

School of Public Health

Prescribing Practices of Australian Dispensing Doctors

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DECLARATION

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgment has been made.

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university.

Signed

Dated

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ABSTRACT

Background:

In response to health workforce shortages policymakers have considered expanding the roles that a health professional may perform. A more traditional combination of health professional roles is that of a dispensing doctor (DD) who routinely prescribes and dispenses pharmaceuticals. A systematic review conducted on mainly overseas DDs' practices found that DDs tended to prescribe more items per patients, less often generically, and showed poorer adherence to best practice. Convenience for patients was cited by both patients and DDs as the main reason for dispensing. In Australia, rural doctors are allowed to dispense Pharmaceutical Benefit Scheme (PBS) subsidised pharmaceutical benefits if there is no reasonable pharmacy coverage. Little was known about the practices of these Australian DDs.

Objectives:

To examine the PBS prescribing patterns of dispensing with matched non-dispensing doctors and identify factors that influence prescribing behaviour.

Method:

A sequential explanatory (QUAN→qual) mixed methodology was utilised. Firstly, rurality-matched DDs' and non-DDs' PBS data for fiscal years 2005-7 were analysed against criteria distilled from a systematic review and stakeholder consultations. Secondly, structured interviews were conducted with a purposive sample of DDs to examine the quantitative findings.

Key findings:

DDs prescribed significantly fewer PBS prescriptions per patients but used *Regulation 24* significantly more than non-DDs. *Regulation 24* biased the prescribing data. DDs prescribed proportionally more penicillin type antibiotics, adrenergic inhalants and non-steroidal anti-inflammatories as compared to non-DDs. Reasons offered by DD-respondents highlighted that prescribing was influenced by an awareness of cost to the patients, peer pressure and confidential prescriber feedback provided on a regular basis.

Implications:

This innovative census study does not support international data that DDs are less judicious in their prescribing. There is some evidence that DDs might reduce health inequity between rural and urban Australian, and that the DD health model is valuable to patients in isolated communities.

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ABBREVIATION

ACRRM	Australian College of Rural and Remote Medicines
ARIA	Accessibility and Remoteness Index of Australia
ASGC	Australian Standard Geographical Classification Remoteness Structure
CPD	Continuing Professional Development
Cth	Commonwealth of Australia
DD	Dispensing Doctor
Department	Department of Health and Ageing, Commonwealth Government of Australia
GDP	Gross Domestic Product
GP	General Practitioner
Guild	Pharmacy Guild of Australia
HIC	Health Insurance Commission
IMG	International Medical Graduate
MBS	Medicare Benefit Scheme
MD	Mean Difference
MeSH	Medical Subject Headings
NPS	National Prescribing Service
NSAID	Non-Steroidal Anti-Inflammatory Drug
NSW	New South Wales
OECD	Organisation for Economic Cooperation and Development
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme
PPI	Proton Pump Inhibitor
QLD	Queensland
QUAN→qual	Sequential Explanatory Mixed Methods

RACGP	Royal Australian College of General Practitioners
RRMA	Rural, Remote and Metropolitan Area classification
SA	South Australia
SED	Standard Deviation of a Difference
SIGN	Scottish Intercollegiate Guidelines Network
Statin	HMG Co-A Reductase Inhibitor
UK	United Kingdom
USA	United States of America
VIC	Victoria
WA	Western Australia

I. INTRODUCTION

A global health workforce shortage exists, and this crisis is expected to worsen (Australian Institute of Health and Welfare 1997; Duckett 2005a, 2006; World Health Organization 2006; Greenhill, Mildenhall, and Rosenthal 2008; National Rural Health Alliance 2008d; *General Practice in Australia, Health Priorities and Policies 1998 to 2008* 2009; Dunbar and Reddy 2009; Gregory 2009; Gorman and Brooks 2009; Wilson et al. 2009; Naccarella, Buchan, and Brooks 2010; O'Toole, Schoo, and Hernan 2010; O'Toole and Schoo 2010). Some government policy-makers have introduced strategies to attract more people into the healthcare professions as well as expanding the roles of existing health workers (Duckett 2005b; Duckett 2005a; Van Der Weyden 2005; Duckett 2006; Gupte 2007; Wakerman et al. 2008; Duckett 2009; Wakerman 2009; Wakerman et al. 2009). These have included the creation of:

- nurse practitioners (Arnold 2004; Australian Medical Association 2005b; Van Der Weyden 2005; Hooker 2006; Hollinghurst et al. 2006; Dunn, Cashin, and Buckley 2008; Thistlethwaite and Topps 2009; Gorman and Brooks 2009; Daele et al. 2009; Eton 2009; Haikerwal 2009b; Parnell 2009; Naccarella, Buchan, and Brooks 2010; Nissen 2010);
- physician assistants (Arnold 2004; Cipher, Hooker, and Sekscenski 2006; Hooker 2006; Anderson, Proudfoot, and Harris 2009; Gorman and Brooks 2009; Thistlethwaite and Topps 2009; Hooker 2010);
- prescribing physiotherapists (Fazey 2008); and
- prescribing pharmacists (Ahlgrimm 1994; Anderson 1994; Ryan and Bond 1994, 1996; Gilbert 1998; Cho 2000; Gilbert 2001; Chapman, Alford, and Brien 2002; Brown 2003; Maher 2004; Clements 2005b; Emmerton et al. 2005; Low 2005; Australian Journal of Pharmacy 2006b; Burton 2006; Kelly 2006; Gupte 2007; Low 2007; Roberts 2007; Fleming 2008; Nissen 2010).

A combination of roles is also evident with a dispensing doctor (DD) who routinely prescribes and dispenses pharmaceuticals to their patients from their on-site dispensary. The phenomenon of doctor dispensing pharmaceuticals is not new and

may be traced back to apothecaries who combined the roles of prescribing and dispensing drugs for their clients (Pharmaceutical Society of Australia ; Roberts 1984; Robinson 1984; Gould and Considine 1987; Madge 1987; Tse and Madura 1987; Weiss 1987; Kapil 1988; Lawborne 1989; Zuckerman 1989; Anderson 1990; Chelsea Pensioner 1990; Clark 1990; Goggin et al. 1990; Henson 1990; Leonard 1990; Millar 1990; Fryklof 1994; Seo 1994; Kernick 1997; Chemist & Druggist 1999a; Gilbert 2001; Levy 2001; Trap and Hansen 2003; Ho 2005; Phelps 2005; Dammary 2008; Gadiel 2008). Currently, in many developing and developed countries¹ DDs dispensed medicines for a variety of reasons. These include insufficient pharmacy coverage, increased drug accessibility and availability for their patients, and for financial gain (Trap 1997; Lim et al. 2010).

The issue of whether DDs should dispense for profit is debated amongst the pharmaceutical and medical professions. Those against DDs have argued that:

- (1) conflict of interest with DDs both owning the dispensaries and prescribing has the potential for less judicious prescribing (Anderson 1986; Glaser 1986; Rundle 1986; American Pharmacy 1987a; Gould and Considine 1987; Karlitz 1987; Olch 1987; Penna 1987; Relman 1987; Robinson 1987a; Robinson 1987b; Weintraub and Lipman 1987; Weiss 1987; Abood 1988; Breschi 1988; Kapil 1988; Trytek 1988; Lawborne 1989; James 1992; Warden 1992; Anderson 1994; Axon 1994; Ryan and Bond 1994; Truter, Wiseman, and Kotze 1995; Nizami, Khan, and Bhutta 1996; Ryan and Bond 1996; Truter and Kotze 1996; Michalik 1998; Shepherd and Blissitt 1998; Chemist & Druggist 1999b; Rodwin and Okamoto 2000; Gilbert 2001; Kwon 2002; Warren 2002; Kwon 2003; Avileli et al. 2004b, 2004a; Lim, Gray, and Roach 2004; Ho 2005; Daily Mail 2006; Neuhauser, Swedlow, and Wynn 2006; Iizuka 2007; Actavis 2008a; Gadiel 2008; Iizuka 2008),
- (2) doctors are not trained to dispense hence, without a secondary check by a pharmacist, there is less judicious dispensing and possibly increased medication errors and abuse (Chambers 1984; Anderson 1986; Archambault 1986; Glaser 1986; American Pharmacy 1987a, 1987b; Calis 1987; Gould and

¹ These include 45 states in the United States of America (USA), 13 cantons in Switzerland, the United Kingdom (UK) and most parts of Asia and South Africa continents.

Considine 1987; Karlitz 1987; Madura and Tse 1987; Tse and Madura 1987; Abood 1988; Lober et al. 1988; Lawborne 1989; Anderson 1990; Chelsea Pensioner 1990; Clark 1990; Disgusted of Dorset 1990; Gall 1990; Goggin et al. 1990; Heller 1990; Galvo and Hyman 1993; Ahlgrimm 1994; Anderson 1994; Axon 1994; Borzo 1994; Ryan and Bond 1994; Brelis 1995; Lee 1996; *Elmfield Drugs Ltd & Anor, R (on the application of) v Family Health Services & Anor* 1998; Bosch 1998; Chemist & Druggist 1998; Cousins and Upton 1999; Gilbert 2001; Pharmaceutical Society of Australia 2001; Ashley, Kirk, and Fowler 2002; Kwon 2002; Warren 2002; Kwon 2003; Avileli et al. 2004b, 2004c, 2004a; Drug Week 2004; Singapore Medical Association 2004; Goh 2006; Rhew 2008; The Atlanta Journal and Constitution 2008; Truesdell 2008; US Fed News Service 2008; Zoltay 2008; Kernick 1997; Millar 1990; Retief 1987; Robinson 1984, 1987a; Robinson 1987b; Rodwin and Okamoto 2000; Seo 1994; Madge 1987; Madge 1990; Smith et al. 2004; Takemasa 1994; Trap 1997; Trytek 1988; Weiss 1987; Williams 1995; Shepherd and Blissitt 1998; Penna 1987; Hunt 2001; Breschi 1988; Relman 1987; Warden 1992; Kapil 1988; Efrat 2004; Ho 2005; Day 2002; Lee 2004; Wong 2004; Taylor, Mrazek, and Mossialos 2004), and

- (3) patients are deprived of choice of those from whom they want their pharmaceuticals dispensed (Langston 1986; Engman 1987; Nelson 1987; Warden 1992; Actavis 2008d).

Advocates for DDs have often contended that doctor dispensing increases patients' compliance and convenience (Nystrom and Clark 2006; Shepherd and Blissitt 1998; Tshabalala-Msimang 2004; Medical Letter on the CDC & FDA 2007; Kistruck 2002; Glaser 1986; Anderson 1986; Collinge 1993; Emrys-Jones 1993; Garrett 1989; Ferguson 1998; Aranson 1987; Levy 2001; Borfitz and Haines 2001; Lee 2000; Jones 2002; Jeffries 2001; Holland 2001; Finlayson 2001; Baird 2000; Efrat 2004; Gerbrands 1994; Shankar 2007; Walters 2003; Cromer Group Practice 2004; Glynn 2003; Keeton 2004; Epilepsy Action 2003; Country Doctor 2004; Rappo et al. 1995; McCormack 1993; McClallen 1914; Wardle 1914; Gould and Considine 1987; Kahn 2004; Ho 2005; James 1992; Kamdar 2001; The Lancet 1973; Faisst, Schilling, and Gutzwiller 2000; Lim, Gray, and Roach 2004; Lim and Russell 2005; Ogbogu et al. 2001; Hyde et al. 1979; Trap 1997; Langston 1986; Furber 1969; The Lancet 1969;

Mabaso and Trichardt 2004; Kapil 1988; Phelps 2005; Dispensing Doctors' Association 2004; Rundle 1986; Borfitz 2001; Actavis 2008c; Lawborne 1989), and that there is no evidence that DDs prescribe less judiciously or are more expensive (Geedes 1992; Stewart-Brown et al. 1996; Willis 1996; Roberts 1992; Smith 1993; Thomas 1992; GP 2008; Tennant 2008; Ward 2003, 2004; Baker 2008; Tennant 2006b, 2007; Actavis 2008b; Vos 2004; Wilcock and Mackenzie 2000; Wilcock 2002; Dunn and Beswick 1993; Wilcock 2003; Ward 2002; Zuckerman 1989; Thomas 2004; Tennant 2006a, 2006c; Meakin 2004; Trap 1997; Lee 2004; Wong 2004).

The practice of doctor dispensing in many countries is subject to legislative control (Aboud 1988; Huston 1987; Lim, Gray, and Roach 2004; Relman 1987; Zuckerman 1989; Efrat 2004; Williams 1995; Seo 1994; Ho 2005; Thomas 2004; Watt 1993; The Lancet 1973; Rodwin and Okamoto 2000; Smetherham 2004; Keeton 2004; Meakin 2003; Rundle 1986; Gilbert 2001; Robinson 1984; Avileli et al. 2004c; Mabaso and Trichardt 2004; *Health Professionals Act 2004 (ACT)* 2004; *Pharmacy Act 1964 (NSW)* 1964; *Poisons and Dangerous Drugs Act 2007 (NT)* 2007; *Health Act 1937 (Qld)* 1937; *Health (Drugs and Poisons) Regulation (Qld)* 1996; *Controlled Substances Act 1984 (SA)* 1984; *Poisons Act 1971 (Tas)* 1971; *Drugs, Poisons and Controlled Substances Act 1981 (VIC)* 1981; *Poisons Act 1964 (WA)* 1964; *National Health Act 1953 (Cth)* 1953; Nystrom and Clark 2006; NHS Employers and British Medical Association 2006; Actavis 2008c; Office of Inspector General 1989; Pharmaceutical Services Branch 2003; East Cambridgeshire and Fenland NHS 2001; Martin 1989; Pharmaceutical Society of Australia 2001; Sullivan 1987; South African Press Association 2004; Robinson 1987a; Blake and Slotnik 1980; *Elmfield Drugs Ltd & Anor, R (on the application of) v Family Health Services & Anor* 1998; *Re HEDGE (as administrator of Goldfields Medical Fund Inc (admin apptd) (No 2)* 2002; Sidley 1996; Keddie 2003). Under current Australian legislation, doctors are only permitted to dispense and supply medicines as pharmaceutical benefits in areas where they practise if there is no pharmacy available within a reasonable geographical distance (Lim, Gray, and Roach 2004). Consequently Australian DDs are often located in isolated rural and remote communities (Pharmaceutical Society of Australia 2001; Efrat 2004; Lim, Gray, and Roach 2004; Lim and Russell 2005; Sunderland, Burrows, and Joyce 2006). They

are generally perceived as integral members of rural healthcare by providing their patients with timely and convenient access to both medical and pharmaceutical care (Lim, Gray, and Roach 2004; Efrat 2004; Leknys 2008). However, there is a general expectation in Australia that DDs do not dispense primarily for income (Efrat 2004; Lim, Gray, and Roach 2004; Gadiel 2008), even though the ability of these rural and remote doctors to earn a profit by dispensing pharmaceutical benefits for their patients may be an important financial incentive in retaining rural doctors in small country towns and in ensuring the viability of what would be an otherwise unviable and therefore unsustainable rural practice (Winstanley 1969; The Lancet 1973; Beecham 1995; Kamdar 2001; Lim, Gray, and Roach 2004; Light 2005b; Lim and Russell 2005; Sunderland, Burrows, and Joyce 2006; Actavis 2008e).

Health expenditure has increased dramatically in all countries in recent times (Anderson et al. 2000; Hailey 1997; Australian Institute of Health and Welfare 2005a, 2006a, 2009; Australian Journal of Pharmacy 2005a; Prados-Torres et al. 2009).

Contributing factors include:

- Demographic change: ageing of the population changes the availability of workforce and the nature of the services required (Duckett 2005a; Hugo 2005; Sewell 2005; Britt et al. 2009; Gunn 2009; Jiwa, Carlsen, and Horner 2009; Scott 2009; Brooks 2010).
- Epidemiologic change: the increase in prevalence of chronic diseases affects the nature and functions of the service model and workforce required (Sewell 2005; Australian Institute of Health and Welfare 2006b; Duckett 2006; Britt et al. 2009; Jiwa, Carlsen, and Horner 2009).
- Workforce values change: intergenerational attitudes towards work, leisure and family are affecting workforce availability and work patterns (Tolhurst and Stewart 2004; Duckett 2005a; Carnell 2006; Gunn 2009), and there is more focus on healthcare teams and new way of working (Gunn 2009; Brooks 2010).
- Lifestyle values change: the formation of more influential sea-change and tree-change communities (Duckett 2005a; Hugo 2005), international migration of health professions (Duckett 2005a; Hugo 2005), and rising community expectations and demand for more proactive care (Sewell 2005).

- Technology change: advances in information and communication technologies have contributed to empowered health consumers and a demand for more efficacious pharmaceuticals which are more expensive (Duckett 2005a).
- Climate change: changing climatic patterns are potentially affecting the nature of diseases and service response required (Green et al. 2009; Inglis 2009; McMichael and Butler 2009; Veitch 2009); this is also likely to exacerbate the uncertainty of climate-dependent outcomes in industries like farming potentiating greater migration of younger people to cities which results in an increasing proportion of older adults in rural communities who might be geographically isolated and have limited social and family networks (Beard et al. 2009).
- Economic change: there is widening health outcome disparity between urban and rural (Gunn 2009; Haikerwal 2009a); the recent 2007-9 global economic crisis has arguably widened the inequities in health between socio-economic groups (Gunn 2009; Scanlan and Bundy 2009; Stocks et al. 2009; Ward 2009) and money required is harder to obtain (Haikerwal 2009a).

In response, policymakers have reacted with a series of healthcare reforms and measures to guarantee the sustainability of their healthcare system (Lee and Crupi 2001; Kwon 2002; Harvey, Harris, and Bulfone 2007; Towler 2007; Australian Medical Association 2009; Bennett 2009; Commonwealth Department of Health and Ageing 2009d; National Health and Hospitals Reform Commission 2009; National Preventive Health Taskforce 2009; Russell, Hogg, and Lemelin 2010). One common measure employed by western countries public health insurers is to significantly increase the amount of co-payment that insurees are required to pay for their pharmaceutical benefits (Crichton 1990; Australian Journal of Pharmacy 2005a, 2005e; Australian Medical Association 2005a; Fleming 2005a, 2005b; Frank 2005; Pharmaceutical Defence Ltd 2005; Walters 2005; Tatchell 2006; Bracey 2007b; Nicholson 2007).

Previous evidence has indicated that pharmaceuticals have low cross-elasticity, unlike other commodities of trades (Tellis 1988). However, recent Australian study has confirmed the suspicion that rising pharmaceutical costs do have a negative impact on patient adherence to medical treatments: patients who struggle to afford their medicines may reduce or skip doses to make prescriptions last longer, or stop

taking some pharmaceuticals altogether (Ross and Macleod 2005; Hynd et al. 2008; Hynd 2008; Tatchell 2008, 2009). Economic crisis is known to impact on the distribution of healthcare utilisation: the use of medical services by lower-income groups is more severely affected than use by high-income groups (Kwon 2002). Therefore, in light of the recent global economic crisis, health disparity between high- and low-income groups may be exacerbated with increased pharmaceutical costs: the poor become poorer in health. There have been suggestions that DDs might be more responsive to patient costs than to their own profits (Lim, Gray, and Roach 2004; Iizuka 2007, 2008).

1. PURPOSE STATEMENT

The objective of this thesis is to conduct a summative evaluation of the prescribing practices of Australian DDs. The study proposed to gather data on differences in pharmaceuticals prescribing between Australian DDs and non-DDs, and to subsequently seek explanation from DDs for the identified differences. This study utilised two-phase sequential explanatory mixed methods (QUAN→qual): firstly, quantitative data from claims made to the Australian national health insurer, Medicare, were analysed; secondly, qualitative interviews were conducted to elaborate on and clarify findings from the quantitative analyses. Outcomes from this study will inform governments' policies on doctor dispensing.

This thesis is structured on the mixed methods publication framework proposed by Onwuegbuzie (Onwuegbuzie and Leech 2006; Onwuegbuzie and Collins 2009). In Chapter II, the dissertation presents a systematic review conducted between November 2007 and January 2009 which systematically and comparatively appraised the research evidence related to the practices of DDs. To present the overall framework of the *Australian Dispensing Doctors* (ADD) Study, Chapter IV outlines the formulation of the research objectives and presents the rationale for mixing quantitative and qualitative methods in this study. Chapter IV also presents the quantitative methodology. Chapter V outlines the quantitative results and initial interpretation of the findings. Chapter VI provides the linkage between the quantitative and the qualitative phases of the study. It outlines the selection of quantitative findings explored through the qualitative phase of the ADD Study and

the qualitative methodology. Chapter VII presents the qualitative results. Chapter VIII provides a general discussion on the prescribing practices of Australian DDs.

II. LITERATURE REVIEW

Knowledge about DD's prescribing habits is very limited and discussions on doctor dispensing are plagued by emotional and anecdotal reports and statement. This systematic review was undertaken with the objective of analysing critically existing data on DDs' prescribing practices.

1. METHODS

For this systematic review, the term 'dispensing doctor' was broadly defined as any medical practitioner who undertakes the role of dispensing pharmaceutical products/benefits in situations that would normally be regarded as the practice of a pharmacist.

1.1. Search Strategy

Potentially relevant papers related to DDs were identified through searches of six common electronic databases (Pro Quest™, Medline™, Science Direct™, Embase™, Web of Science™ and Cochrane Library™) and by direct contact with authors of included papers to obtain further articles. It was reported elsewhere that the sensitivity of a conventional Medline™ search was approximately 51% (Dickersin, Scherer, and Lefebvre 1995)(p27), therefore additional searches were also conducted using Google Scholar™ and Yahoo™. The "snowball" method was also utilised: bibliographies of all included papers were further examined and additional articles were then retrieved. The final search included publications until December 2008. See Figure 2.1 for the selection process of eligible papers.

The search terms used in the electronic search were:

- *dispensing doctor,*
- *dispensing physician,* and
- *dispensing practice.*

The Medical Subject Headings (MeSH) include:

- *prescription practice,*
- *prescribing behaviour,*
- *general practice, and*
- *physician.*

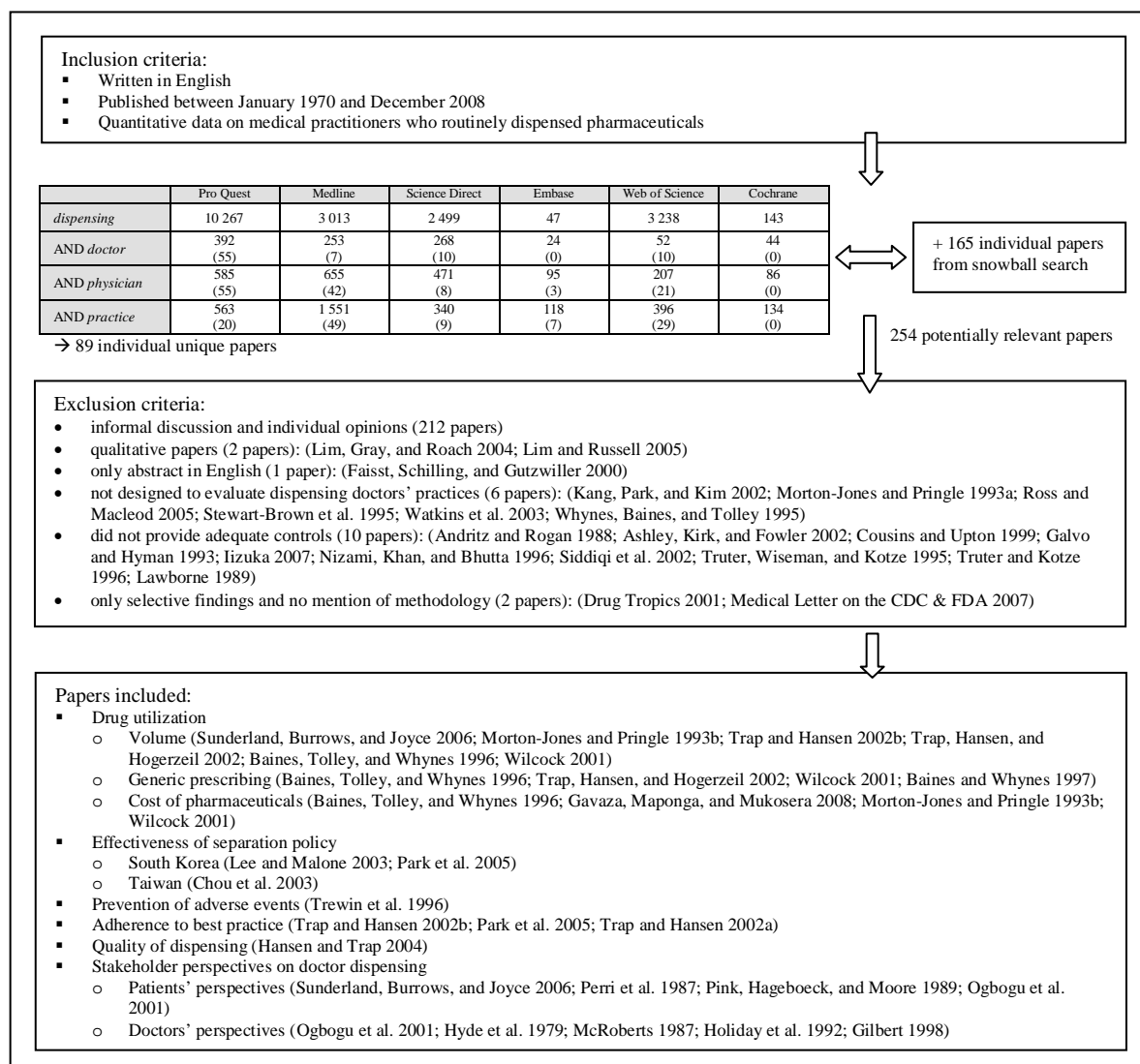


Figure 2.1: Selection process of eligible papers.

1.2. Inclusion and Exclusion Criteria

Inclusion criteria for paper selection were that they:

- were written in English;
- were published between January 1970 and December 2008; and
- provided quantitative data comparing the practice of DDs and non-DDs as part of ordinary clinical practice.

Exclusion criteria used for publications were that they:

- were opinions or editorials about the dispensing profession and/or practice; or
- were not designed to specifically evaluate DDs' practices.

1.3. Data Extraction

Potentially relevant papers from database searches were reviewed at abstract level. Abstracts of articles deemed relevant were retrieved and reviewed. Full articles of original papers were obtained and analysed according to relevance and types of information based on the hierarchy of study design used by the Scottish Intercollegiate Guidelines Network (SIGN) (Harbour and Miller 2001).

A specifically-developed data extraction sheet (see Appendix B), which was consistent with the Quality of Reporting of Meta-analyses (QUOROM) statement (Moher et al. 2000) was used to collect information on all analytical papers. This included the country, sample demographics, study design, methodology, detailed wordings of the original authors' conclusions and findings. The decision whether a paper was to be included and the SIGN ranking were reached by consensus by at least two of the investigators.

2. RESULTS

The initial database search identified 89 individual papers and the subsequent snowball-search of these papers provided another 165 papers (see Figure 2.1).

Of the 254 papers retrieved and assessed for quality, 212 belonged to SIGN levels 3 and 4, namely: political discussions, discussions related to professions, individual opinions and views, brief descriptions of regulations and laws pertaining to dispensing, papers addressing historical aspects of DDs, articles related to pharmaceutical repackaging, mail order or media reports. These did not include primary data suitable for the purpose of this review and were excluded. No systematic reviews or meta-analyses published on DDs could be found. Two qualitative papers (Lim, Gray, and Roach 2004; Lim and Russell 2005) were identified from the search but due to the methodologies employed, they did not meet inclusion criteria. It was also decided that a meta-ethnography was premature at this time.

Of those remaining, one paper was excluded as only the abstract was in English (Faisst, Schilling, and Gutzwiller 2000), and six papers were excluded as the studies were not designed to specifically evaluate the practices of DDs (for example effects of fund-holding on practices across catchments) (Kang, Park, and Kim 2002; Morton-Jones and Pringle 1993a; Ross and Macleod 2005; Stewart-Brown et al. 1995; Watkins et al. 2003; Whyne, Baines, and Tolley 1995). Ten papers were excluded due to the absence of an adequate comparison group (for example comparing dispensing general practitioners vs. non-dispensing medical specialists) (Andritz and Rogan 1988; Ashley, Kirk, and Fowler 2002; Cousins and Upton 1999; Galvo and Hyman 1993; Nizami, Khan, and Bhutta 1996; Siddiqi et al. 2002; Truter, Wiseman, and Kotze 1995; Iizuka 2007; Lawborne 1989); and two papers did not describe their methodology (Drug Tropics 2001; Medical Letter on the CDC & FDA 2007).

Finally, 21 papers were included in this systematic review on the comparisons of DDs and non-DDs' practices. The selected papers summarised in Table 2.1 were

from the USA (6), the UK (5), Zimbabwe (5), South Korea (2), Australia (1), South Africa (1), and Taiwan (1). The papers were categorised into the following areas:

- drug utilisation,
- effectiveness of separation policy,
- prevention of adverse events,
- adherence to best practice,
- quality of dispensing, and
- stakeholder perspectives on DD.

Paper	Methodology	Sample	Period	Country	SIGN
(Sunderland, Burrows, and Joyce 2006)	Postal survey	7 DDs vs. 7 non-DDs	January – December 2003	Australia	2+
(Gilbert 1998)	Semi-structured interview	45 DDs vs. 53 community pharmacists	--	South Africa	3
(Lee and Malone 2003)	Comparative study	44481 pre- vs.50680 post-policy claims	January and December 2000	South Korea	2++
(Park et al. 2005)	Comparative study	26414 pre- vs. 24585 post-policy claims	January 2000 and January 2001	South Korea	2++
(Chou et al. 2003)	Comparative study	2 DDs vs. 2 non-DDs	December 1996 – June 1998	Taiwan	2++
(Morton-Jones and Pringle 1993b)	Comparative study	59 DD practices vs. 49 non-DD practices	1990/1	UK	2+
(Baines, Tolley, and Whynes 1996)	Comparative study	59 DD practices vs. 49 non-DD practices	1990/1 – 1993/4	UK	2+
(Trewin et al. 1996)	Comparative study	906 DDs' patients vs. 3448 community pharmacists' clients	July 1984 – November 1993	UK	2+
(Baines and Whynes 1997)	Comparative study	55 DD practices vs. 50 non-DD practices	1993/4	UK	2+
(Wilcock 2001)	Comparative study	10 DDs vs. 10 non-DDs	1997/8	UK	2++
(Hyde et al. 1979)	Postal survey	16 practices	1976	USA	3
(McRoberts 1987)	Telephone survey	203 doctors	--	USA	3
(Perri et al. 1987)	Telephone survey	539 households	--	USA	2-
(Pink, Hageboeck, and Moore 1989)	Postal survey	2400 adults	1987	USA	2-
(Holiday et al. 1992)	Postal survey	800 doctors	--	USA	3
(Ogbogu et al. 2001)	Postal survey	168 doctors	1998	USA	3
(Trap, Hansen, and Hogerzeil 2002)	Comparative study	29 DDs vs. 28 non-DDs	April – July 1997	Zimbabwe	2++
(Trap and Hansen 2002b)	Comparative study	29 DDs vs. 28 non-DDs	April – July 1997	Zimbabwe	2++
(Trap and Hansen 2002a)	Comparative study	28 DDs vs. 25 non-DDs	April – July 1997	Zimbabwe	2+
(Hansen and Trap 2004)	Comparative study	29 DD dispensaries vs. 20 pharmacies	1997	Zimbabwe	2-
(Gavaza, Maponga, and Mukosera 2008)	Comparative study	23 DD dispensaries vs. 35 pharmacies	--	Zimbabwe	2-

Table 2.1: Summary of papers included in the systematic review.

2.1. Drug Utilisation

Seven papers provided empirical data on drug utilisation of DDs. See Table 2.2 for the summary of findings. These papers were from the UK (3), Zimbabwe (3) and Australia (1).

2.1.1. Volume

Trap conducted a comparative study of 29 DDs and 28 non-DDs in Harare, Zimbabwe for her PhD (Trap 2001). On average 30 patients' records were randomly selected and retrospective data collected from each doctor. The author found that DDs prescribed significantly more pharmaceutical items per consultation than non-DDs (2.3 [2.1 – 2.6] vs. 1.7 [1.5 – 2.0], $p = 0.001$) (Trap, Hansen, and Hogerzeil 2002). This included more injections (0.30 [0.20 – 0.41] vs. 0.10 [0.04 – 0.15], $p = 0.002$) and mixtures (0.43 [0.33 – 0.53] vs. 0.25 [0.19 – 0.31], $p = 0.005$). A further analysis of these patients' records found that DDs prescribed more pharmaceutical items than non-DDs in the treatment of upper respiratory tract infections (total drugs: 2.77 [2.49 – 3.06] vs. 1.96 [1.77 – 2.16]; injections: 0.38 [0.25 – 0.50] vs. 0.13 [0.05 – 0.21]; mixtures: 0.92 [0.73 – 1.12] vs. 0.57 [0.44 – 0.70]) (Trap and Hansen 2002b).

Findings from England were somewhat similar. Morton-Jones and Pringle (1993b) accessed the prescribing data for all 108 general practices within Lincolnshire Family Health Services Authority catchments and found that DDs prescribed more pharmaceutical items per patient than non-DDs (9.55 vs. 8.32, $p < 0.05$) in the 1990-1 fiscal year. This was reaffirmed by Baines et al. using 1993-4 fiscal year prescribing data from the same health catchments (11.5 vs. 9.7, $p < 0.05$) (Baines, Tolley, and Whynes 1996). In a separate study, Wilcock (2001) analysed the prescribing data for ten matched pairs of DDs and non-DDs within Cornwall and Isles of Scilly Health Authority catchments and found that DDs prescribed 13% more pharmaceutical items per patient than non-DDs (11.82 [10.97 – 13.48] vs. 10.44 [8.76 – 11.44], $p = 0.007$).

Preliminary findings from Australia conversely seemed to suggest otherwise. Sunderland et al. in a survey of seven matched pairs of DDs and non-DDs in Western

Australia (WA), found that 78,186 prescriptions were dispensed by DDs as compared with 84,720 prescriptions dispensed in towns with a pharmacy (non-DDs) (Sunderland, Burrows, and Joyce 2006; Sunderland, Burrows, and Joyce 2005).

2.1.2. *Generic Prescribing*

The use of generic pharmaceuticals is of interest to health economics because generic pharmaceuticals are usually cheaper than branded pharmaceuticals, and hence contribute to a sustainable health system (Glasson 2004; Stokes 2008; Lofgren 2002; Nicholson 2007; Searles et al. 2007; Nicholson 2008; Gupte 2008; Mouala et al. 2008; Stewart-Brown et al. 1996; Clarke and Fitzgerald 2010).

In Zimbabwe, Trap et al. reported that 43.7% of DDs' prescriptions were prescribed generically as compared to 43.6% of non-DDs' (Trap, Hansen, and Hogerzeil 2002). In England, Morton-Jones found that DDs prescribed less often generically than non-DDs (26.5% vs. 42.0%, $p < 0.001$) (Morton-Jones and Pringle 1993b). This was further supported by Baines et al. (28.9% vs. 46.5%, $p = 0.00$) (Baines, Tolley, and Whyne 1996) and Wilcock (45.0% vs. 63.3%, $p = 0.007$) (Wilcock 2001).

2.1.3. *Cost of Pharmaceuticals*

Gavaza et al. conducted a price survey of 35 pharmacies and 23 DDs' dispensaries across five different provinces in Zimbabwe (Gavaza, Maponga, and Mukosera 2008). The authors reported that of the 37 generic essential pharmaceuticals surveyed, 18 - 22 of them were significantly more expensive from DDs than in pharmacies. No further information was provided and the principal author has not responded to repeated requests for more information.

Across the Lincolnshire Family Health Services Authority, Morton-Jones and Pringle reported higher net ingredient costs per patient from DDs than non-DDs (1990-1: £54.78 vs. £48.47, $p < 0.05$) (Morton-Jones and Pringle 1993b). This was confirmed by Baines et al. (1991-2: £67.80 vs. £58.20, $p < 0.05$; 1992-3: £75.60 vs. £64.50, $p < 0.05$; 1993-4: £85.60 vs. £70.01, $p = 0.003$) (Baines, Tolley, and Whyne 1996).

However, Wilcock reported no statistically significant differences in the Cornwall and Isles of Scilly Health Authority: £101.69 vs. £102.14, $p = 0.333$ (Wilcock 2001).

2.1.4. Summary

As outlined in Table 2.2, there is some level B evidence to indicate that DDs' practices prescribed more items per patient per year (mean difference [MD] = 2.00, standard error of a difference [SED] = 0.22, $d = 1.04$ [0.79 – 1.29], $t = 8.93$, $p = 0.035$), and had modestly higher pharmaceutical costs per patient per year (MD = 8.36 [SED 1.48], $d=0.45$ [0.29 – 0.61], $t = 5.64$, $p = 0.012$). There was no statistical significant evidence that DDs prescribed generic pharmaceuticals less frequently (MD = -8.55 [SED 0.16], $d=0.35$ [0.33 – 0.36], $t = -54.05$, $p = 0.410$).

	DD	NDD	P	Diff (%)	Sample	Ref
Mean number of items prescribed per patient per annum (heterogeneity $\chi^2=0.073$, $p=0.035$)	11.50	9.70	0.001*	+15.65	1993-4: 59 DD practices vs. 49 non-DD practices	(Baines, Tolley, and Whynes 1996)
	8.85	5.26	-	+40.56	29 DDs vs. 28 non-DDs	(Trap, Hansen, and Hogerzeil 2002)
	9.55	8.32	<0.05*	+12.88	1990-1: 59 DD practices vs. 49 non-DD practices	(Morton-Jones and Pringle 1993b)
	11.82	10.44	0.007*	+11.68	10 DDs vs. 10 non-DDs	(Wilcock 2001)
Mean net ingredient cost per patient per annum (£) (heterogeneity $\chi^2=0.002$, $p=0.012$)	58.40	50.30	0.001*	+13.87	1990-1: 59 DD practices vs. 49 non-DD practices	(Baines, Tolley, and Whynes 1996)
	67.80	58.20	0.00*	+14.16	1991-2: 59 DD practices vs. 49 non-DD practices	(Baines, Tolley, and Whynes 1996)
	75.60	64.50	0.00*	+14.68	1992-3: 59 DD practices vs. 49 non-DD practices	(Baines, Tolley, and Whynes 1996)
	85.60	70.10	0.003*	+18.11	1993-4: 59 DD practices vs. 49 non-DD practices	(Baines, Tolley, and Whynes 1996)
	54.78	48.47	0.002*	+11.52	59 DD practices vs. 49 non-DD practices	(Morton-Jones and Pringle 1993b)
	101.69	102.14	0.333	-0.44	10 DDs vs. 10 non-DDs	(Wilcock 2001)
Percentage of items prescribed as generic (heterogeneity $\chi^2=0.596$, $p=0.410$)	28.9	46.5	0.00*	-60.90	1993-4: 59 DD practices vs. 49 non-DD practices	(Baines, Tolley, and Whynes 1996)
	43.7	43.6	-	+0.23	29 DDs vs. 28 non-DDs	(Trap, Hansen, and Hogerzeil 2002)
	26.5	42.0	<0.001*	-58.50	59 DD practices vs. 49 non-DD practices	(Morton-Jones and Pringle 1993b)
	43.5	62.5	-	-43.68	10 DDs vs. 10 non-DDs	(Wilcock 2001)
	97.73	88.49	-	+9.45	Peptic ulcer scripts: 4481 DDs' vs. 50680 non-DDs'	(Lee and Malone 2003)
Percentage of antibiotics prescribing not justified (heterogeneity $\chi^2=0.184$, $p=0.292$)	39.4	28.9	NS	+26.65	29 DDs vs. 28 non-DDs	(Trap and Hansen 2002b)
	80.8	72.8	<0.001*	+9.90	Scripts: 26414 DDs' vs. 24585 non-DDs'	(Park et al. 2005)
	41.4	43.5	NS	-5.07	28 DDs vs. 25 non-DDs	(Trap and Hansen 2002a)

Table 2.2: Summary of factors identified for dispensing and non-dispensing doctors. The asterisk (“*”) denotes statistical significance ($p \leq 0.050$).

2.2. *Effectiveness of Separation Policy*

Three papers were identified that studied the effects of a government policy to separate the roles of dispensing from prescribing (Chou et al. 2003; Lee and Malone 2003; Park et al. 2005). These papers were from South Korea (2) and Taiwan (1).

2.2.1. *South Korea*

There have been global interests in separation of dispensing and prescribing (Lee and Crupi 2001; Kwon 2002, 2003; Seo 1994; Rodwin and Okamoto 2000; Iizuka 2008; Ho 2005; Tan 2006; Goh 2006). In recent times South Korea introduced a controversial compulsory separation of dispensing from prescribing policy in July 2000 (Watts 2000; Lee and Crupi 2001; Ahmad 2000; Kwon 2003; Cho 2000; Watts 2001). This policy prevented all doctors from dispensing pharmaceutical products to their patients. It was expected that following the implementation of the policy, the use of pharmaceuticals in South Korea would decrease since pharmacists would alert doctors and patients to possible adverse reactions, thus reducing the use of pharmaceuticals.

Lee and Malone (2003) used the South Korean national health insurance claims data to assess changes in peptic-ulcer medication prescribing six months before and after the implementation of this policy. It was found that whilst the number of all prescriptions increased by 13.9% following the implementation of the policy, the total number of peptic-ulcer medication prescriptions decreased by 39.8%. Interestingly, pharmaceutical expenditure for peptic-ulcer medications increased by 98.4% during this period despite the decreased prescription volume. The authors attributed this phenomenon to increased use of branded peptic-ulcer medications: DDs profited from direct selling of pharmaceutical products hence a preference towards generic products which on average had a higher profit margin; once the financial incentive was removed, it appears that doctors preferred to prescribe branded drugs that may be more familiar to patients. Other possible reasons for this change could also exist.

Park et al. (2005) also utilised the same databank for the same period but focused instead on the prescribing of antibiotics for respiratory tract, urinary tract and soft tissue infections. The authors found that following the separation policy, the proportion of antibiotic prescriptions for likely bacterial and viral illnesses decreased (bacterial: 92% to 90%, RR 0.98 [0.97 - 0.99], $p = 0.017$; viral: 81% to 73%, RR 0.89 [0.86 - 0.91], $p < 0.001$), with a greater reduction seen in viral illness ($p < 0.001$). The authors also reported a decrease in antibiotic polypharmacy in both likely bacterial and viral illness (bacterial: 1.7 to 1.6 antibiotics per episode, ratio 0.94 [0.92 - 0.96], $p < 0.01$; viral: 1.5 to 1.4, ratio 0.92 [0.90 - 0.95], $p < 0.01$), but there was no significant difference between the two groups ($p = 0.357$). The authors concluded that the separation policy had improved the quality of antibiotic prescribing.

2.2.2. Taiwan

Unlike South Korea, Taiwan phased in its separation policy on an incremental basis over four years beginning March 1997 (Chou et al. 2003). To compensate for the loss of revenue from pharmaceutical dispensing, doctors' consultation fees were increased and pharmacist's dispensing fees were doubled (Chou et al. 2003).

Chou et al. (2003) utilised the difference-in-difference framework to analyse the impact of the separation policy on Taiwan's health and pharmaceutical expenditure. Using the Bureau of National Health Insurance claims data the authors found decreased pharmaceutical expenditure (mean: -US\$1.21 [SE 0.24], $p < 0.001$), primarily through reducing the probability of providing a prescription by some 17% to 34% across sites. Total health expenditure did not significantly decrease (mean: -US\$0.72 [SE 0.71], $p = 0.312$).

2.2.3. Summary

Level C evidence suggested that government policy to terminate doctor dispensing may have reduced total prescribing but with less predictable effects on health expenditure that may be country specific.

2.3. *Prevention of Adverse Events*

An issue often included in the debate over doctor dispensing is the importance of a secondary check by a pharmacist. To compare the effectiveness of pharmacists and DDs in reducing adverse drug events, Trewin et al. (1996) examined 4,544 UK hospital admissions for adverse drug effects over a ten-year period. The authors measured drug levels of digoxin, phenytoin and theophylline in patients admitted for adverse drug events and found that DDs had no statistically significant difference to pharmacists in contributing to the rate of hospitalisation from adverse drug events (9.4% vs. 8.4%) or in the proportion of patients found non-compliant (1.8% vs. 1.3%). A power determination could not be made from the data provided and the authors were unable to provide further information citing lapse of time.

2.4. *Adherence to Best Practice*

Three papers investigated the quality of DDs' use of antibiotics as a surrogate measure of adherence to best practice (Trap and Hansen 2002b; Park et al. 2005; Trap and Hansen 2002a). These papers were derived from two comparative studies based in South Korea and Zimbabwe (see Table 2.2).

As mentioned previously, Park et al. (2005) inferred improved quality of antibiotic prescribing from a reduction in the rate of antibiotic use in probable viral illnesses and antibiotic polypharmacy following the South Korean separation policy. The authors found decreased proportion of antibiotic prescriptions, especially for likely viral illnesses (RR 0.89 [0.86 - 0.91], $p < 0.001$).

In Zimbabwe, Trap and Hansen (2002b) compared retrospective patients' records to assess antibiotics used in upper respiratory tract infections. The authors reported that antibiotic prescribing was not justified in 39.4% of the DDs' cohort compared with 28.9% from the non-dispensing cohort. The authors stated that 'the difference was not significant'; no power or other statistical data were provided. Trap and Hansen (2002a) also investigated the frequency of sub-curative dosages of antibiotics (≤ 2.5 days) and found DDs were less likely to prescribe curative dosages (45.2% [33.9 –

56.5] vs. 74.2% [64.6 – 83.7], $p = 0.0003$). This was confirmed by a sub-analysis of cotrimoxazole use (58.0% [46.9 – 69.2] vs. 72.6% [64.5 – 80.7], $p = 0.047$).

In summary, level C evidence suggests that DDs' practices were associated with modestly poorer adherence to best practice especially in terms of antibiotic prescribing (MD = 5.47 [SED 0.86], $d = 0.24$ [0.17 – 0.31], $t = 6.39$, $p = 0.292$).

2.5. *Quality of Dispensing*

Hansen and Trap (2004) conducted an observational study of 29 DDs' dispensaries and 20 community pharmacies in Zimbabwe to assess the quality of dispensing services in general accordance with the World Health Organization's *Good Pharmacy Practice in Community and Hospital Pharmacy* (World Health Organization 1996). The modified standard assessed:

- (a) service quality (10 indicators) including affordability, patient care and availability;
- (b) quality of medicines (20 indicators) including stock management, storage, packaging and quality assurance; and
- (c) dispensing quality (14 indicators) including information, labelling, staffing and privacy.

The authors reported that dispensing doctors' dispensing quality was low due to inadequate information, inadequate labelling and lack of hygiene (Hansen and Trap 2004). However, neither this paper nor Trap's PhD thesis (Trap 2001) presented comparative data on Zimbabwe pharmacies.

2.6. *Stakeholder Perspectives on Doctor Dispensing*

2.6.1. *Patients' Perspectives*

Four papers were identified on patients' attitudes towards doctors' dispensing. These papers were based on questionnaire surveys conducted in the USA (Perri et al. 1987; Pink, Hageboeck, and Moore 1989; Ogbogu et al. 2001) and Australia (Sunderland, Burrows, and Joyce 2006; Sunderland, Burrows, and Joyce 2005).

Respondents generally indicated convenience as a main factor for them to have prescriptions filled by dispensing doctors:

- (Sunderland, Burrows, and Joyce 2006; Sunderland, Burrows, and Joyce 2005): 61% of respondents from dispensing doctor towns disagreed with “*There is too long a delay for obtaining my medication*”;
- (Perri et al. 1987): 70.3% agreed with the statement “*Having the doctor fill my prescription would be more convenient than having it filled at a pharmacy*”;
- (Pink, Hageboeck, and Moore 1989): 46.6% expressed “*less convenient*” having “*prescription refills from your doctor’s office?*”; and
- (Ogbogu et al. 2001): 23% listed “*convenience*” as reasons for office purchases of pharmaceuticals.

Both Ogbogu et al. and Pink et al. indicated that patient-respondents perceived doctors to be more knowledgeable about pharmaceuticals than pharmacists ((Ogbogu et al. 2001): 55%, (Pink, Hageboeck, and Moore 1989): 50.1%). Regardless of this, patients prefer the dispensing of pharmaceuticals to be performed by a pharmacist:

- (Sunderland, Burrows, and Joyce 2006; Sunderland, Burrows, and Joyce 2005): 62.0% of respondents from dispensing doctor towns ‘*thought their town needed more access to pharmacy services*’;
- (Perri et al. 1987): 56.4% agreed with the statement “*I would prefer a pharmacist dispense my medicine rather than a physician*”; and
- (Pink, Hageboeck, and Moore 1989): 68.7% agreed with the statement that “*there is a health benefit from having the doctor write the prescription and a pharmacist (druggist) check and fill it*”.

Only one of the included papers directly addressed the patient’s perspective of doctor dispensing for profit and approximately 56.4% of the respondents were against the idea (Perri et al. 1987).

2.6.2. *Doctors' Perspectives*

This search included five papers on doctors' attitudes towards dispensing. These papers were based on surveys conducted in the USA (Ogbogu et al. 2001; Hyde et al. 1979; McRoberts 1987; Holiday et al. 1992) and South Africa (Gilbert 1998).

Similar to the earlier patient's findings, DDs generally perceived patient convenience as the main reason for them to dispense pharmaceutical products (Hyde et al. 1979; Ogbogu et al. 2001).

Despite increased numbers of DDs in some countries (Dispensing Doctors' Association 2004; Sullivan 1987; Gilbert 1998; Morton-Jones and Pringle 1993b; Ryan and Bond 1994, 1996; Abood 1988; Weiss 1987; Holiday 1989), surveys of doctors who were not currently dispensing found that 100% of surveyed South African doctors (Gilbert 1998) and some 85.5% (Holiday et al. 1992) to 94% (McRoberts 1987) of surveyed USA doctors perceived dispensing as the role of pharmacists and had no desire to engage in doctor dispensing. Of those doctor-respondents who expressed an interest in dispensing ((Holiday et al. 1992): 10.5%) they were more likely to be solo practitioners, see more than 100 patients per week, and to have less access to medical support personnel (Holiday et al. 1992).

2.6.3. *Summary*

Level B evidence indicates that convenience was cited as the main reason by both patients and doctors for the dispensing of pharmaceuticals from DDs' dispensaries.

3. DISCUSSION

From the analysis (see Table 2.1), there was level B evidence that internationally, DDs tended to prescribe more pharmaceutical items and incurred higher pharmaceutical costs than their non-dispensing counterparts. There was some evidence to suggest that DDs prescribed antibiotics less judiciously and were associated with poorer dispensing standards. Despite the different national health systems in which DDs practiced, there was reasonable consistency among the studies included to support the notions of DDs dispensing for profit and for patients' convenience.

The critical question for policy-makers is whether the practice of doctor dispensing should be supported: balancing health outcomes and costs against workforce shortages and patient convenience.

There are significant ongoing concerns over the lack of healthcare professionals in rural areas and the well-documented health disparity between urban and rural residents. In many countries DDs are located in rural and remote areas of unmet need where there is inadequate access to pharmacies and doctors. Therefore the unconventional practice of doctor dispensing pharmaceutical benefits provides rural and remote patients with timely and convenient access to both medical and pharmaceutical care.

However, the question remains: do increased pharmaceutical utilisation and costs associated with DDs' practices warrant, when balanced against patient convenience and workforce retention, interventions to separate dispensing from prescribing? There is a recognised shortage of doctors internationally. Can, then, the doctor's time be better utilised than in dispensing? Evidence from government separation policies has suggested that separation of prescribing from dispensing may indeed reduce the level of prescribing and may even promote more judicious habits. However, the effects on overall healthcare costs are less predictable.

The analysis has shown that DDs prescribed more than their non-dispensing counterparts and at greater cost to the healthcare system but there is only limited

evidence that DDs prescribed less judiciously or had poorer dispensing standards. Patient convenience is an important factor for doctors in dispensing pharmaceuticals particularly in areas of pharmacist and medical workforce shortage. Therefore the separation of prescribing and dispensing practice is not clearly supported, particularly in areas where workforce needs are unmet.

There are limitations relating to the conduct and interpretation of a systematic review of this nature. Firstly, the practicality and appropriateness of the SIGN grading by the researchers are open to debate. This is because the SIGN system lacks precision in allocating the grading. Secondly, in the process of conducting this systematic review a general lack of high SIGN quality papers was identified. Thirdly, in this review other domains of 'quality' such as interpersonal communication between DDs and patients, and structural aspects of care which include factors that may influence DDs' prescribing and dispensing were excluded.

Based on experience gained from conducting this systematic review, a different study design is needed to better encapsulate the effectiveness and efficiency of DDs' practices in Australia. The proposed methodology would have to incorporate measures of efficiency such as cost-effectiveness to the public insurer (Campbell, Roland, and Buetow 2000) and outcome measures of effectiveness such as disease-state management. At the same time, findings from Australia must be capable of being compared with overseas findings so as to provide a more comprehensive international understanding of doctor dispensing within a health policy context. The proposed study method would also need to include other domains of 'quality' such as equity of access and continuity of care; these would assist in having a contextual understanding of this somewhat politically sensitive topic.

III. BACKGROUND

The findings from the systematic review reported above were based on overseas studies in which each jurisdiction studied has own unique healthcare arrangements. The purpose of this chapter is to provide a brief introduction to the Australian healthcare system. It aims to provide a context for the research question (Chapter I) and the ADD Study protocol outlines in Chapter IV. This background chapter to the Australian healthcare system will focus primarily on roles of general practitioners (GPs) and pharmacists, the general issue with rural and remote areas, and the Pharmaceutical Benefits Scheme (PBS).

1. AUSTRALIA: A FEDERATION OF STATES AND TERRITORIES

Australia is a relatively young country and the health system in place today has evolved from its humble beginnings as a penal colony of the British Empire (Sax 1984) from which Australia inherited much of its legislative framework. Even today, the healthcare system in Australia is similar in many respects to its UK counterpart (Sax 1984; de Voe and Short 2003; Crichton 1990).

Modern Australia has arguably one of the world's best healthcare model. It is "*based on whole person, continuing, comprehensive and coordinated care [and] has produced international benchmark results in longevity, patient-doctor satisfaction, and preventable death rates*" (Royal Australian College of General Practitioners 2009d)(p1).

Australia's national health outcomes have compared favourably with most major Organisation for Economic Cooperation and Development (OECD) countries (Donato and Scotton 1998; Hussey et al. 2004; Australian Commission on Safety and Quality in Healthcare 2009; Joumard, André, and Nicq 2010; Davis, Schoen, and Stremikis 2010) but, as a proportion of Gross Domestic Product (GDP), Australia's spending on health care has been higher than many of its OECD counterparts (Anderson and Poullier 1999; Richardson, Walsh, and Pegram 2004; Australian Institute of Health and Welfare 2005a; Tatchell 2007).

Australia has a complex multi-jurisdictional healthcare funding system with governments taking a major role in the financing of health services. It involves three levels of governments: Commonwealth, State and Local (Western Australian Centre for Remote and Rural Medicine 2005; Newman, Baum, and Harris 2006; Davies et al. 2009).

Local government authorities (e.g. municipal or shire councils) have no duty to provide health services to their communities but may play an active role in ensuring adequate health services are maintained in their catchments (Western Australian Centre for Remote and Rural Medicine 2005). This varies across local governments dependent on need. For instance, a number of local governments provide free or subsidised accommodation and/or direct financial incentives to attract a long-term doctor, pharmacist or other healthcare provider to their catchments (Western Australian Centre for Remote and Rural Medicine 2005; Davies et al. 2009).

Respective State Governments have jurisdictional responsibility to provide healthcare services, such as public hospitals, and public health protection services, such as health promotion and registration of health professionals (Davies et al. 2009). The registration of health professionals was transferred to the Commonwealth Government from July 2010. There is a recent move by the Commonwealth Government to take over aspects of public hospitals; details of the proposed 'nationalisation' (if that is what it proves to be) are yet to be formally released.

Pursuant to the Constitution of Australia, the Commonwealth Government has concurrent power to provide for the "peace, order and good government" of the Australian federation (*Commonwealth of Australia Constitution Act 1900* 1900). Since the 1946 constitutional amendment, Commonwealth Government has taken over the role of payment for hospital, pharmaceutical and several social welfare benefits and provision for medical and some dental services (Clinton 1998). Through the funding and control of subsidised health expenses, the Commonwealth Government plays a dominant role in influencing the use of health services in Australia (Kelly 2008): on average the Commonwealth Government funded 68% of

national health spending (Tatchell 2007), of which 5% was via the Medicare rebate (Australian Institute of Health and Welfare 2005a).

2. MEDICARE AUSTRALIA

The Federal Labor (Whitlam) Government first established a statutory body, the Health Insurance Commission (HIC) to provide for a public-funded health insurance scheme in 1974 (Crichton 1990). Through the work of HIC, *Medibank* was conceived and this provided universal access to hospital treatment through a compulsory taxation levy proportionate to income (de Voe and Short 2003). Under a subsequent Federal Labor (Hawke) Government, *Medibank* underwent a name change to *Medicare* in 1984, and the PBS was established (Crichton 1990). Since then there has been another name change in 2005 to *Medicare Australia* as a reflection of the Federal Liberal (Howard) Government commitment to universal health care.

The statutory body Medicare Australia has responsibility for administering the Medicare Benefit Scheme (MBS) of which the PBS is one component. Medicare Australia is in turn managed by an executive body, the Commonwealth Department of Health and Ageing (the “Department”).

The MBS rebates some of the costs of medical and some allied health services provided by practitioners in private settings on a fee-for-service basis (Van Der Weyden and Chew 2004). Providers may set their own fees and patients are required to meet the difference between the provider’s fees and the rebate.

Medicare Australia also administers the Australian Childhood Immunisation Register, the Australian Organ Donor Register, the Practice Incentive Program for general practice, the rebate on health insurance, and incentives assigned under the Community Pharmacy Agreements and section 100 *National Health Act 1953* (Cth) for indigenous health (the “Section 100 Scheme”).

2.1. *Pharmaceutical Benefits Scheme*

Approximately 13.5% of the national health spending is on pharmaceuticals, of which 84% has been funded by the Commonwealth Government through a PBS rebate (Australian Institute of Health and Welfare 2005a; Edmonds et al. 1993; Beilby and Furler 2004). In real monetary terms, the Commonwealth Government paid just over AUD\$6 billion in PBS subsidies in the 2005-6 fiscal year (Minister for Health and Ageing 2006). This represented nearly 12% of total recurrent government expenditure on health (Gadiel 2008; Anderson et al. 2000).

The PBS is a national scheme which aims to provide the Australian community with universal and comprehensive pharmaceutical coverage through subsidised access to necessary pharmaceutical benefits which are affordable, available and of acceptable standards (Harvey 2005; Commonwealth Department of Health and Ageing 2009a).

A computer record is kept of all PBS prescription claims submitted by authorised community pharmacies or DD dispensaries to the Department for payment of a PBS subsidy (Commonwealth Department of Health and Ageing 2009a). The Department summarises these data on the basis of the date of dispensing/ supply, the pharmaceutical code, minimum recipient information and prescriber information.

The PBS data are potentially valuable sources of information, despite not being a complete data set for all community dispensed pharmaceutical products. This is described in more detail under the *Discussion* section of Chapter V. Nevertheless, analysis of PBS drug utilisation data allows trends and patterns of pharmaceutical use to be followed and the impact of interventions monitored (Horn et al. 2006; Mandryk et al. 2006; Wutzke et al. 2006). This is also often used as a basis for pharmacoeconomic analysis (Edmonds et al. 1993).

Internationally, pharmaceutical expenditure as a proportion of GDP and of total health expenditure has increased during the last 30 years, and it is expected to continue to rise (Prados-Torres et al. 2009). In Australia, the PBS reportedly has the highest average annual growth rate over the last decade (around 12% per annum: (Greenwood 2009)); and it peaked at 16.9% in March 2003 (Australian Institute of

Health and Welfare 2005a)). This is compared to 6% per annum for public hospital services, and 5% per annum for medical services (Harvey 2005). There was a fear that, based on the projected growth of the PBS, by the year 2022 more would have been spent on PBS pharmaceutical benefits than on both public hospital and medical services together (Harvey 2005; Minister for Health and Ageing 2006). Therefore in recent times the sustainability of the PBS has become a major consideration for the Commonwealth Government (Australian Journal of Pharmacy 2005a, 2005e, 2005b; Australian Medical Association 2005a, 2006; Bracey 2007b; Burge 2005b, 2005a; Fleming 2005a, 2005b; Frank 2005; Grogan 2007; Hynd et al. 2008; Minister for Health and Ageing 2006; Nicholson 2007; Pharmaceutical Defence Ltd 2005; Stokes 2008; Tatchell 2006; Walters 2005). In response the Commonwealth Government in recent times had reduced the amount of rebate payable (Scott 2005). This has included a significant increased consumer co-payment, thereby shifting some of the cost of rising pharmaceutical care from the taxpayer back to the consumer.

The Commonwealth Government subsidizes each PBS pharmaceutical item when the price of the item exceeds the patient co-payment amount. In 2010, patients in the general category paid up to a maximum of AUD\$33.30 for a pharmaceutical item listed on the PBS Schedule², while patients in concessional categories (primarily social security recipients or veteran affairs beneficiaries) paid a maximum of AUD\$5.40. During the ADD Study period, the general category co-payments were AUD\$28.60 in 2005 and AUD\$29.50 in 2006, and the concessional co-payments were AUD\$4.60 in 2005 and AUS\$4.70 in 2006 (Minister for Health and Ageing 2006).

There is also a safety-net provision under the PBS which operates for each of these categories of patient in any one calendar year. When the limit is reached, pharmaceutical benefits are either free or have a much reduced co-payment for the remainder of the safety-net period (Beilby and Furler 2004).

² Previously known as the 'yellow book'.

3. ROLES OF GENERAL PRACTITIONERS AND PHARMACISTS

In Australia, primary care is a complex multidimensional system with GPs³ often being the first point of contact for health concerns (Allan, Ball, and Alston 2009; Gunn et al. 2008; *General Practice in Australia, Health Priorities and Policies 1998 to 2008* 2009; Beilby and Furler 2004; O'Halloran et al. 2003; Powell-Davies and Fry 2004) and the empirical gatekeepers for the health system (Martin and Sturmberg 2005; Powell-Davies and Fry 2004; Allan, Ball, and Alston 2009; McGrail and Humphreys 2009b; Barron 2006; Royal Australian College of General Practitioners 2009b; Davies et al. 2009; Kringos et al. 2010) whilst pharmacists⁴ adopt the role as gatekeepers for the PBS (Eton 2007a; Nicholson 2007).

3.1. *Roles of General Practitioner in Australia Healthcare*

General practice delivers the lion's share (90%) of primary healthcare (Sanci, Kang, and Ferguson 2005; Australian Commission on Safety and Quality in Healthcare 2009) but the direct costs of care in general practice only averaged 5.5% of the total healthcare expenditure (Harris and Harris 2006; Australian Institute of Health and Welfare 2005a). GPs also exercised a significant influence on pharmaceutical (24%), specialist care (10%) and hospitalisation (29%) expenses (Australian Institute of Health and Welfare 2005a). In both a medical and social sense, general practice plays an important role in determining health and health inequalities (Furler 2006; Furler and Palmer 2010). Evidence has suggested that increasing the number of GPs actually increases overall quality of care as compared to increasing the number of other medical specialists (Starfield 1994; Starfield and Shi 2002; Radford 2009; Royal Australian College of General Practitioners 2009a; Stange 2009; Scott 2009; Kringos et al. 2010). However, there is also the contrary view that underemployed GPs can potentially 'over-service' patients (Weller and Maynard 2004; Wong, Bentzen, and Wang 2008).

³ Also known as 'family doctor', 'family physician', 'primary care doctor' and 'primary care physician'.

⁴ Also known as 'chemist' or 'druggist'.

Even though the core concept of primary care and the GP is generally not well appreciated nor understood by the public (Stange 2009), the role of the GP is often perceived to be the team leader or coordinator of patient care (Light 2005a; Fitzgerald 2006; Royal Australian College of General Practitioners 2005). He/she works collaboratively with other health professionals, not in competition (Thistlethwaite and Topps 2009; Fitzgerald 2006; Carnell 2006; Kringos et al. 2010), to provide accessible and comprehensive care for common problems and continuity of care (Wearne 2009; Fitzgerald 2006; Dowrick 2006; Royal Australian College of General Practitioners 2005; Gunn et al. 2008; Kringos et al. 2010), and early detection of chronic disease and disease prevention (Dowrick 2006; Van Der Weyden 2005; Carnell 2006; Kringos et al. 2010).

An important strength of GP care is his/ her ability to flexibly tailor and integrate different aspects of care, adopting a whole person multi-system approach (Gunn 2009; Kringos et al. 2010). A GP is able to take a broad view of a patient's needs and yet be able to selectively narrow and prioritize care, thus moving beyond a disease-by-disease approach but rather specialising in the care as a whole of the person they are treating (Radford 2009; Stange 2009).

3.1.1. *General Practitioner and Rural Health*

More than one-third of the Australian population resides outside major cities (Wakerman et al. 2008; Hugo 2005; Wakerman et al. 2009; Strasser 2000; Fatovich 2009; Western et al. 2000; Phillips 2009; Dunbar and Reddy 2009), but only 17% of the GP population is based in rural and remote Australia (Britt, Miller, Charles, Henderson et al. 2008; Australian Bureau of Statistics 2002; Towler 2007). Other than the maldistribution of GPs, the GP-utilisation rate per head of population is lower in rural areas (3.2 - 3.6 in remote vs. 5.2 - 5.7 in urban areas) (O'Halloran et al. 2003; Beilby and Furler 2004; Britt, Miller, Charles, Bayram et al. 2008; *General Practice in Australia, Health Priorities and Policies 1998 to 2008* 2009). The reported level of less frequent annual visits per patient suggests that there is less continuity of care for patients as the remoteness from services increases (Knox et al. 2005).

The notion of inverse care, where people most in need of healthcare are frequently least likely to receive it (Hart 1971), is ever more evident in rural Australia where there is an ever increasing health inequality between urban and rural dwellers in regard to health and access to health services (Maxwell 2006; Wakerman et al. 2008; Strasser 2000; Hugo 2005; Newman, Baum, and Harris 2006; Commonwealth Department of Health and Ageing 2009b; Dunbar and Reddy 2009; Wakerman and Humphreys 2002). For instance, there is a higher proportion of indigenous Australians living outside of metropolitan areas and a higher proportion of Medicare concessional card holders and higher levels of unemployment. Rural residents as compared to their urban counterparts, tend to:

- be older,
- have shorter life expectancy,
- a higher morbidity and mortality rate,
- be more likely to have a disability or be chronically ill, and
- be more likely to place themselves at higher risk of poor health, including because of smoking, being overweight and having excessive alcohol consumption

(Phillips 2005; Newton et al. 2007; Wearne and Wakerman 2004; Simpson 2006; Knox et al. 2005; Hugo 2005; Ball 2007, 2009; Strasser 2000; Bayram et al. 2007; Smith et al. 2008; Smith, Humphreys, and Wilson 2008; Australian Institute of Health and Welfare 2005b; Lavelle 2003; Wakerman and Humphreys 2002).

Rural residents are less inclined to seek health services (Australian Institute of Health and Welfare 2005b; Phillips 2009; Wong and Regan 2009; Beard et al. 2009; Dunbar and Reddy 2009), probably due to greater difficulties in accessing health services: road travel distances and speeds on them are greater, and road conditions are arguably worse (Phillips 2009; Greenhill, Mildenhall, and Rosenthal 2008; Hugo 2005; Smith 2010). This is despite recent advances in technology (Gregory 2009). Consequently trauma and road accidents contribute to higher mortality due to distances from healthcare facilities (Reavy 2009; Fatovich 2009).

In addition, the mean weekly family income is lower (AUD\$700 - AUD\$799 in rural vs. AUD\$1,000 - AUD\$1,199 in urban) (Hugo 2005) but the costs of health services

are higher (Rural Doctors Association of Australia 2005; National Rural Health Alliance 2008b; Wakerman et al. 2008; Zhao and Malyon 2010).

Rural health services are characterised by multiple and fragmented funding streams (Commonwealth Department of Health and Ageing 2009b) and service delivery arrangements are inflexible and poorly coordinated (Commonwealth Department of Health and Ageing 2009b; Wakerman et al. 2008).

Workforce shortages exist across most primary health care professions and are exacerbated by maldistribution (Gorman and Brooks 2009; Scott 2009; Sims and Bolton 2004; Wilson et al. 2009; Wilson, Oldenburg, and Lopez 2003; O'Toole, Schoo, and Hernan 2010; Wibowo 2007).

These self-perpetuated issues maintain the vicious cycle of health inequality in rural Australia.

3.1.2. *Rural Index*

There is no Australian definition of 'rural' (Fatovich 2009) but arguably there are two distinct elements to the term 'rural'. One is the concept of 'rural' as distinct from 'metropolitan', which has predominately been addressed by distinguishing between city and country, and focusing on a normative construct that constitutes 'city' through criteria such as population numbers (McGrail et al. 2005). The other concept is of accessibility to services and remoteness (Fantus and Foley 2008). There is no essential rural or metropolitan, but rather a continuum based on population numbers, accessibility of services, and attitudes or values. (McGrail et al. 2005).

In Australia, several different indexes of rurality are used as proxy measurements. These indexes include the Rural, Remote and Metropolitan Area (RRMA) classification which was first developed in 1991. The RRMA categorises areas into one of seven levels, mostly based on population size. It is widely used by governments as proxy measures of access to refine health funding (McGrail and Humphreys 2009b).

The Accessibility and Remoteness Index of Australia (ARIA) was developed in 1997 as a strictly geographic measurement of remoteness from goods and services. Rather than the population size that the RRMA is based on, ARIA uses road distance from four levels of neighbouring service centres to calculate a remoteness score which is then categorised into five levels of remoteness (Knox et al. 2005).

The Australian Standard Geographical Classification (ASGC) Remoteness Structure with five ordinal remoteness categories was released in 2001 (Australian Bureau of Statistics 2003). As compared to the ARIA, the ASGC uses distance from five rather than four classes of service centres.

Despite the simplicity of use, a key disadvantage of using any of the rurality indexes is that populations of most rural communities are not homogenous; either within or among communities (Hugo 2005) and that requirements of rural and remote communities are diverse (Ball 2006). None of the existing rurality classifications were designed specifically to guide health resource allocation, and all exhibit strong weaknesses when applied for this purpose (McGrail and Humphreys 2009a; Dugdale 2007). In addition, there is no 'one size fits all' health service model (National Rural Health Alliance 2008b; Alfred, Kalucy, and McIntyre 2008; Bracey 2008). Often, rural and remote communities are too small to support traditional models of health delivery locally so residents have to access health care from larger regional towns or even from urban centres which are generally able to support a wider range of health services (Wakerman et al. 2008). It has been estimated that the critical minimum population base of 5,000 inhabitants for rural areas and 2,000 - 3,000 people for remote communities is necessary to support a comprehensive and sustainable range of primary health care services (Wakerman et al. 2005; Wakerman et al. 2008; Wakerman et al. 2009; Berbatis et al. 2007; Wibowo 2007).

Whilst remoteness may play a major role in determining the health outcomes, nature and level of access and provision of health services (Phillips 2009; Dunbar and Reddy 2009), rurality by itself does not always translate into health disadvantage (Smith, Humphreys, and Wilson 2008); rather, it has been argued that rurality exacerbates the negative effects of remoteness such as socio-economic disadvantage,

ethnicity, poorer service availability and higher personal risk. For instance, evidence from past economic crises has demonstrated that the worst health outcomes were observed in mining towns and rural areas where drought had already taken its toll (McCredie 2009; Ostry 2009; Reavy 2009); consequently, residents were forced to choose between buying much-needed medications and shoes for children against high petrol prices, raising household costs, as well as the increased co-payments for medicines and safety net threshold for the PBS. The *Medical Observer* annual survey found that 83% of GPs had seen patients refuse optimal treatment because of costs (Fleming 2006). A recent qualitative study also found that lack of flexibility in rural health care services delivery influenced whether patients experienced economic hardship (Jeon et al. 2009) since social determination of health and primary healthcare services are not mutually exclusive (Rasanathan et al. 2009). This suggested that what is needed in rural Australia is a flexible healthcare service model (Rural Pharmacy workforce Program 2009; Emerson, Bell, and Croucher 2001; Bracey 2008; National Rural Health Alliance 2008c, 2008b, 2008a; Alfred, Kalucy, and McIntyre 2008; O'Toole, Schoo, and Hernan 2010).

Rural GPs, with their traditional involvement in 'cradle-to-grave' activities, have assumed the role of healer, carer, counsellor and friend in many country communities where they practice (Humphreys, Mathews-Cowey, and Weinand 1997; Page 2005). However, with the uneven distribution of higher morbidity and mortality in rural Australia, the clinical workload of a rural GP is more complex than that of his/her urban counterpart (Wearne and Wakerman 2004; Western et al. 2000; Britt et al. 2009), requiring "*a higher level of clinical acumen to diagnose and manage illness, as there are often no pathology, radiology or other usual clinical diagnostic support and specialist services, and the ultimate responsibility lies with the remote doctors*" (Smith et al. 2008)(p159).

Consequently rural GPs work longer hours (Phillips 2005; Schofield et al. 2006; Holden 1990; Western et al. 2000; Britt et al. 2009; Humphreys et al. 2002), have heavier clinical loads (Knox et al. 2005; Western et al. 2000; Ashworth and Armstrong 2006), but receive lower incomes (Kamien 2004; Page 2005). Other barriers that rural GPs face include: greater involvement in all aspects of patient treatment in the absence of other medical specialists, personal and professional

isolation, lack of access to educational opportunities, and difficulty in getting a locum (Page 2005; Playford, Larson, and Wheatland 2006; Lavelle 2003; Coote 2009; Knox et al. 2005; Western et al. 2000; Humphreys et al. 2002).

These factors could explain the high turnover of GPs reported across rural and remote Australia (Schofield et al. 2006; Bayram et al. 2007; Eley and Young 2008; Western et al. 2000). The higher turnover of GPs and higher proportion of retiring GPs in rural communities (average 51 years old in rural vs. 49 years old in urban) has created difficulties in maintaining a continuous relationship that is vital for primary care, especially so for those needing continuous management for their chronic conditions (Wong and Regan 2009; Britt et al. 2009; Carnell 2006).

3.1.3. *International Medical Graduates*

The medical workforce shortage has reached critical levels in rural and remote Australia (Arnold 2005; Bracey 2008; Avon Valley Advocate 2009). Incentives to lure doctors to rural Australia include increased rural GP training places, compulsory GP-registrar training deployment to rural general practices, retention payments for rural GPs, higher MBS rebates, rural scholarships for undergraduate medical degrees, and recruitment of international medical graduates⁵ (IMGs) (Lokuge, Denniss, and Faunce 2005; Wearne 2009; Wearne and Wakerman 2004; Elliot et al. 2009).

Many of the rural communities now depend on salaried practice arrangements or IMGs practising on restricted provider numbers to meet their communities' primary care needs (Jones, Humphreys, and Adena 2004; Overs 2008; McNutty 2008; Bayram et al. 2007; Naccarella, Buchan, and Brooks 2010; Gorman and Brooks 2009; Joyce 2004). Currently about 40 - 50% of rural GPs have graduated overseas (Maxfield 2009; Gregory 2009; Joyce 2004), mostly in South Africa and India (Birrell 2004; Western Australian Centre for Remote and Rural Medicine 2005).

The Commonwealth Government's policy of compulsory rural IMG placement has failed to build a permanent skilled rural medical workforce (Maxfield 2009) but this

⁵ Also referred to in the literature as 'overseas-trained doctors'.

short-term solution of recruiting foreign doctors from countries that experience a dire shortage of doctors themselves and where such doctors are arguably much more needed, and forced rural deployment have raised an ethical dilemma (Rosenberg 2008; Maxfield 2009; Wilson et al. 2009; Levy 2010). Nevertheless, it appears that the Australian rural health medical workforce is likely to be heavily dependent on IMG for some time to come (Van Der Weyden and Chew 2004; Bayram et al. 2007) since it takes nearly 10 years of intensive study to become a GP (Saratchandran 2005).

IMGs are a very diverse group with variable needs for training and up-skilling (Alexander and Fraser 2007). Some commentators have argued that the background training, communication skills, clinical skills and orientation to the Australian healthcare system can vary markedly among IMGs hence the government policy of placing IMGs in rural and remote Australia may actually compromise patient safety (McGrath 2004). The current process of placing IMGs directly into areas of unmet need positions or districts of workforce shortage has meant that there is virtually no funding for pre-employment assessment, support, training and appropriate supervision (McGrath 2004). In addition, IMGs also have reported significant discrimination from both the medical fraternity and the communities which they themselves have serviced (McNulty 2008; McKenzie 2010b; Wilson 2010b, 2010a).

3.2. *Roles of Community Pharmacists in Australia Healthcare*

There are some 4,800 community pharmacies in Australia (Williams 2004), and they serve an important link between doctors and patients. The shop-front feature of community pharmacy presents itself as a convenient first point of contact for patients without a formal appointment (Selya 1998; Hittner 1996; Benrimoj and Frommer 2004; Sunderland et al. 2006; Australian Journal of Pharmacy 2007b; McIntosh and Kiernan 2008; Barber 2009; Roughead, Semple, and Vitry 2004). Pharmacists have been continuously ranked highly on most trusted professionals surveys (Eaton 2005; Strasser 2000).

The dispensing of PBS pharmaceutical benefits may represent up to 75% of a community pharmacy's business (Casey, Klinger, and Moscovice 2002; Gottlieb

2004; Williams 2004; Berbatis et al. 2007; Wibowo 2007; Gadiel 2008), but with the falling PBS profit margin in recent years pharmacists have been urged to move beyond reliance on PBS alone and see themselves as valued health professionals (Grogan 2007; Doyle 2009b; Annabel 2006; Australian Journal of Pharmacy 2005c; van Grootheest and de Jong-van den Berg 2005; Cipolle, Strand, and Morley 1998; Annabel 2007; Tatchell 2006; Australian Journal of Pharmacy 2005d, 2006a).

Pharmacists by virtue of their five years of training in areas such as clinical chemistry, pharmaceuticals, therapeutics, pathophysiology, clinical pharmacology and principles of pharmaceutical care are equipped to complement doctors in a wide range of pharmaceutical care roles (Annabel 2006; Doyle 2009a; Cipolle, Strand, and Morley 1998). Pharmacists are ideally placed as consultant on pharmacotherapy offering medication risk-management functions for the individual patient (Grogan 2005; van Grootheest and de Jong-van den Berg 2005; Roberts and Stokes 1998; Doucette, Nevins, and McDonough 2005; Muller and McDanel 2006; Sclavos 2006). Many out-patients often only visit one community pharmacy (Sunderland et al. 2006; Australian Journal of Pharmacy 2007b; Doucette, Nevins, and McDonough 2005) so that pharmacists are best suited to identify patients with risk factors for disease prevention (Grogan 2006; Martin 2005, 2007; Sunderland et al. 2006; Joyce et al. 2007; Berbatis and Sunderland 2008) and to serve as a conduit between the doctor and the patient (Bracey 2007a; Roberts 2006; Parker 2005; Doucette, Nevins, and McDonough 2005; Muller and McDanel 2006).

However, pharmaceutical care and dispensing of pharmaceutical products are two very different activities (Cipolle, Strand, and Morley 1998). There are inherent tensions in the role of a community pharmacist as both a private retailer and a health professional (Taylor, Mrazek, and Mossialos 2004) such as in the potential conflict of interest when prescribing and dispensing (Keddie 2003; Williams 2004; Smith 2007).

Gadiel (2008) who contributed towards the Pharmacy Guild of Australia (the “Guild”) cost-benefit study on S2 and S3 pharmaceuticals⁶ commented that, the protectionist-

⁶ S2 and S3 refer to Schedules 2 and 3 of the Standard for the Uniform Scheduling of Drugs and Poisons. This document is produced by the National Drugs and Poisons Scheduling Committee, a

style regulatory framework currently in place to govern the community pharmacy industry resulted in Australia's most protect industries. It was argued that whilst there are benefits in regulating pharmacy quality standards, there can be none for restricting entry and ownership of community pharmacy:

“the welfare loss from restrictions on where consumers may shop, the inflated prices they consequently pay, and the inefficient use of labour and capital associated with local or quasi-monopoly profits are likely to be a considerable economic burden.” (Gadiel 2008)(p3).

3.2.1. Pharmacy Guild of Australia

The Guild was established to represent all the community pharmacy owners in Australia (Emerson, Bell, and Croucher 2001; Keddie 2003; Royal Australian College of General Practitioners 2009c). Non-pharmacy owners and pharmacy owners can hold membership of other pharmacist professional bodies such as the Pharmaceutical Society of Australia and/or the Australian College of Accredited Pharmacy [sic].

The Guild is a very powerful political lobbyist and has successfully negotiated with successive Commonwealth Governments on a series of Community Pharmacy Agreements. The Guild offers a powerful political bargaining chip in dealing with governments by influencing what is dispensed or bought by patients (Maher 2004; Roberts 2006; Eton 2007b; Sanofi-Aventis Australia 2007). The negotiated terms contained in the Community Pharmacy Agreements over prices, protection of pharmacy ownership, and infrastructure support have given pharmacy owners a collective advantage that doctor groups do not get because of their diverse representation (Keddie 2003; Burge 2005c; Moxham 2005; Coote 2009; Van Der Weyden 2009).

Pursuant to the Community Pharmacy Agreements, the number of rural community pharmacies has increased (Pharmacy Review 2003; Tatchell 2005).

committee of the Therapeutic Goods Administration. The document is used in the regulation of drugs and poisons in Australia. S2 is known as Pharmacy Medicine and S3 as Pharmacist Only Medicine.

3.3. *Doctor-Pharmacist Relationships*

Until recently, there have been significant tensions between doctors and pharmacists in Australia (Kernick 1997; Edmunds and Calnan 2001; Royal Australian College of General Practitioners 2009c).

Pharmacists have blamed GPs for the PBS blow-out and inappropriate prescribing (Australian Medical Association 2006) and have pushed to be given more professional rights such as the ability to perform basic medical services like immunisation (Maher 2004) and prescribing of PBS items (Clements 2005b; Low 2005; Australian Journal of Pharmacy 2006b; Vitry et al. 2006; Low 2007).

In retaliation, doctors have accused pharmacists of wanting to become ‘super pharmacies with medical services’ (Clements 2005a; McCrory 2005). Under amended legislation because of the Community Pharmacy Agreements, pharmacists can now own medical practices but not vice versa (Glasson 2004). Many doctors still perceive the pharmacist’s role to be dispensing of pharmaceuticals, checking prescriptions, and providing compliance instructions and drug information to patients (Matsumoto, Shimizu, and Fukuoka 2003). As commentators have said,

“Whereas in the past pharmacists enjoyed a high status because of their understanding of an exclusive field of knowledge, it is now thought that they have become overqualified for their roles and ‘over-educated’ distributors of medicines. ... [This led to the] political struggle to attain and maintain control and autonomy in a specific field and to protect territory in the labour market in order to secure higher income and more control over working conditions.” (Edmunds and Calnan 2001)(p944).

According to a *Medical Observer* survey more than half the GPs surveyed stated that a greater role for pharmacists in patient care was inappropriate (Light 2005a).

Despite the tension between the two professions, both doctors and pharmacists are important stakeholders in the Australia healthcare system (Rural Doctors Association of Australia 2006). It has been acknowledged that further emphasis on differences

between those who make up the healthcare team would only damage collective efforts to create a continually improving healthcare system whilst recognition, mutual respect, and an appreciation of the constant redefinition of boundaries among the two professions are the key to a healthy healthcare system (Royal College of Physicians 2005; Rural Doctors Association of Australia 2006).

IV. METHODOLOGY

The aim of the ADD Study is to compare the PBS prescribing habits of Australian DDs with non-DDs. However, the evaluation of the appropriateness of prescribing is a complex issue. As indicated above, international studies on the prescribing of DDs have mostly focused on costs and volume. The meta-analysis in Chapter II was limited by lower levels of good quality papers and was based across different healthcare systems. The purpose of this chapter is to outline the methodological approach utilised for the ADD Study, how this study intended to build on what was already known about the topic of doctor dispensing and to contextualise it into the Australia context. It presents the ADD Study protocol and the methodology for the first phase (quantitative) of the study. The methodology for the second phase (qualitative) of the study is presented in Chapter VI.

1. CHRONOLOGICAL SEQUENCE OF EVENTS

This study first started as a stakeholder study on Australian DDs (February 2003 to March 2004) funded by the Rural Alliance of Chief Executives (Lim, Gray, and Roach 2004). The report was subsequently used by the Australian College of Rural and Remote Medicine (ACRRM) and Rural Doctors Association of Australia (RDAA) in a joint submission to the Department during the Fourth Community Pharmacy Agreement between the Commonwealth Government and the Guild.

Subsequently a parliamentary paper was prepared (June to August 2005) for the Federal Minister for Health and Ageing in regard to the automatic disqualification of a DD's dispensing licence should a community pharmacy open up in a DD's catchment (Lim and Russell 2005).

Independently, one of the ADD Study investigators, Sunderland received a grant from the Guild in 2003 to conduct a comparative evaluation of pharmacy services in seven DD towns in WA (Sunderland et al. 2006; Sunderland, Burrows, and Joyce 2005).

Through the earlier studies, several key stakeholders were identified. They were:

- Medical practitioners and medical profession organisations
 - DDs
 - Non-DDs
 - Australian Medical Association
 - ACRRM
 - RDAA
 - Royal Australian College of General Practitioners (RACGP)
- Pharmacists and pharmacist profession organisations
 - Community pharmacists
 - Guild
 - Pharmaceutical Society of Australia
- Health services providers
 - Nurses
 - Hospital pharmacists
 - Other rural and remote primary healthcare providers
 - Health Department, State Governments
- Policy makers and advisory
 - Divisions of General Practice and other primary healthcare support organisations
 - National Prescribing Service (NPS)
 - Health Department, State Governments
 - Department of Health and Ageing, Commonwealth Government of Australia
- Consumers/ Patients

Unanimously, stakeholders identified the need for a better summative evaluation of DD's practices in Australia. Several research questions were identified which included:

- Who are the DDs?
- Are there any differences between the quality of DDs' prescribing and dispensing?
- How effective is the DD care model?
- What influences DDs' prescribing and dispensing?

- Where do DDs source their information?
- Why do DDs dispense?

Since November 2004 preliminary talks have been held with the Drug Utilisation Sub-Committee of the Pharmaceutical Benefits Advisory Committee in regard to technical feasibility in conducting such summative evaluation of DD practices.

The formal negotiation with the Department commenced in August 2006 with representatives from:

- Pharmaceutical Access and Quality Branch,
- Pharmaceutical Benefits Branch,
- Pharmaceutical Policy and Analysis Branch, and
- Legal, Privacy and Information Services Branch.

After a significant delay, consequent upon the change of Commonwealth Government in 2007, the final release of the aggregated de-identified data were secured in October 2008.

It was identified earlier that due to the political sensitivity of the research topic, funding from mainstream political lobbying organisations such as the Guild or Australian Medical Association would be inappropriate. Consequently the ADD Study was taken up as a student project. A research development grant was received from Primary Health Care Research, Evaluation and Development in 2007 for a period of 12 months. An Australian Postgraduate Award and a Curtin Research top-up Scholarship were also received for the study period January 2008 – April 2010. No other research funding was received for this study.

2. METHODOLOGICAL DILEMMA

As outlined in the background chapter (Chapter III), tension exists between pharmacist and doctor groups in Australia. It was understood at the onset of this ADD Study that findings from the study would not necessarily be welcomed by either group and would be subjected to extensive scrutiny, especially should the

findings not conform with expectations from either group. Consequently the methodology employed for the ADD Study would have to be credible, dependable and replicable. In addition, coupled with the technical difficulty and practicality of this study, the methodology framework proposed would have to be flexible and inclusive.

The research aim was clear but the research objectives to be addressed by the ADD Study would need to:

- Firstly, include the interests and concerns of the key stakeholder groups;
- Secondly, address the QUOROM statement (Moher et al. 2000) directly, especially with regards to transparency and acknowledge biases in its proposed methodology, since the systematic review above (Chapter II) revealed a lack of good SIGN quality papers;
- Thirdly, include different sources and types of information to adequately inform policy (Lavis 2009), since the ADD Study is fundamentally a legislative evaluation of the Commonwealth Government policy to allow doctors to dispense PBS pharmaceutical benefits; and
- Fourthly, be able to compare with overseas studies on DDs, with respect to the Australian data generated, as well as incorporate what has already been done on this topic in Australia.

There existed significant practical and technical difficulties with regard to the above considerations. For instance, stakeholder analysis may be the methodology of choice for analysing the interests and role of key players in a specific policy domain (Ranson and Bennett 2009), and can constitute broad groups: visible or hidden, active or passive, internal or external (Mehrizi, Ghasemzadeh, and Molas-Gallart 2009). However, stakeholder methods are often applied as a static framework and are unable to analyse changes in the policy process (Mehrizi, Ghasemzadeh, and Molas-Gallart 2009; Brugha and Varvasovszky 2000), and they are plagued by the time-dimension context (Brugha and Varvasovszky 2000; Ranson and Bennett 2009) and by stakeholder groups' self-interest (Hasman 2003; Ranson and Bennett 2009). DDs are a minor group in Australia, unrepresented by mainstream political lobbyists, and are often shunned by both pharmacists and non-DDs, mainly because of their

role in dispensing for profit. Should the ADD Study adopt a strict stakeholder methodology, the voices of DDs would mostly likely be silenced and arguably further marginalised.

Practically, a consent-driven quantitative comparative study between DDs and matched non-DDs is likely to result in a study beset by lower statistical power because of the low number of DDs practising in Australia, as well as the commonly known fact that doctors are notoriously difficult to collect survey data from: averaging only a 57.5% response rate despite various reinforcement strategies (Cook, Dickinson, and Eccles 2009; Converse et al. 2008). There also exists the highly probable selection bias of self-selecting DDs who are arguably better prescribers. Alternatively, a covert-type study methodology of recruiting participants but not informing them of the true purpose of the study, such as that utilised in the Zimbabwe study on DDs (Trap 2001; Trap and Hansen 2002a; Trap and Hansen 2002b; Trap, Hansen, and Hogerzeil 2002) is unlikely to be approved by any human research ethic committees in Australia.

Technically, the PBS and MBS data are managed by Medicare Australia. Release of data is subjected to strict secrecy⁷ and privacy⁸ legislative protection (Legal Privacy and Information Services Branch 2005). The request for Medicare data is subjected to lengthy administrative protocols and justification of public interest test:

- Will it support health professionals in their clinical practice?
- Will it support health care consumers to make more informed choices about their health care?
- Will it support stakeholders in the health industry to develop and monitor initiatives aimed at improving Australia's health?
- Will it support partnerships within the health sector?
- Will it support initiatives aimed at increasing the knowledge base of Australia's health sector, and sharing that knowledge within relevant parts of the sector? (Legal Privacy and Information Services Branch 2005).

⁷ *National Health Act 1935* (Cth) sections 135A and 135AAA.

⁸ *National Health Act 1935* (Cth) sections 135A and 135AA, *Health Insurance Act 1973* (Cth) section 130, *Privacy Act 1988* (Cth).

Additionally, the Department could often reject requests on the basis of “*insufficient resources to commit to your request at this time*” (Holman 2008). This in itself is not judicially reviewable under sections 24(1) and/or 41 of the *Freedom of Information Act 1982* (Cth).

Even if Medicare data are to be released, it is further subjected to what the Department or Medicare Australia can and choose to provide, and further subject to cost of data retrieval and administration.

Consequently it was identified early on, after stakeholder consultation, that any further project on DDs would need to be conducted as a student project. Being a student project, the methodology should ideally be relatively straight-forward and manageable within the usual three-year timeframe. Any findings from such proposed study would likely be heavily scrutinized because of their political implications, so that a popular methodology which is credible and easily understandable would need to be utilised. Also, rather than formulating new variables to be tested, consideration needs to be given to what has already been done so as to minimise the need to justify the variables chosen.

3. ADD STUDY PROTOCOL

To understand whether DD’s ability to dispense PBS pharmaceutical benefits relates to their prescribing, the ADD Study aims to answer the following research questions:

- What differences currently exist between the prescribing of DDs and non-DDs?
- How does dispensing impact on DDs prescribing?

The ADD Study elected to use sequential explanatory mixed methods (QUAN→qual) design. The QUAN→qual methodological design is relevant because of its straightforwardness and manageability, since data were only collected as needed and in two distinct phases (Creswell 2009; Tashakkori and Teddlie 1998). The QUAN→qual strategy offers opportunities for the exploration of the quantitative results in more detail through the qualitative phase, especially if unexpected results arise from the earlier quantitative study (Ivankova, Creswell, and Stick 2006;

Tashakkori and Teddlie 1998). The theoretical perspective for QUAN→qual can be implicit (Kushman 1992; Creswell 2009); this design can therefore provide more defensible understanding of findings, with stronger validity, credibility and less known bias (Caracelli and Greene 1993; Giacomini and Cook 2000). QUAN→qual design has previously been undertaken successfully in health and policy research (O'Cathain, Murphy, and Nicholl 2007; Zanberg and Berkowitz 2009; Warner 2009; Pearson and Godby 2009; Schattner et al. 2009; Stoller et al. 2009; Nastasi et al. 2007), and a mixed methods approach inherently lends itself to legislative research (Lim and Lewis 2009; Plano Clark 2009) and to studies of vulnerable population and health disparities (Stewart et al. 2008; Christ 2007; Hodgkin 2008; Moffatt et al. 2006). The purpose of employing QUAN→qual design for ADD Study is the desire to survey a large sample of individual DDs then follow-up with a few of them to obtain their specific language and voices about the topic. By collecting both closed-ended quantitative data and open-ended qualitative data, answers to the study's research question are capable of being generalised while also developing a detailed view of the meaning of the studied phenomenon (Creswell 2009). This approach also aims to minimize any potential researcher bias with the interpretation of findings. However, limitations of employing QUAN→qual design in the ADD Study are: firstly the heavy reliance and dependence on release of PBS data by the Department; secondly, the longer time duration required to complete the research; and thirdly, there is a possibility that the two methods might yield heterogeneous results.

During the study period, all the DDs in Australia were registered and practising as GPs hence for the purpose of the ADD Study, the term 'DD' was broadly defined as any GP who undertakes the role of dispensing PBS pharmaceutical benefits in situations that would normally be regarded as the practice of a community pharmacist.

There were two phases to the ADD Study. Phase I of the research consisted mainly of analysing quantitative data (PBS pharmaceutical benefits claimed data). Phase II of the research involved collecting and analysing qualitative data (interviews with DDs) which would help to explain and elaborate on the quantitative results obtained in the first phase. The second (qualitative) phase builds on the first (quantitative)

phase and the two phases are connected in both the intermediate stage and final stage of the study (see Figure 4.1).

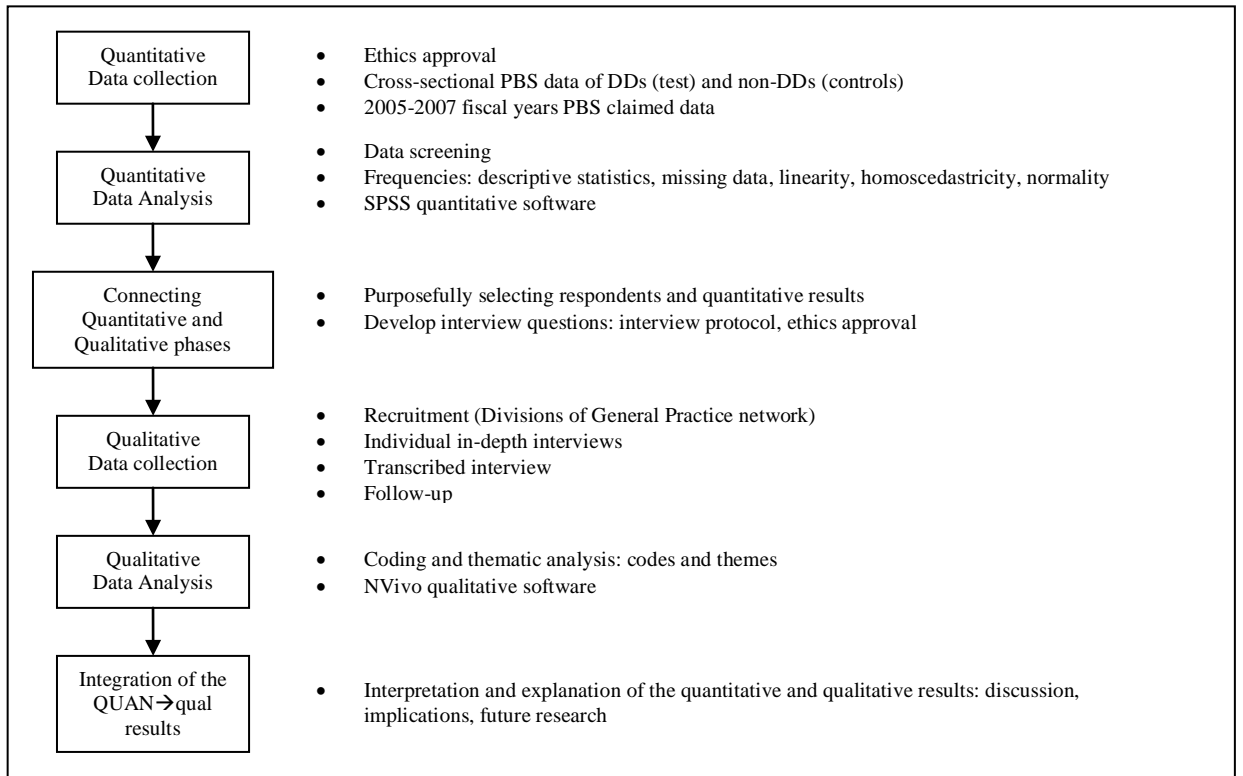


Figure 4.1: Visual model for sequential explanatory mixed methodology design procedure in the comparison of DDs' practices.

4. QUANTITATIVE METHODOLOGY

The first phase of the study, as reported here, comprised a retrospective drug utilisation study with an emphasis on evaluating aspects of prescribing standards. Ethics approval was obtained from the Curtin University Human Research Ethics Committee (HR 38/2007).

4.1. Data Source

An extract of PBS claims data for the index period 1 July 2005 to 30 June 2007 was used for this study. When a PBS-listed pharmaceutical benefit is dispensed and subsequently claimed for by the authorised pharmacist or DD from the Department, an electronic record is kept at the Department. Each claim represents an episode of supply of a PBS pharmaceutical benefit (a 'script').

The PBS claim data were extracted by the Department in accordance with the legislative secrecy and privacy provisions. Data were extracted using the unique individual prescriber number. The extracted data were de-identified by the Department so that reverse identification of any individual prescriber (doctor) was not possible. The de-identified data were then pooled by the Department into two categories: 'rural' (prescribers in RRMA 4 and 5) and 'remote' (prescribers in RRMA 6 and 7) before being released for subsequent analysis.

4.2. Statistical Analysis

Sample size was calculated by Power and Sample Size Calculator software (version 2.1.31, Vanderbilt University, Nashville, TN, USA) (Dupont and Plummer 1990). The primary outcome of the study was the number of PBS scripts per 1,000 patients. This was a census study of DDs who were in practice in the two fiscal years studied. Based on 72 DDs and 1,080 non-DDs, this study had a power of 100% to detect a 5% difference in the PBS prescribing data at a significance level of 0.010 (CI 99%). This calculation was based on two British studies which used administrative data from 59 DD practices vs. 49 non-DD practices (Baines, Tolley, and Whynes 1996; Morton-Jones and Pringle 1993b): mean difference of 1.23 - 1.80 (SD 0.42) items prescribed per patient.

Data were analysed using SPSS for Windows software (version 17.0). Syntax was utilised to manage the large dataset as described elsewhere (Kelman et al. 2007; Zhang et al. 2007). The normality of all the numerical variables was examined by normality test, histograms and normal $q-q$ plots, showing no severe skewness of these variables. The pre-determined outcome variables (indicators) were distilled

from the systematic review outlined above. For the comparison of differences between volume and other outcome variables, a Student's *t*-test was employed. The methodology and statistical approach employed for this study was consistent with overseas studies on DDs' prescribing (Lim et al. 2009). All results were reported as statistically significant at 0.010 levels.

4.3. Volume Indicators

The purpose of the quantitative phase of the ADD Study was not to focus on inventing new measures of evaluating DD practices but rather on incorporating overseas methodology to enable comparison. Therefore the volume indicators explored were:

- Number of individual patients per doctor (prescriber)
This was an indicator used in the Zimbabwe (Trap 2001) and UK studies (Dispensing Doctors' Association 2004; Tennant 2006b).
- Proportion of concessional and over-65 years old patients per doctor
These two indicators were used in the Zimbabwe (Trap 2001; Trap, Hansen, and Hogerzeil 2002) and UK studies (Morton-Jones and Pringle 1993a; Baines and Whyne 1997; Watkins et al. 2003).
- Number of PBS scripts per doctor
The script per doctor indicator was used in Zimbabwe (Trap, Hansen, and Hogerzeil 2002), Pakistan (Siddiqi et al. 2002; Nizami, Khan, and Bhutta 1996), Taiwan (Chou et al. 2003), UK (Ward 2004; Tennant 2006b; Morton-Jones and Pringle 1993a; Morton-Jones and Pringle 1993b; Whyne, Baines, and Tolley 1995; Wilcock 2001) and Australia studies (Sunderland, Burrows, and Joyce 2006; Sunderland, Burrows, and Joyce 2005).
- Number of PBS scripts per 1,000 patient
The scripts per patient indicator was used in Zimbabwe (Trap, Hansen, and Hogerzeil 2002) and UK studies (Morton-Jones and Pringle 1993b; Baines,

Tolley, and Whynes 1996; Wilcock 2001; Stewart-Brown et al. 1995; Ward 2003).

- Proportion of concessional scripts per 1,000 concessional patients
It was reported in the Zimbabwe (Trap 2001; Trap, Hansen, and Hogerzeil 2002) and UK studies (Morton-Jones and Pringle 1993a; Baines and Whynes 1997; Watkins et al. 2003) that concessional status was associated with higher volume of prescribing by DDs.
- Proportion of *Reg24* scripts
This unique Australian indicator was requested by the stakeholders during the consultation phase. *Reg24* is made pursuant to regulation 24 of the *National Health (Pharmaceutical Benefits) Regulations 1960* (Cth) whereby a prescriber may direct the supply on a single occasion the maximum quantity of a pharmaceutical benefit (original and all repeats) prescribed. These are counted as two scripts (one for the original script and one for all the repeat scripts) (Titulaer 2010). In the fiscal years studied, the number of authorised repeats varied from one to five, with most chronic medications having five repeats. Under the legislation, *Reg24* may only be authorised for: (i) treatment of chronic illness or where patients cannot gain reasonable access to a pharmacy; and (ii) great hardship in obtaining the required quantity.
- Proportion of proton pump inhibitors (PPIs) prescribed
This was a volume indicator used in South Korean (Lee and Malone 2003), South Africa (Truter, Wiseman, and Kotze 1995) and UK studies (Baines and Whynes 1997; Wilcock 2001).

4.4. Prescribing Indicators

The following prescribing indicators were used to compare DDs with non-DDs:

- Proportion of antibiotics prescribed per 1,000 scripts
A common indicator used in South African (Truter, Wiseman, and Kotze 1995), Zimbabwe (Trap and Hansen 2002b; Trap, Hansen, and Hogerzeil 2002),

Pakistan (Siddiqi et al. 2002; Nizami, Khan, and Bhutta 1996), South Korean (Park et al. 2005) and UK studies (Whynes, Baines, and Tolley 1995). A lower prescription rate of antibiotics is indicative of better quality use of medicines.

- Proportion of penicillins and cephalosporins prescribed per 1,000 scripts
The appropriateness of antibiotic prescribing was reported in both Zimbabwe (Trap and Hansen 2002a; Trap and Hansen 2002b) and South Korean studies (Park et al. 2005).
- Proportion of analgesics per 1,000 scripts
This indicator was used in South African studies (Truter, Wiseman, and Kotze 1995; Truter and Kotze 1996).
- Drug classes which are commonly implicated in medication adverse effects
A number of potential adverse drug events indicators were explored in relation to the appropriateness and the prevention of adverse events since a factor often raised in the debate over doctor dispensing is the importance of the secondary check by a pharmacist. The increased use of the following drug classes had been reported to be associated with high rate of medication misadventure:
 - Cardiovascular drugs (Wester et al. 2008; Australian Journal of Pharmacy 2007a; Pirmohamed et al. 2004; Zhang et al. 2007; Trewin et al. 1996; Roughead, Barratt, and Gilbert 2004; O'Halloran et al. 2003; Howard et al. 2007; Preen et al. 2008; Jenkins 2008; Truter, Wiseman, and Kotze 1995),
 - Hypoglycaemic agents (Australian Journal of Pharmacy 2007a; Brvar et al. 2009),
 - Antidepressants (Wester et al. 2008; Australian Journal of Pharmacy 2007a; Jenkins 2008),
 - Analgesics (Wester et al. 2008; Australian Journal of Pharmacy 2007a; Pirmohamed et al. 2004; Zhang et al. 2007; Robertson et al. 2002; Howard et al. 2007; Jenkins 2008; Truter, Wiseman, and Kotze 1995; Pearson et al. 2009; Brvar et al. 2009; Dowden 2009),

- Respiratory drugs (Roughead, Barratt, and Gilbert 2004; Trewin et al. 1996; Whynes, Baines, and Tolley 1995; National Prescribing Services Ltd 2006; Robertson 2009; Robertson et al. 2002),
- Fluoroquinolone antibiotics (Adverse Drug Reactions Advisory Committee 2008; Robertson 2009).

The next chapter (Chapter V) will present the results of the quantitative phase of the study.

V. QUANTITATIVE

This chapter presents the quantitative findings from the analysis of PBS claims data for the 2005-7 fiscal years.

1. PATIENT DATA

The data reported are for dispensed prescriptions from rurality-matched 72 DDs and 1,080 non-DDs that were submitted to the PBS for payment. Each item represents a dispensing occasion of an original or repeat prescription. The mean (\pm SD) data for patients per doctor and prescription items dispensed are presented in Table 5.1.

DDs prescribed to significantly fewer patients than non-DDs' (1,137 vs. 1,718, $p = 0.000$). The most tenable explanation is that there were smaller patient populations in DDs' areas than non-DDs. However, the proportions of concessional patients and patients aged over 65 years old were similar between DDs and non-DDs (concessional: 711 vs. 680, $p = 0.076$; >65yo: 285 vs. 293, $p = 0.597$).

2. VOLUME INDICATORS

In general, DDs prescribed fewer PBS items per doctor than non-DDs (aggregate: 11,691 vs. 24,888, $p = 0.000$; rural: 11,338 vs. 26,147, $p = 0.002$). However, it was noted that a statistically non-significance different occurred between DDs and non-DDs in the remote cohort (12,045 vs. 23,629, $p = 0.014$).

The fewer PBS scripts per doctor can be partially explained by the lower number of individual patients per doctor at DDs' sites (aggregate: 1,137 vs. 1,718, $p = 0.000$; rural: 1,180 vs. 1,775, $p = 0.000$; remote: 1,094 vs. 1,662, $p = 0.000$).

However, DDs also generally prescribed proportionally fewer PBS items per 1,000 patients than non-DDs (aggregate: 9,452 vs. 15,057, $p = 0.003$; remote: 11,072 vs. 15,233, $p = 0.008$). Statistically a non-significant difference was noted in the rural

cohort (7,832 vs. 14,882, $p = 0.048$) due to the wide standard deviation among the rural DDs population (6,534 vs. 3,076).

There were generally no statistically significant differences in the prescribing of PBS concessional items per 1,000 concessional patients between DDs and non-DDs (aggregate: 10,939 vs. 16,190, $p = 0.111$; remote: 7,077 vs. 12,983, $p = 0.194$). A statistically significant difference in the rural cohort was noted, with rural DDs prescribing fewer concessional scripts per 1,000 concessional patients (14,801 [SD 1,069] vs. 19,398 [SD 230], $p = 0.005$).

These results are likely to be influenced by *Reg24* use. In the current study, DDs generally prescribed significantly more *Reg24* PBS scripts per 1,000 scripts than non-DDs (aggregate: 314 vs. 67, $p = 0.008$; rural: 546 vs. 66, $p = 0.001$). The findings are likely to be influenced by the substantial wide standard deviation in the pooled (265 vs. 4) and rural (148 vs. 3) cohorts. The increased *Reg24* use was not statistically significant in the remote cohort (81 vs. 67, $p = 0.563$) probably due to the somewhat narrower standard deviation among remote DDs population (54 vs. 4) as compared to the other cohorts.

An arbitrary correction factor of four (maximum variation) was applied to the DDs' data and the amended findings, as presented in Table 5.2, indicated that in general DDs prescribed similar number of items per doctor, but probably more scripts more scripts per 1,000 patients, and more concessional scripts per 1,000 concessional patients. The latter findings were not echoed in the remote cohort.

3. PRESCRIBING INDICATORS

Table 5.3 summarises the prescribing indicators used in this study. For the drug classes which were reportedly associated with more frequent errors in medication safety, there were no statistically differences observed between DDs and non-DDs prescribing of:

- cardiovascular drugs: β -blockers, antithrombotic agents, cardiac glycosides (digoxin), HMG Co-A reductase inhibitors (statins), and frusemide diuretics,
- hypoglycaemic agents: insulin and oral anti-diabetics agents,

- antidepressants,
- opiate analgesics,
- glucocorticoid inhalants,
- theophylline,
- fluoroquinolone type antibiotics, or
- PPIs.

DDs tended to prescribe statistically significantly more non-steroidal anti-inflammatory drugs (NSAIDs) (aggregate: 45.41 vs. 39.08 items per 1,000 scripts, $p = 0.001$) despite no statistical significant differences being observed in either of the rural (46.14 vs. 37.50 items per 1,000 scripts, $p = 0.076$) or remote (44.88 vs. 40.52 items per 1,000 scripts, $p = 0.185$) cohorts.

DDs in general prescribed more adrenergic inhalants than non-DDs (aggregate: 44.36 vs. 40.44 items per 1,000 scripts, $p = 0.010$; rural: 44.22 vs. 37.69, $p = 0.001$). There was no statistical significant difference noted in the remote cohort (45.00 vs. 42.96 items per 1,000 scripts, $p = 0.500$).

In terms of antibiotic prescribing, the overall antibiotics prescribing appeared comparable with the exception that DDs prescribed more penicillin-type antibiotics than non-DDs (aggregate: 33.39 vs. 23.47 items per 1,000 scripts, $p = 0.000$; rural: 31.64 vs. 22.09, $p = 0.002$; remote: 35.66 vs. 24.72, $p = 0.000$).

The current study was unable to apply any meaningful correction to the above prescribing indicators to correct for the higher *Reg24* use among some DDs reported earlier. Nevertheless, the antibiotic variables were considered less likely to be influenced by *Reg24* and there was no substantial difference between DDs and non-DDs. Overall the remote data were also less likely to be influenced by differences in *Reg24*.

	<i>Aggregate</i>				<i>Rural</i>				<i>Remote</i>			
	DD	Non-DD	Diff	P	DD	Non-DD	Diff	P	DD	Non-DD	Diff	P
Patients per doctor	1 137 (143)	1 718 (72)	-581 (-664, -498)	0.000*	1 180 (171)	1 775 (41)	-595 (-739, -451)	0.000*	1 094 (103)	1 662 (46)	-568 (-656, -479)	0.000*
Concessional patients per 1,000 patients	711 (41)	680 (39)	30 (-3, 64)	0.076	711 (28)	679 (30)	32 (-6, 69)	0.087	711 (54)	682 (50)	29 (-37, 96)	0.351
>65yo patients per 1,000 patients	285 (48)	293 (23)	-8 (-41, 24)	0.597	301 (31)	308 (16)	-7 (-40, 24)	0.664	270 (59)	280 (21)	-10 (-72, 52)	0.707
Scripts per doctor	11 691 (5757)	24 888 (6603)	-13 197 (-18 447, -7 946)	0.000*	11 338 (4945)	26 147 (7105)	-14809 (-22 814, -6 803)	0.002*	12 045 (6 940)	23 629 (6 453)	-11 584 (-20 210, -29 58)	0.014
Scripts per 1,000 patients	9 452 (4863)	15 057 (2669)	-5605 (-8 983, -2 227)	0.003*	7832 (6 534)	14882 (3 076)	-7 050 (-14 000, 101)	0.048	11 072 (1 747)	15 233 (2 478)	-4160 (-6961, -1360)	0.008*
Concessional scripts per 1,000 concessional patients	10 939 (5334)	16 190 (3706)	-5 251 (-11 940, 1 438)	0.111	14 801 (1069)	19 398 (230)	-4597 (-6 840, -2 354)	0.005*	7 077 (5 047)	12 983 (161)	-5 905 (-16 416, 4 605)	0.194
<i>Reg24</i> per 1,000 scripts	314 (265)	67 (4)	247 (79, 415)	0.008*	546 (148)	66 (3)	480 (325, 636)	0.001*	81 (54)	67 (4)	14 (-43, 71)	0.563

Table 5.1: PBS patients and scripts data (means) between DDs and non-DDs. The asterisk (“*”) denotes statistically significant ($p \leq 0.010$).

	<i>Aggregate</i>		<i>Rural</i>		<i>Remote</i>	
	DD	Non-DD	DD	Non-DD	DD	Non-DD
Scripts per doctor	26 375	31 558	36 100	33 050	15 948	29 962
Scripts per 1,000 patients	21 324	19 092	24 937	18 811	14 659	19 315
Concessional scripts per 1,000 concessional patients	24 678	20 529	47 126	24 519	9 370	16 462

Table 5.2: Amended patients and scripts data after arbitrary adjustment for *Reg24*.

	Aggregate				Rural				Remote			
	DD	Non-DD	Diff	P	DD	Non-DD	Diff	P	DD	Non-DD	Diff	P
Cardiovascular drugs:	35.34 (3.12)	35.05 (0.52)	0.29 (-2.07, 2.65)	0.799	34.23 (4.75)	35.00 (0.35)	-0.77 (-1.07, 9.14)	0.839	36.31 (1.16)	35.10 (0.74)	1.21 (-0.48, 2.90)	0.130
• β -blockers												
• Antithrombotic agents	32.65 (2.44)	34.53 (2.24)	-1.88 (-4.15, 0.39)	0.099	32.68 (1.50)	36.24 (1.64)	-3.56 (-7.25, 0.13)	0.055	32.26 (4.03)	32.97 (1.84)	-0.71 (-6.13, 4.71)	0.760
• Digoxin	2.41 (0.24)	2.62 (0.32)	-0.21 (-0.47, 0.06)	0.115	2.36 (0.30)	2.77 (0.11)	-0.41 (-1.05, 0.23)	0.149	2.50 (0.16)	2.48 (0.43)	0.02 (-0.54, 0.58)	0.931
• Statins	111.51 (13.94)	108.58 (9.74)	2.92 (-9.04, 1.49)	0.614	104.02 (10.92)	100.31 (4.04)	3.70 (-1.96, 2.70)	0.681	121.59 (16.73)	116.15 (7.51)	5.45 (-1.70, 2.79)	0.574
• Frusemide	8.29 (0.62)	8.32 (1.04)	-0.04 (-0.81, 0.74)	0.924	8.27 (0.44)	8.65 (0.02)	-0.38 (-1.29, 0.53)	0.307	8.28 (0.94)	8.02 (1.51)	0.26 (-1.92, 2.44)	0.783
Hypoglycaemic agents:	3.45 (1.45)	3.58 (0.66)	-0.14 (-1.29, 1.02)	0.807	2.81 (1.00)	2.96 (0.19)	-0.15 (-2.26, 1.96)	0.857	4.39 (1.97)	4.15 (0.35)	0.24 (-2.20, 2.69)	0.818
• Insulin												
• Oral anti-diabetics agents	34.24 (5.40)	31.88 (3.55)	2.36 (-2.21, 0.69)	0.293	31.31 (7.51)	28.55 (1.27)	2.76 (-1.30, 1.85)	0.652	37.15 (3.76)	34.92 (1.91)	2.24 (-2.92, 0.74)	0.330
Antidepressants	64.43 (8.84)	69.10 (6.29)	-4.68 (-1.23, 0.29)	0.214	59.53 (7.16)	66.85 (0.35)	-7.32 (-2.22, 0.76)	0.245	71.32 (9.91)	71.17 (8.98)	0.16 (-1.62, 1.65)	0.982
Analgesics:	45.41 (3.78)	39.08 (3.37)	6.33 (2.85, 9.81)	0.001*	46.14 (4.62)	37.50 (2.58)	8.65 (-1.46, 0.19)	0.076	44.88 (4.18)	40.52 (4.05)	4.36 (-2.70, 0.11)	0.185
• NSAIDs												
• Opiates	45.32 (8.45)	41.12 (2.36)	4.20 (-2.29, 0.11)	0.191	52.50 (8.00)	43.14 (2.03)	9.35 (-7.39, 0.26)	0.196	36.30 (2.00)	39.27 (1.07)	-2.97 (-5.74, -0.19)	0.040
Respiratory drugs:	44.36 (3.09)	40.44 (2.79)	3.91 (1.06, 6.77)	0.010*	44.22 (0.70)	37.69 (0.93)	6.53 (4.69, 8.36)	0.001*	45.00 (5.61)	42.96 (0.79)	2.03 (-4.90, 8.96)	0.500
• Adrenergic inhalant												
• Glucocorticoid inhalant	15.88 (1.51)	16.20 (0.80)	-0.32 (-1.55, 0.91)	0.591	16.15 (0.24)	15.68 (0.44)	0.47 (-0.26, 1.20)	0.149	15.71 (2.76)	16.67 (0.88)	-0.96 (-4.51, 2.59)	0.533
• Theophylline	1.80 (0.59)	1.34 (0.33)	0.47 (-0.02, 0.95)	0.060	1.78 (0.47)	1.09 (0.04)	0.69 (-0.30, 1.68)	0.123	1.86 (0.86)	1.57 (0.33)	0.30 (-0.83, 1.43)	0.542
Antibiotics:	67.22 (13.06)	58.05 (1.35)	9.16 (-0.66, 18.98)	0.066	69.48 (16.14)	58.86 (1.27)	10.62 (-23.03, 44.27)	0.430	64.56 (12.03)	57.31 (1.29)	7.24 (-7.56, 22.05)	0.276
• Total												
• Fluoroquinolones	1.53 (0.43)	1.58 (0.28)	-0.05 (-0.41, 0.31)	0.770	1.35 (0.41)	1.43 (0.01)	0.08 (-0.94, 0.78)	0.819	1.81 (0.46)	1.73 (0.36)	0.08 (-0.63, 0.79)	0.794
• Penicillins	33.39 (2.25)	23.47 (1.56)	9.93 (8.00, 11.86)	0.000*	31.64 (1.79)	22.09 (0.58)	9.54 (5.75, 13.33)	0.002*	35.66 (1.49)	24.72 (1.12)	10.94 (8.67, 13.22)	0.000*
• Cephalosporins	15.32 (3.85)	13.06 (1.82)	2.27 (-0.82, 5.35)	0.140	18.61 (2.13)	14.67 (0.15)	3.94 (-0.50, 8.39)	0.069	10.86 (2.40)	11.58 (1.40)	-0.72 (-4.16, 2.71)	0.624
PPIs	93.43 (5.96)	87.38 (2.61)	6.05 (1.31, 10.78)	0.015	90.19 (4.40)	86.49 (2.09)	3.70 (-5.80, 13.19)	0.341	98.05 (7.06)	88.19 (3.32)	9.86 (0.31, 19.40)	0.045

Table 5.3: Prescribing indicators (per 1,000 scripts) between DDs and non-DDs. The asterisk (“*”) denotes statistically significant ($p \leq 0.010$).

4. SENSITIVITY ANALYSIS

Table 5.4 summarises the sensitivity analysis conducted to compare the main volume indicators across the two fiscal years so as to ensure the validity of the PBS data provided by the Department. There were no significant statistical differences observed between the fiscal years studied.

	2005-6	2006-7	Diff	P
Patients per doctor	1 175 (845)	1 117 (734)	-57 (-1 350, 1 235)	0.894
Concessional patients per 1,000 patients	691 (9)	698 (8)	8 (-24, 39)	0.331
>65yo patients per 1,000 patients	282 (21)	296 (21)	14 (-42, 69)	0.911
Scripts per doctor	17 371 (12 004)	18 072 (12 539)	701 (-23 161, 21 759)	0.923
Scripts per 1,000 patients	18 185 (2 585)	18 357 (3 234)	173 (-29 229, 28 884)	0.958
Concessional scripts per 1,000 concessional patients	13 957 (4 644)	14 069 (4 775)	112 (-17 596, 17 819)	0.978
<i>Reg24</i> per 1,000 scripts	193.44 (230.43)	199.73 (226.66)	6.29 (-287.92, 300.50)	0.952

Table 5.4: Sensitivity analysis of the PBS data by fiscal years.

Table 5.5 summarises the comparison between ADD Study data and Pharmaceutical Benefits Pricing Authority (PBPA) summary for the 2005-6 fiscal year based on the top five commonest drug classes (Pharmaceutical Benefits Pricing Authority 2006). With the exception of lower antibiotics use identified in this study, there does not appear to be much dissimilarity between the two data sources. Statistical

comparisons between the PBPA and these data are not possible since PBPA data are provided as actual number without interquartile ranges or confidential intervals.

Drug class	ADD Study (%)	PBPA (%)
Statins	10.399	10.317
PPIs	8.991	8.127
Antibiotics	4.922	6.717
Anti-diabetes agents	3.633	3.272
Anti-thrombotic agents	3.305	3.268

Table 5.5: Comparison of the ADD Study PBS data against Pharmaceutical Benefits Pricing Authority (PBPA) data for the 2005-6 fiscal year.

5. DISCUSSION

In this innovative study on Australian DDs, DDs prescribed to fewer individual patients than non-DDs, and consequently there were fewer PBS scripts per doctor. The study findings are at variance with international data, where DDs were found to prescribe at higher rates. The data were potentially biased by a higher *Reg24* use among DDs. In this study accurate correction factor to the script-denominator could not be applied due to the data format that was made available from the Department. Correction for *Reg24* was not routinely performed by the Department due to the low frequency of its use nationally (Titulaer 2010). Nevertheless, when the most stringent correction for *Reg24* to the script-denominator was applied, it was found that marginally higher rates of prescribing by DDs could have occurred in the rural cohort. The wider standard deviation observed among the rural DD cohort suggested that some DDs used *Reg24* more frequently than other DDs. Therefore, the actual prescribing rates may lie somewhere between those presented in Tables 5.1 and 5.2.

In this study, DDs had a smaller patient population as compared to those of their non-dispensing peers. With the similar proportion of concessional and over 65 years old patients, DDs may have fewer non-concessional (general category) patients per doctor than their rurality-matched non-dispensing peers. It was reported previously

in the survey of seven WA DDs' towns that 21.2% of respondents "never" attend their local DD's medical practice (Sunderland, Burrows, and Joyce 2005)(p55). In the same report, a significant proportion of spillage from DDs to pharmacists' towns for their scripts to be filled was also noted (11.5% - 59.3%). Therefore, a plausible explanation could be that non-concessional patients are more mobile and travel to larger regional towns for both their medical and pharmaceutical care. This in turn may explain the increased *Reg24* use among the DD cohorts: DDs' patients have less ability to travel hence this justified the use of *Reg24*.

The data captured and subsequently analysed above were based solely on PBS pharmaceuticals that were dispensed; they therefore do not include doctors' prescriptions that were supplied to patients but which patients had opted not to fill at either a community pharmacy or a DDs' dispensary. Hence PBS claimed data are more accurately a measure of community drug utilisation and exposure rather than a prescriber's prescribing frequency. Nevertheless, a pilot study conducted of 25 GPs in rural WA, which compared a selected number of respiratory pharmaceutical items prescribed but not dispensed found, a spillage rate of some 5-10% (Lim and Rowett 2006); this suggests that analysis of PBS utilisation data may have higher correlation to prescribing rates in country Australia than one might have otherwise expected.

The PBS datasets do not capture the indication/s for use (Robertson et al. 2002; Legal Privacy and Information Services Branch 2005; Kelman et al. 2007) and the data were based on claims made against the PBS. Therefore data for prescriptions that was for less than the cost of stipulated co-payments may not have been captured. This is especially an issue for the NSAID and antibiotic prescribing indicators since the majority of the antibiotic classes investigated fell below the general co-payment threshold (2005: AUD\$28.60; 2006: AUD\$29.50). An earlier study by NPS claimed that only 56% of community antibiotics usage were successfully captured through the PBS (Wutzke et al. 2006). Nevertheless, those prescribed to in the concessional category should be fully captured (2005: AUD\$4.60; 2006: AUD\$4.70).

Similarly there was a potential bias in relation to capture of adrenergic inhalants data. In Australia, short-acting β_2 -adrenergic salbutamol inhalants can be dispensed by community pharmacists over the counter as a pharmacist-only medication (S3)

without the need for a doctor's prescription therefore this is not captured by PBS. Alternatively, the doctors might prescribe the salbutamol inhalants as a PBS subsidised pharmaceutical benefit and the data is captured by the PBS. There are differences between the dispensing of a salbutamol inhalant as a S3 medication or as a PBS pharmaceutical benefit. For instance, in some states of Australia, DDs are not allowed to dispense over-the-counter medications and therefore DDs can only prescribe and dispense under the PBS. This could potentially lead to bias and overestimation of rates of adrenergic inhalants and NSAIDs use by DDs as observed in this study.

Despite limitations with administrative datasets, PBS claimed data remain an important source of information on drug utilisation since approximately 86% of all community pharmaceutical prescriptions in Australia are dispensed under this scheme (Wutzke et al. 2006). Analyses of PBS datasets are used widely to evaluate trends and patterns of pharmaceutical use (Horn et al. 2006; Mandryk et al. 2006; Wutzke et al. 2006; Robertson et al. 2002; Lu, Williams, and O'Day 2006; Lynd et al. 2002; Ampon et al. 2009) and as a basis for pharmacoeconomic analysis (Edmonds et al. 1993). For the ADD Study the number of rurality-matched controls (non-DDs) was intentionally increased so as to enhance this study's precision (Dhaliwal and Campbell 2010). This was opted for as a trade-off against the inherent limitations with the PBS dataset. No formal adjustment for statistical multiple testing was conducted since the predicted variables were pre-determined (that is informed by systematic review and stakeholder consultations). Therefore the current study was performing multiple tests of specific hypotheses (performing single test of multiple hypotheses as compared to performing multiple tests of a single hypothesis) (Saville 2003; Bender and Lange 2001; Strug and Hodge 2006; Perneger 1998; Bland and Altman 1995; Rothman 1990). Methods to adjust for multiple testing may not further assist validity of the statistical inference. This statistical approach was consistent with overseas studies on DDs (Lim et al. 2009).

The PBS administrative data for the 2005 to 2007 fiscal years were chosen for three reasons. Firstly, at the time of negotiation for release of data, these two fiscal years represented the most comprehensive data that was available at that time. Secondly, the investigator was made aware that in the subsequent 2007-8 fiscal year; at least

four DDs in WA had lost their PBS dispensing licence because of a new pharmacy opening up in the respective DD's catchment, whereas between 2005 and 2007 there had been no change in the actual DD numbers. Thirdly, the 2004-5 fiscal year data were not included as it is highly probable that the substantive 24% increase in patient co-payments in 2004 could have influenced PBS usage in that fiscal year (Hynd 2008; Hynd et al. 2008; Hynd et al. 2009). Furthermore, sensitivity analyses of this study's PBS data did not reveal substantive differences across the fiscal years under study or when measured against similar administrative data source.

The current study did not find substantive differences in many aspects of prescribing between DDs and non-DDs. This is in contrast to the systematic review which was based on overseas DDs who practised in somewhat different healthcare systems than is Australia. However, further study into this topic is warranted to test the validity of these preliminary findings and explore factors that might explain the variability observed in some of the volume and prescribing indicators between the rural and remote cohorts.

VI. CONNECTING THE QUANTITATIVE AND QUALITATIVE METHODS

By virtue of the mixed methods definition, the integration⁹ of quantitative and qualitative methodology is a vital part of mixing the methods (Bazeley 2009; Creswell 2009; Bryman 2007; Teddlie and Yu 2007; Ivankova, Creswell, and Stick 2006; Teddlie and Tashakkori 2009; Lingard, Albert, and Levinson 2008). Integration between quantitative and qualitative methods may entail selection of statistically significant (and non-significant) results (Ivankova, Creswell, and Stick 2006; Creswell and Plano Clark 2009), development of interview question to focus on the significant (and non-significant) predictors (Creswell 2009), and/or selection of participants (Creswell 2009). In this chapter, the qualitative methodology of the ADD study is presented.

1. SELECTION OF QUANTITATIVE RESULTS FOR INTERVIEW QUESTIONS

1.1. Accuracy of PBS Data

There are inherent limitations with PBS administrative data, explanations offered by DDs would provide in-depth understanding of why and what influences their prescribing.

The PBS data provided for the ADD Study were extracted and pooled into rural and remote. Pooling of PBS data may decrease the sensitivity of analysis to detect small area variations such as differing levels of morbidity and access to services, and may disguise real differences e.g. between GP practices in coastal centres and inland rural towns (McGrail and Humphreys 2009b; Ferguson 2009) or if the GP is procedural or non-procedural (Ferguson 2009). However, the analysis of data aggregated at the national level is a compromise: the coarser the level of analysis the less an individual doctor's prescribing habits affect the overall picture (Wilcock 2001, 2002, 2003; Wilcock and Mackenzie 2000). It was a fundamental assumption that patient demography would be similar in the same RRMA classification. The original ADD

⁹ The word "integration" is used generically rather than semantically as proposed by (Mason 2009).

Study protocol submitted to the Department for ethics and research considerations had initially asked for the DDs to be matched based on the ARIA which is arguably more sensitive because the ARIA takes account of availability of services in addition to patient population. An assumption is that DDs' towns are more isolated and have less access to essential services, and consequently more reliance on DDs' services. This might explain the increased use of *Reg24* by DDs. Other explanations may exist and need to be explored.

1.2. Disease State Management

There were no statistically significant differences observed across many of the prescribing indicators. The qualitative interview would provide an understanding from DDs where they sourced their knowledge of pharmaceuticals and pharmacotherapeutics, as well as unique factors that might influence their prescribing habits.

1.3. Why Dispense

A key consideration for incorporating the qualitative phase to the ADD Study was to ascertain why DDs choose to dispense. There are strict administrative requirements for seeking the PBS dispensing licence by a medical practitioner, and there are also onerous administrative reporting requirements for making claims against the PBS. It is of interest to the stakeholders why DDs have taken on this additional role, what motivates them and what enablers and barriers there are to doctor dispensing.

1.4. Summary

The quantitative variables which would be explored in more details through the qualitative phase of the ADD Study are as follows:

- How does the DD perceive his/her prescribing volume as compared to their non-dispensing peers?
 - Scripts per doctor: 11,691 vs. 24,888
 - Scripts per 1,000 patients: 9,452 vs. 15,057
 - Patients per doctor: 1,137 vs. 1,718

- Why is there large variability in the rate of *Reg24* use? When does a DD use *Reg24*?
 - *Reg24* per 1,000 scripts: 314 vs. 67
 - Standard deviation of *Reg24*: 265 vs. 4

- What influences a DD's prescribing? Where or how does the DD source information?
 - NSAIDs per 1,000 scripts: 45.41 vs. 39.08
 - Adrenergic inhalants per 1,000 scripts: 44.6 vs. 40.44
 - Penicillin type antibiotics per 1,000 scripts 33.39 vs. 23.47
 - See also other non-statistically significant prescribing indicators in Table 5.3.

- Why does a DD dispense?

- What barriers and enablers are there to doctor dispensing?

2. QUALITATIVE METHODOLOGY

For this second phase of the ADD Study, separate ethics approval was granted by Curtin University Human Research Ethics Committee (SPH-0048-2008).

2.1. Study Design

An iterative, qualitative descriptive methodology as described elsewhere by Sandelowski (2000) was utilised. The strength of qualitative methodology is that it provides thick description and understanding of complex human phenomena especially where subjectivity is involved and flexibility is required (Speziale and Carpenter 2003; Miles and Huberman 1994; Gobo 2005; Caelli, Ray, and Mill 2003). Qualitative research techniques are increasingly advocated for research on and in general practice (Chew-Graham, May, and Perry 2002; Jacoby, Smith, and Eccles 2003; Jaye and Tilyard 2002; Watkins et al. 2003; Meyer 2000; Frederiksen, Kragstrup, and Dehlholm-Lambertsen 2009). A further benefit of using a qualitative

descriptive study design is that it stays close to the data and to the surface of words and events, thereby producing a complete and valued end-point in itself, rather than serving as an entry point to further qualitative research (Sandelowski 2000; Caelli, Ray, and Mill 2003).

2.2. *Sampling*

The aim of sampling in quantitative methodology is to achieve representativeness whilst in qualitative methodology this involves saturation of information (Coyne 1997; Teddlie and Yu 2007). In mixed methods, researchers combine both quantitative and qualitative sampling in order to generate complementary databases that include information that have both depth and breadth regarding the phenomenon under study (Teddlie and Yu 2007).

In a QUAN→qual design, the qualitative phase involves using a subsample of the quantitative sample (Teddlie and Yu 2007). Therefore the sampling of respondents for the qualitative phase was drawn from DDs who had dispensed in the 2005-7 fiscal years. This may potentially restrict the number of respondents one can recruit for the ADD Study but it remains the aim of the qualitative phase to achieve both saturation¹⁰ of information and equal representativeness of respondents.

Interviews were conducted with a purposive sample of DDs. Maximum variation sampling was utilised to include:

- all states of Australia;
- practices that are classified as 'rural' (RRMA 4 and 5) and 'remote' (RRMA 6 and 7);
- male and female;
- current and past DDs who had dispensed in 2005-7 fiscal years; and
- DDs who obtained their medical qualification in Australia or overseas (IMGs).

Currently all Australian DDs specialised as GPs through the RACGP or ACRRM pathways. The DD-respondents were recruited through Divisions of General

¹⁰ Defined as when no new theme emerged from respondents who were interviewed late in the sequence.

Practice network and the RACGP. Please refer to Appendices C and D for the letter of invite and information sheet.

Doctors are notoriously hard to recruit for research (Cook, Dickinson, and Eccles 2009). The respondents who participated in this research were awarded 40 Category 1 points under the RACGP Quality Assurance and Continuous Professional Development (CPD) Scheme for reviewing their own prescribing practices. This activity was audited by the RACGP in 2009. No financial or other incentives were offered to the respondents for participation in this study.

2.3. *Data Collection*

Data were collected through in-depth interviews with DD-respondents. The interview was open-ended and informed by the quantitative findings.

Written fax-back consent was received from the respondents before the interview was scheduled. Before each interview was audiotaped, further verbal consent was sought from the respondents. The respondents were assured they could withdraw from the study at any time without penalty and that confidentiality of information would be maintained.

After each interview, the audiotaped conversation was transcribed verbatim on the Microsoft Word program within 24 hours, following which the language text was imported into NVivo software (version 8) for data management.

A mixture of face-to-face interviews and telephone interviews was conducted to capture the data. The use of telephone interviews was a practical solution as the respondents were geographically dispersed. Recent evidence has indicated that telephone interview is a productive and valid methodological tool (Holt 2010): it enables a greater degree of control for the participants and is ideal for busy participants.

Interviews with respondents were conducted between August 2009 and February 2010, at a date and time of the respondent's choice. In total, 25 formal interviews

were conducted with the 20 respondents. Saturation of data was reached. Ten face-to-face interviews were held at the DDs' medical practice and lasted 45 - 60 minutes. Fifteen interviews were conducted by phone and averaged 30 minutes; these included five subsequent formal follow-up interviews after the initial face-to-face contact. Once the preliminary analysis process was completed, a draft outline of the results was made available to the respondents for respondent validation. The respondents were offered an opportunity to make further comments; four respondents provided minor clarification and all feedback was incorporated into the final interpretation of the results. Two other respondents who were not interviewed due to data saturation were also sent analyses of qualitative findings for validation.

2.4. *Data Analysis*

Data collection, coding and analysis were conducted concurrently throughout the stages of the study. Content analysis guided the interpretation of data. A combination of processes using qualitative content analysis (Sandelowski 2000; Miles and Huberman 1994) and constant comparison (Strauss and Corbin 1990; Glaser and Strauss 1967) were utilised to analyse the interview transcript thematically.

Qualitative data analysis is data-driven and yet dynamic, as it allows researchers to continuously modify their treatment of data to accommodate new data and new insights about those data (Sandelowski 2000; Patton 1990; Pope, Ziebland, and Mays 2000; Sivesind 1999; Bazeley 2007). Differences and commonalities among sub-groups of the respondents were noted. Data saturation was considered to have been reached when the information began to be repetitive.

Qualitative content analysis firstly involved familiarisation of the data through reading of transcripts. Open coding of the transcript gave each discreet phrase a name that represented the phenomenon under study. This allowed the data to be examined closely with emphasis on detail. The data were examined phrase by phrase to ascertain codes (free nodes) that described the meaning of what was occurring in the data. The code words were often the very words or phrase used by the respondent. Phrases and sentences within the data were given multiple codes if they

were identified as describing more than one meaning. Many free nodes were subsumed into broader code words of higher conceptual level (tree nodes) as concurrent analysis of further data supported or modified the number of the codes.

Secondly, the fractured data were put together in a ways that allowed connection to be made between categories and their sub-categories. This involved displaying the preliminary analyses in a matrix, whereby every respondent is allocated a row and each column denotes a tree node. This formed the basis for further inspection of data to identify links, patterns and contradictions within and between respondents, and development of main categories.

Thirdly, respondent verification of factual and interpretive aspects of results was conducted for accuracy and credibility of findings. Further data collection modified the advancing themes which involved asking questions more pertinent to the focus of the study. The identification of further themes was grounded in the quantitative data.

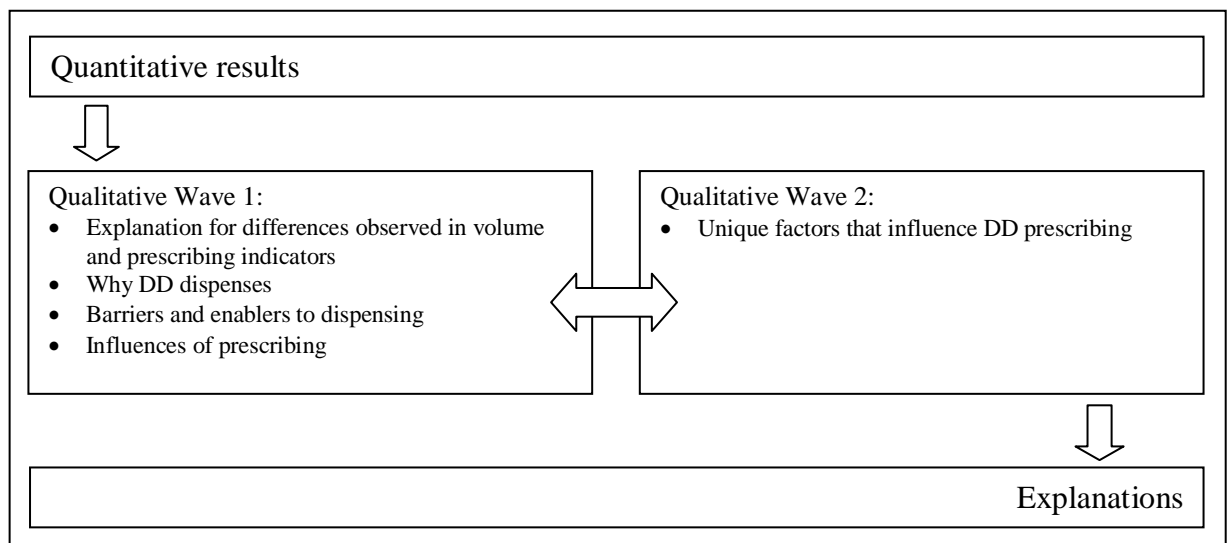


Figure 6.1: Model of the qualitative phase.

The next chapter will present the qualitative results and a brief discussion of the findings.

VII. QUALITATIVE

This chapter presents the results and discussion of the qualitative phase of the study.

1. RESPONDENTS

DDs represented a very small group of GPs in the rural landscape. Therefore, in pursuant to the privacy legislation (*Privacy Act 1988 (Cth)* 1988; *WL v La Trobe University* 2005; Holman 2010) and to protect the respondents' identity, identifiable demographic data of the participants would not be provided. Nevertheless, the respondents practised across all states of Australia. Eight respondents (40%) practised in remote Australia and the remaining 12 respondents practised in rural Australia. This concurred with the distribution of DD practices in Australia in which 42% were classified as rural and 58% as remote. There were six female respondents (30%), consistent with findings that one-third of country GPs are female (Health Workforce Queensland and New South Wales Rural Doctors Network 2009; Van Der Weyden 2005). Eight of the respondents (40%) had completed their medical qualification outside Australia, consistent with similar reports that IMGs constituted 40 - 50% of country GPs (Maxfield 2009; Gregory 2009). Four respondents (20%) were no longer dispensing as at the time of the interview: two had recently retired and the others had lost their dispensing rights because a community pharmacy had opened up in the respective DD's catchment area (Medicare Australia 2009).

2. EXPLANATION FOR THE QUANTITATIVE FINDINGS

2.1. *Proportionally Fewer Scripts*

All respondents perceived that they had fewer patients "*on the books*" than their neighbouring non-dispensing counterparts with a pharmacy in town. A majority of respondents (80%) did not think that their patient demographic spread was different to their non-dispensing peers as evidenced by NPS prescriber feedback and Medicare's Program Incentive Payment statement which all GPs routinely received. Four respondents perceived that they might have fewer chronically ill patients on

their patient list, because the patients who required more intensive care tended to “*ship out early*” to bigger towns with more available health services.

Two respondents indicated that they intentionally prescribed less so as to generate less paperwork, since “*the more you prescribed the more you have to dispense*”. According to all respondents, there were significant amounts of administrative “*paperwork*” associated with PBS dispensing; this was in addition to their usual medical practice. Having to both prescribe and dispense meant that the respondents had to double-up on their time with each patient. As one of the respondents indicated,

If you are seeing patients both medically and as a pharmacist [sic] then you won't much time to be a doctor, aren't [sic] you? So there are 40 hours in a week and if you are doing 10 hours dispensing then you are only able to do 30 hours doctoring, aren't you?

The proportionally fewer scripts per DD observed in the earlier quantitative phase of the ADD Study may be explained by DDs having smaller patient populations, fewer medically ill patients and the desire to generate less administrative paperwork. It is also plausible that DDs were spending less time with patients due to the administrative processes associated with dispensing PBS pharmaceutical benefits.

2.2. Variability in Reg24 Use

All respondents were aware of the legislative requirements for the use of *Reg24*. The respondents, however, indicated that they only tended to use *Reg24* for eligible patients with stable chronic conditions, pharmacotherapy that does not require regular monitoring, and those whom the respondents can “*trust*”; suggesting a further three caveats to use of *Reg24*, namely:

- (i) chronic illness that had been stabilised,
- (ii) pharmacotherapy that has a wide therapeutic index or that does not require stringent monitoring, and
- (iii) patients whom the respondent perceived to be in concordance and compliance with their medical treatment/s.

One respondent expressed concern over the use of *Reg24*, since having all repeats and original pharmaceuticals dispensed to the individual patient at one time meant that the patient had to bear the cost of paying for all pharmaceuticals at one. Consequently this respondent imposed a further caveat to *Reg24*, i.e. ability to pay.

Nine respondents (45%: 6 rural and 3 remote) expressed a preference for using *Reg24* since that would mean less unnecessary travel for their patients. Three respondents (15%: 2 rural and 1 remote) candidly admitted that for those eligible patients, use of *Reg24* meant that they were able to increase pharmaceutical stock turnover despite losing out on dispensing fees associated with dispensing repeats.

Three other rural respondents were frustrated that their *Reg24* scripts which were provided to their patients and subsequently filled at a community pharmacy had been cancelled by the pharmacist. As one respondent indicated,

the pharmacist cancelled my Reg24, [this] happens a bit too frequently and you start to wonder why. ... If a pharmacist is to cancel Reg24 they don't call to tell me.

The respondents were unable to provide further details as to why the pharmacist had cancelled his/her *Reg24* scripts.

The increased use of *Reg24* by DDs as observed in the quantitative study may be explained by the patients having less accessibility to health services. The wide variability in the use of *Reg24* by some DDs may be explained by the additional criterion that DDs imposed on themselves before ordering *Reg24*. There was a suggestion that some DDs might also use *Reg24* to increase their stock turnover.

2.3. *Similar Prescribing*

The respondents indicated that with the PBS dispensing licence, there was no requirement for them to attend additional CPD¹¹. In addition, with the exception of a specific dispensing course previously coordinated by Health Workforce Queensland, there were also no training programs available which were specifically designed for DDs in regards to their dispensing role.

All the respondents used different computer clinical software for prescribing and dispensing, and had policy and procedures in place with regard to dispensing.

Other influences on prescribing set out below provided a further explanation for the general similarity in the prescribing outcome variables observed in the quantitative analysis.

3. MAIN INFLUENCES ON PRESCRIBING

With respect to what influences DDs' prescribing, the respondents reported four main themes. These were:

1. peer pressure from non-DDs and pharmacists on prescribing,
2. lack of support from the Guild for dispensing,
3. availability of pharmaceutical stock, and
4. perceived patient needs for doctor dispensin.

3.1. *Peer Pressure on Prescribing*

All respondents maintained there was a widely held view that DDs dispensed for profit and consequently their practices were associated with poorer quality use of medicines. In support of this notion, the respondents reported various degrees of peer pressure and hostility from those against doctor dispensing. These included

¹¹ Also referred to as Continuing Medical Education (CME). It refers to all in-service training programs that supplement basic medical education and post-vocational training throughout a doctor's professional working life. In Australia, GPs are required to participate in a compulsory minimum number of CPDs for ongoing registration.

pharmacist groups, non-DDs and in some instance, their own patients. Most respondents reported that pharmacists were generally against doctor dispensing as the dispensing of pharmaceuticals was considered to be the sole providence of the pharmacy profession. The respondents indicated that pharmacists were concerned that if the doctor dispensed what he/she prescribed then there was no secondary check by a pharmacist; hence there was an elevated risk of medication error. There also existed the potential for DDs to overprescribe and over-service. For the non-DDs, dispensing pharmaceuticals as part of routine medical practice was considered not the norm and not best practice, since DDs might be influenced by the additional source of revenue. For the patients, the respondents indicated that some patients would still prefer pharmacist dispensing, not so much because of better pharmaceutical care, but rather because this would mean having an additional business in the town and an additional family for their isolated community.

All the small country towns are very devoted to their community and any extra business is welcome. They would all prefer have a separate pharmacy, which would mean another family coming into town which would help their town community infrastructure and viability.

DDs who represented a very small proportion of GPs and respondents generally stated they were inadequately represented by mainstream medical lobbyists and had no voice in the primary health care landscape. These barriers made DDs a vulnerable target. This vulnerability promoted a number of responses. All respondents reported the need to be particularly vigilant about monitoring their own prescribing habits. For instance, through the confidential NPS prescribing feedback, which provided each individual prescriber with a breakdown of his/her own prescribing volume as compared to their peers in similar rurality. DDs were often provided with assurance that they were “*within the norm*”. On the infrequent occasions when the respondents were outside of the interquartile range, the prescribing feedback provided a basis for self-reflection and consequent correction.

If I am a bad doctor the whole region knows about it. Dispensing doctors are already susceptible and other people are watching you.

All respondents felt they had to be proactive in acquiring knowledge about pharmacotherapy and most perceived themselves to be better informed about pharmaceuticals especially in terms of price and brand substitution.

Additionally most respondents stated they needed to make an extra effort to foster professional relationships with existing health service providers in their catchments. Some respondents had even implemented a policy of not dispensing to patients who were residents of a neighbouring pharmacy town:

We discourage people who live in the nearby town which has a pharmacist from having scripts filled here. It is a public relations thing.

For those respondents who were also the medical officer for their local hospital, all reported a positive collaborative working relationship with the hospital. This included sharing pharmaceutical supplies between the DD's dispensary and the hospital dispensary, since the hospital's ability to source pharmaceutical supplies was often slower and involved more paperwork than that of the DD.

Generally, respondents were not threatened by the prospect of a pharmacy opening up in their catchment despite the fact that this would mean an end to their PBS dispensing licence. According to the respondents, since the Third Community Pharmacy Agreement was signed between the Commonwealth Government and the Guild in 2001, there had been at least eight DDs' sites that had lost their PBS licences because of new community pharmacies. The respondents generally saw pharmacists as valued health professionals.

3.2. *Lack of Support for Dispensing*

All except two of the respondents owned their own pharmaceutical stock. This represented a significant financial investment. The two respondents who did not own their stock offered affordability as an explanation. Having a significant investment in pharmaceutical stocks was felt to contribute to remaining in that practice, and therefore professional retention. Nevertheless, most respondents lamented that they could only hold a limited range of pharmaceuticals because of the high cost.

Consequently almost all of the DDs interviewed did not stock non-PBS subsidised pharmaceuticals. This might also be partly due to respective state regulations on doctor dispensing.

The respondents were annoyed that unlike the community pharmacists, DDs were not eligible for financial incentives to sustain their dispensary under any of the Community Pharmacy Agreements. Under the Fourth Community Pharmacy Agreement (2005 – 2010), financial assistance to rural pharmacy practice included:

- the rural pharmacy maintenance allowance (AUD\$3,000 - AUD\$38,000 per annum);
- the pharmacy start-up allowance (AUD\$100,000); or
- a succession allowance when buying out an existing pharmacy (AUD\$60,000) (Anderson 2005; Tatchell 2005; Minister for Health and Ageing 2005b; Pharmacy Review 2003; Minister for Health and Ageing 2007).

Community pharmacies were also provided with:

- AUD\$14.5 million for broadband internet access (Minister for Health and Ageing 2005a),
- allowable extra fees of AUD\$3.79 per item should the PBS dispensed price be below the general patient co-payment of AUD\$32.90 (Commonwealth Department of Health and Ageing 2009a; Jensen 2009), and
- a loading based on the pharmacy's ARIA (Jensen 2009).

According to the respondents, under the Fourth Community Pharmacy Agreement, the only financial incentive that DDs did receive was the capture of the patient's Medicare card number; however, with the cessation of this incentive under the Fifth Community Pharmacy Agreement (commenced July 2010), DDs would not be entitled to any incentives under the Community Pharmacy Agreement. All respondents felt frustrated that due to their lack of representation, they were unable to utilise any of the Commonwealth Government's incentives to promote community-based pharmaceutical care. For some of the respondents, dispensing was a "*money losing business*" because of significant investment tied up with stock and

yet they were not entitled to any of the incentives contained in the Community Pharmacy Agreement.

I think it is unfair [emphasis added] that we don't get the same amount of support as pharmacist. They get decent funding when they set up a business and ongoing funds. In reality, dispensing is a money losing business as far as I am concerned unless you ignore medical ethics and prescribe medications for whatever the condition.

The respondents also expressed concern over uncertainty in regard to some aspects of their dispensing rights, such as whether their practice nurse could assist with dispensing, similar to the arrangements in community pharmacy, where some aspects of dispensing were often delegated to the pharmacy assistant while still under the direct supervision of the pharmacist.

3.3. Availability of Pharmaceutical Stock

Respondents felt that they had been marginalised by the pharmaceutical suppliers because of their low buying power. This was compared to the majority of community pharmacies that are part of a marketing chain with better bargaining power. Pharmaceutical suppliers also imposed restrictions on DDs such as delivery of pharmaceutical supplies only on a fixed routine basis; usually once a week. This is compared to the daily courier services that can be expected by a community pharmacy. The major pharmaceutical suppliers also restricted the returns of unused pharmaceuticals from DDs. This meant that DDs had to bear the cost and risk associated with holding their stock, for example when specially ordered pharmaceuticals lay unclaimed by patients or when the pharmaceutical reached its expiry date. All respondents indicated that these factors influenced the type of pharmaceuticals they had in stock. For instance, as one respondent indicated,

I am probably more anti-insulin. As you know insulin is an expensive drug to get, expensive drug to keep. Need refrigeration. To buy insulin need a couple of hundred dollars, so we are always very careful about ordering insulin making sure that people will definitely get it. You don't want to get insulin and then people don't get it. That can happen.

There was a lack of general agreement among the remaining respondents in regards to use of insulin. No statistically significant differences in the prescribing of insulin between DDs and non-DDs was noted in the quantitative findings (3.45 vs. 3.58 items per 1,000 scripts, $p = 0.807$). The respondent's comment above could be partly explained by further comments that rural doctors are generally more likely to prescribe therapy which required less monitoring.

The respondents felt that they were penalised by having to compete with a neighbouring community pharmacy and/or mail-order pharmacy for price especially in regard to pharmaceuticals that cost less than the PBS co-payment. Due to the combination of restrictions placed on pharmaceutical suppliers on supply and patients on demand, DDs generally had very low mark-up: *"usually about 5%, no more than 10%"*. In most instances this resulted in the respondents having to sell pharmaceuticals at cost price, which *"does not cover the cost of purchase and storage"*. To compound matters, according to the respondents, patients also had expectations that DDs would stock a wide range of pharmaceuticals, and they complained when DDs did not carry the particular branded pharmaceuticals they were prescribed by a specialist.

With the limited stock range that DDs stock and have readily available, the respondents were generally not concerned that some 10 – 80% (median 40%) of their scripts ended up being dispensed by a neighbouring community pharmacy or via mail-order pharmacy. Most acknowledged that patients would take their routine non-urgent PBS scripts with them to be filled by the community pharmacy in a major regional centre when they next travelled there for routine shopping. Consequently DDs' patients tended to utilise the DDs' dispensary for more urgent medications such as adrenergic inhalants and antibiotics.

Since the DDs own and manage the stock, they were more aware of pharmaceutical costs and availability. Respondents reported stocking mainly generic pharmaceuticals. With the different proprietary names, the respondents indicated that they were conscious of the potential for confusion and consequently spent more time explaining the purpose/s of use and brand substitution to their patients. Nevertheless, the respondents indicated that the ultimate preference remained with

the patient and DDs would either specifically order the particular branded pharmaceutical in for the patient, or provide the patients with a script to be filled elsewhere. Some respondents reported contacting the neighbouring community pharmacy to ensure that the particular branded pharmaceutical was available before dismissing the patient with the relevant script.

3.4. Patients' Needs for Doctor Dispensing

When asked why they took on the additional dispensing role respondents universally acknowledged that the main reason was for the convenience and benefit of their patients and to ensure continuity of care. DDs' communities were generally more isolated and smaller when compared to their non-dispensing counterparts. In terms of distance, the respondents indicated that the nearest neighbouring community pharmacy ranged from 50 to 200km (median 70km) away from their practice. Therefore the respondents viewed their dispensary as a service to the community.

Respondents indicated that because of their prescribing and dispensing roles they had more contact with patients, more comprehensive knowledge of their conditions, and consequently were better placed to aid compliance. Additionally, when dispensing repeat prescriptions they were also able to take advantage of the opportunity to informally consult and counsel their patients. For instance,

When someone comes in and said, they bought two Ventolin [salbutamol: short-acting β_2 -adrenergic inhalant] puffers in the last two weeks, then you say you have to come in. Very often it is opportunistic; you can check the asthma out. Gives you a good opportunity to opportunistically see people. If someone is coming in to get too many cold-and-flu's then you know they are stocking up on their codeine tablets whilst if you are non-dispensing doctors, you won't see that. Unless the chemist specifically sent a message to the doctor concerning the patients' consumption then you don't know. They have to be quite bad before a chemist does that; so you can pick up the inappropriate counter stuff earlier.

All respondents felt that they had a better appreciation of patients' social needs and were in a better position to respond, particularly to the patient's economic needs.

If the patient said I can't afford or I would come back another day to pick it up or something like that, I would actually enquire if they have problem with money or what the problem was or something like that. We try to help out to make sure that they have their medication. Look, if there was time when I thought it was really important I ended up paying for it. So right from dispensing them that knowing I wasn't going to get paid right through to organising a generic or ringing up to get a special authority or something like that to help people. Particularly in the case of the children, there have been times when I knew that the parents either couldn't or wouldn't be able to afford to buy antibiotics or such stuff for their kids. At the end of day I make sure they get it.

4. SUMMARY OF FINDINGS

Prescribing is a complex decision making task. There are many factors that can influence prescribing (Jacoby, Smith, and Eccles 2003; Tobin et al. 2008; Jaye and Tilyard 2002; Cutts and Tett 2003a, 2003b; Cockburn and Pitt 1997; Henriksen and Hansen 2004; Hemminki 1975; Maronde et al. 1971; Lim and Rowett 2006; Mansfield 2008; Stocks et al. 2009; Puspitasari, Aslani, and Krass 2009; Frich et al. 2010; Breen 2004; Lundin 2000; Kringos et al. 2010). In this study four major factors which were unique to DDs and not previously described elsewhere, were identified.

Respondents believed that there were expectations from their peers (non-DDs and pharmacists) that DDs over-serviced their patients and prescribed less judiciously. To protect themselves, respondents were more vigilant about their own prescribing and actively sought knowledge about pharmacotherapy.

As an individual group, DDs were professionally isolated, and felt unrepresented and almost invisible to their professional bodies and to policy makers. Consequently, respondents actively foster working relationships with existing health professionals, including pharmacists and local hospitals. Respondents viewed pharmacists as valuable professional colleagues.

Respondents were committed to their patients despite the significant barriers that they confronted with their dispensing function. DDs did not receive support, professionally or financially for their dispensing role. However, it was noted that respondents who invested heavily in their pharmaceutical stock were more prepared to stay in their community.

The ability of DDs to prescribe and dispense meant that the respondents were able to offer a one-stop shop for their patients in terms of their medical and pharmaceutical care. Respondents indicated that they had more comprehensive knowledge of their patients' medical and social needs, and were in better position to be able to respond.

Theme	Quote
Peer pressure on prescribing	<p><i>If I am a bad doctor the whole region knows about it. Dispensing doctors are already susceptible and other people are watching you ...</i></p> <p><i>We discourage people who live in the nearby town which has a pharmacist from having scripts filled here, it is a public relation thing.</i></p> <p><i>All the small country towns are very devoted to their community and any extra business is welcome. They would all prefer have a separate pharmacy, which would mean another family coming into town which would help their town community infrastructure and viability.</i></p>
Lack of support for dispensing practice	<p><i>I think it is unfair that we don't get the same amount of support as pharmacist. They get decent of funding when they set up business and ongoing funds. In reality dispensing is money losing business as far as I am concerned unless you ignore medical ethics and prescribe medications for whatever the condition.</i></p> <p><i>HIC funding for community pharmacies specifically excludes dispensing GPs. This includes the start-up grant, which is basically aimed at allowing you to buy base stock. I know that for me there was no way that I could afford that baseline stock, which is why I run the pharmacy but xxx funds it all, and hence gets any profit from it.</i></p>
Availability of pharmaceutical stocks	<p><i>As a DD I am probably more anti-insulin. Insulin is an expensive drug to get, expensive drug to keep. Needs refrigeration. To buy insulin you need a couple of hundred dollars, so we are always very careful about ordering insulin making sure that people will definitely get it. You don't want to get insulin and then people don't get it. That can happen.</i></p> <p><i>Dispensing GPs are compelled to sell expensive medicines at cost price or others at \$4.85, both of which do not cover the costs of purchase and storage.</i></p>
Patients' needs for doctor dispensing	<p><i>If the patient said I can't afford ... we try to help out to make sure that they could have their medication. Times when I thought it was really important, I ended up paying for it: from dispensing them and knowing I wasn't going to get paid, right through to organising a generic or ringing up to get a special authority or something like that to help people. Particularly in the case of the children, there have been times when I knew that the parents either couldn't or wouldn't be able to afford to buy antibiotics for their kids. At the end of day I make sure they get it.</i></p>

Table 7.1: Example of quotes for the main themes identified.

VIII. DISCUSSION

Health inequity exists between urban and rural Australians (see Chapter III). A multidisciplinary model of organising and providing care has been proposed as a means to decrease the health gap (Duckett 2005a; Van Der Weyden 2005; Wakerman et al. 2005; Duckett 2006; Gupte 2007; National Rural Health Alliance 2008a; Wakerman et al. 2008; Dunbar and Reddy 2009; Wakerman 2009; Wong and Regan 2009; Smith 2010) but this is not feasible for all rural communities because of rural health workforce shortages and higher costs of providing health services in rural Australia (Wakerman and Humphreys 2002; Wilson, Oldenburg, and Lopez 2003; Sims and Bolton 2004; Dunbar et al. 2007; Towler 2007; Gorman and Brooks 2009; Scott 2009; Wilson et al. 2009; Haines et al. 2010; O'Toole, Schoo, and Hernan 2010).

Amongst the options, flexibility and expansion of the range of tasks that a health professional can undertake have been proposed. DDs in Australia are a long standing example of an application of such flexibility through an expansion of normal GP roles. The granting of a PBS dispensing licence to a rural GP is intended to improve rural community access to pharmaceutical care where there is no pharmacy within a reasonable geographical distance.

Doctor dispensing of pharmaceuticals is not new. In Australia for example almost all doctors have dispensed pharmaceuticals for their own patients at one time or another. Often this has taken the form of drug samples or starter packs which are offered to patients without charge. Reasons for doctors dispensing starter packs include trials of new pharmacotherapy, familiarising themselves with the efficacy and tolerability of a new pharmaceutical, increased access to pharmaceutical care for patients who cannot or are unable otherwise to afford it, and access to pharmaceuticals that are not yet on the PBS. The practice of doctor dispensing starter packs is the subject of much controversy. These include their use as a marketing tools for the pharmaceutical industry and the potential for medication errors (Ashley, Kirk, and Fowler 2002; Hall, Tett, and Nissen 2006; Patounas and McGuire 2007; Spurling and Kyle 2007; Kyle, Nissen, and Tett 2008).

An even more contentious issue is that of doctors dispensing pharmaceuticals for profit. In Australia, between 2005 and 2007, there were 72 DDs who routinely dispensed PBS subsidised pharmaceutical benefits to their patients and in return were remunerated with a dispensing fee.

In a systematic review on DD practices internationally, it was reported that overseas DDs tended to prescribe more pharmaceutical items, incurred higher pharmaceutical costs and were less likely to prescribe generically than their non-dispensing counterparts. There was also evidence that DDs prescribed antibiotics less judiciously and were associated with poorer dispensing standards.

In the quantitative phase of the ADD Study, PBS administrative data for the 2005-7 fiscal years were analysed against pre-determined volume and prescribing indicators. Pre-determined indicators were chosen so as to enable comparison with overseas DD findings. In this study, there were no substantive differences between the PBS prescribing practice of DDs and non-DDs with the exception of fewer patients per doctor, fewer PBS scripts per doctor, more *Reg24* use among DDs, more adrenergic inhalants, and more NSAIDs and penicillin-type antibiotics. The validity of the number of PBS prescriptions per doctor was affected by the increased rate of *Reg24* use among DDs. Arbitrary adjustment of the volume indicator suggested that DDs' prescribing might be similar to those of non-DDs. This study was limited by what can be done to correct the data: for instance modelling could not be performed to explain the variability in *Reg24* use. Notwithstanding this, the study finding was at variance with overseas findings.

The DD-respondents in the qualitative phase of the ADD Study validated that they had smaller patient populations than their non-dispensing peers. The increased *Reg24* use was due to the accessibility issue since DD practices were more remote and isolated. A wide confidence interval among DD cohorts for *Reg24* use was noted in the quantitative analysis. This might be due to the issue of matching based on rurality. The study had initially asked for matching based on the ARIA whereas the actual data released by the Department was extracted based on the RRMA index of the individual prescriber. The ARIA was preferred over the RRMA for this study

since the former included road distance to goods and services as well as population size in its criteria. An early descriptive study conducted in WA observed that DD practices were more remote and had fewer available services in their towns as compared to similar medical practices in the same RRMA (Lim, Gray, and Roach 2004). This was affirmed in this study. Therefore it is possible that the variability in access to other goods and services was not appropriately corrected for based on RRMA. This in turn might explain why a statistically significant difference was noted in the rural cohort and not in the remote cohort. Regardless of this, it is not possible to correct completely for all the differences in rurality since rural communities are not homogeneous.

There was some suggestion from respondents that some DDs might prefer to use *Reg24* to increase stock turnover. However, the respondents defended their use of *Reg24* by imposing upon themselves stringent criteria above and beyond those required by the legislation such as the patients' ability to pay, patients whom DDs can trust, and medical condition/s which was/were stable and treatment regimens which did not require stringent follow-up. The increased use of *Reg24* posed important quality use of medicines considerations: medication wastage from expired drugs, inappropriate storage, and change in patients' medical condition. There is also the issue of heightened risk of medication misadventure due to having more pharmaceuticals physically available. Home Medicines Review¹² has been shown to reduce medication misadventure (Rowett 2005) and would be beneficial to DDs' patients. DDs have reportedly used this in the past.

Key findings from the qualitative study were that with smaller patient population per doctor, the ability of DDs to dispense had made it attractive for local residents to continue to visit and support their local GPs (DDs) knowing that they (the residents) can have immediate access to medical and pharmaceuticals benefits if required. Without the DD dispensary, the residents would have to travel a great distance to a neighbouring pharmacy town for their pharmaceutical care. In addition, respondents

¹² Also known as 'Domiciliary Medication Management Review' was funded since the Third Community Pharmacy Agreement whereby a pharmacist would visit the patient's home to document medication related issues and a report generated by a consultant pharmacist will be then forwarded to the GP. The intention is such that both pharmacist and GP work collaboratively in managing patient's pharmaceutical care.

who invested heavily in their pharmaceutical stock were more prepared to stay in their community. It is possible that the model of doctor dispensing actually contributed to sustainability of what would be otherwise unviable rural general practice through a combined revenue source from two unviable stand-alone practices. This proposition might be attractive if there was a small patient population and the “*free time*” that the rural GP has from consulting is spent instead on dispensing, but it remains unclear at what threshold the patient population does not justify such a practice and the GP’s time is better spent consulting rather than in the combination of the two activities.

A key reason offered by the respondents for why they choose to dispense was the ability to better respond to patients’ needs. From the literature, there was strong evidence that comprehensiveness of care is a strength of primary care. Primary care and social determinants of health share much in common and health services which do not consciously address social determinants exacerbate poor health outcomes. Respondents indicated that through both prescribing and dispensing, DDs were more familiar with their patient’s medical and social needs. Consequently DDs were in a better position to respond to patients needs. Therefore the model of doctor dispensing provided a consistent and coherent approach to management continuity in rural Australia.

Dispensing of PBS pharmaceutical benefits for DDs is not without its difficulties. For instance, the Commonwealth Government granting of a PBS dispensing licence to a doctor-applicant is subject to strict administrative criteria, which include no objection from neighbouring community pharmacies, and the doctor-applicant establishing needs and public interest benefits. Furthermore, the DD’s PBS dispensing licence is automatically cancelled without warning should a pharmacy open up in that area. Despite this, there appears to be no animosity evident towards the pharmacy profession. Instead the respondents actively fostered professional relationships with existing rural health professionals through the policy of not dispensing to patients from pharmacy-towns and sharing of pharmaceutical stock with their local hospital. Issues with inter-professional conflict pertain to the lack of financial support from the Pharmacy Guild for DD’s dispensing roles. Regardless of

this, it may not be feasible for the Guild to support DDs as doing so would mean endorsing an alternative model of pharmacy practice in Australia.

Other barriers that were experienced by DDs were similarly experienced by rural community pharmacies, for instance the cost of owning one's stock and the risk associated with it. DDs may arguably have lower risk than rural community pharmacies since DDs are able to prescribe what they have in stock. A plausible explanation for why the majority of the respondents ranked stock holding as a major barrier is suggested that some respondents were not used to managing a commercial business with significant stock holding. Previously under the Fourth Community Pharmacy Agreement, community pharmacies were offered a financial incentive to assist Aboriginal Medical Services with managing their stock holding under the Section 100 Scheme (Emerson, Bell, and Croucher 2001; Emerson, Croucher, and Burchell 2001; Loller 2003; Hope 2010). A future Pharmacy Agreement should consider a similar scheme to assist DDs in managing their stock without diminishing the DDs' important contribution to their community.

Respondents indicated that due to the cost of pharmaceutical stock they tended to prescribe and dispense generically. Consequently the respondents spent more time explaining and discussing generic substitution with their patients. Health literacy among mainstream health consumers on generic substitution is low and verbal instruction can significantly increase health literacy (Emery et al. 2010; Emmerton, Kairuzm, and McKauge 2010; McKenzie 2010a) and reduce potential for adverse drug events (Travaglia 2010). Therefore DDs' increased use of generics may contribute to a more sustainable PBS (Clarke and Fitzgerald 2010) and improve rural health literacy regarding generic substitution.

In terms of potential medication misadventure, there was no strong evidence in the quantitative analysis that DDs prescribed significantly differently to non-DDs measured against the study's pre-determined prescribing indicators. The increased proportion of NSAIDs, adrenergic inhalants and penicillins used was explained by the respondents by their inability to dispense non-PBS subsidised pharmaceuticals. In addition, all respondents prescribed electronically. Electronic prescribing had been previously shown to reduce medication errors (Powell-Davies and Fry 2004;

Deans 2005; Bomba and Land 2006; McInness, Saltman, and Kidd 2006; Ammenwerth et al. 2008; Moxey et al. 2008; Pirotta 2010). Furthermore, respondents concomitantly used separate dispensing and prescribing software, so that this is also likely to further minimise medication errors since prescribing software has high sensitivity but low specificity compared with dispensing software, which has low sensitivity but high specificity (Sweidan et al. 2008; Sweidan et al. 2009). DDs having both electronic infrastructures might be well placed to adapt to the new Commonwealth Government e-health initiative (Haikerwal 2009a).

As compared to overseas DD health models, there appear to be sufficient safeguards in place to assist Australian DDs. These include the routine NPS prescriber feedback (administrative), and the self-perceived need to be better prescribers in order to protect themselves from peers' scrutiny (psychology). Overall, the section 92¹³ doctor dispensing model is:

- Appropriate: there is no strong evidence to suggest that DDs prescribed differently.
- Efficient/ cost-effective in use of resources: the small DDs' community size would not be able to support a viable community pharmacy and through doctor dispensing, patients have ready access to pharmaceuticals should they desire them (ensuring continuity of pharmaceutical care). The revenue from dispensing combined with that from the general practice sustains what would be an otherwise unviable rural practice.
- Responsive/ choice of provider: respondents indicated that the patients have the choice from whom and where they want the script to be filled. This is also supported by the previous pilot study on WA DDs (Sunderland, Burrows, and Joyce 2005; Sunderland, Burrows, and Joyce 2006).
- Accessible: respondents indicated that they were better aware of the patient's medical and social needs, and had dispensed at no cost on occasion to ensure access to pharmaceuticals.
- Safe care: the quantitative study suggested that DDs' PBS prescribing was similar to that of rurality-matched non-DDs.

¹³ *National Health Act 1953 (Cth)*.

- Continuous/ coordinated care: respondents indicated they actively fostered working relationships with other health providers. The respondents also indicated that in instances when their dispensary did not stock a particular pharmaceutical, they would call ahead to the neighbouring community pharmacy to ensure that stock was available or alternatively order in the pharmaceutical specifically for the patient concerned.
- Capable: respondents indicated that they were more knowledgeable about pharmaceuticals than their non-dispensing peers and had proactively sought out information on pharmacotherapy. This echoed overseas studies that DDs were more knowledgeable (Pink, Hageboeck, and Moore 1989; Faisst, Schilling, and Gutzwiller 2000; Ogbogu et al. 2001).
- Sustainable: having invested heavily in the pharmaceutical stock, respondents were prepared to stay in their community. Surveyed patients in the pilot study generally supported DDs' general practice (94.1% DDs' vs. 95.6% non-DDs') (Sunderland, Burrows, and Joyce 2005).

Unfortunately, according to the respondents, there is no evidence of endorsement for this valuable service in rural and remote Australia. As a unique group, Australian DDs are largely invisible in the mainstream health system, representing only 0.36% of the Australian GP population (based on 2010 RACGP membership).

1. CONCLUSION

No substantive evidence was found that rural and remote DDs prescribed at significantly higher rates than their non-DD colleagues. The major difference was on *Reg24* use by rural DDs. As a model for delivering primary care in remote areas it appears to operate satisfactorily for the DDs and their communities.

The current PBS remuneration system depends on throughput to generate revenue. This fee-for-service model may encourage DDs to prescribe more and hence dispense more. However, there is no strong evidence from the ADD Study to support this assumption or that DDs prescribe significantly differently from non-DDs. DDs are not a threat to the pharmacy profession and DDs choose to dispense not solely for personal gain, and are doing so in the absence of financial support. DDs

commented that, by their investing heavily in their pharmaceutical stock, they are ready, willing, and able to stay in rural Australia. This is of particular importance in light of difficulties in recruiting and retaining rural health professionals. The model of doctor dispensing may potentially provide one interim solution to recruitment and retention of rural doctors. For instance, one of the respondents had practised in the same dispensing practice his entire medical career (>46 years)! With the recent reductions in income from the PBS to community pharmacies, and rumours of further reductions in PBS remuneration (Australian Journal of Pharmacy 2010; Eton 2010; Sclavos 2010), this has meant that the role of DDs may become more important in rural Australia should community pharmacies close down, as they did in the 1980s. Therefore, if governments are genuinely interested in the value of primary care and rural health, the model of doctor dispensing should not be ignored.

2. RECOMMENDATIONS FOR PRACTICE

2.1. *Acknowledgement of DD Services*

Primary care was offered by the current Federal Labor (Rudd) Government as the solution to address many of its health reform priorities (National Preventive Health Taskforce 2009; Commonwealth Department of Health and Ageing 2009d, 2009c; Royal Australian College of General Practitioners 2010; Australia Medical Association 2009; National Health and Hospitals Reform Commission 2009). The Australian DD health model, until now, has been an isolated and poorly documented general practice model in Australia. To sustain the current DD services in rural and remote communities, governments, pharmacy and medical regulatory authorities firstly need to recognise and acknowledge the existence and contribution that DDs make to their community.

2.2. *Support Structures to be Formulated to Assist DDs*

Significant barriers currently exist to doctor dispensing. The actual number of DDs practising in Australia is small, and therefore the cost of supporting DDs is not expensive, considering that infrastructure already exists to support rural community pharmacies. DDs should be able to tap into these support infrastructures such as the

Section 100 Scheme to assist them with managing their pharmaceutical stock, and be able to directly refer patients for the Home Medicines Review Service. This may be ideally be facilitated through a medical organisation such as Rural Doctors Association of Australia, instead of the Guild, for political reasons.

2.3. *Support for Practice Nurse or Dispensary Assistant*

The extent to which a DD can delegate his/her dispensing to a practice nurse or dispensary assistant needs to be clarified by the Commonwealth and respective State Governments. Curricula and supports for training practice nurses or dispensary assistants in dispensing are already in place for training community pharmacy assistants. The support for such training schemes, which is currently available from the Pharmacy Guild through Community Pharmacy Agreements, should also ideally be extended to DDs' practice nurses or dispensary assistants to ensure that DDs' staff have minimum accredited training. This does not diminish the responsibilities and obligations that a DD has over his/her dispensary such as the need to supervise the dispensing and be available for providing further information and consultation with a patient.

2.4. *Standardisation of Dispensing Requirements*

Currently DDs are subjected to both Commonwealth legislation for their PBS dispensing licence and respective State Government legislation for holding a poisons licence. This has resulted in most DDs being unable to dispense non-PBS subsidised pharmaceutical benefits. Being able to dispense non-PBS subsidised pharmaceuticals would improve DDs' patients' access to a wider range of pharmaceuticals products. Currently DDs' patients are accessing non-PBS pharmaceuticals through mail-order or when they travel next to a pharmacy town (Sunderland, Burrows, and Joyce 2005). The ability of the DD to stock non-PBS subsidised pharmaceuticals such as simple analgesics would mean less cost to Medicare.

3. RECOMMENDATIONS FOR RESEARCH

3.1. *DDs' Dispensing Standards*

The focus of this study was on the evaluation of DDs' PBS prescribing and did not focus specifically on DDs' dispensing. Observational data from Zimbabwe suggested that their DDs' dispensing was contrary to best dispensing practice (Hansen and Trap 2004; Trap 2001). Therefore evaluation of Australian DDs' dispensing would provide a more comprehensive picture as to the appropriateness of DDs' service in country Australia. It may be difficult to obtain agreement for this to occur.

3.2. *Reduction in Health Gap*

Respondents from the current study stated that they were better able to respond to a patient's medical and social needs. Other gaps remained such as access to medical specialists and allied health professionals. Due to issues with privacy and confidentiality, this study was unable to perform any modelling of the quantitative findings or be able to link prescribing accurately. Therefore a future study focusing on patient's outcomes would be able to ascertain objectively the clinical effectiveness of the Australian DD health model and whether this is a plausible means to reduce health inequity between rural and urban communities.

As suggested earlier, an economic modelling study may be warranted to ascertain whether there is an optimal patient number to justify DDs in their dual roles and at what point, after that number, DDs would be overwhelmed, overworked and negatively impact on their standard of care.

3.3. *Influences of DDs' Prescribing*

As indicated above in the systematic review, there has been no study that expressly addresses what influences DDs' decision-making process when prescribing. Much remains unknown about whether the four unique influences identified in this study are consistent with overseas DD models.

3.4. *Other Methods of Pharmaceutical Delivery*

A future study should examine whether the DD model is most appropriate for small communities as compared to other options such as mail-order, use of pharmacy depots, medicine-dispensing ATMs, telemedicine and telepharmacy. Another alternative is the script collection services practised in some rural Australia towns and in parts of the UK where a nearby pharmacy collect the script (physically or electronically) from the general practice, have the pharmaceuticals ready to be picked up or home delivery the next day or use of a non-pharmacy depot (Australian Journal of Pharmacy 2006a).

APPENDIX A – Publication

1. PEER REVIEWED JOURNAL

- Lim, D., Emery, J., Lewis, J., and Sunderland, V.B. 2009. A systematic review of the literature comparing the practices of dispensing and non-dispensing doctors. *Health Policy* 92, 1-9.
 - Impact factor 1.334. This paper was published in January 2009 and the systematic review was based on papers published between 1970 and November 2008. The Chapter II Literature Review covered papers published between 1970 and December 2008.
- Lim, D., Emery, J., Lewis, J., and Sunderland, V.B. A comparative analysis of dispensing doctors' prescribing: quantitative findings from the Australian Dispensing Doctors (ADD) Study. *Medical Journal of Australia* (Pending revision).
- Lim, D., Emery, J., Lewis, J., and Sunderland, V.B. Influences of dispensing doctors' practice: qualitative findings from the Australian Dispensing Doctors (ADD) Study. *Medical Journal of Australia* (Pending revision).

2. PEER REVIEWED CONFERENCE

- Lim, D., J. Emery, J. Lewis, and B. Sunderland. 2010. Old Players, New Findings from a sequential explanatory mixed methods study on the prescribing practices of dispensing doctors: Australian Dispensing Doctor (ADD) Study. In *National Medicines Symposium 2010: the Medicines Environment is changing Daily. Are you keeping up?* National Prescribing Service and National Medicines Policy Committee, Melbourne, Victoria.
 - This symposium was attended by 560 delegates from 15 countries.
- Lim, D., J. Lewis, and V. B. S. J. Emery. 2009. Why doctors dispense? In *2009 State PHCRED Conference: The Future of Primary Health Care - Working Together*. Royal Australian College of General Practitioners & Primary Healthcare Research, Evaluation and Development (PHCRED) WA, Floreat, Western Australia.

- This conference was attended by 60 primary healthcare practitioner delegates from Perth. This paper presentation was based on preliminary findings from Chapter VII Qualitative on why DD dispensed.
- Lim, D., J. Emery, J. Lewis, and B. Sunderland. 2009. Dispensing in the bush: a comparison of prescribing patterns between dispensing and non-dispensing doctors. In *Australia in GP'09: the Conference for General Practice 2009*. Royal Australian College of General Practitioners, Perth, Western Australia.
 - This conference was attended by 750 general practitioner delegates across Australia. This poster presentation was based on differences observed in DDs' and non-DDs' PBS prescribing (volume indicators and antibiotics prescribing indicators) as was presented in Chapter V Quantitative.
- Lim, D., and Lewis, J. 2009. Could mixed method be the solution to political sensitive research: experience from the Australian Dispensing Doctors Study. In *5th Annual Mixed Methods Conference*. University of Leeds, Harrogate, England.
 - This conference was attended by 200 academic delegates from 32 countries. This oral presentation presented the methodology for the ADD Study and built a case for mixed methods design study in legislative evaluation.
- Lim, D., Sunderland, V.B., and Emery, J. 2008. Practices of dispensing doctors. In *2008 State Conference: Primary Health Care MATTERS!*. Royal Australian College of General Practitioners & Primary Healthcare Research, Evaluation and Development (PHCRED) WA, Fremantle, Western Australia.
 - This conference was attended by 80 primary healthcare practitioner delegates from Perth. This paper presentation presented partial findings from the systematic review contained in Chapter II Literature Review. This presentation was voted best new research by conference organisers.

APPENDIX B – Systematic Review Data Extraction Sheet

SOURCE	SIGN Rating:
Funding source	
Country	
Sample	
Source of data/ Study type	
Design method	
Objective(s)	
Statistical analysis	
Results	
Authors' specific comments/ conclusion	
Reviewer's comments	
SIGN levels	<div style="margin-bottom: 10px;"> <input type="checkbox"/> randomisation: <small>Comments:</small> <input type="checkbox"/> high <input type="checkbox"/> moderate <input type="checkbox"/> low quality/ not applicable </div> <div style="margin-bottom: 10px;"> <input type="checkbox"/> controls: <small>Comments:</small> <input type="checkbox"/> high <input type="checkbox"/> moderate <input type="checkbox"/> low quality/ not applicable </div> <div style="margin-bottom: 10px;"> <input type="checkbox"/> bias: <small>Comments:</small> <input type="checkbox"/> low <input type="checkbox"/> moderate <input type="checkbox"/> high risk </div> <div style="margin-bottom: 10px;"> <input type="checkbox"/> probability that relationship causal: <small>Comments:</small> <input type="checkbox"/> high <input type="checkbox"/> moderate <input type="checkbox"/> low probability </div> <div> <input type="checkbox"/> study design and quality: <small>Comments:</small> <input type="checkbox"/> high <input type="checkbox"/> moderate <input type="checkbox"/> low quality </div>

Table B.1: Sample of a data extraction sheet used for the systematic review.

SIGN levels of evidence	
1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews or RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case-control or cohort studies, or high quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2+	Well conducted case-control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2-	Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies e.g. case report
4	Expert opinion

Table B.2: Scottish Intercollegiate Guidelines Network levels of evidence (Harbour and Miller 2001).

SIGN grades of recommendations	
A	At least one meta-analysis, systematic review or RCT rated as 1++ and directly applicable to the target population <i>or</i> a systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+ directly applicable to the target population and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++ directly applicable to the target population and demonstrating overall consistency of results <i>or</i> extrapolated evidence from studies rates as 1++ <i>or</i> 1+
C	A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results <i>or</i> extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4 <i>or</i> extrapolated evidence from studies rated as 2+

Table B.3: Scottish Intercollegiate Guidelines Network grades of recommendations (Harbour and Miller 2001).

APPENDIX C – Letter to Dispensing Doctors



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[Date]

Dear Doctor,

My name is David Lim and as part of my Doctor of Public Health thesis entitled "Prescribing Practices of Australian Dispensing Doctors" I am seeking opinions from GPs who dispensed PBS pharmaceuticals to their patients. The objective of this study is to provide a more accurate picture of dispensing doctors' prescribing practices in Australia through the analysis of national PBS claims data.

We have recently analysed the pooled, de-identified 2005-7 PBS scripts for dispensing and non-dispensing GPs. We would very much like to have your input so as to have a better contextual understanding of the result.

I hope you will consider participating as your opinions are important to us. This project has been approved by Curtin University Human Ethics Committee (HR38/2007 and SPH48/2008) and qualifies for 40 (Category 1) RACGP QA&CPD points (2007-9 triennium, activity number 742557).

For more information, please do not hesitate to contact me on mobile 0429 922 033 or email chee.lim@postgrad.curtin.edu.au

Yours faithfully,

David Lim

APPENDIX D – Letter to Divisions of General Practice



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[Date]

Dear [Division of General Practice],

My name is David Lim and I am a doctoral student in the School of Public Health at Curtin University in Western Australia. As part of my Doctor of Public Health thesis entitled "Prescribing Practices of Australian Dispensing Doctors" I am seeking opinions from rural and remote doctors who dispensed PBS pharmaceuticals to their patients.

Some international studies have demonstrated differences in prescribing between dispensing and non-dispensing doctors. I have recently compared some characteristics of PBS scripts between Australian dispensing and non-dispensing doctors, nationally; and would like to speak with dispensing doctors to seek their opinions about the differences observed as well as to gain a better insight into issues that may influence prescribing.

I have attached to this letter a letter of invitation to participate. It would be very much appreciated if you can forward this to your dispensing doctor/s.

This project has been endorsed by some dispensing doctors and Divisions of General Practice. This project has been cleared by Curtin University Human Ethics Committee and RACGP QA&CPD points have been allocated for participation.

Should you require more information please do not hesitate to contact me on mobile 0429 922 033 or email chee.lim@postgrad.curtin.edu.au

Yours faithfully,

David Lim

APPENDIX E – Consent Form



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INFORMED CONSENT

The purpose of the interview is to seek your opinions as to the practices of dispensing doctors in Australia and to help explain the differences in the characteristic of PBS pharmaceuticals prescribed and dispensed by dispensing doctors.

The phone interview should take approximately 30 minutes and will be audio-taped. After the interview, the conversation will be transcribed and any identifiable information about you or your practice will be removed. Following transcription, the audio-recording will be destroyed. De-identified transcribed files will be maintained on a password protected computer at Curtin University. Access to the computer will be restricted to David Lim and his supervisors. The data collected will be analysed in aggregate terms only.

Participation in this research is strictly voluntary. All information that is collected is confidential and at no time will your individual comments or identity be released to a third party. Please understand that you are free to withdraw at any time during this research if you so wish and to remove any opinions that you may have contributed.

Any questions concerning this research can be directed to David Lim on 0429 922 033 or email chee.lim@postgrad.curtin.edu.au or supervisor Jan Lewis on (08) 9266 2075.

I (the informant) have read the information above and any questions I have asked have been answered to my satisfaction. I agree to participate in this research with the express understanding that I may withdraw at any time without bias. I agree that the research gathered for this study may be published provided that I am not identifiable.

Name ___/___/200__

Signature

Please contact me/ my receptionist on (phone/ email)
_____ to organise a suitable date and time for the phone
interview.

Fax-back to: **(08) 9452 2862**

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