are considered by the Priorities Forum. If there is good evidence, this tends to mean that the intervention is funded. Importantly, “good evidence” here is often understood to be evidence from large-scale controlled clinical trials (or the systematic analysis of a range of such trials). Oxfordshire PCT has explicitly ranked the various kinds of evidence and associated them with likely funding outcomes **(p.228)** (NHS Oxfordshire, 2010). This means that research funding is very important for the kind of treatments that will be funded down the line: if there is a significant amount of funding for a particular stream of research, it is likely that the quality of the evidence produced by that research will be better.

There are a number of difficulties with this approach to what counts as “good evidence.” First, we might be skeptical that evidence should be ranked in the way that it tends to be: it might be that evidence from randomized controlled trials is not the “gold standard” for some treatments in some clinical contexts.

Controlled trials are designed to answer certain, often narrow, questions that are not always relevant to the patient and the care pathway in which the intervention is used. Second, privileging certain kinds of evidence disadvantages interventions for which that kind of evidence is unobtainable. Many of the interventions considered by the Priorities Forum are brought to the committee precisely because evidence is difficult to obtain for various reasons: the conditions treated might be very rare, the intervention might be difficult to test in a controlled way (this can be true of non-pharmaceutical interventions like wheelchairs or hearing aids for children), or there might be ethical reasons why a controlled trial cannot be conducted. In each of these cases a lack of particular kind of evidence of effect does not mean a lack of effect, nor should it mean lack of funding.

Opportunity Cost

The Priorities Forum suffers from a similar “opportunity cost” problem as that faced by NICE. Opportunity costs arise in this context because the policies are one-off decisions rather than in-budget tradeoffs. Like NICE the Priorities Forum does not have a budget and makes policy recommendations outside the context of a budget (albeit a little closer to the decision-makers). In some Trusts a Director of Finance sits on the Priorities Forum and can provide more of a budgetary context for the policies. It remains the case, however, that the Forum advises about, rather than decides, priorities. Any guidance it offers, because it is outside of a specific budget, runs the risk of underestimating the costs of failing to fund an alternative intervention. The real prioritizing (and genuine appreciation of the opportunity costs) happens when it is clear what will not be funded as a result of funding a particular treatment. This can happen only in the context of decisions about a full budgetary allocation. One solution here is for the Priorities Forum to produce more nuanced guidance that will be of more assistance (than “low priority”) in ranking and trading off between treatments. This would mean that the Forum could operate more effectively as an advisor to the Clinical Executive.

Rescue

The existence of IFR panels connects importantly to the considerations about rescue and, in our view, is the best way to understand the proper operation of the moral claims lying behind the rule of rescue. It seems clear that there is some obligation to “rescue” those who are unfairly overlooked by the policymaking process, but this does not preclude there being a robust policy for considering and indeed appropriately limiting such circumstances.

The big question for IFR panels is what is to count as exceptional. Exceptions arise where there is a case to be made by an individual that his or her situation is relevantly different from the circumstances considered in the formation of the policy and captured in the decision that led to the policy. Given this, what counts as exceptional looks to be either indefinable or very nearly so. Any definition,

given in advance, would need to capture all the ways in which an individual might unjustly fall outside of the policy. Some of the difficulties here involve whether social or cultural considerations should play a role in assessing the patient's ability to benefit or whether the special nature and welfare of caregivers should be included in such considerations (Newdick 2006).

Overall, the importance of the policy stage of priority-setting is very important for IFR panels: the better specified the policy is, the more closely circumscribed the conditions of exceptionality. If the policy has the appropriate nuance and desiderata, then cohorts of patients will form part of the original decision and the policy will reflect the state of knowledge of effectiveness, cost-effectiveness, and need (etc.) of the condition and its management. In this way the IFR panel as well as the patient and his or her clinician can better understand the reasoning behind the decisions and the ways in which an individual might be exceptional. On this account, IFR panels should not make policy, nor should they consider cases about which there is no policy.

(p.229) Conclusion

This chapter has provided a general outline of the processes by which resource-allocation decisions are made in the NHS, with particular attention to the ethical principles governing those decisions. These processes should be of interest to anyone concerned with how rationing should be tackled in practice. Although there are many unresolved issues, the NHS has made serious attempts to develop proper processes and principles within the practical and political constraints that health care providers have to face.

The importance of the NHS as a national icon will mean that the processes of decision-making within it will continue to receive significant attention and will continue to develop, being shaped, as always, by the broader political and economic climate. As the capacity of medicine improves and broadens, costs and expectations will continue to rise—new technologies will mean more can be done to prevent and treat illness and disease, and more can be done in health terms to affect people's overall welfare. It is likely that the importance of these decision-making processes will only increase.

As things stand, more conceptual work is needed in articulating and clarifying the practical issues that arise in resource-allocation decision-making at the various levels, so that the process can be made as consistent and robust as it should be. Concepts such as need, equity, effectiveness, and exceptionality need to be better understood in the practical resource-allocation context. In a similar vein, our reflections on the UK system point to the importance of building the cohesion of the policy- and decision-making structure. This will help the process to be flexible enough to handle future trends and constraints and to deliver decisions that are just.

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