

Controversies in Treatment

How can hospitals ration drugs?

When drug budgets are unable to accommodate all new drug requests, a dilemma arises when additional funds become available—which drugs should receive priority? The drug committee at Royal Adelaide Hospital devised a scheme, which they describe here, to rank drug requests to obtain the greatest benefit for the most patients for each dollar spent. We asked a health economist, a clinical pharmacologist, and a moral philosopher to give their perspectives on this form of rationing, and we then gave the authors an opportunity to respond.

Drug rationing in a teaching hospital: a method to assign priorities

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The cost of all aspects of health care in developed countries is increasing at an alarming rate.¹ Meeting these costs is becoming more difficult, and a variety of cost containment measures is being considered at national and regional levels.^{2,3} The continuing introduction of new technologies and drugs is one of the factors in the escalating cost of health care. These new treatments are often incompletely evaluated, and estimates of cost-benefit are lacking or poorly documented. This situation has resulted in a vigorous debate about the need for, ethics of, and possible methods for cost containment and rationing of health services.⁴⁻⁸

Hospitals have responded to shrinking financial resources by increasing day patient or outpatient services; transferring outpatient services to the community; imposing waiting lists; making services available only as long as funds are available; and withdrawing some services altogether. The last two options, and to some extent the imposition of waiting lists, are usually unplanned since cuts in hospital or divisional budgets often occur with little warning, and they can be regarded as arbitrary and unfair. Those patients who are excluded from the curtailed or reduced service are often those who were the last to join the queue.

The Royal Adelaide Hospital is a tertiary referral hospital of about 900 beds. The annual allocation for drugs is 4.6% of total expenditure and has remained more or less fixed since 1988, when the administrators decreed that expenditure on drugs was not to exceed this allocation. The hospital's drug committee introduced several strategies to deal with what was essentially a reduction in its allocation, given that it had to continue to satisfy the demand for new drugs. These measures included continuing the formulary system, some administrative changes, and implementing an ongoing drug utilisation review programme.⁹ These measures were reasonably successful until the middle of 1991, when it became apparent that unless additional funds were made available it would be impossible to introduce new drugs or new indications for existing drugs. Since additional money was not available, all

requests for new therapeutic initiatives, which by this time were considerable (table 1) and would have cost an additional \$730 000 annually (just under 10% of the drug budget), were refused until funds could be liberated from other sources. The drug committee was therefore faced with the dilemma of which new drugs to include in the formulary if additional funds became available.

A method (to be called the funding model) to assign ranking priorities by means of a formal scoring system was used for previously unfunded initiatives to allow their serial and orderly introduction into the hospital formulary. We report our experience and the initial responses from the hospital staff to an activity that was, in essence, overt and explicit rationing.

TABLE 1—Unfunded initiatives, in alphabetical order, and their projected cost and indications in the 1992-3 financial year

Drug	Indication	Cost (\$A)
Antithymocyte globulin	Aplastic anaemia	32 000
Botulinum A toxin	Dystonias	10 000
Budesonide turbuhaler	Asthma	4 000
Carboplatin	Neoplasms (general use)	45 000
	Cisplatinum contraindicated	3 000
Desmopressin	Postoperative bleeding (cardiothoracic surgery)	10 800
Fluconazole	Fungal infection	40 000
Fluoxetine	Depression	10 000
Low molecular weight heparin	Hip replacement	15 000
Interferon	Haemodialysis	30 000
	Chronic myeloid leukaemia	240 000
	Hairy cell leukaemia	12 000
	Hepatitis C	56 000
	Hepatitis B	30 400
Midazolam	Endoscopy	5 000
Morphine slow release	Cancer pain	100 000
Octreotide	Acromegaly	68 000
Ondansetron	Emesis induced by chemotherapy	16 000
Oxpentifylline	Bone marrow transplantation	2 850
Total		730 050

Methods

THE DRUG COMMITTEE

The drug committee must ensure that drug availability and prescribing in the Royal Adelaide Hospital conforms to the highest contemporary standards. The committee is composed of nine elected members representing clinicians (two physicians, two surgeons, one haematologist, one radiotherapist, one clinical pharmacologist, one occupational physician, one nurse) and four ex officio members representing the pharmacy department (two), the medical administration (one), and the finance department. The committee is thus composed predominantly of people involved in patient care and regular drug prescribing.

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Several steps take place before the final inclusion (or otherwise) of a drug in the hospital's formulary. These are application from members of the consultant staff for a drug; development of treatment and usage guidelines by the relevant experts (almost always drawn from the hospital's staff); consideration by the committee of the request and its guidelines; the decision to accept or reject the application, based on clinical and scientific grounds; and evaluation of the financial impact of inclusion of the drug into the formulary.

THE RANKING MODEL

Principles

The ranking model was based on six principles. Firstly, a treatment should be based on careful deliberation of clinical, professional, scientific and health economic considerations and should not be dominated by cost factors alone. Secondly, protocols and treatment guidelines should be established for all drug treatments at the hospital (this principle presumes that such protocols or guidelines will lead to improved standards of patient care and would form the basis for clinical education, future medical audits, or drug utilisation reviews). Thirdly, protocol and treatment guidelines should be explicit and should clearly define how the experts believe the new drug should be used in the hospital in relation to all of the elements described in box 1. Fourthly, a request for inclusion into the formulary and subsequent ranking by the model would proceed only if the drug qualified on clinical and scientific grounds based on the criteria in the box. Fifthly, the use of investigational therapies such as new drugs or established drugs for new indications or in new protocols (after appropriate ethical review) should not be discouraged. Sixthly, priorities in allocating resources for all treatments should be determined by the hospital's clinicians and by multidisciplinary consultation.

At an operational level, the guiding principles were that the ranking of drug requests is based on the need to obtain the greatest benefit for the most patients for each dollar spent¹⁰ and that the ranking model takes into account the quality and cost of the treatment and must be sufficiently robust to minimise subjectivity and enhance consistency in decision making. Thus the ranking model should enable the hospital (through its drug committee) to decide whether to fund, for example, ondansetron for an estimated 55 patients annually at a cost of \$16 000 or midazolam for an estimated 4000 patients at an annual cost of \$5000. The model was modified several times before it was considered suitable for application. The version in current use is described.

Box 1—Information required for drug inclusion into formulary

- Description of new treatment
- Treatment indications
- Patient selection (inclusion and exclusion) criteria
- Treatment objective
- First, second, and other treatment options
- Precise treatment end points
- Drug dosage and schedule (including duration of treatment)
- Anticipated annual patient numbers
- Safety and efficacy considerations (including comparisons with other treatments)
- Financial considerations including comparisons of cost differentials with other treatment options (including non-drug options)

Box 2—Derivation of final ratio score

Quality score

1 Outcome

- 1.1 Patient benefit
 - Cure/prevention (30)
 - Prolongation of life (15)
 - Palliation/symptom control (7)
 - Placebo (0)
- 1.2 Mortality/morbidity
 - High risk (9/5)
 - Moderate risk (6/3)
 - Low risk (3/1)
- 1.3 Response
 - Expected response rate based on the scientific literature

Outcome score = $(1 \cdot 1 + 1 \cdot 2) \times 1 \cdot 3$

2 Type of treatment

- Established indication (5)
- New therapy (3)
- Trial/investigational (1)

3 Clinical comparison with other treatments

- No alternative (15)
- New treatment > existing (10)
- New treatment = existing (5)
- Existing treatment > new (0)

Final quality score = outcome + treatment type + clinical comparison

Cost score

Comparison with other treatments

- New treatment less expensive (0)
- No alternative (2)
- New treatment = existing (5)
- New treatment more expensive (10)

Total cost per year (in \$7500 increments) (1-7)

Cost per patient (in \$750 increments) (1-7)

Final cost score = cost comparison + total cost per year + cost per patient

Final ratio = total quality score / total cost score

- The higher the ratio, the higher the priority to provide funds

Calculation of score value to assign ordered ranking

The final score (or ratio) has two components. The numerator consists of a quality score and the denominator of a cost score. The process of determining the score is summarised in box 2.

The quality score has three elements. The first is the outcome score. For individual patient benefit, values are assigned as follows: if the drug results in cure (for example, fluconazole for fungal infection) or is used for prophylaxis (low molecular weight heparin in hip replacement) the value is 30; if the drug prolongs life, the value is 15; if it causes palliation or symptom control, it achieves a value of 7; and if it is no better than placebo, it is assigned a score of 0. Mortality/morbidity of the disease or condition for which the drug is indicated attracts scores as follows: 9/5, 6/3, and 3/1 for conditions of high (> 75%), moderate (35-75%) or low (< 35%) mortality/morbidity respectively (mortality score relates only to the cure/prevention outcome). The third component is response: for example, if the treatment results in an average 90% cure rate the assigned value is 0.9. The score is calculated as the sum of the scores obtained from the individual patient benefit and mortality/morbidity categories multiplied by the response score.

The second element is the type of treatment. A score of 5 is allocated for an indication which is well

established or for which the drug has proved effectiveness; 3 if it is a new treatment; and 1 if it is a trial or investigational drug.

The third element is the clinical comparison with other treatments available and takes into account such factors as efficacy, adverse effects, attributes that may affect patient compliance, and ease with which the drug can be given to patients. Scores of 15 are assigned if there is no alternative to the new treatment; 10 if the new treatment is better than existing treatment; 5 if the treatment equals existing treatment, and 0 if the existing treatment is better than the new treatment.

The final quality score is the sum of the scores obtained from the outcome, type of treatment and clinical comparison scores. An example of how this can be derived is shown in box 3.

Box 3—Example of how various elements of numerator and denominator were derived to obtain final score

Fluconazole
 Indication: cryptococcal meningitis where amphotericin is contraindicated
 Outcome score:
 Cure of disease of high mortality with 85% response rate = $(30+9) \times 0.85 = 33.15$
 Quality score:
 Outcome (33.15) + established effectiveness (5) + new treatment > existing (10) = 48.15
 Cost score:
 Cost per patient: \$750-1500
 Number of patients per year: 35
 Total cost per year: \$40 000-\$45 000
 No alternative treatment (2) + \$40 000-\$45 000 annually (6) + \$750-\$1500 per patient (2) = 10
 Final ratio: $48.15/10 = 4.8$

The cost score also contains three elements. The first is the cost comparison with alternative or existing treatments. Scores of 0 are allocated if the new treatment is less expensive than existing treatment; 2 if there is no alternative to the new drug; 5 if the new drug cost equals the cost of existing treatment, and 10 if the new treatment is more expensive than currently available treatments.

The second element is the total cost per year for the newly introduced drug at the Royal Adelaide Hospital. This cost is based on the cost of the drug multiplied by the total number of patients who qualify for the drug. Scores ranging from 1 to 7 are allocated for each of seven bands, with each band equating to \$7500. For example, a score of 1 is assigned for a drug costing less than \$7500 annually, 6 for a cost of \$37 500 to \$45 000

annually, and 7 for a drug costing more than \$45 000 annually. Higher scores for a greater annual cost beyond \$45 000 are not assigned, since this would result in cost and not clinical considerations becoming the dominant factor in arriving at the ranking score. The cost used is the marginal or incremental cost resulting from replacing an existing treatment with a new one. If no new treatment is being replaced, the marginal cost equals total new drug cost. This provides a measure of the additional impact on the total drug budget.

The third element is the cost per individual patient for a completed treatment course. Here also scores ranging from 1 to 7 were allocated for each of seven bands, with each band representing \$750. A treatment costing less than \$750 was assigned a score of 1, and one costing more than \$4500 a score of 7. For the same reasons as given above, a score higher than 7 was not assigned if the treatment cost exceeded \$4500.

The final cost score is the sum of the scores obtained from the three elements just described. All costs are expressed in Australian dollars. Box 3 contains an example of how the cost score was derived.

The final ratio score is calculated as the quality score divided by the cost score (see box for example).

Results

The quality, cost, and ratio scores and the final ranking of the 19 unfunded initiatives (alphabetically listed in table I) are shown in table II. The ranking can be used to allocate available resources in order of the priority. Additional resources became available in June 1992 (coinciding with the end of the Australian financial year) to fund the first 11 initiatives in table II, and these were introduced into the hospital's formulary. The version of the model reported here evolved from several earlier versions, none of which produced ratio scores which discriminated sufficiently between drugs. The model has been widely disseminated and debated by the hospital staff. At the time of writing this report, there was general agreement that demand for services was outstripping the available resources; that some measures were needed to remedy the immediate situation; that the principles on which the model was based were appropriate; that a model such as this one, although simplistic, deserved a trial; and that the ethics of resource rationing needed close scrutiny and debate in the hospital and, equally importantly, in the community.

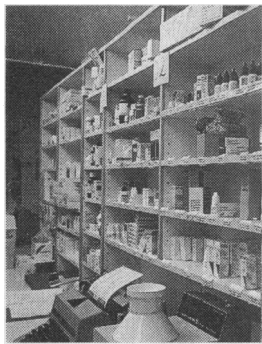
Discussion

Most teaching hospitals are likely to be faced with the dilemma of shrinking resources. One solution is to obtain increased funding; another is to impose measures to enable targeting of available resources to activities that are considered to be the most cost effective. Since the first option is becoming increasingly difficult to achieve, and in the view of some^{8 11} to justify, this realistically leaves only the second option if teaching hospitals are to continue their traditional roles. The imperative to improve methods by which allocation and rationing decisions are made has been enunciated for at least a decade in the context of national and regional health delivery programmes.^{1 5 10 12-17} Thus the development of this model can be seen as occurring in a climate of acceptance, albeit reluctant, of the need to consider rationing. The decision to create a model for more equitable and transparent means to distribute drugs was driven by the administration's mandate for a balanced drug budget, akin to the situation described for the state of Oregon.¹⁴

The introduction of the ranking model was under-

TABLE II—Final ranking of the 19 unfunded initiatives, giving the numerator (quality), denominator (cost), and final ratio scores

Priority No	Drug	Quality score	Cost score	Ratio score
1	Oxypentifyline	25.2	2	12.6
2	Interferon (hairy cell leukaemia)	52.4	10	5.2
3	Fluconazole	48.2	10	4.8
4	Botulinum A toxin	22.2	5	4.4
5	Low molecular weight heparin (hip replacement)	41.4	13	3.2
6	Budesonide turbuhaler	31.2	12	2.6
7	Interferon (hepatitis C)	29.0	12	2.4
8	Low molecular weight heparin (haemodialysis)	36.4	16	2.3
8	Interferon (hepatitis B)	32.6	14	2.3
8	Antithymocyte globulin	38.4	17	2.3
11	Octreotide	36.0	16	2.3
12	Carboplatin (cisplatin contraindicated)	22.5	12	1.9
13	Ondansetron	25.8	14	1.8
14	Interferon (chronic myeloid leukaemia)	27.2	16	1.7
15	Desmopressin	20.0	13	1.5
15	Midazolam	18.0	12	1.5
17	Morphine slow release	24.9	19	1.3
17	Fluoxetine	17.0	13	1.3
19	Carboplatin (general use)	17.5	19	0.9



pinned by some important principles, which had already been accepted by the hospital's staff. The first is that provision of services must be based on the best currently available scientific evidence. The adoption of the criteria in box 1 has led to a far more critical appraisal of the potential of a drug or treatment. Unless a drug was considered satisfactory by these criteria, it was rejected for inclusion in the formulary, even if the cost was minimal. Secondly, these criteria are central to the hospital's ongoing drug utilisation review programme, which has resulted in increased awareness of the need for frequent re-evaluation of current practices, improved patient care, and, coincidentally, cost savings.⁹ Thirdly, although calculation of the ranking score ratio was initially based on the principles of cost effectiveness analysis,¹⁸⁻²¹ cost was not allowed to dominate the final result, since this would have denied certain patient groups potentially life saving but expensive treatments and would have been contrary to the "rule of rescue," which dictates that there is a perceived duty to save endangered life where possible. A similar circumstance occurred when the planners in Oregon had to modify the initial list of priorities to raise certain life threatening conditions above less important ones.²⁰⁻²²⁻²³ It would have proved difficult, if not impossible, to obtain the agreement of the clinicians on the drug committee and the hospital to proceed with the development and implementation of the ranking model if cost had dominated the final outcome. This observation is in accord with the contention that "a rational plan needs to have medical and ethical, not simply economic, justification."²⁴

Any model which reduces matters of life, death, or morbidity to a numerical value must be simple to use and must be clinically relevant if it is to find acceptance. Whether our model satisfies these requirements will depend on several of the "input" variables. Are the patient outcome data robust?²⁵ How can degrees of morbidity or suffering be measured and how can these subjective variables be compared across different patients and disease states (see below)? How reliable are estimates of numbers of patients needing the new treatments? The committee acknowledged that even the best available evidence was often incomplete or inconclusive. Despite these deficiencies and the relative simplicity of the model, it was felt that the experiment was worth pursuing, rather than continuing to apply arbitrary and sometimes arguably unfair decisions to drug availability. The fact that the hospital community has so far accepted ranking decisions which have resulted from application of the model suggests that there is some clinical validity to the process. The final scores were obtained from data which for the denominator were specific to the drug budget of the Royal Adelaide Hospital. There is no reason why the model could not be transportable to other institutions, and possibly even to other areas of health care delivery and resource planning. The only requirement is that the information that is incorporated into the model should be scientifically sound and be relevant to the setting in which it is to be used.

COMPARING SUBJECTIVE VARIABLES

There was considerable debate about how to estimate and compare potential benefits to patients suffering from different conditions of differing severity for which different treatments were indicated. The committee wished to have a method that would be as precise as possible, since the quality score (numerator) incorporates elements of patient outcome in each of the three components. Incorrect assessment of outcome in a pessimistic or optimistic direction could substantially distort the numerator score and render the model useless. The data used in the denominator were

considered to be less subjective and more easily quantifiable. We rejected the use of the quality adjusted life year (QALY) as an outcome measure for three reasons: explicit QALY information for most drug outcomes is not yet available; assigning a QALY to a drug intervention is likely to be as subjective and potentially inaccurate²⁶ as the method currently used, since assessment of quality of years must be embedded in a knowledge of the likely disease process¹⁰⁻²⁶ and this could be highly variable from patient to patient; and there are interventions for which QALYs are difficult to measure, especially those that reduce short term disabilities such as nausea or vomiting and pain.²⁷

The probabilities assumptions about effectiveness and outcomes were taken from the best published evidence and extrapolated to apply to the patient population in our hospital. The final weightings we applied to the various categories in the numerator were arbitrary but were based on the principle that a treatment which resulted in cure or prevention of a condition with high mortality should be accorded a higher score than one that was only palliative. This is reflected in the approximate doubling of the relative weightings between each category in the individual patient benefit scores and the deliberate overlap between mortality and morbidity scores.

QUESTIONS ABOUT RATIONING

Medical practitioners will always feel uncomfortable when faced with a decision that may deny an individual patient a potential benefit. Thus, rationing brings into sharp focus the conflict between a practitioner's responsibility to the individual and to the society in which we live.¹⁹⁻²⁸⁻²⁹ Given that covert rationing has been in force in most if not all societies, should rationing decisions be more explicit, and who should participate in the debate that leads to the final decisions about which services will be provided, reduced, or removed? There is a strong argument that the decision making process should be made more open, transparent, and explicit.¹⁻³⁻¹¹⁻²⁶⁻³⁰⁻³¹ Our hospital community was widely consulted about the need for and proposed methods to achieve the ranking model described here. There were inevitably arguments of competing priorities, but decisions arising from application of the ranking model have so far been accepted.

Who should arbitrate about what is to be rationed? There are four interested parties to consider: politicians (the ideologues), administrators (the health funders), clinicians (health deliverers), and patients (health recipients). In this instance, the administrators issued the mandate not to exceed budgetary allocations, thus implicitly imposing rationing decisions on the clinicians. This can be defended³¹⁻³² since it is the clinician who has day to day contact with the patient and who is in the best position to be able to arrive at such decisions. A contrary view has been put by Leeder and by Sulmasy, who contended that clinicians should not have to act as restrictive gatekeepers.³³⁻³⁴ These opposing views were strongly represented among the hospital's staff, but there was a final consensus that clinicians must take part in such a process.

Where does this leave the patient? It has been stated that rationing should not be the exclusive domain of managers and professionals,³⁵⁻³⁶ since it is the patient who is the final beneficiary (or otherwise) of such decisions. In the long run, rationing by patient choice³⁵ seems not only logical, but equitable. Substantial methodological issues must be considered, however, before such a situation can become a reality.³⁵ We did not involve patients nor their representatives in the development of this model. It is hoped that debate generated by the introduction of the model will flow on

to the community served by the hospital, and thus enlist the recipients and politicians in crucial decision making processes on the delivery of health care.

Finally, is the model and its application fair? The answer to this lies partly in whether rationing can be considered as fair. It has been stated that "unfairness lies also in doing things until the money runs out"¹¹ and that "rationing becomes a morally acceptable option if the need is great enough and if other methods have been exhausted."³³ In our case the need had become acute, other methods were not sufficient to meet our requirements, and we could not wait for the ultimate cost saving benefits of the drug utilisation review programme to take effect. A method was therefore needed to provide a more equitable approach to this decision making process.

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Formulate, don't formularise

Cam Donaldson

Too often decisions about the allocation of scarce resources are being formularised (that is, crammed into formulas) rather than formulated (structured on the basis of thought). Those who use the formula of Bochner *et al* uncritically will be guilty of this. Many users of economic criteria, such as QALY league tables, also fall into this trap. The aim of this commentary is to outline, from an economic perspective, why this is a problem and what can be done about it.

Formularising hides subjectivity . . .

Clinicians and pharmacists are hard people. They are taught to think that subjectivity is "woolly." This leads to a desire to quantify all relevant considerations in a formula in the belief that this somehow makes things objective. This quantification goes on regardless of whether the elements of the formula overlap (as they do in the case of Bochner *et al*) and of whether it is in fact theoretically or practically relevant to combine these elements in the way formulas do. There is a failure to recognise that all resource allocation is (and must be) based on subjectivity, whether or not a formula is used. The will-o'-the-wisp pursuit of objectivity through formulas hides this fact in a way which is unhelpful.

. . . so let's formulate . . .

Without clear thinking, formulas can be constructed on arbitrary bases. In such cases decision making will not be improved. Less effort should go into fine tuning the elements of formulas and more into thinking about what their devisers were trying to achieve in the first place. In this regard, unmasking some of the arbitrary and subjective constructs of the formula of Bochner *et al* can help us discard some of the elements it contains. For instance:

- Is a cure for a high risk condition causing morbidity (with a score of 150) worth more than prolongation of life for a moderate risk condition (with score of 90)? (The formula says "Yes"; I say "probably not"; what does the reader think?)

"Less effort should go into finetuning the elements of formulas and more into thinking about what their devisers were trying to achieve."

- Of two new drugs which are otherwise equivalent, is drug A of higher priority than drug B because B's total costs are greater? (The formula says "Yes"; I say "No"; what does the reader think?)

In the first case too much emphasis is placed on "risk" and on "curing." In the second case, drug B may marginally increase costs over its already expensive alternative, while drug A could increase costs tenfold over its cheap alternative and still be valued higher than B. Total cost is distorting the result when it should not be counted at all. In both cases, progress can be made by thinking about the problem and