



What reasons do those with practical experience use in deciding on priorities for healthcare resources? A qualitative study

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ABSTRACT

Background: Priority setting is necessary in current healthcare services. Discussion of fair process has highlighted the value of developing reasons for allocation decisions on the basis of experience gained from real cases.

Aim: To identify the reasons that those with experience of real decision-making concerning resource allocation think relevant in deciding on the priority of a new but expensive drug treatment.

Methods: Semistructured interviews with members of committees with responsibility for making resource allocation decisions at a local level in the British National Health Service, analysed using modified grounded theory.

Results: 22 interviews were carried out. 14 reasons were identified. Four reasons were almost universally considered most important: cost effectiveness; clinical effectiveness; equality and gross cost. No one reason was considered dominant. Some considerations, such as political directives and fear of litigation, were thought by many participants to distort decision-making. There was a substantial lack of agreement over the relevance of some reasons, such as the absence of alternative treatment for the condition.

Conclusions: There is a clear consensus on the importance and role of a limited number of reasons in allocation decisions among participants. A focus on the process of decision-making, however, does not obviate the need for those involved in the process to engage with problematical ethical issues, nor for the importance of further ethical analysis.

Over the past few decades, financial pressures have led governments and healthcare organisations to adopt systematic approaches to priority setting. Priority choices involve ethical values and a persisting challenge for policy-makers is to specify an appropriate package of health services that is ethically defensible.¹

One response has been to make processes for priority setting more transparent and accountable.^{2,3} This increasing accountability has affected public healthcare systems such as the British National Health Service (NHS), private healthcare systems such as Kaiser Permanente in the United States and mixed systems such as in Canada.⁴

This focus on process was partly a response to the problem that there is no clear consensus on the right theoretical approach to resource allocation. Each of the major theories of resource allocation, such as welfare theory,⁵ needs theory⁶ and the use of a lottery,⁷ faces difficulties. Daniels and Sabin² specify four conditions for a fair allocation process.

Three of these are straightforward: public accessibility; an appeals procedure and enforcement of these conditions. The fourth condition, “reasonableness”, is more problematical. This condition has been explained in various ways, including: “The rationales for coverage decisions should aim to provide a reasonable construal of how the organisation should provide “value for money” in meeting the varied health needs of a defined population under reasonable resource constraints. Specifically, a construal will be “reasonable” if it appeals to reasons and principles that are accepted as relevant by people who are disposed to finding terms of cooperation that are mutually justifiable.”²

Martin and colleagues⁸ have argued that the range and type of expertise of the members of the decision-making group are important in judging the reasonableness of the process. There is another crucial issue: if those involved in the decision-making process are serious-minded people of integrity they will struggle with just the problems that are at the heart of the limitations to the various theories of resource allocation, with what is a “reasonable construal” of how the organisation should provide value for money.³

There are two distinct ways of interpreting this “reasonableness” condition. The first is as a theoretical heuristic device. On this interpretation through an analysis of what it is to be a person “disposed to finding terms of cooperation that are mutually justifiable” it can in theory be possible to identify what reasons and principles are acceptable to such a person.

The alternative view is that the “reasonableness” criterion has an empirical component. That it is possible to identify “people who are disposed to finding terms of cooperation” and to find out what reasons and principles such people actually find relevant. Daniels,⁹ it appears, has this second view in mind. He wrote, “Accountability for reasonableness... does call for transparency about reasoning that all can eventually agree is relevant. Since we may not be able to construct principles that yield fair decisions ahead of time, we need a process that allows us to develop those reasons over time as we face real cases. *The social learning that this approach facilitates provides our best prospect of achieving agreement over sharing medical resources fairly.*” (our italics).

It is this empirical approach that is the focus of this paper.

The main aim of this study was to articulate those reasons that experienced decision-makers

think relevant in making allocation decisions. We focused on the question of whether or not to fund innovative drug treatments because in practice this is a common issue and because it provided an explicit setting in which participants could discuss their views. Innovative drug treatments were defined as new pharmaceutical products that either have some advantages compared with existing treatments, or treat illness and disability that has previously been left untreated and are more expensive than any treatment they would replace.

The state-funded British NHS budget is devolved to a local level, which therefore has primary responsibility for priority setting. Some local areas set up formal committees to advise on priorities for funding. As the advice from these committees was almost always acted upon they were de facto priority committees. The empirical study reported here centred on the experiences of people involved in two such committees: the Oxfordshire Priorities Forum and the Berkshire Priorities Committee and members of another local advisory board that considers the balancing of the financial pressures caused by meeting government targets (the primary care trust (PCT) financial department).

Before establishing the National Institute for Health and Clinical Excellence (NICE) these local committees were the only formal and transparent bodies that explicitly made resource priority decisions. NICE now makes recommendations about the use of a limited number of healthcare interventions within the NHS, but it is not responsible for managing a budget. Local organisations within the NHS, notably PCT remain responsible for managing the NHS budget, for interpreting NICE guidelines in day-to-day patient care and for the many allocation decisions that NICE has not addressed. PCT are the local bodies that contract with general practitioners (primary care doctors) and a large part of the health budget is devolved to these bodies. At the time of this study there were in the region of 50 general practitioners serving a population of 100 000 people for each PCT, although there was (and is) considerable variation in size between PCT.

METHODS

Sample

Current and former members of Oxfordshire Priorities Forum, the Berkshire Priorities Committee and the PCT financial department were invited by letter to take part in the study.

Interviews

Data were collected in face-to-face interviews. Participants were asked questions about their experience with priority setting and their perspective in the decision-making process (ie, whether their background was mainly clinical, managerial or within public health). The interviewer then asked: "What do you personally think are relevant reasons for giving some new drug treatments priority over others when scarce healthcare

resources are allocated?" and recorded the themes occurring as the participant answered the question. Participants were repeatedly asked to think of further reasons, and once no more new reasons appeared the interviewer returned to each reason and probed for elaboration, concrete examples and reflections on relevance. After all reasons had been revisited in this manner, the participant was presented with a "check-list" of reasons, identified as potentially relevant on the basis of the literature, pilot and previous interviews. The participants were finally asked to indicate whether some reasons were particularly important or whether all reasons were equally important and whether some of the reasons would only be relevant in specific circumstances.

Data analysis

The data collected through the interviews were analysed using a simplified and modified form of grounded theory.¹⁰ Because the interviews focused narrowly on reasons and the description of reasons, full transcripts were not needed to identify and account for categories of reasons. Instead, all interviews were audio recorded and then one of the authors (AH) listened to the tapes using a low-speed tape recorder and wrote a note each time a reason was given for making an innovative drug treatment a priority for funding. In this way a written "manuscript" was created for each interview that listed the reasons given and summarised the salient points of the discussion. After all interviews had been recorded in this manner, the descriptions of reasons were cut out of the manuscripts and re-assembled under common headings or categories in the course of the analysis.

The analysis was carried out in accordance with the basic principles of grounded theory and had three consecutive components: open coding, axial coding and modified selective coding. In open coding, data from the interviews were broken into discrete parts (for example distinct points made, arguments, reflections, or anxieties raised) in order to expose the thoughts, ideas and values contained in the data. Similar parts were grouped under abstract headings called "main categories".^{10 11} The discrete parts categorised under the same main category were related to each other through their dimensions.¹⁰ Main categories were integrated and refined during selective coding, with the aim of giving the best description of the reasons given by participants. Two analysts met to ensure that the qualitative results were appropriately derived from the data and established a subset of reasons that were seen as particularly important by the participants.

After the 22 interviews that resulted from the initial recruitment, the research team judged that data saturation was reached: that is, no additional reasons occurred in the last few interviews that contributed to, or refined, the empirically generated list. The sample seemed sufficient, therefore, to establish the main theoretical components of the process of reasoning on priority setting, at least as experienced in the setting of local decisions within the British NHS.

Table 1 Participants' background and affiliations

	Total	Clinicians	Clinician /managers	Managers	Lay representatives	Other
Oxfordshire Priorities Forum	10 (45)*	2 (10)	3 (13)	1 (5)	4 (18)	0 (0)
Berkshire Priorities Committee	7 (32)	3 (13)	2 (10)	1 (5)	0 (0)	1 (5)
PCT financial department	5 (23)	0 (0)	0 (0)	5 (23)	0 (0)	0 (0)
Total	22 (100)	5 (23)	5 (23)	7 (32)	4 (18)	1 (5)

*Approximate percentage of total in brackets.
PCT, primary care trust.

Table 2 Main reasons and illustrative examples

Reasons	Illustrative examples
Cost effectiveness	A drug treatment gives a good return on the money it costs in terms of health outcome An independent expert on health economics recommends the drug treatment
Equality	A drug treatment helps to break down barriers to healthcare Funding a drug treatment helps rectify disparities in health status among members of the population Funding a drug treatment helps rectify disparities in the level of healthcare provision across regions Funding a drug treatment helps rectify disparities in resources available in different clinical specialties
Clinical effectiveness	There is a net health benefit to those treated with a drug, either as prolonged life or improved quality of life A drug treatment increases patients' chances for an independent life A drug treatment is lifesaving An independent scientific expert recommends a drug treatment
Gross cost	The amount of money that it costs to offer a drug treatment The total cost to the organisation, as a percentage of resources available, of offering a drug treatment The net cost to society of offering/not offering a drug treatment
Political directive	Funding a drug treatment will help the organisation meet a performance target or comply with NICE guidelines
Appropriateness	A drug treats a condition that the general public considers an illness or disease Patients cannot be expected to pay for a drug treatment themselves
Patient choice	A drug treatment is a high priority within a clinical specialty for patients and patient representatives Funding a drug treatment will offer patients a choice of when, where and how health services are provided Patients should be allowed to refuse treatment A drug treatment that delivers the best health improvement, based on patient-centred outcome measures, should have high priority for funding
Delayed effects	A drug treatment has immediate effect The service is a preventive measure that will save health resources in the long term
Fear of litigation	It is likely that not funding a drug treatment will lead to a legal challenge
Internal and external pressures	Internal pressure from clinicians can lead to the legitimacy of decision-makers setting priorities being questioned External pressure from patient interest groups and the media can lead to the legitimacy of decision-makers setting priorities being questioned
Age	There is a special responsibility to treat young children because they have their lives in front of them There is a special responsibility to treat the elderly because they have contributed to society
No alternative	Denying services will take away the last hope The health service owes patients at least to do something
Responsibility	People who take risks with their health are not eligible for the same treatment as people who do not
Value to medical research	Funding this drug would enable research that will benefit people in the future

NICE, National Institute for Health and Clinical Excellence.

This study was approved by the appropriate research ethics committee (the Applied and Qualitative Research Ethics Committee, Oxford).

RESULTS

Participants

Twenty-two out of 29 (76%) of those invited to take part were interviewed after giving valid and signed consent.

The participants' backgrounds are given in table 1. Clinicians were typically hospital consultants, general practitioners, nurses and head pharmacists. Clinicians/managers were either directors of public health, medical directors or directors of nursing. Managers in most cases were chief executives, directors of finance, directors of strategic planning or directors of commissioning or service development.

Reasons

Fourteen reasons were identified as relevant to drug priority setting by the participants (summarised in table 2). Those interviewed gave a clear indication that some reasons are more important than others, but also that no single reason dominated decision-making. Most participants considered clinical effectiveness, cost effectiveness, gross cost, equality and political directive as the most important considerations in most situations. Concerns for patient choice, age, fear of litigation, internal and external pressures, appropriateness and delayed effects, were seen as situation specific and not universally applicable. Most, but not all, participants considered responsibility, no alternative and concerns for the cost of medical research to be reasons of little or no importance in practice, but there was some disagreement over this.

Reasons relating to clinical-effectiveness focused on the efficacy of healthcare treatments and concerned the extent to

which new drugs sufficiently and adequately improve health. When assessing clinical effectiveness most participants balanced the benefit expected from a drug treatment with the risk of adverse effects and harm to the patient. Benefit and harm were generally seen in terms of both quality and quantity of life. Improvements in quality of life were defined in different ways, eg, generic measures such as the Short Form 36 scale or the quality-adjusted life-year (QALY), or a treatment's capacity to create an "opportunity for the patient to live independently", save lives or "a dignified death". One implication in separating clinical effectiveness from cost effectiveness is that a drug that is highly effective and benefits relevant patients very significantly might be given higher priority than a more cost-effective but less clinically effective treatment.

Most participants spoke of the importance of cost effectiveness: the relation between the cost and the outcome, in either health or social terms. Most participants argued that health economic data, such as "cost per QALY", require careful assessment and are not the sole relevant source of information. Participants generally felt poorly equipped to assess QALY data and recommendations from experts in the field of health economics, who have local knowledge, were thought to be essential. When asked how data on the cost per QALY affected decisions, many participants gave a threshold of approximately £30 000 per QALY. The quality, and especially the source, of the evidence of cost effectiveness was an additional consideration for some participants, with a low value assigned to evidence from manufacturers and clinicians who plead on behalf of their patients.

Participants referred to the gross cost of introducing a new drug treatment in different ways. Some participants spoke simply of the amount of money that the drug costs to buy and prescribe. Others defined total cost much more widely as the net cost to society of offering or not offering the treatment. In most cases, however, participants considered the total or gross cost of offering a new drug in terms of a fraction of the budget available for service developments (so-called "growth monies") within their organisation. Reasons were therefore centred on the cost of an intervention but separate from the outcome, which those services have. The general view was that decision-makers would not be prepared to spend a large proportion of the money available for growth on a single intervention (or interventions aimed at a single patient group), however effective or cost effective. In this context approximately 20% was seen as too large a proportion of any growth monies to spend on a single intervention. A related reason, according to some interviewees, for rejecting NHS funding on cost grounds is if the drug is inexpensive for individuals, but would be expensive for the health service in cases in which very large numbers of patients would benefit (for example, aspirin).

As a reason, equality related to concerns for inequality in the distribution of health or access to healthcare or utilisation of services, or concerns about unfair distribution (inequity). A distinction is sometimes made between inequality and inequity: the former being purely descriptive (that two things are not the same with regard to some characteristic or in the way that they are treated), the latter being a normative judgement (that one group is being unfairly treated compared with another). In the context of this study, participants were concerned with normative judgements about the fairness of resource distribution. We have used the term "equality" to cover this group of reasons because the term "equity" has strong legal connotations that are not relevant. For some participants the examples related to inequalities in geographical distribution; other

participants spoke about inequalities between clinical areas and still others focussed on inequalities between people of different ethnicity, or social status, or life-style choices.

Political directives from central government or government agencies were referred to by almost all participants as having an important impact on priority decision-making. Participants disagreed, however, as to whether political directives are an appropriate reason in priority setting. Some acknowledged that directives can help reduce regional variation in access to services on the NHS ("postcode rationing"). Others argued that political directives lead to the wrong decisions. Targets were seen as often too crude and less subtle or rich than the kinds of outcomes that their priority committees take into account. They were also concerned that top-down political directives skew priorities and lead to opportunity costs being neglected.

Appropriateness related to a number of statements about the kind of services the NHS should or should not offer. On elaboration some participants reiterated the importance of clinical effectiveness. Others interpreted appropriateness as a social judgement based on the views of the general public. One participant argued that if a sizeable portion of the general public perceives an innovative treatment as inappropriate for the NHS to provide then it should not be provided because the NHS is publicly funded. Examples given of services that should be excluded from NHS funding because of public opposition included cosmetic surgery, such as hair transplantation and tattoo removals, fertility treatment and gender reassignment. Most participants rejected this view arguing that it is unethical to set priorities solely in accordance with public opinion. Some believed that when appropriateness is used as a reason in priority setting it easily becomes a vehicle for prejudice and social, religious, or sexual discrimination.

Although patient choice was identified as a consideration in priority setting there was little clarity about its precise role. Most participants dismissed the idea that respecting choice is simply a question of allowing patients to choose treatments freely. Some participants restricted patient choice to include only those situations when two treatments for the same condition cost roughly the same or when patients refuse the treatment on offer. Other participants argued more positively that patient choice is about giving patients the opportunity to decide where, when and how services (that are offered by the NHS) are delivered. On this interpretation patient choice might increase costs. Some participants interpreted respecting patient choice as emphasising the need for patient-centred outcome measures in healthcare evaluation and assessment. According to this interpretation patient choice is a reason to give high priority to those treatments that contribute the best improvements in health as perceived by patients.

Interviewees also made frequent reference to the age of the patient group as a reason in priority setting, but there were varying views on how it is relevant. There were three somewhat contradictory views: reluctance to treat the elderly in particular (due to shorter life expectancy and "fair innings"); inclination to treat the elderly in particular (entitlement as a consequence of past tax payments); and inclination to treat the very young in particular (capacity to benefit).

Participants raised the issue of the fear of litigation and expressed concern that legal action might be taken by patients denied care as a result of priority setting, with resulting costs to their organisations, both financially and in terms of bad publicity. Undue priority might then be given to an intervention that benefited patient groups perceived as likely to pursue litigation. Several participants gave examples of antenatal and

perinatal care and treatment for breast cancer as running particularly high risks of litigation.

Some interviewees also referred to various internal and external pressures, for example from local hospital consultants, patients' interest groups, the pharmaceutical industry and the media. Some participants believed that opposing these pressures may convey an impression to the public that decision-makers are negligent in their duty of care, whereas others believed that these pressures are not legitimate grounds for affecting priority.

Interventions with delayed effect on a health outcome were considered by some participants to have a lower priority than interventions with more immediate effect. Others, however, took the opposite view, arguing that long-term preventive measures should be given priority over acute treatments on the grounds that such measures on the whole are likely to lead to future cost savings and better outcomes for patients.

Most participants thought personal responsibility for one's own ill health was theoretically relevant when patients knowingly take risks with their health, leading to additional NHS costs. Examples given were of smokers, weekend drug users, obese people, skiers and mountaineers. In practice, however, most participants thought responsibility to be an unimportant reason in priority decision-making. Three reasons were given. First that people do not have a genuine free choice to avoid risky behaviour. There may be both genetic and social reasons for a person's behaviour and increased risk. Second, the consequences of risk behaviour are not always clear before the person becomes ill or in need of healthcare. Third, as everybody indulges in unnecessary risky behaviour, it would be both unfair and present practical difficulties to single out some people for lower priority for healthcare.

Some interviewees argued that an innovative drug treatment should be given priority if there is no alternative available either because having no therapeutic option would have negative psychological effects or because it would be inhumane not to provide some hope of recovery. Others argued, however, that it is irrational to offer a less (cost-)effective drug at the expense of a more (cost-)effective drug for a different condition.

Funding some treatments might facilitate research that could lead to future benefit for other patients. This value to medical research, however, was rejected by almost all participants as relevant to priority setting because the remit for the NHS budget is to deliver the best care for current patients.

DISCUSSION

The impetus for this study was the view that to develop reasoning about resource allocation it will be valuable to learn from the experience of real processes and those involved in them.²

The main limitation of the study is that the relevant experience of the participants is limited to the British NHS and to a limited geographical area within the United Kingdom, although one with both rural and urban areas. There are in addition problematical conceptual and methodological issues concerning the identification and classification of different reasons. We have, for example, used the category "no alternative available" as separate from that of "equality". The argument, however, that giving a drug treatment priority on grounds that no other treatment is available for the relevant condition (which is what is meant by "no alternative available") might be seen as an example of applying a particular notion of equality. A methodological problem arises from the judgement made at the time of the interview about how much to probe reasons. Without some probing it would often have

been difficult to understand exactly what participants meant. Too much probing risked entering into discussions that could effectively develop and change the participants' views. An example of when this issue, together with that of how to classify reasons, is problematical is with regard to delayed effect. As presented in the Results section, some argued that drug treatments with immediate effect, and others that those with delayed effect, should have priority. The grounds for these different views were obtained but participants were not challenged to defend their views in the light of further arguments. Did those, for example, who argued that interventions with delayed effects should have priority, because they were likely to save costs in the long run, believe that drugs with immediate effect should have higher priority if there really were no difference overall in (cost) effectiveness, or not? The level of probing does not allow us to untangle the various reasons and the weights given to them by participants at this level of analysis.

There were four reasons that almost all participants considered key reasons that should be taken into account: cost effectiveness, clinical effectiveness, equality and gross cost.

Neither the idea that a health system should do what is best for the individual patient regardless of cost, nor sole reliance on cost effectiveness, were endorsed by the participants in the study reported here. Political directives, such as targets, which often come with financial incentives and penalties, were considered by almost all participants as a major factor in practice, but many participants believed that such directives distort decisions about resource allocation. The majority of participants believed that although fear of litigation and "internal and external pressures" did affect decisions, ideally they should not.

Several other empirical studies have been carried out that include identifying reasons that a particular group of people consider important in making resource allocation decisions in healthcare. These have included studies of doctors,¹²⁻¹⁵ the general public¹⁶ and, like this study, members from a variety of backgrounds who are involved in processes that make real resource allocation decisions.^{8 17-19} A consistent finding across these latter studies is the large number of reasons considered relevant by expert groups involving people from varying backgrounds. These expert groups do not, it appears, adopt a single or even a small number of specific theories (such as maximising health gain). Instead they take potentially many factors into account in coming to a judgement.

The closest comparable study to this one is that by Martin and colleagues,¹⁸ who describe the working of a Canadian committee that made decisions about funding new drugs for treating cancer. They list seven reasons identified as relevant to the decisions made. The most important was "benefit to patients", which is similar to our category of clinical effectiveness. The quality of evidence was also identified—an issue frequently mentioned by the participants in our study. Two further reasons identified in both studies was the total cost of the intervention—an issue not highlighted by the major theories of resource allocation—and external pressures. These latter were principally from physicians and patients in the study by Martin and colleagues,¹⁸ whereas in our study political pressures from the central NHS and litigation fears were more prominent. There were also differences in the reasons and the balance of reasons identified in the two studies. Cost effectiveness was more salient in our study as was the issue of appropriateness. This probably illustrates the importance of the context of the studies in generating the reasons. The participants in our study

were directly advising the authorities that had direct responsibility for the budget and they dealt with a much broader range of interventions across the whole of healthcare.

This study leads to five main conclusions: first, decision-makers take several main reasons into account in making allocation decisions—there is no one dominant reason. Second, there is broad agreement on the four principal reasons, although there is variation in precisely how they are interpreted in specific situations. Third, the political and bureaucratic structures themselves affect the reasons that are taken into account. Participants believed that this often worked in ways that distorted the ethically right decisions. Therefore, in thinking about the right processes of resource allocation it is not only relevant to focus on the process itself but also on the wider context in which that process takes place. Political directives, the guidance from national bodies and fear of litigation might affect the decisions in ways that are not ethically justified. Fourth, there remain areas of “reasonable disagreement” in which different people, all of whom are experienced, simply disagree over whether and how a factor should be relevant to the question of priority. Fifth, those in our sample were sometimes themselves uncertain in the course of their work as to what reasons were important and relevant and how they should balance competing claims. A focus on the right decision-making process, therefore, does not avoid the problem of ethical uncertainty for those who are part of the process. Neither empirical research, nor a focus on process, obviates the need for continuing normative analysis.

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