Access to High Cost Medicines in Australian Hospitals

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BPharm

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Faculty of Pharmacy

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To my brother Juan Felipe………
Statement of originality

The research presented in this thesis was carried out under the supervision of Professor Jo-anne Brien (Chair of Clinical Pharmacy, The University of Sydney and St Vincent’s Hospital), Doctor Susan Taylor (Senior Lecture, The University of Sydney) and Associate Professor Paul McNeill (Associate Professor, University of New South Wales)

To the best of my knowledge and belief, the work presented in this thesis is original; except as acknowledged in the text. Full acknowledgement has been made where the work of others have been cited or used. This thesis has not been submitted in part or in whole for the award of any other degree or diploma at any university or institution.

Gisselle Gallego

2006
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Communications arising from this thesis

The work described in this thesis has been presented as follows:

PEER REVIEWED PUBLICATIONS


PUBLISHED ABSTRACTS


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2004  Gallego G, Taylor S, Brien JE. Equity of access to high cost drugs (HCDs) a case study. 8th World Conference on Clinical Pharmacology and Therapeutics (Incorporating the Annual Scientific Meeting of ASCEPT). Sydney (Australia)


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Abstract

In the public hospital sector in Australia there is no dedicated scheme to offset costs associated with high cost medications (HCMs) to the institution or the public. (1) Concerns exist as to the equity of access and appropriate mechanisms to manage access to HCMs in public hospitals. (2) There are gaps in the literature as to how decisions are made, and in particular, decision-making processes by which ethical, clinical and economic considerations maybe taken into account.

To date, limited work has been conducted regarding the use and funding of HCMs in public hospitals. There are no published data on perceptions, concerns and attitudes, among health care decision-makers or among the community-at-large about access to HCMs in public hospitals.

The research reported in this thesis describes the decision-making process and criteria used by health care decision-makers to allocate resources to HCMs in public hospitals. The investigation triangulated quantitative and qualitative methods used to collect and analyse data. Four studies were conducted to describe the decision-making process and explore the perceptions, concerns and attitudes of health care decision-makers and the perceptions of members of the general public regarding access to HCMs in public hospitals.
The first study, reported in Chapter Three, was a review of individual patient use (IPU) requests for non-formulary HCMs. This study showed that these requests had a significant impact on the capped expenditure of a public hospital. Subsequent to this review, a new policy and procedure for managing requests for HCMs for IPU was established. A high-cost drugs subcommittee (HCD-SC) operating under the auspices of the Drug and Therapeutics Committee (DTC) was created.

The second study, reported in Chapter Four, described the operations of the newly formed HCD-SC. This study also evaluated the decision-making process using the ethical framework “accountability for reasonableness”. (3) Different factors were involved in decisions about access to HCMs and decisions were not solely based on effectiveness and cost. HCD-SC members considered it was important to have consistency in the way decisions were being made. The evaluation of this process allowed identification of good practices and gaps which were considered as opportunities for improvement.

The third study, reported in Chapter Five, found that health care decision-makers in an Area Health Service echoed the concerns and agreed about the problems associated with access to HCMs expressed by the HCD-SC members. These studies concluded that the majority of decision-makers wanted an explicit, systematic process to allocate resources to HCMs.

These studies also identified tensions between funding systems and hospital decision-making. According to participants there were no mechanisms in place to systematically capture, analyse and share the lessons learned between the macro
level (ie. Federal, Pharmaceutical Benefits Scheme - PBS) and the meso level (ie. Institution, public hospital) regarding funding for HCMs. Furthermore, decision-makers considered there are strong incentives for cost-shifting between the Commonwealth and the States.

Health care decision-makers also acknowledged the importance of public participation in decision-making regarding allocation of resources to HCMs in public hospitals. However the results of these studies showed that those decisions were not generally made in consultation with the community. Decision-makers perceived that the general public does not have good general knowledge about access to HCMs in public hospitals.

A survey of members of the general public, reported in Chapter Six, was then conducted. The survey aimed to gather information about the knowledge and views of members of the general public about access to HCMs in public hospitals. Results of this fourth study showed that respondents had good general knowledge but were poorly informed about the specifics of funding of hospitals and HCMs in private and public hospitals. The results also offered support for the development of a process to involve community members in discussion on policy on the provision of treatment and services within health care institutions and specifically, to seek the views of members of the public on the provision of HCMs and expensive services within public hospitals.

In summary, the research reported in this thesis has addressed the gaps in the literature as to how decisions are made, and in particular, the decision-making
process and criteria used by health care decision-makers to allocate resources to HCMs in public hospitals. In a move towards more explicitness in decision-making regarding the allocation of scarce health care resources, the findings from these studies provide an evidence base for developing strategies to improve decision-making processes regarding access to HCMs the public sector.
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## Glossary of abbreviations

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<tr>
<td>$\chi^2$</td>
<td>Chi-squared test</td>
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<td>A4R</td>
<td>Accountability for reasonableness</td>
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<tr>
<td>ABS</td>
<td>Australian Bureau of Statistics</td>
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<td>ADEC</td>
<td>Australian Drug Evaluation Committee</td>
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<td>AHCA</td>
<td>Australian Health Care Agreement</td>
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<td>AIHW</td>
<td>Australian Institute of Health and Welfare</td>
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<td>APS</td>
<td>Authority Prescribing System (APS)</td>
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<td>ARTG</td>
<td>Australian Register of Therapeutic Goods</td>
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<td>CAPPS</td>
<td>Consumer and Provider Partnerships in Health Project</td>
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<tr>
<td>CAD</td>
<td>Coronary Artery Disease</td>
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<td>CHF</td>
<td>Consumers' Health Forum</td>
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<td>CTN</td>
<td>Clinical Trial Notification</td>
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<tr>
<td>CTX</td>
<td>Clinical Trial Exemption</td>
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<tr>
<td>DoP</td>
<td>Director of Pharmacy</td>
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<td>DTC</td>
<td>Drug and Therapeutics Committee</td>
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<td>DUSC</td>
<td>Drug Utilisation Sub-Committee</td>
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<tr>
<td>ENL</td>
<td>Erythema Nodosum Leprosum</td>
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<td>ESC</td>
<td>Economic Sub-Committee</td>
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<td>GDP</td>
<td>Gross Domestic Product</td>
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<td>GVHD</td>
<td>Graft Versus Host Disease</td>
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<td>HCM</td>
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<td>HIC</td>
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<td>Health Technology Assessment</td>
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<td>MRSA</td>
<td>Methicillin-resistant <em>Staphylococcus aureus</em></td>
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NSW  New South Wales
NSW TAG  New South Wales Therapeutics Advisory Group
          (formerly known as NSW Therapeutic Assessment Group)
OECD  Organisation for Economic Co-operation and Development
P&TC  Pharmacy and Therapeutics Committee
PAH  Pulmonary Arterial Hypertension
PBAC  Pharmaceutical Benefits Advisory Committee
PBMA  Program budgeting and marginal analysis
PBS  Pharmaceutical Benefits Scheme
PFP  Patient Familiarisation Program
PHI  Private Health Insurance
QoL  Quality of life
QUM  Quality Use of Medicines
RA  Rheumatoid Arthritis
S100  Section 100
SAS  Special Access Scheme
SESAHS  South East Sydney Area Health Service
SPSS  Statistical Package for the Social Sciences
SVH  St Vincent’s Hospital
TGA  Therapeutic Goods Administration
UK  United Kingdom
USA  United States of America
VIC  Victoria
VicTAG  Victorian Therapeutics Advisory Group
WHO  World Health Organisation
Preface

The studies that form part of this thesis were conducted to investigate the decision-making process for allocation of resources to high cost medications (HCMs) in public hospitals in Australia. Multiple methodological approaches have been used to develop understanding of the perceptions, concerns and attitudes of healthcare decision-makers and members of the general public regarding this process.

The research was undertaken using both quantitative and qualitative methods. Qualitative methods involved case study and grounded theory approaches. The qualitative analysis followed inductive reasoning and employed ‘triangulation’ to describe health care decision-maker’s perceptions, concerns and attitudes regarding access to HCMs. Quantitative data on perceptions of the members of the general public were collected using a survey instrument.

The thesis is divided in three parts. Part one describes the literature and includes Chapters One and Two. Part two, Chapters Three and Four describes the decision-making process to access HCMs in public hospitals. Part three explores the decision-making process to allocate resources to HCMs and explores the perceptions, concerns and attitudes of health care decision-makers and the general public regarding access to HCMs in public hospitals.
Chapter One describes the Australian health care system and mechanisms for access to medicines. Chapter Two describes the literature on levels of decision-making, priority setting in health care and the role of the general public in setting these priorities.

Chapter Three is a retrospective study that describes the Individual Patient Use (IPU) scheme in a public hospital and provides a review of the impact of this scheme on medication expenditure.

Chapter Four is a case-study that describes the operation of the first reported High Cost Drug Subcommittee (HCD-SC) in a public hospital in Australia. This case study uses a mixture of qualitative and quantitative methodologies and offers an insight into how decisions are being made regarding access to HCMs in a public hospital.

Through a qualitative research approach, Chapter Five describes the perceptions, concerns and attitudes of health care decision-makers regarding access to HCMs in public hospitals.

The survey presented in Chapter Six describes the perceptions of members of the general public regarding access to HCMs in public hospitals. Chapter Seven draws conclusions and comments on implications of this work.
The work undertaken in this thesis increases the understanding on how decisions are being made in public hospitals regarding access to HCMs. It provides an understanding of the perceptions, concerns and attitudes of health care decision-makers about the allocation of resources to HCMs in public hospitals.