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ANALYSIS

“No decisions about us without us”? Individual healthcare rationing in a fiscal ice age

Jill Russell and colleagues examine whether patients and the public should be involved in rationing decisions about individual patient access to healthcare interventions

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Healthcare rationing is high on the political and public agenda in the United Kingdom. The English National Health Service (NHS) is undergoing major restructuring aimed at improving efficiency. From 2013, responsibility for commissioning NHS services look set to shift from primary care trusts (PCTs) to general practitioner (GP) commissioning consortiums, which will also take over funding decisions on new clinical interventions from the National Institute for Health and Clinical Excellence (NICE). The coalition government's comprehensive spending review (which demands savings of £20bn (€23bn; \$32bn) over four years) will take the NHS into a “fiscal ice age.”¹ Patient and public involvement in decision making remains a central part of the NHS mission and is a statutory responsibility for commissioners of NHS care.² However, although patient and public participation in national and local decisions is widely accepted, there is a lack of consensus on whether and how they should be involved in rationing decisions at the individual level,³ and uncertainty about what involvement means in practice.

Tough decisions about individual treatments

Rationing decisions involve hard choices. A particularly tough subset of decisions comprise individual funding requests (IFRs) for NHS services which fall outside agreed contracts between local commissioning bodies and healthcare providers (table). These requests are to fund an investigation or treatment as a one-off for a particular patient even though it is not routinely funded by the NHS. The request is submitted by the patient's doctor (consultant or general practitioner) and is usually considered by a panel comprising PCT staff, local clinicians, and (sometimes) lay people or their advocates. Some requests (such as those for cancer or loss of vision) attract substantial media attention, often articulated in the language of rescue (patients are depicted as being denied treatment that could prevent death or blindness).

Although their numbers are relatively small (about 26 000 cases in England a year),⁴ IFRs have a substantial effect on patients and their clinicians and take up a great deal of clinical and managerial time (most PCTs deal with 100-200 requests a year, but the range is 0-1000, with approval rates also varying from 0-100%).⁴⁻⁷

IFRs illustrate the conundrum of patient and public involvement in financial, clinical, and ethical aspects of NHS resource allocation and how all these aspects are interwoven. For example, they highlight the tension between an individual rights based and utilitarian (population, “greatest good”) ethical position,⁸ and they raise questions about the different, often conflicting roles of healthcare professionals, NHS managers, and lay people as public servants and patient advocates.

IFR panels thus represent a forum in which the tension between individual rights and population interests in healthcare rationing is played out. By requiring increased NHS efficiency and increased emphasis on patients' rights and choices, the coalition government has raised the stakes on both sides of this tension. We anticipate that the work of IFR panels will be subject to growing public scrutiny. Below we explore the ways in which patients and the public can be involved in the process (box) and review the (relatively sparse) evidence for current practice.

Bedside rationing

Medicine is traditionally depicted as a (knowledgeable) doctor making practical and ethical judgments on behalf of a (less knowledgeable) patient. Given the current emphasis on shared decision making, should doctors tell patients that possibly useful investigations or effective treatments exist that are not routinely funded locally and discuss whether and how to present their case to an IFR panel? Furthermore, should doctors discuss treatments with their patients that others may consider effective but they do not? Empirical studies of patients' reactions to

How patients and the public are involved in individual healthcare rationing decisions

- A patient's doctor may share information, seek the patient's opinion, or invite shared decision making before making a request for individual funding
- Once a request has been submitted, the patient may be included in some or all of its processes (eg, copied into correspondence or invited to be represented at or attend the meeting)
- Members of the public may be included in the panel (lay members)
- Patient organisations may help patients prepare their case for funding and occasionally help bring such cases to judicial review

“bedside” rationing decisions in relation to their own healthcare are few. One found that most patients considered implicit rationing paternalistic and disempowering; they wanted doctors to be explicit and transparent about such decisions, but not all perceived their doctor to be so.^{9 10}

In 2007, Marcus argued that patients had a right to know about all available interventions and doctors had a duty to share such knowledge.¹¹ Holt has argued that “rationing by ignorance” denies patients their rights to “freedom of thought” (the right to know the truth), “freedom of speech” (the right to be angry and say so), and “creative problem solving” (for example, to purchase treatment privately or negotiate with a drug company). The UK's statutory regulator of medical practice, the General Medical Council, recommends that doctors inform patients of all appropriate treatment options to meet their clinical needs, including “any treatments that you believe have greater potential benefit for the patient than those you or your organisation can offer.”¹²

This guidance is in line with an increasing consensus within academic debate that explicit and systematic “bedside” rationing is preferable to the implicit and unsystematic rationing that has historically been the norm.¹³ Others argue that doctors have a “responsibility beyond the patient” to take account of the constrained financial budgets within which they have to make clinical decisions, and that the uncertain and time consuming individual funding process may cause harm—for example, the emotional effect of patients knowing about a treatment for which they must struggle and may not eventually receive.^{9 14} Almost one third of oncologists in one survey said they did not discuss unfunded drugs with their patients.⁴ A study of general practitioners found a considerable gap between the principle of explicitness and reported practice and tension between their role as patient advocate and their wider responsibilities for budgets, populations, and society in general.³

Much research has been undertaken on healthcare rationing at national and PCT levels, but there is surprisingly little detailed research on bedside rationing decisions. We do not know, for example, how clinicians internalise and take account of resource constraints in their clinical judgments or “the extent to which this results in the denial of potentially beneficial treatment [rather than] a sensible reluctance to engage in heroic medicine regardless of the cost.”¹¹

Should patients be allowed to attend IFR panels?

Some IFR panels do not allow patients or the referring clinician to make direct representations. Others identify patient input, usually in writing and occasionally in person, as a feature of good practice. One pioneering PCT reports that the benefits of direct patient representation include (for patients) reassurance that their case is being taken seriously and (for the panel) clarification of details and greater awareness of the person about

whom the decision is being made.¹⁵ Set against these benefits, one of the few empirical studies of patients' experiences of rationing decisions reported that those who had attended IFR panels found it difficult and sometimes distressing.⁹ And for some critics, patient representation risks pulling panel members away from rational decision making towards an emotional, “rule of rescue” response,¹⁶ although some ethicists believe this is morally justified in some cases.^{16 17}

Although IFR panels are not legally required to be open to patients and the public, the NHS constitution seems to promise patients the right of access: “You have the right to be involved in discussions and decisions about your healthcare, and be given information to enable you to do this.”¹⁸ Some argue that this increased emphasis on an individual's right to a voice may erode healthcare purchasers' fortitude to consider the complex issues of opportunity costs and community interests, with planned expenditure being diverted to individual cases.¹⁹ Thus, Newdick argues, an individualised, consumerist model of care comes to be privileged over the notion of social citizenship, and the needs of individuals with the capacity to express their rights (sometimes helped by drug companies) win over the needs of patients less able to do so.⁸

Should IFR panels include lay people?

As the debate about rationing has progressed beyond an early naive faith in the ability of evidence based medicine and economics to tell us what to do when faced with complex rationing decisions,²⁰ so attention has turned to the necessary conditions and procedures for fair and reasonable decision making—namely, transparency, accountability, and broad stakeholder involvement.²¹ Involvement of lay people is seen as desirable because it potentially improves both quality and legitimacy of decisions.²² NHS policy guidance uses the term “lay involvement” frequently, but we have been unable to find a definition, explanation, or justification of this term within policy documents. In the case of IFR panels, there is explicit advice about how panels should be constituted, what processes they should follow, and how best to make “rational” decisions,^{23 24} but advice on lay involvement is provided only in the most general and abstract terms: “PCTs may . . . wish to consider lay membership and the potential value of individuals attending with ‘observer’ status.”²⁴ There is no discussion of lay members' role, who individuals with “observer status” might be, or what value they potentially bring. Guidance on the new Cancer Drug Fund (which adds an additional layer of complexity to IFR decisions) contains no reference to lay membership.

In a 2008 Department of Health survey, one third of IFR panels included “patients/advocacy representatives” but most of these were PCT “patient advocacy leads” (that is, PCT staff), and only two of the 130 PCTs reported having “lay members” on their panels.⁵ In 2011, IFR panels increasingly seek (and some formally include) lay members (voting or non-voting), but considerable variation remains (JR and TG, unpublished data).

We could find no published research on what and how lay members contribute to decision making; what if any support and training is available to them; or how variation in practice is justified in local policies. Given the limited evidence base, PCTs are vulnerable to accusations that lay members' involvement in IFR decisions may not merely be tokenistic but used (in some circumstances at least) to give an appearance of democracy to difficult and unpopular rationing decisions.^{25 26}

In studies of public views about involvement in healthcare rationing, many people were keen to participate in decisions about overall service priorities but most preferred to leave decisions about individual patients to health professionals, whom they viewed as having the appropriate knowledge, skills, qualifications, and experience (including the ability to deal with the emotional impact of the decision).^{1 26 27 28} Lack of public appetite for involvement in IFRs has been attributed to reluctance to confront the "disutility" (adverse effects) from denying treatment or to acknowledge that constraints on health services are necessary.^{29 30}

The limited empirical research findings and polarised opinions about lay representatives on rationing panels raise more questions than they answer. Who do they represent, and for whom do they speak? What is the value of the "common sense" and "life experience" that they are said to bring to the table?²² How well equipped are they (and indeed non-specialist clinicians and managers) to cope with the complexity of the science under discussion?³¹ How and by whom should they be selected and managed and have their performance evaluated? What measures are needed to ensure that the lay voice is not marginalised or dismissed? What can we learn from PCTs that have pioneered approaches to working with lay people?

Rationing and reform

This paper is not intended to offer guidance on how to involve patients and the public in individual NHS funding decisions but to highlight the gaps in evidence and ethical controversies in order to open up debate on this topic. Rhetorical slogans like "No decision about us without us" appeal to widely shared norms and values of transparency and patient centredness. But patient and public involvement in rationing decisions is both practically and ethically complex and may or may not be in the best interests of the sick or dying patient. The UK national cancer director has called for specific training for clinicians in this particularly difficult aspect of doctor-patient communication,⁴ and it is now addressed in the Department of Health advanced communication skills training programme.

As we move rapidly towards a restructured NHS in which, according to the government, decision making will be "in the hands of professionals and patients,"³² the power dynamic in healthcare rationing is set to shift significantly with worrying potential consequences. General practitioners, in taking on the work of PCTs in telling patients which treatments the NHS can and cannot afford, may come to embody and enact the tensions implicit in the new NHS structures—perhaps by taking sides against one another in individual versus collective responsibilities. Furthermore, as escalating financial pressures, the lifting of the mandatory status of NICE technology appraisal guidance, government promotion of patient choice, and an increasingly competitive market combine to make it harder for local health organisations to achieve rational commissioning, local variation in access to certain treatments and contested "exceptional" cases may increase. This could make patient involvement in NHS rationing decisions more complex, more adversarial, and more polarised towards the information rich.

Involving patients and the public in carefully controlled, small scale discussions about individual funding requests (democratic deliberation) is no substitute for the urgent public debate (deliberative democracy) that is needed on how and where we should draw the boundaries around publicly funded healthcare.³²

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Competing interests: All authors have completed the ICJME unified declaration form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare no support from any organisation for the submitted work; AB is an executive director of Barnet PCT and chair of its individual funding request panel. JM is chair of the board of Hampshire PCT, which considers individual funding requests, and as a board member is occasionally involved in hearing appeals against refusals of funding.

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Table

Table 1 | Examples of treatments that attract NHS funding in some cases but not others, typically after individual funding requests

Type	Descriptor	Examples
New treatments	High cost drugs and other interventions not yet appraised by NICE	Dasatinib for chronic myeloid leukaemia
		Ranibizumab for wet age related macular degeneration (until approved by NICE in 2011)
		Surgical interventions such as trans-catheter aortic valve implantation or endovascular fenestrated aortic stents for suprarenal aortic aneurysm
Treatments outside NICE guidance	Use of approved interventions outside defined clinical criteria	Bevacizumab for wet age related macular degeneration
	Treatments rejected by NICE	Sorafenib for liver cancer
Low priority treatments	PCTs have drawn up lists of treatments they no longer routinely fund. They must, however, give consideration to the funding of "exceptional" cases	Breast modification surgery, bariatric surgery, inpatient treatment for chronic fatigue syndrome, and inpatient therapy for eating disorders in children
Rare conditions	Medical conditions or clinical presentations for which the PCT has no policy (and no contract with a provider) because they are rare	Treatment of angiosarcomas