Access to High-Cost Drugs: Decision Makers' Perspectives

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ABSTRACT

Aim: To explore the attitudes, perceptions and concerns among decision makers about equity of access to high-cost drugs in public hospitals.

Method: 25 in-depth, semi-structured interviews were conducted with senior hospital administrators, directors of pharmacy and senior medical doctors. Topics included the decision-making process and associated problems, and solutions to issues of access to high-cost drugs. Interviews were audiotaped, transcribed verbatim and thematically analysed.

Results: Healthcare funding models were perceived as obstacles to equity of access to high-cost drugs. Participants were concerned that there were inequities in decisions for individual patients according to public or private sector status. Tertiary public hospitals were seen to be at the 'cutting edge' and therefore were required to fund new and expensive drugs. This meant prioritising between patient groups and individuals. Participants had difficulty in identifying solutions. They suggested that ethical principles should be considered in addition to safety, efficacy and cost. Most wanted a transparent, accountable, evidence-based decision-making process.

Conclusion: Decision makers were concerned about equity of access to high-cost drugs in public hospitals. They were also concerned about processes for decision making and the outcomes of these decisions.

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INTRODUCTION

Australians have access to medicines through different schemes. The Pharmaceutical Benefits Scheme (PBS), funded by the federal government, subsidises drugs prescribed in the community.[1] Private hospitals, as well as some public hospitals, have implemented the PBS as a funding mechanism for outpatient and discharge drugs.[2] Pharmaceuticals supplied by public hospitals are funded primarily by the state-based hospital funding.[3] The clinical status of an inpatient differs from non-hospitalised patients—the illness is likely to be more acute and other issues can affect access to medicines.[4]

Funding for public hospitals is given to the states and territories by the federal government and this represents the largest single component of health expenditure.[3] Pharmaceuticals represent one of the highest costs within this category.[5]

How do hospitals deal with capped budgets and scarce resources? Multidisciplinary drug and therapeutics committees (DTCs) address cost priorities and aim to ensure quality use of medicines.[6] Analysis of drug use suggests that DTCs have become more involved in cost containment and predicting budgetary needs.[7] However, the decision-making process is a complex task and there are frequent additions of innovative, high-cost drugs. Economic, ethical and legal aspects may be considered, as well as the clinical and science-based evidence for drug use.[8] Expending resources for the benefit of some patients by depriving others is challenged as unethical.[9,10] The appropriate decision-making process is described as transparent, allowing fair allocation of resources to achieve the greatest benefit for patients.[11] High-cost drugs, which may be defined through a number of mechanisms, may also be associated with low levels of evidence for the specified indication, and are often for 'off-label' use.[12] Recognition of these issues does not easily translate to day-to-day management of drug access issues for individuals, institutions and policy makers.

Decisions are not based on financial cost alone, as social, legal and ethical aspects may play significant roles. Published reports have focused on different mechanisms of rationing and principles such as distributive justice.[11,13] Limited work has been conducted regarding use and funding of high-cost drugs in public hospitals. There are no published data on attitudes and concerns regarding access to high-cost drugs.

The aim of this study was to explore the attitudes, perceptions and concerns among decision makers about equity of access to high-cost drugs in public hospitals. This study is part of a larger research program investigating attitudes, perceptions and concerns of the community. Our specific objectives were to:

- investigate the understanding of decision makers about high-cost drugs;
- investigate their perceptions, concerns and attitudes regarding the use of high-cost drugs;
- investigate current problems and possible solutions;
- investigate the criteria currently used to allocate resources to high-cost drugs; and
- explore the role of economic evaluation (and other data) in the decision-making process.

METHOD

Qualitative techniques were used for data collection and analysis. In-depth, semi-structured interviews were conducted between August 2003 and April 2004. All interviews were conducted by the same researcher and were of about 35 minutes duration.

A purposive sample of key decision makers within the Sydney Area Health Service was identified. This included senior hospital administrators, directors of pharmacy and senior medical doctors. A letter of invitation which outlined the objectives of the study was sent and a reminder letter was sent if no response was obtained within four weeks. A 'patient information' statement and a consent form were provided.

Interviews were audiotaped and transcribed verbatim. When new themes were no longer occurring data collection was considered complete. The data were coded and analysed through the strategies of grounded theory.

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This is a standard technique used to establish a theoretical framework from collected data.

The characteristics of the participants, including age, gender, position, organisation and education background were recorded. Data were analysed using the Statistical Package for the Social Sciences (version 10).

This study was approved by the Human Research Ethics Committees of The University of Sydney and St Vincent's Hospital, Sydney and endorsed by the Chief Executive Officer of the Sydney Area Health Service.

RESULTS

Thirty-four people were invited to participate (Table 1) and 25 semi-structured interviews were conducted. One participant declined to be audiotaped and another was interviewed twice to clarify previous answers.

Table 1. Characteristics of participants

Characteristics	
Age (years)	
Mean	51
Median	52
Range	30-72
Gender (male)	54%
Organisation	
Public hospital	88%
Area health service	8.3%
Advisory body	4.2%
Position	
Administrative	42%
Senior medical doctor	25%
Director of hospital pharmacy	21%
Other (deputy director of pharmacy, area advisor)	12%
Education	
Medicine	46%
Management	29%
Pharmacy	25%

Defining High-Cost Drugs

Participants were initially asked to define a high-cost drug. Most defined these in two ways: drugs with a high acquisition cost used in low volume or drugs with low acquisition cost but used in high volume. A minority attempted to give a dollar value to the definition. They were ultimately concerned about drugs that had an impact on the capped and limited budgets. *So I think you have to talk about the two situations, one being that a drug that costs a $1000 is given for a short period of time, and other drugs which cost less than that are given over larger periods of time. The more common thing that I worry about is in an individual case. You have something that is say over $15 000 per year— that is the sort of figure that I start getting worried about. The high-cost drugs that we tend to focus on are those in which the individual doses or courses are expensive and as a consequence a small variation in the number of eligible patients makes a large variation in the hospital's budgetary position.*

Associated Problems and Solutions

Participants were asked about what they perceived to be the main problems and their concerns with regards to access to high-cost drugs. One of the main themes that arose was the tension between funding models. They perceived the current healthcare funding model as an obstacle to equity of access to high-cost drugs. *But because it's high cost to us and therefore there's a question of can we afford to use it and what are its indications, etc. In the private sector that's a non-question because it's PBS listed and the Commonwealth simply pays for it. The anomaly we see and the system which appears to be lacking at a federal/state interface level is that the decisions of the federal government are not binding on the state government and hence the decision that the taxpayer should not pay for this dug is overturned at hospital level and the same taxpayer pays for the drug.*

Participants were also concerned that there were inequities in decisions for individual patients according to public or private sector status. *There are issues of equity of access, particularly with drugs that are available in the PBS and available to the people in private hospitals but the public hospital can't make the same drugs available; there's a lot of issues with funding. There are issues relating to equity and access between private hospitals and public hospitals. There are a number of drugs which are available on the PBS and in some cases not available in public hospitals because they have been deemed too expensive or their use may be restricted.*

Some respondents thought that public hospitals had to be at the 'cutting edge' and therefore were required to fund new, expensive drugs. A major concern for respondents was that, as a consequence, this meant prioritising between patient groups and individual cases. *So, by and large, teaching hospitals are where new and expensive therapies are used first to the utmost degree of good. Why is one patient group more important than another patient group and how do we decide which drugs should be available to each patient?*

The majority of participants identified problems but had difficulty in identifying solutions. Some perceived that having a single body to fund pharmaceuticals would overcome the problems. *Universal funding of pharmaceuticals by the Commonwealth. It would be easier to make it transparent and equitable decisions by having a single funding body.*

Adopting the decision of the Pharmaceutical Benefits Advisory Committee (PBAC) model was also suggested. *It would simplify matters enormously if the States and the Commonwealth agreed that a PBAC listing that a particular drug should not be publicly funded meant exactly what it said and that there was no debate at state level or area level or hospital level.*

They also commented on having a state-based approach to dealing with high-cost drugs and the involvement of advisory bodies. *Well if we're still having separate funding for hospitals, I think some of these issues should be a state approach because it's not ... it's inequitable. I think the New South Wales Therapeutic Assessment Group, although they are not a government body, they have almost a direct pharmacy [sic] on them and they have the skills to see whether these drugs, high-cost drugs, are they, well, worthwhile, and what it is all about. And make an appropriate recommendation.*

Allocating Resources

Participants described criteria such as safety, effectiveness, efficacy and cost. Although it seemed like cost was the main criteria used by them it was perceived unethical to consider it as the sole driver for the decision.

A utilitarian goal was in mind—'the greatest good for the greatest number'. *Efficacy, safety and cost effectiveness would have to be included as they are in the PBAC. So it's total cost that's the most important driver as far as the hospital relates. Evidence, costing, number of patients per year, alternatives that have been used to date and why, why this drug is needed for that person. Cost isn't an appropriate way of rationing the resources. You can't just deal with the costs alone, there has to be cost versus the clinical benefit. We do apply roughly the same criteria, philosophical criteria, in the sense that we try to get the maximum benefit for the greatest number.*

Economic Evaluation

Participants were asked if economic evaluation was used as a criterion to allocate resources to high-cost drugs. No attempt was made to verify their understanding of pharmacoeconomics. Pharmacoeconomics is currently not used as a criterion in the decision-making process in public hospitals. Interviewees identified three main barriers to its use:

- Lack of expertise and knowledge to analyse the data derived from pharmacoeconomic studies.
- Most pharmacoeconomic studies were sponsored by pharmaceutical companies.
- Most pharmacoeconomic studies are conducted from the societal perspective, and are available for PBS subsidy criteria. This perspective differs to that of public hospitals.

And we don't have enough expertise. We'd oversee so called pharmacoeconomic evaluations and you can't directly relate them to the Australian scenario; it is very, very hard, there are so many issues. It would be nice to have access to cost-effectiveness analysis done by professionals. Doing economic studies as to the reductions of length of stay and all of those sorts of things. But of course that is completely useless to a public hospital point of view.

DISCUSSION

Despite many allusions to cost of health care there are no generally accepted definitions of high-cost drugs. This may be important in the interpretation of data and development of policy.[14-17] In this study, participants unanimously defined high-cost drugs as those which could have an impact on capped and limited budget holdings. Similar definitions have been previously described.[18] They were principally concerned with those with a high acquisition cost and a low volume of usage.

Dealing with high-cost drugs was considered difficult for a number of reasons. These included the complex healthcare systems, federal government and state as well as public and private systems.[3,4,19] A single funding system was seen by some as a way to overcome the previous problems.[20] However, participants achieved no consensus and other approaches were described.

As expected, cost was described as a major criterion when deciding if a high-cost drug should be available at a public hospital. Participants acknowledged that there was rationing of resources and they had difficulties describing how this should be achieved. There was a utilitarian viewpoint expressed where they wanted to achieve 'greatest good for the greatest number'.

Pharmacoeconomic data were not being used in the decision-making process—lack of expertise and knowledge were identified as barriers. Similar results were obtained when exploring the role of economic evaluation for health services.[21] Biased information and lack of pharmacoeconomic analysis conducted from the hospital's viewpoint were also identified as barriers to use.

Qualitative research is not intended to produce results which can be generalised. It allows the exploration of people's views.[22] In this study a description of attitudes, perceptions and concerns among decision makers about access to high-cost drugs has been provided.

Limited work has been conducted on the use and funding of high-cost drugs in public hospitals. It is important to evaluate how individual perceptions may influence and assist in the decision-making process. Understanding the role of these perceptions in decision making will assist in future management of high-cost drugs.

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