



New treatments: costs, benefits and decision-making procedures

One hallmark of modern medicine is the ever-rising cost of providing life-saving or life-extending treatments. Advances in medical care and the ability to improve the duration and quality of life, combined with the expectations of both doctors and patients that all new modalities of treatment developed will be implemented in everyday practice, are the major reasons for modern medicine's becoming so expensive. In these circumstances resource allocation decisions need to be made and appropriate priority-setting processes developed. This challenge faces all societies but most agonisingly middle-income countries like South Africa where the expectations of physicians and patients are geared to the best that can be achieved in any country — even the wealthiest.

Expensive, new or established standard treatments that may benefit patients may be considered in at least two categories. The first is when each individual patient will be a direct beneficiary. This applies, for example, when a pacemaker or orthopaedic prosthesis is installed, when an organ such as a kidney, heart or liver is transplanted, or when chronic renal dialysis is initiated. While such treatments have some mortality and a measure of sub-optimal results, good outcomes are the rule.

The second category is when an expensive new or standard treatment is used to achieve a statistically demonstrable benefit for a patient population. A characteristic feature of such treatments is that many patients must be treated to save one life or prevent one adverse event. Most often it is not possible to determine in advance, or even retrospectively, to which patients the benefits accrue. Examples include new drugs for malignant disease and for such chronic diseases as rheumatoid arthritis, hyperlipidaemia, hypertension and coronary vascular disease. The new drug described by Richards and colleagues (p. 416) for reducing the mortality rate from severe sepsis is another example. In the case of drotrecogin alfa (Xigris), 16 patients with severe sepsis must be treated at a cost of R55 000 each to save one life. Thus it would cost R880 000 to save the life of one unidentifiable person.

Consider the dilemma posed for a public hospital or medical aid scheme faced with this choice. On the one hand clinicians seek increased budgets for renal dialysis, pacemaker insertions and hip prostheses. For example, nephrologists argue that it is possible to prolong the life of one identifiable patient by renal dialysis for about R60 000 a year (in the public sector). Moreover, each such patient will also be given the opportunity to have a transplant, which will cost about R30 000 in the first year with approximate subsequent costs of R15 000 in the second year and even less each year thereafter. So if R880 000 were allocated to a renal unit, several

identifiable patients who would otherwise die could be given many additional years of high-quality life. Similar arguments can be made on behalf of patients eligible for a pacemaker or an artificial hip.

On the other hand, the critical care team requests an additional R880 000 to save the life of one unidentifiable person over the period of time needed to treat 16 patients with the new drug. It could be argued that a potentially life-saving modality should be included in a therapeutic regimen to meet the rights of all patients who may benefit. Some also contend that intensivists must have access to new therapies to advance the quality of practice in the ICU. However, others will respond that, on the grounds of overall utility and benefit to society, the additional resources could better be used to prolong or save the lives of many identifiable persons.

Another version of this debate has played out in the context of limited resources available for neonatal ICUs. In the columns of this journal one set of paediatricians argued that the expenditure of about R20 000 per newborn baby weighing less than 1 000 g could save 2 244 extra lives each year. However, 7 low-birth-weight babies must be treated to save one life.¹ Another group responded that allocating the same expenditure to babies weighing over 1 000 g who require ICU care could save the lives of many more babies.² If overall benefit to society and the largest number of needy babies is the standard for choosing, surely the latter choice is the most justifiable?

Another example of a tough choice is whether to spend resources saving a few lives or spending the same resources to improve the quality of life of many people. Consider the paucity of facilities to ensure good palliative care at the end of life — in particular for patients with HIV/AIDS or malignant disease. Would it not be better to spend R880 000 on improved palliative care for, say, 100 identifiable patients than to save the life of one unidentifiable person? The former choice would not only reduce the pain and suffering of many people but could extend life by a few months for several.

These are all difficult choices and require value judgements in addition to such technical procedures as calculations of cost-effectiveness and estimates of life-years saved. To facilitate such decisions in a manner that is both rational and accountable to the public, Daniels and Sabin have devised a process that they have called 'Accountability for Reasonableness'. This framework requires that a fair priority-setting process meets four conditions. First, the rationale for decisions must be publicly accessible. Second, the decisions about meeting health care needs must be contextually relevant to fair-minded people. Third, allowance must be made for appeals so that previous decisions can be reconsidered in the



light of new evidence or arguments. Fourth, there must be a process of enforcement that facilitates the implementation of the last three conditions.³

Ideally this process, which ensures fairness, transparency and accountability, should be used by *both* public and private health care providers who together administer the country's limited medical resources. Failing this, resource allocation will continue to be viewed by doctors, health care administrators and the public as irrational and potentially subject to hidden political and interest group manipulation. Neither will this flawed type of allocation produce the greatest social benefits for the largest number of people who need care. Instead it will only exacerbate the twin burdens faced by both public and private health care providers — heightened expectations on the part of patients unfairly denied benefits, and drastically rising costs as advocacy groups mount challenges to irrational medical decision-making. This outcome would be a formula for widespread loss of confidence in both public and private sector institutions, as taxpayers and medical aid members are called on to bear unsustainable costs for a chaotically administered health system.

Explicit, transparent and accountable rationing processes are not yet being widely used — although there is a growing tendency to do so in some countries,⁴ and at least one recent example has been documented in South Africa.⁵ South Africa's Constitutional Court has on one occasion approved a hospital policy, forced by shortages of funding, equipment and personnel, to limit dialysis for chronically ill patients only to those eligible for transplants. All who failed medical criteria were denied life-saving dialysis.⁶

Until open, accountable, explicit priority-setting procedures based on sound scientific data (and a single trial seldom provides this) and ethically principled criteria become more widely used, scarce resources will continue to be channelled towards those patient populations and drug companies who make the loudest noises and to those medical disciplines most vociferous about advancing practice in their domain. No ethical, medical or scientific rationale supports this type of arbitrary and unaccountable means of allocating scarce public or private health care resources.

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1. Smith J, Pieper CH, Kirsten GF. Born too soon, too small, to die — a plea for a fair innings. *S Afr Med J* 1999; **89**: 1148-1151.
2. Rothberg A, Cooper PA. Rationing versus equity — the South African dilemma. *S Afr Med J* 1999; **89**: 1151-1153.
3. Daniels N, Sabin J. Limits to health care: fair procedures, democratic deliberation and the legitimacy problem for insurers. *Philosophy & Public Affairs* 1997; **26**(4): 303-350.
4. Ham C. Priority setting in health care: learning from international experience. *Health Policy* 1997; **42**: 49-66.
5. Benatar SR, Fleischer TE, Peter JC, Pope A, Taylor A. Treatment of head injuries in the public sector in South Africa. *S Afr Med J* 2000; **90**: 790-793.
6. *Soobramoney v. Minister of Health, KwaZulu-Natal* 1998 (1) SA765 (CC).

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Reduction in perinatal mortality feasible without incurring major costs

A third Perinatal Care Survey workshop was held at the Hammanskraal campus of the University of Pretoria, 18 - 20 November 2002. Like the previous two, this workshop brought together the users of the Perinatal Problem Identification Programme (PIPI), the national and provincial Maternal, Child and Women's Health (MCWH) units, the national and provincial Health Information and Epidemiology units, and the Medical Research Council (MRC) Research Unit for Maternal and Infant Health Care Strategies to discuss perinatal care based on an audit of perinatal deaths in South Africa.

It is not possible at this stage for South Africa to have confidential enquiries into all perinatal deaths, like the one into maternal deaths, because of the magnitude of the task. A solution, however, has been developed whereby the national basic perinatal data (i.e. data from every site where babies are

born) and data from sentinel sites around the country that have confidential enquiries into all the perinatal deaths in their areas, are combined. The basic perinatal data is a minimum dataset that includes all births and deaths in weight categories. The data from the sentinel sites add descriptive data of causes and avoidable factors to the basic perinatal care indices. This gives a good reflection of the magnitude of the problem of perinatal care in the country, and also provides information on why the infants are dying by including details on pathology and health system failure. The combination of both sets of data gives a reliable picture of perinatal care in the country and can direct health workers to areas where the greatest improvements can be made. The reports published under the 'Saving Babies' banner are available for 2000 and 2001 from the National Department of Health.^{1,2} The third report, involving 73 sentinel