

Pharmacopolitics and deliberative democracy

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ABSTRACT – Setting priorities in healthcare has become a highly politicised activity. Traditionally it has been undertaken by government and the health professions but there is an increasing imperative to involve the public. The National Institute for Health and Clinical Excellence (NICE) has established a Citizens' Council as an attempt to capture the informed views of the public in shaping the Institute's social value judgements. Although, in the future, better ways of involving the public may emerge, NICE's approach represents one way in which ordinary citizens can engage in the process of prioritising healthcare.

KEY WORDS: distributive justice, NICE, pharmacopolitics, procedural justice, social value judgements in healthcare

One of the features of modern pharmacology is the range and number of subdisciplines it has spawned, including pharmacokinetics, pharmacogenetics, pharmacoepidemiology, pharmacovigilance and pharmacoconomics. There is now emerging interest in pharmacopolitics.^{1,2}

Politics generally is about expressing and resolving conflicts within society without recourse to physical violence.³ The subject of pharmacology has become politicised to a greater extent than any other biomedical discipline because of its global importance and impact and the controversies that the discipline arouses. Pharmacopolitics is concerned, for example, with finding an appropriate balance between the risks and benefits of drug therapy, with resolving the competing claims of profit for the pharmaceutical industry and the wider public interest, and with determining how or whether society should attempt to control the use of drugs for recreational purposes.

This article is concerned with a different pharmacopolitical problem. How, as a society, should we set priorities for the medicines we use? Although this question is a microcosm of the general debate about setting priorities in healthcare, the difficulties and possible solutions apply equally to other aspects of modern medicine.

Distributive justice in healthcare

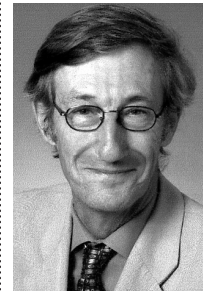
The approaches that societies might most appropriately take in the distribution of their available resources are described by political and moral philosophers as the problem of distributive justice. Three moral theories of distributive justice – libertarianism, utilitarianism and egalitarianism – have a particular resonance for setting priorities in healthcare.⁴

Libertarianism is based on the premises that individuals should be able, and expected, to finance their healthcare through their own efforts and that market forces should enable them to do so at a reasonable price. With the commitment of the National Health Service (NHS) to social solidarity, libertarianism has little to offer as a solution to the problem of distributive justice for the UK's healthcare system.

Utilitarianism in its purest form considers distributive justice to be best served by maximising social utility. Utilitarians expect expenditure on health to be distributed in a manner that maximises the welfare of the population as a whole. The principle is often expressed as 'the greatest good for the greatest number' and has unquestionable attractions. It places a premium on the efficiency of a healthcare system, and it asserts that using ineffective or costly interventions in one area of medical practice will remove the availability of cost-effective interventions in another.

Utilitarianism, however, has disadvantages. It can allow the interests of minorities to be overridden by the majority. It has little to offer in eradicating health inequalities. Its emphasis on efficiency can, moreover, produce perverse solutions. The prioritised list of healthcare services in the scheme developed by the State of Oregon, USA, based on efficiency, produced a rank order that most would consider unacceptable;⁵ tooth-capping, for example, was ranked above emergency surgery both for ectopic pregnancy and for acute appendicitis. Utilitarianism, therefore, is not a panacea for setting priorities.

Egalitarianism is about fairness, either in equality of opportunity or in equality of outcome. What is sometimes known as 'qualified egalitarianism' seeks for resources to be distributed so that each can have a fair share of the opportunities available in a particular society. This has become known as the 'fair



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opportunity rule'. This rule was developed by the American philosopher John Rawls,⁶ whose work, although not concerned specifically with healthcare, has been interpreted as equality of access to adequate care.⁷

However, egalitarianism has its problems. The definition of 'adequate' healthcare, the distinction between what is fair and unfair, and the distinction between the unfair and the unfortunate all lack clarity.⁴ Similar problems confront the NHS: the NHS Act (1977) places a duty on the health service to provide care that is 'necessary and appropriate' without defining clearly what is either 'necessary' or 'appropriate'.

The tensions between utilitarianism and egalitarianism can be overstated. Many utilitarians accept that social values could (and should) be incorporated into their approach to distributive justice. Qualified egalitarians accept the concept of 'opportunity costs', with all its moral implications. There is, however, no formal synthesis of these two theories of distributive justice. Both theories clash at some point with the convictions of many people, but each articulates ideas that most would be reluctant to relinquish. Often, where one theory is weak, the other is strong.⁴

In the absence of a unifying moral principle underpinning distributive justice in healthcare, a groundswell of opinion has emerged that believes that if there is to be confidence in the legitimacy of decisions on setting priorities, then some middle way has to be found.

Procedural justice

This 'middle way' is procedural justice. Rather than debate interminably the merits and demerits of utilitarianism and egalitarianism, there has been a move among some political and moral philosophers to outline the procedures for setting healthcare priorities that allow the best of both theories to be accommodated within decision-making processes. Procedural justice is an uncomfortable concept for some people; it has been described as 'muddling through elegantly'.⁸ Procedural justice is an attempt to achieve a pragmatic resolution to the demands of utilitarianism and egalitarianism.

Norman Daniels, a bioethicist, and his colleague James Sabin, a psychiatrist, have proposed that procedural justice for setting healthcare priorities requires four conditions to be met if decisions are to meet their test of 'accountability for reasonableness'.⁹ Daniels and Sabin assert – and others agree with their approach¹⁰ – that if priority-setting is to gain broad acceptance and legitimacy, then the process must ensure publicity, relevance, revision and regulation.⁹

'Publicity' requires that both the decisions themselves and the reasons for making them are made public. This in turn means that the evidence underpinning decisions should be in the public domain – a condition that too often has been honoured in the breach, especially as far as pharmaceuticals are concerned. Transparency of decision-making is, therefore, crucial. Chalmers is right when he asserts that failure to place the results of a clinical trial in the public domain is unacceptable.¹¹

'Relevance' insists that the grounds for making decisions are

those that fair-minded people would agree are relevant for meeting healthcare needs, especially in circumstances where resources are constrained. A particular feature of this condition is its focus on the importance of deliberation about the limits of the common good. It emphasises that deliberative democracy needs to involve not only decision-makers but also the people who may be affected by the decisions. For the NHS, this must mean both current and future patients. Moreover, the need to involve the public is heightened by the fact that the service is funded through general taxation.

'Revision' refers to the premise that there must be opportunities for challenging decisions and mechanisms for resolving disputes. 'Regulation' requires that there should be either voluntary or statutory regulation of the process, in order to ensure that the three other conditions are met.

The processes that the National Institute for Health and Clinical Evidence (NICE) has adopted in developing its guidance match, in most respects, the Daniels-Sabin conditions for 'accountability for reasonableness'. I believe that the broad support that NICE has gained from the professions, the public and politicians of all persuasions is due to the Institute's adoption of these. This has given NICE a legitimacy that it would not have acquired otherwise. This does not mean that the advice of NICE is not sometimes controversial: it is, and it always will be.

Scientific and social value judgements

The setting of priorities in healthcare requires two types of judgement to be made.¹² Scientific value judgements are concerned with interpreting the significance of the available scientific and clinical data. Experts do not, however, base their conclusions solely on the basis of evidence. While evidence (rather than intuition and prejudice) is crucial, the evidence base is never enough: judgements also have to be made. In the context of medicines, experts have to make judgements about issues such as the validity of a surrogate marker as an indicator of real therapeutic benefit, and whether the results of formal randomised controlled trials can be generalised to routine clinical care.

Social value judgements, however, relate to society rather than basic or clinical science.¹² They take account of the ethical principles, preferences, culture and aspirations that should underpin the nature and extent of the care provided by a health service. They include matters such as whether special priority should be given, by the NHS, to children and young people, and whether the health service should be prepared to pay premium prices for drugs to treat very rare serious diseases.

Scientists and clinicians involved in priority-setting should be selected for their ability to make scientific value judgements and to evaluate evidence. In general, the public appears to accept that judgements of this type are best made by those who are experts in the underpinning disciplines.¹² Expert scientists and clinicians, however, have no special legitimacy to impose their own social values on the NHS. These should reflect those held by people who are using, or who will use, the service. Only in this way can legitimacy be earned and retained. The question,

therefore, is not whether but how the views of the public should be taken into account.

Ascertaining the social values of the public

If, as I assert, the social values of the NHS should reflect broadly those of the public, then how might these be acquired? Various approaches have been advocated.¹³ It might be claimed that this should be the role of either Parliament or the government of the day. Parliament makes laws, raises taxes and decides how tax revenues should be spent. Whether it has any special legitimacy to make social value judgements for the health service is unclear. Experience suggests that politicians find it extraordinarily difficult to make such decisions in the face of electoral pressures.

Public meetings are a time-honoured way in the NHS to sound out public opinion. They provide little opportunity, however, for reflection or deliberation, and attendees are usually dominated by those with a vested interest in the issue under discussion.

Opinion polls and surveys, when conducted competently, can elicit the public's immediate preferences on particular issues. Responses, however, may be coloured by inaccurate current media activity, and there is no opportunity for discussion or considered thought. Replies, moreover, are exquisitely sensitive to the precise manner in which the question is phrased or framed. Polls and surveys do not provide the public's considered conclusions based on deliberation about the complexities surrounding priority-setting in healthcare.

A better understanding of the reasons underlying the public's immediate preferences can be elicited from focus groups. These groups provide insights into why the public feels as it does. Focus groups, however, are an extension of polling, and the time available (usually not more than two to four hours) does not allow much opportunity for discussion and deliberation.

A more promising approach has been the use of citizens' juries.¹⁴ In this technique, between 12 and 16 members of the public are asked a question, often framed as it would be in a criminal trial, ie as a 'charge'. Juries usually meet over three to four days. They are often provided with background material and they are always, as in a legal trial, given the opportunity to cross-examine expert witnesses. They are provided with time to deliberate among themselves. At the end, they produce a 'verdict'. Citizens' juries have been used widely to elicit the views of the informed public on a wide range of policy issues in the USA, Germany and Britain.¹⁴ Coote and Lenaghan showed that UK citizens can engage and deliberate on difficult matters related to healthcare and that they can reach well-argued and, in some cases, novel conclusions.¹⁴

NICE Citizens' Council

When NICE was set up in 1999, it was appreciated that, at some stage, the Institute would need to establish the social values that would inform its advisory bodies. NICE was impressed by the experience of citizens' juries but believed that the approach had to be modified if it was to meet the requirements of NICE.

It was felt that a larger number of participants were required so that the group could be more representative of a cross-section of the adult population. The size chosen (30 members) was a compromise: anything less would have made it almost impossible to achieve broad demographic representation; much more would, in our judgement, have seriously diminished the prospect of real deliberation between members.

Additionally, in order to achieve continuity, NICE decided that rather than assemble a new group for each meeting (the convention for citizens' juries), members would be appointed for three years, with one-third retiring annually. This would allow members to gain knowledge of the health service and NICE and to gain experience in deliberation. A changing membership would also ensure that the Council would be refreshed annually with new blood.

NICE was particularly anxious to avoid contaminating members' views with its own prejudices. To avoid 'capture', it arranged for the meetings to be facilitated by an independent organisation, with only one or two members of its staff present throughout the meetings.

Finally, because these efforts at deliberative democracy were untried, an independent organisation was commissioned to evaluate the scheme. This has now been completed.¹⁵

Members of the Council were recruited by advertisements in the national and regional media. Applications were encouraged from anyone, provided that they were not involved personally in healthcare or the healthcare industries. Thirty-five thousand people expressed an initial interest, and nearly 4,500 made full applications. Those appointed reflected the demographic structure of England and Wales, with respect to gender, age, ethnic background, socio-economic status and disability. Their ages ranged from 18 to 76 years. Members included a cab driver, a scaffolder, a single parent and a retired airline pilot.

The Council and its reports

The Council has produced four reports.¹⁶⁻¹⁹ What have they said? What has been done with them? What lessons has NICE learned? And what will NICE do in the future?

The first report,¹⁶ on 'clinical need', was deliberately more discursive than the others. Its primary purpose was to identify areas where the Council's views would be most useful and relevant to the Institute and its advisory committees.

The question posed in the second report,¹⁷ and emanating directly from the first report, was: 'Are there circumstances in which the age of a person should be taken into account when NICE is making a decision about how treatments should be used in the National Health Service?' Previous work based largely on polling had suggested that the public is very uncertain as to how, or even whether, age should be taken into account in setting healthcare priorities.²⁰ For this reason, six days (spread over two three-day meetings) were allowed for the Council to discuss and reflect on the issue. The Council's conclusions were as follows:¹⁷ First, health should not be valued more highly in some age groups than in others, ie one year of life is of the same 'value' whether a person is 3 years old or 83 years old. Second, individuals' social

roles at different ages should not influence considerations of cost-effectiveness, ie people with young children and people with special professional responsibilities should not be given priority. Third, where age is an indicator of either benefit or risk, discrimination (either positive or negative) is appropriate; the targeting of people aged over 65 years for influenza immunisation is an example of this approach.

By a separate but parallel process, the Council also had the views of nearly 200 children available to them. These were derived from a special study undertaken by the National Children's Bureau.¹⁷ Children reached similar conclusions.

The Council's third report was about the use of confidential clinical data by each of the three national confidential enquiries.¹⁸ At the time the question was put to the Council, NICE had overall responsibility for their conduct and funding. From 1 April 2005, this role has passed to the National Patient Safety Agency. The enquiries use the medical records of patients without the knowledge or consent of either them or their families. Although they are anonymised for analysis, patient identifiers remain during the collection and collation of personal medical records.

The use of medical data for research purposes, without seeking permission, has attracted criticism. NICE needed to know whether this practice, at least in respect of the confidential enquiries, had public support. Much of the enquiry work involves scrutiny of the records of deceased patients, and it had been felt that seeking consent from families would consume considerable resources and be intrusive. The majority of the Council, having heard evidence from many sources, concluded that the enquiries should not be required to seek prior informed consent before using patients' medical records.¹⁸ Despite the overall positive verdict, a minority of members, although recognising the value and importance of the enquiries, felt uncomfortable about using patients' medical records without their knowledge or consent. This is a warning. Although most members of the Council accepted in this case that the ends justified the means, this should not be assumed.

At its most recent meeting, the Council was asked whether the NHS should be prepared to pay premium prices for drugs to treat very rare diseases.¹⁸ Funding extremely expensive treatments for very rare diseases poses a dilemma for all healthcare systems. Enzyme-replacement therapies for conditions such as Gaucher disease and Fabry's disease may cost between £50,000 and £200,000 per patient per year. These sums are an order of magnitude greater than those ordinarily accepted by the appraisal committee of NICE as being cost-effective for the health service. Although there are no more than a few hundred patients with these conditions, the overall budgetary impact may run to tens of millions of pounds. This is a very obvious example of the conflict between utilitarians, who point to the opportunity costs of treating these disorders, and egalitarians, who seek a 'fair opportunity' for those with these miserable conditions.

The majority of the Citizens' Council concluded that the NHS should be prepared to pay premium prices, but they added conditions:¹⁸

- 1 The disease should be severe or life-threatening.
- 2 The treatment should produce real and demonstrable improvements in health.
- 3 Some limit had to be placed on the amount that the health service should be asked to pay for these treatments in the future.

A minority (7 of 27) of the members, however, did not consider it appropriate for the NHS to pay such premium prices to treat people with these very rare diseases. Although very sympathetic to the plight of individuals, they were concerned about the opportunity costs for others.

The views of the Council are important. While accepting the need (on the grounds, in effect, of Rawls' 'fair opportunity rule') for the NHS to pay exceptional prices, they also accepted that there must be limits. When presented with the facts and an opportunity to deliberate on them, people understand and accept that a publicly funded healthcare system cannot provide unrestricted resources without incurring unacceptable penalties for others.

Discussion

The Council's conclusions have been embodied in a document, intended for those who develop NICE guidance, to use as a point of reference on social value judgements. Like all NICE guidance, this document will not mandate our advisory committees and guideline development groups, for sometimes there may be very good reasons to override them. However, NICE does expect its advisory bodies to adopt the principles and to explain the reasons for any significant departures from them.

I have learned much from my attempts at promoting deliberative democracy, but three issues are striking. First, people who volunteer for this type of endeavour are unquestionably forthright and unafraid to express their views. In this respect at least, they may not be representative of the general population. Second, at the start, some members were clearly suspicious about the motives behind the establishment of the Council. Although they were pleased to be invited to take part, some suspected that they might be being used – that at best their views would be ignored and that at worst they would be expected to endorse decisions that had already been made. I believe all members of the Council now accept that NICE is making a genuine attempt to reach out to the public, but their attitude emphasises the gulf between those who make decisions and those who are affected by them. It is an example of what some call the 'democratic deficit'. And it is a warning, not only to those involved in healthcare, of the public's distrust of those they perceive to be in authority. Finally, I have learned that ordinary citizens from wide backgrounds can, if given the chance, make extraordinary contributions. With knowledge and experience, they can help breach the democratic deficit.

There are many other subjects about which NICE needs to capture the social values of society and to reflect these in the guidance that it produces. How, for example, should we apply 'the rule of rescue', which asserts that a physician's first duty is

to rescue identifiable individuals facing avoidable death. If we should apply this rule, what, if any, are the limits? Furthermore, NICE now has responsibility to public health as well as clinical guidance. This raises social value judgements that have been ignored almost completely in the past. They include problems such as where does the balance of interest lie when mandatory public health measures are proposed or implemented? How should we trade the interests of the majority against the rights of minorities when advocating measures such as fluoridation of water or the fortification with folate of cereal products?

In the future, better approaches to deliberative democracy will likely emerge. In particular, there is a need to develop techniques that involve larger numbers of people, and developments in information technology may facilitate this. In the meantime, NICE will continue with the arrangements it has in place.

Conclusions

The principles behind the experience of NICE with deliberative democracy are not new. Not long before his death, Thomas Jefferson wrote:

*I know of no safer repository of the ultimate powers of society but the people themselves. And if we think them not enlightened enough to exercise that control with a wholesome discretion, the remedy is not to take it from them, but to inform their discretion by education.*²¹

A member of the Citizens' Council is quoted as saying:

*I've learned again that difficult decisions have to be made in the NHS. Too often they are made in secret. But the NHS should know that we do support them; we know they have to keep within a budget. The NHS shouldn't be frightened of the public finding out about this – they should discuss it more with us. They'll only keep our confidence if they level with us about the difficult choices that have to be made.*¹⁹

I have no doubt that Jefferson, the author of the American Declaration of Independence, would have endorsed these sentiments.

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