



Accountability for reasonableness

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BMJ 2000;321:1300-1301
doi:10.1136/bmj.321.7272.1300

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when initially assessing patients as suggested in the joint recommendations.¹⁰

The importance of considering a secondary cause of dyslipidaemia should not be underestimated. Most patients who are admitted to hospital with a myocardial infarction have their lipid concentrations checked within 24 hours of the onset of symptoms. If these measurements are abnormal then treatment with a statin is started. When these patients are later seen in primary care it is important not only that they continue taking their medication and that their cholesterol is monitored but that a full assessment of their dyslipidaemia is made to exclude a secondary cause, such as hypothyroidism.

Despite strong evidence of the benefit of lowering lipid concentrations and using statins, a reactive approach has not worked. A proactive approach designed to seek out adults with, or at high risk of developing, cardiovascular disease that is similar to that used for cervical screening or breast screening should be adopted. Such a programme will have to be appropriately funded and developed if the targets set in the national service framework are to be met.

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DM has chaired some educational meetings that were sponsored by pharmaceutical companies and for which he received an honorarium. These companies included Bristol-

Myers Squibb; Sanofi; Merck, Sharp and Dohme; SmithKline Beecham; GlaxoWellcome; Hoechst Marion Roussel; and Pfizer.

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Accountability for reasonableness

Establishing a fair process for priority setting is easier than agreeing on principles

All health systems struggle with the issue of meeting population health needs fairly under resource constraints. Decisions about the implementation of new technologies provide a useful window into the larger issue, and a paper in this week's journal provides a valuable insight into the elements of decision making that decision makers themselves think important in trying to reach fair decisions on applying new technologies in health care.¹

In mixed systems, like that in the United States, decisions whether to fund new technologies—drugs, devices, procedures—are made both by public agencies, such as the Health Care Financing Administration or the Veterans Administration, and by private indemnity insurers and managed care organisations. In the universal coverage systems of most developed countries such decisions are made by public agencies or authorities. Distrust has grown in all these settings.^{2,3} Clinicians, patients, and the public—propelled by the media, the internet, and direct to consumer advertising—often believe these decisions are guided solely by the “bottom line,” not patient welfare. The moral legitimacy of limits and priorities thus involves not just who has moral authority to set them, but how they are set.

Some countries with universal coverage systems initially tried to address this problem of legitimacy by setting up national commissions to articulate principles that should govern the setting of priorities. Holm has argued that these principles proved too general and too unclear in practice.⁴ More generally, we prob-

ably lack consensus on principles capable of resolving disputes about rationing.⁵ A second wave of efforts to address priority setting has thus focused on developing fair, publicly acceptable processes for making these decisions. In the United States an active consumer movement has also focused on a patients' bill of rights as a vehicle for fair process. In the United Kingdom, awareness of the need for clear process is reflected in the establishment of the National Institute for Clinical Excellence (NICE) to handle some aspects of rationing.^{6,7}

In pluralist societies we are likely to find reasonable disagreement about principles that should govern priority setting. For example, some will want to give more priority to the worst off, some less; some will be willing to aggregate benefits in ways that others are not. In the absence of consensus on principles, a fair process allows us to agree on what is legitimate and fair. Key elements of fair process will involve transparency about the grounds for decisions; appeals to rationales that all can accept as relevant to meeting health needs fairly; and procedures for revising decisions in light of challenges to them.⁸ Together these elements assure “accountability for reasonableness.”⁹

Fair procedures must also be empirically feasible. They must involve practices that can be sustained and that connect well with the goals of various stakeholders in the many institutional settings where these decisions are made. The value of the study by Singer et al in this issue is that it points to key elements of actual decision

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making processes that can be further improved to achieve legitimacy and fairness (p 1316).¹ An ethical approach to fair process must build on their findings.

A fair process requires publicity about the reasons and rationales that play a part in decisions. There must be no secrets where justice is involved, for people should not be expected to accept decisions that affect their well being unless they are aware of the grounds for those decisions. The study found that transparency was important to participants in the decisions, though it did not state whether the rationales for decisions were then made transparent to all affected by them. This broader transparency is a hallmark of fair process. Fair process also involves constraints on reasons. Fair minded people—those who seek mutually justifiable grounds for cooperation—must agree that the reasons, evidence, and rationales are relevant to meeting population health needs fairly, the shared goal of deliberation. The kinds of reasons described in the study meet this condition, but the institutions studied—committees concerned with implementing new technologies—did not face the more difficult task of comparing quite different benefits across different groups of patients under budget limits.

Fair process also requires opportunities to challenge and revise decisions in light of the kinds of considerations all stakeholders may raise. Though the committees studied by Singer et al gave evidence that decisions improved—that is, became more sensitive to patient variations—through revision, there should be a mechanism for appeals to decisions by those affected by them. The fact that a single lay member of the cardiac committee did not function as effectively as the three lay members of the cancer committee is a lesson that must be taken seriously in designing fair procedures.

Accountability for reasonableness makes it possible to educate all stakeholders about the substance of deliberation about fair decisions under resource constraints.

It facilitates social learning about limits. It connects decision making in healthcare institutions to broader, more fundamental democratic deliberative processes.

Accountability for reasonableness also occupies a middle ground in the debate between those calling for “explicit” and “implicit” rationing.¹⁰ Like implicit approaches, it does not require that principles for rationing be made explicit ahead of time. But, like explicit approaches, it 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.

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The endometrium and embryo implantation

A receptive endometrium depends on more than hormonal influences

How embryos attach and implant remains a mystery. Implantation represents the remarkable synchronisation between the development of the embryo and the differentiation of the endometrium. As long as these events remain unexplained, improvement in the success of in vitro fertilisation treatment and the development of contraception that modifies implantation is likely to be difficult.

In most animals, the endometrium undergoes a series of changes leading to a period of uterine receptivity called the “window of implantation.” Outside of this time the uterus is resistant to embryo attachment. In a study by Hertig et al in 1956, women were asked to record their menstrual pattern and dates of unprotected intercourse before they had a hysterectomy for benign gynaecological disease.¹ With their informed consent, their uteruses were carefully examined after operation, and the authors found that a number of them had conceived just before surgery. In these cases, embryos found in the uterus before the 20th day of

the menstrual cycle were “free lying”—that is, not attached to the endometrium. Embryos found on or after the 21st day of the menstrual cycle were attached. Naturally, such research would not be performed today, but data from in vitro fertilisation programmes have substantiated these findings.² During in vitro fertilisation treatment embryos replaced before the 20th day may implant; those replaced after the 24th day do not.

The architectural changes that occur to the endometrium during a 28 day menstrual cycle were also investigated in the 1950s using light microscopy.³ Alterations in the endometrium during days 16 to 20 mainly affect the epithelial glands, which show increased secretory activity, prominent subnuclear vacuoles, and a decrease in mitotic activity. The stroma abruptly becomes oedematous on day 21. In the 1980s, electron microscopy studies identified epithelial protrusions into the uterine cavity called pinopodes; these appear between day 19 and day 21.⁴ In animals