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# **Access to High Cost Medicines in Australian Hospitals**

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**BPharm**

**A thesis submitted in fulfilment of the requirements for the degree of  
Doctor of Philosophy**



**Faculty of Pharmacy**

**The University of Sydney**

**2006**

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

## Acknowledgements

It is a pleasure to thank the many people who made this thesis possible with their encouragement support and assistance - colleagues, family and friends.

I am firstly indebted to my supervisor, Professor Jo-anne Brien. It is difficult to overstate my gratitude to Jo. She provided me with inspiration, invaluable support and advice. I especially thank her for her patience during the challenging times. Throughout my PhD, she provided encouragement and sound advice.

I also thank Dr. Sue Taylor my co-supervisor who got me passionate about research, guided me through my first year and provided constant advice through my thesis-writing period. I thank A/Professor Paul McNeill who provided important advice on the general public study. I thank him as a co-supervisor and a friend.

All of my colleagues at the Therapeutics Centre at St. Vincent's Hospital and Sydney Uni, Abd, Bek, Chris, Clare, David, Ee Lyn, Fiona, Meredith, Sally and Sasha for their constant support and encouragement. Thank you for putting up with me in the good and especially during the bad times. Thanks Ee Lyn for teaching me how to format and for setting such a great example to all of us. I would also like to express my gratitude to Clare who provided her statistical advice but more importantly I thank her for her friendship.

No words can express my gratitude to my three guardian angels: Sasha, Fiona and Sev. They gave emotional support, entertainment, and care. Their love and friendship kept me going and sane all this years. Fernando and Alex thanks for teaching me perseverance and not letting me give up.

Thanks to Tony Ovadia who proof read earlier drafts of this thesis and provided valuable feedback. I would also like to thank Dr. Evan Doran for introducing me into the joys of grounded theory and Dr. Richard Ashcroft for his useful comments on “accountability for reasonableness”.

I would not be able to complete this thesis without the financial support of the International Postgraduate Research Scholarship (IPRS). A DBL grant from the Society of Hospital Pharmacists of Australia (SHPA) provided funding for the decision-makers study and finally St. Vincent’s Hospital provided me with the opportunity to present my work at an International Conference.

My mother, my father, my baby brother, my aunts and Lucho always made me feel that I was a source of pride for them. I am forever indebted for their understanding, endless patience and encouragement when it was most required. They provided the love and emotional support necessary to carry on. Thanks to my sister, nephews and friends Catalina and Rene for their prayers and words of encouragement. Finally, I would like to express my endless gratitude to Luca, for his understanding, patience, tolerance and love.

Thank you Lord for your faithfulness and grace.

## Communications arising from this thesis

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

### PEER REVIEWED PUBLICATIONS

- 2005 Gallego G, Melocco T, Taylor S, Brien JE. "Access to High Cost Medications (HCMs): Decision-Makers' perspectives" *J Pharm Pract Res* 2005; 35 (1):18-20
- 2004 Gallego G, Melocco T, Taylor S, Brien JE. Impact of High Cost Drugs for Individual Patient Use. *J Pharm Pract Res* 2004; 34 (2): 100-03

### PUBLISHED ABSTRACTS

- 2004 Gallego G, Taylor S, Brien JE. Equity of Access to High Cost Drugs (HCDs) a Case Study. *Clin Exp Pharmacol Physiol* 2004; 31 (Supplement 1) PO-129.
- 2004 Gallego G, Taylor S, Brien JE. Decision-makers Perceptions of Access to High Cost Drugs (HCDs) in Public Hospitals in Australia. *Value in Health*. 2004; 7(3): 224-225
- 2004 Brien JE, Taylor S, Gallego G. Equity of Access to Oncology High Cost Drugs (HCDs): An Australian Perspective. *J Oncol Pharm Pract* 2004; 10(2): 94

## SCIENTIFIC PRESENTATIONS – Australasian Conferences

- 2002 Gallego G, Brien JE, Taylor S, Melocco T. The financial impact of approval of high cost drugs for individual patient use (IPU) at a Sydney teaching hospital. Society of Hospital Pharmacists of Australia (NSW Branch) Conference. Leura
- 2002 Gallego G, Brien JE, Taylor S, Melocco T. The financial impact of approval of high cost drugs for individual patient use (IPU) at a Sydney teaching hospital. Australasian Pharmaceutical Sciences Association Conference. Melbourne
- 2003 Gallego G, Melocco T, Taylor S, Brien JE. Access to high cost drugs in public hospitals: the Australian scenario. St. Vincent's & Mater Health Sydney. Research Symposium. Sydney.
- 2003 Gallego G, Taylor S, Melocco T, Brien JE. Clinical decisions, ethical challenges: the role of a high cost drug subcommittee (HCD-SC). Federal Conference of the Society of Hospital Pharmacists of Australia. Canberra
- 2003 Gallego G, Taylor S, Melocco T, Brien JE. High cost medications & decision-makers. What's going on in Australia? Australasian Pharmaceutical Sciences Association Conference. Sydney
- 2004 Gallego G, Taylor S, Brien JE. Is Equity of access to high cost drugs (HCDs) a QUM issue? National Medicines Symposium. Brisbane
- 2004 Gallego G, Taylor S, Brien JE. Decision-makers' perceptions of access to high cost medications (HCMs) in public hospitals. 4<sup>th</sup> College of Health Sciences Research Conference (The University of Sydney). Leura
- 2004 Gallego G, Taylor SJ, McNeill P, Brien JE. Access to high cost medicines (HCMs) in public hospitals. What does the general public know? Australasian Pharmaceutical Sciences Association Conference. Melbourne

## SCIENTIFIC PRESENTATIONS – International Conferences

- 2003 Gallego G, Melocco T, Taylor S, Brien JE. Access to high cost drugs in public hospitals: the Australian scenario. 63<sup>rd</sup> World Congress of the International Pharmaceutical Federation (FIP). Sydney (Australia)
- 2004 Brien JE, Taylor S, Gallego G. Equity of access to oncology high cost drugs (HCDs): An Australian perspective. International Society of Oncology Pharmacy Practitioners (ISOPP) IX. Turin (Italy)
- 2004 Gallego G, Taylor S, Brien JE. Decision-makers perceptions of access to high cost drugs (HCDs) in public hospitals in Australia. International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Virginia (USA)
- 2004 Gallego G, Taylor S, Brien JE. Equity of access to high cost drugs (HCDs) a case study. 8<sup>th</sup> World Conference on Clinical Pharmacology and Therapeutics (Incorporating the Annual Scientific Meeting of ASCEPT). Sydney (Australia)
- 2004 Gallego G, Taylor S, Brien JE. Decision-makers views of priority setting for high cost medicines (HCMs) in public hospitals in Australia. 5<sup>th</sup> International Conference on Priorities in Health Care. Wellington (New Zealand)
- 2005 Gallego G, Taylor S, Brien JE. Decision-makers views of access to high cost medicines (HCMs) in public hospitals in Australia. 65<sup>th</sup> World Congress of the International Pharmaceutical Federation (FIP). Cairo (Egypt)
- 2005 Gallego G, Taylor S, Brien JE. Paying for medicines used in hospitals in Australia. 65<sup>th</sup> World Congress of the International Pharmaceutical Federation (FIP). Cairo (Egypt) (Invited Speaker)



## **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

$\chi^2$	Chi-squared test
A4R	Accountability for reasonableness
ABS	Australian Bureau of Statistics
ADEC	Australian Drug Evaluation Committee
AHCA	Australian Health Care Agreement
AIHW	Australian Institute of Health and Welfare
APS	Authority Prescribing System (APS)
ARTG	Australian Register of Therapeutic Goods
CAPPS	Consumer and Provider Partnerships in Health Project
CAD	Coronary Artery Disease
CHF	Consumers' Health Forum
CTN	Clinical Trial Notification
CTX	Clinical Trial Exemption
DoP	Director of Pharmacy
DTC	Drug and Therapeutics Committee
DUSC	Drug Utilisation Sub-Committee
ENL	Erythema Nodosum Leprosum
ESC	Economic Sub-Committee
GDP	Gross Domestic Product
GVHD	Graft Versus Host Disease
HCD-SC	High Cost Drug Subcommittee
HCM	High Cost Medication
HIC	Health Insurance Commission
HMOs	Health Maintenance Organisations
HSD	Highly Specialised Drug
HTA	Health Technology Assessment
IPU	Individual Patient Use
MCO	Managed Care Organisations
MRSA	Methicillin-resistant <i>Staphylococcus aureus</i>
NMP	National Medicines Policy

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.