Priority setting in a hospital drug formulary: a qualitative case study and evaluation

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Abstract

Dramatically rising costs for new drugs are posing major challenges for hospital budgets. In response to these pressures, hospitals must set priorities for which drugs they will list on their formularies. While there have been studies relevant to decision making in hospitals regarding drugs, none have described how priority setting for drugs in hospitals is done and evaluated it against a framework of how it should be done. In this paper we describe the process of priority setting for new drugs in a hospital formulary and evaluate it using a leading conceptual framework for healthcare priority setting—Daniels and Sabin’s ‘accountability for reasonableness’. The findings from this study provide an evidence base for developing strategies to improve this hospital’s priority setting regarding its drug formulary. The process we utilized here, describing using case study methods and evaluating using ‘accountability for reasonableness’, is a generalizable process for improving the fairness of priority setting in hospital drug formularies.

Keywords: Priority setting; Hospital drug formulary; Case study; Accountability for reasonableness

1. Introduction

Dramatically rising costs for new drugs are posing major challenges for hospital budgets.

"[F]aced with the appearance of new and ever more expensive medicines on the market well after budgets have been set during the financial year . . ., hospitals have introduced a variety of measures to limit the financial impact of their use. These have included
hospital formularies and other forms of guided selection that restrict the right to prescribe certain medicines” [1].

In response to these pressures, hospitals must set priorities for which drugs they will list on their formularies. While there have been studies relevant to decision making in hospitals regarding drugs, none have described how priority setting for drugs in hospitals is done and evaluated this against a framework of how it should be done. Foy et al. described a collaboration between a specialist cancer hospital and six regional health authorities in the UK with respect to funding new cancer drugs and found that decisions regarding new cancer drugs were based on “evidence thresholds”, cut-off points determined from information on effectiveness [2]. Sloan et al. conducted a telephone-survey of 103 US hospitals to examine their use of various techniques to control drugs costs and found that most hospitals used some form of therapeutic interchange and generic substitution, and “(a) most cost-effectiveness was a minor tool in pharmaceutical decision making in hospitals” [3]. Luce and Brown studied the use of technology assessment in hospitals and other health care organizations, and found that hospital pharmacy decision makers appear to use health technology assessment more often than those in other parts of the hospital [4]. A few studies (for example, Pearce and Begg [5], Segal et al. [6], and Barriere [7]) have focused narrowly on a few drug decisions, decision making techniques, or on limited quantitative survey data describing decisions in relation to pharmacy costs. None of these studies described the actual process of priority setting for drugs in a hospital. Formal pharmacoeconomic analyses (e.g. cost-effectiveness analysis) have been proposed for drug formulary management in some contexts [8], but studies have shown that its use is limited—for example, in Canadian provincial formularies [9], and specialist networks for cancer or cardiac disease [10,11]. Despite this growing literature, there is no in-depth description of the priority setting process for drugs in a hospital formulary.

Describing the actual process of priority setting is a necessary first step toward improving it. As a second step, because hospital formulary committees may not ‘do’ what they ‘should do’, it is necessary to go beyond description to evaluate priority setting for drugs in hospitals. We used ‘accountability for reasonableness’ (described below) since it has been widely recognized as an conceptual framework for priority setting in health care institutions [12,13]. To date, it has not been used to evaluate priority setting for drugs in hospitals.

The purpose of this paper is to describe priority setting for new drugs in a hospital, and to evaluate this process using ‘accountability for reasonableness’.

2. Methods

2.1. Study design

This was a qualitative case study of priority setting for new drugs in a hospital formulary. A case study is “an empirical inquiry that investigates a contemporary phenomenon within its real-life context” [14]. This is the appropriate method because priority setting in hospitals is complex, context-dependent, and involves social processes.

2.2. Setting

The setting for this study was the University Health Network (UHN), a network of three teaching hospitals in Toronto, Canada. This study was conducted between April and September 2001 and focused on committees involved in formulary management within the hospital. The process of drug approval is described in Box 1.

2.3. Data collection

This study used three primary data sources: (1) key documents (e.g. minutes of Pharmacy & Therapeutics Committee (P&T) meetings)—we obtained 20 documents; (2) interviews with key informants (e.g. P&T committee chair) which were audiotaped and transcribed—we conducted 18 interviews; and (3) observations of group deliberations (e.g. P&T meetings)—we observed three meetings. Interviews were conducted using a
Box 1. The process of priority setting for a hospital formulary

Initial consideration of new drugs occurs at the Pharmacy and Therapeutics Committee (P&T), which monitors, regulates, and approves all current and new drugs used in the hospital formulary. The P&T Committee consists of 14 physician representatives from all the medical and surgical specialties in the UHN, two pharmacists, and one nurse. The P&T meets once a month to review all modifications, additions or deletions to the hospital formulary. The P&T is also responsible for advising the Medical Advisory Council (MAC), of which it is a subcommittee, with regard to all formulary modifications, additions, or deletions. The MAC has authority to approve all medically-related decisions in the UHN, including all recommendations of the P&T. The MAC consists of physicians and heads of hospital units, including the physician-in-chief, and the CEO. The UHN formulary, though part of a provincial health care system, is nevertheless distinct from other hospital and provincial formularies, such as the provincial formulary of Ontario, maintained by the Drug Quality and Therapeutics Committee of Ontario (DQTC) [9].

Requests for formulary modifications or additions are made by UHN physicians or pharmacists. The P&T then reviews all relevant information pertaining to the drug request such as intended use, patient need, toxicity, drug-administration, effectiveness compared with similar drugs, and cost-related information.

In March 2001, the UHN began implementation of a new Drug Management Framework (DMF)—a drug cost-control mechanism. The essential features of the framework are: (1) new drugs estimated to cost less than $50,000 per year are approved within the existing P&T/MAC regulatory framework; and (2) new drugs estimated to cost more than $50,000 per year must be approved by both P&T/MAC committees and a committee managing the hospital site where the new drugs will be used. During the study period, no new drugs were considered under the new framework.

2.4. Data analysis

Data analysis proceeded in two steps. First, using a modified open coding technique [15], the data were examined and elements of the priority setting process were identified and described. Second, the description was compared with the conceptual framework, 'accountability for reasonableness' (described below), to identify areas of fit and misfit—areas of misfit were considered as ‘opportunities for improvement’ regarding the priority setting process.

We addressed the ‘validity’ of our findings in three ways [16]. First, data was obtained from three different sources (documents, interviews, and observations) to maximize comprehensiveness and diversity [17]. Second, the results of the study were distributed to participants from the case study as a “member check” [18] and they verified the accuracy of our findings. Third, members of an independent multidisciplinary research group, consisting of a philosopher, nurse, hospital administrator, physician and bioethicist, enhanced the “reflexivity” in the analysis by becoming familiar with the data and participating in the data analysis. Thus the role of prior assumptions and experience, which can influence any inquiry, were acknowledged and, when necessary, discarded.

2.5. The conceptual framework: accountability for reasonableness

‘Accountability for reasonableness’ is a conceptual framework that can be used to improve priority setting processes in healthcare organizations [19,20]. It was developed in the context of US Health Maintenance Organizations and so is relevant to real-world priority setting processes [21]. It is theoretically grounded in justice theories emphasizing democratic deliberation [22,23]. It has ‘traction’ among decision makers and is the preferred framework of leading priority setting researchers [24–26].
A common priority setting goal in every healthcare organization, in every health system, is fairness. ‘Accountability for reasonableness’ specifies conditions that operationalize the concept of fairness [27]. Improving priority setting in a healthcare organization, for example a hospital, using ‘accountability for reasonableness’ entails improving the fairness of their priority setting processes, and a fair priority setting process meets four conditions (described in Table 1): relevance, publicity, appeals, and enforcement.

Daniels and Sabin, who developed the framework, suggest that ‘accountability for reasonableness’ is relevant to pharmaceutical priority setting:

“Managing access to pharmaceuticals is a microcosm of the limit-setting problems of health care systems as a whole... If we are right that accountability for reasonableness is a solution to the legitimacy problem in health systems as a whole, then it should be possible to illustrate what such accountability would mean in practical terms in pharmacy benefit management” [28].

According to ‘accountability for reasonableness’, an institution’s priority setting decisions may be considered legitimate and fair to the degree it satisfies four conditions: relevance, publicity, appeals, and enforcement—described in Table 1.

2.6. Research ethics

This study was approved by the University Health Network Research Ethics Board. Written informed consent was obtained from each individual prior to being interviewed. Permission to observe group deliberations was obtained from the group prior to observation. All raw data was protected as confidential and available only to the research team. No individual participants have been identified.

3. Results

In this section we describe our evaluation of the priority setting process using the four conditions of accountability for reasonableness: relevance (in particular, the elements of reasons, goals and participants), publicity, appeals, and enforcement (see Table 1). We have also used verbatim quotes from participants to help explain their perspectives.

3.1. Relevance

3.1.1. Reasons

Formulary decisions were based on a complex cluster of factors. These included: benefit, which is viewed in terms of (a) type, and (b) amount; evidence—the degree of certainty of which the benefit is known; toxicity—adverse drug side effects; number of patients requiring the drug; availability of alternative drugs similar to the drug in question; ability of the nurse or medical attendant to administer the drug; cost of the drug to the hospital; comparative drug use in other hospitals and internationally; advantages over other drugs-comparative efficacy; elimination

Table 1
The four conditions of accountability for reasonableness

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
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<tbody>
<tr>
<td>Relevance</td>
<td>Priority setting decisions must rest on reasons (including evidence and principles) that fair-minded participants can agree are relevant to meeting context-specific goals under resource constraints. Fair-minded participants are stakeholders who are predisposed to decision making according to rules of mutual cooperation and can involve managers, clinicians, patients, and consumers in general (three key foci are underlined)</td>
</tr>
<tr>
<td>Publicity</td>
<td>Priority setting decisions and their rationales must be publicly accessible</td>
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<tr>
<td>Appeals</td>
<td>The priority setting process must include a mechanism for revising decisions in light of further evidence or principles that other stakeholders might contribute</td>
</tr>
<tr>
<td>Enforcement</td>
<td>Their must be voluntary or public regulation of the process to ensure that the first three conditions are met</td>
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of similar drugs from the formulary; prescribing restrictions; and cost of the drug compared with current drug cost—informal cost-effectiveness. The committee would not necessarily review all twelve factors, but a cluster of factors relevant to each decision—thus indicating the highly contextual nature of the decision-making process [11].

Formal pharmacoeconomic analyses (e.g. cost-effectiveness analysis) were seldom used. However, cost data and informal cost-comparisons were considered. One participant commented, “We try to collect any information that is available regarding cost-effectiveness from a comparison stand point, for example comparing the drug being reviewed with others already on the formulary, [but] this information may not be available...Pharmacy and Therapeutics committee (P&T) rarely does a cost-effectiveness analysis with respect to cost of carrying a drug versus the clinical implications of not carrying it at all... P&T does not have enough information regarding budgets etc. to be able to make a decision re: can the hospital really afford to carry a drug”?

3.1.2. Goals

The goals of the committees involved in formulary decisions were unclear. The mandate of the P&T was to focus on the clinical nature of drugs, to approve drugs that were safe and effective, and not be “influenced” by issues pertaining to the funding of drugs. However, this did not match the reality of decisions of the P&T, which clearly involved financial factors. The tensions between the explicit goal of drug efficacy and safety, and the implicit goal of cost at the P&T can be illustrated by two comments from a particularly influential P&T member:

“[O]ur issue is safety. Safety, efficacy, standard of care is what we care for. The financial aspect of the whole thing is totally out of our hands. We do not get involved with that. Otherwise there would be conflict”.

This same participant also stated that the P&T had to be aware of the costs of drugs because the hospitals must budget for them: “So we’re looking only at the safety, efficacy and impact on the hospital” (i.e. cost).

A member of the Medical Advisory Committee (MAC) further commented that the goals of both the P&T and the MAC were essentially the same:

“To pass a medical or expert opinion on whether the drug in question is effective and in particular, cost effective. I think their [P&T, MAC] goals are the same... They make a judgment and a recommendation based on whether the effectiveness is worth the extra money”.

Just as at the P&T, there was confusion as to the degree of financial emphasis placed at the MAC level.

3.1.3. Participants

The full range of stakeholders was not represented in the decision making. Consequently, the full scope of factors may not have been raised or considered relevant. As noted, the P&T membership consisted of 14 physicians, two pharmacists and one nurse. There were no patients or community members on the P&T or MAC.

Many participants felt that patients or community members should not be included on the P&T because lay members would not understand the data being discussed, and would represent a biased opinion by solely arguing for the merit of the particular therapy or drug for which they were concerned. One participant expressed concern about patient “grandstanding”. Another participant, a physician, stated that patients are biased and emotional, while doctors are less biased and are able to make neutral, non-emotional decisions.

On the other hand, there were several participants who favored the inclusion of lay participants on the P&T. One participant commented:

“I think it’s [lay participation] good because these decisions are about the availability to the public of various forms of treatment
options, and that in the end, it’s a public institution and hence it has a public board [the Board of Trustees]. And it’s open public board meetings and it’s funding from the taxpayers, so I think that’s perfectly logical to have members of the public [who are] not involved in the hospital’s administration or expert line, participate”.

3.2. Publicity

The reasons for formulary decisions were not easily accessible. The P&T’s decisions and some, but not all, of the reasons for these decisions were made available to P&T members through the distribution of the committee’s minutes. P&T decisions, but not the reasons, were publicized in the Medical Staff Bulletin used to communicate changes in formulary drugs to hospital staff. The minutes of P&T meetings were not easily accessible to members outside the committee. While drug decisions involving clinical care were posted in the relevant hospital departments in which these drugs were used, the deliberative processes through which these decisions were made, and the reasons for the decisions, were not. Therefore, despite being cited by committee members as “public documents”, P&T minutes were not easily accessible by anyone outside the committee, including most hospital staff, patients, families, and community members.

3.3. Appeals

A new Drug Management Framework (implemented 3 months before this study) includes an appeal mechanism whereby a two-member panel (the hospital CEO and the chair of the MAC) hears and addresses disputes. At the time of this study, there had not yet been an appeal. Opportunities for appeals by patients or community members were not included in this mechanism. The mechanism does not specify appropriate grounds for appeals.

3.4. Enforcement

Accountability for priority setting for new drugs was spread across different groups in the hospital including P&T, MAC, the Planning and Priorities Council (PPC) (a senior administrative body responsible for securing global UHN funds), the site directors, and hospital units. How well these accountabilities were aligned with each other was unclear.

Most participants commented that the primary goal of the MAC was to endorse or reject the recommendations of the P&T. They said that in essence the MAC was a “rubber stamp” for the recommendations of the P&T, completely relying on the P&T for their expertise, and rarely did the MAC reject a recommendation of the P&T.

Drug funding issues were primarily addressed by the PPC, a group of senior management including Vice Presidents and chaired by the CEO of the hospital. The PPC negotiates funding for UHN from the Ministry of Health.

The Site Directors aimed to ensure a “balanced budget” for the site in question. However, they also considered P&T’s additional factors to some degree when making decisions. As one Site Director stated:

“We are interested in giving safe and appropriate care. We want to be giving the most effective drug. But we also want to be giving the ones that are the most cost-effective. That’s very important for the site. And we need to know that there’s a monitoring system for drug usage because the managers and the administrative team are accountable for the budgets, but we don’t write the orders and drive it—the physicians do that. So, we do have to oversee what they’re doing and have the confidence that we have appropriate decision making into those orders being written”.

The Nurse Manager or Unit Director, facilitated by the Director of Operations for the hospital, had the main goal of maintaining a balanced budget for the overall hospital. The Nurse/Unit Managers did not have authority to refuse prescriptions or
affect drug decisions made at other levels. This creates a difficult predicament. Drug-costs are dramatically increasing but the Nurse/Unit Managers must find funds for these drugs, and must, therefore, ‘give-and-take’ within their fixed budget in relation to the funds allocated for all other services.

4. Discussion

In this paper we have provided, to our knowledge, the first in-depth empirical description of an actual process of priority setting for new drugs in a hospital. We also evaluated the priority setting process using ‘accountability for reasonableness’. This process of description and evaluation led to recommendations for improving the fairness of priority setting for new drugs. Other hospitals may benefit from the specific lessons we identify. In addition, the process we used can be a used by other hospitals to improve priority setting for new drugs. Gaps between the description and evaluation, using the four conditions of ‘accountability for reasonableness’ (relevance, publicity, appeals, and enforcement), provide the evidence base for recommendations—opportunities for improvement.

4.1. Relevance

4.1.1. Reasons

The finding that formal pharmacoeconomic analyses (e.g. cost-effectiveness analysis) played a limited role was not surprising as it has been shown in other contexts [9,11]. As our analysis shows, cost-effectiveness analysis, and the value of efficiency, is a necessary but not sufficient foundation for priority setting decisions. The Institute of Medicine Panel on Cost-Effectiveness argued that, “... CEA [should] be used as an aid to decision makers who must weigh the information it provides in the context of... other values” [29].

4.1.2. Goals

The hospital should clarify whether the P&T should or should not consider financial factors in its decision making. Many participants believed the goal of the P&T was to make decisions based on evidence of safety and efficacy, but in practice the committee was also considering cost-related factors.

4.1.3. Participation

The P&T should include some lay participation, both patients and community members, and Nursing and Pharmacy representation on the P&T should be expanded. This would improve the decision making by enhancing and broadening the scope of factors considered relevant by the committee. For example, in response to heavy criticism for rejecting the multiple sclerosis drug beta-Interferon, the UK’s National Institute of Clinical Excellence (NICE) set up a ‘citizen’s council’ to include a lay perspective in its priority setting process [30]. In addition, as we noted in a previous study, critical mass is important to remedy potential power imbalances when lay members sit on committees with ‘professionals’ or ‘experts’—tokenism is insufficient [31].

4.2. Publicity

P&T decisions and the reasons for those decisions should be made accessible both inside and outside the hospital. When appropriate, minutes of both the P&T and MAC should be made available to all Nursing staff and posted on the hospital website, and hospital Staff Bulletins should contain not just priority setting decisions but the reasons for decisions. This would improve the priority setting by engaging all stakeholders (e.g. hospital staff, patients, family, media, etc.) in a kind of policy learning about appropriate limit setting decisions regarding drugs.

4.3. Appeals

The hospital should refine its appeals mechanism by expanding the opportunities for others, in particular patients and members of the public, to contribute relevant considerations to each decision, and by specifying the grounds for appeals (i.e. new information or arguments). This will show respect to all stakeholders who are not members of any of the decision making commit-
tees and, by opening the process to others, help improve the quality of the decision making process.

4.4. Enforcement

The hospital should explicitly identify who is accountable for which decision with regard to priority setting decisions for new drugs, and this should be communicated throughout the institution.

4.5. Limitations

The primary limitation of this research is its generalizability. The results from our study may not be generalizable to other hospitals. However, the goal of qualitative research is not generalizability, but to provide rich description of context-specific phenomena that have independent, valuable, and significant meaning [32]. Nevertheless, as priority setting for drugs is something that all hospitals must face, it is likely that hospitals may 'see themselves' in the findings. In particular, physicians, who are the primary decision makers regarding hospital drug formularies and whose practice is affected by these decisions, may benefit from the lessons we identify. More importantly, the process outlined here—description using case study methods and evaluation using 'accountability for reasonableness'—can be used by others to lead to local recommendations for improvement.

5. Conclusion

The findings from this study provide an evidence base for developing strategies to improve this hospital’s decision making process regarding its drug formulary. The process we have shown here, describing using case study methods and evaluating using ‘accountability for reasonableness’, is a generalizable process for improving the fairness of priority setting in hospital drug formularies.

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