The Use of Written Medicine Information by Consumers

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A thesis submitted to the University of Sydney
in fulfilment of the requirements
for the degree of Doctor of Philosophy
within the Faculty of Pharmacy

September 2005

DECLARATION

This thesis describes research undertaken in the Faculty of Pharmacy at the University of Sydney under the supervision of Dr Parisa Aslani and the associate supervision of Associate Professor Ines Krass, and with permission of the former Dean of the Faculty, Professor S.I. Benrimoj and present Acting Dean of the Faculty, Associate Professor Iqbal Ramzan.

To the best of my knowledge, the work presented in this thesis is original, except as acknowledged in the text. Where the work of other researchers has been cited, full acknowledgements have been made.

This thesis has not been submitted in part or in whole for the award of a degree at any other university.

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ACKNOWLEDGEMENTS

The work conducted in this PhD would not have been possible without the assistance from the following groups:

To all the study participants, rheumatologists and staff of the participating hospitals, and pharmacists and staff of the participating community pharmacies, thank you for your invaluable time, input and co-operation with the study.

To Dr Suzanne Miller and colleagues, thank you for the permission to use the MBSS and for the advice with its administration.

To the Commonwealth Department of Health and Aged Care, thank you for the financial assistance with the CMI Study.

To the Australian Department of Education, Training and Youth Affairs, the University of Sydney and the National Health and Medical Research Council of Australia, thank you for the financial support during my PhD candidature. My appreciation, too, to Professor Charlie Benrimoj and the Faculty of Pharmacy for stepping in with financial support during my transition between scholarships.

There are also many individuals who have been instrumental in supporting and assisting me throughout my PhD.

To Parisa and Ines, a very special thank you for your unwavering support, guidance, assistance and friendship during my candidature. Couldn't have done it without the both of you!

To my corner buddies, Alison and Geraldine, thank you for being there and for sharing all the ups and downs. Thanks for all the support and encouragement you have given, and for being my source of words and ideas. You have been instrumental in preserving my sanity over the past few years!

To Bek, Cassie and Simon as well as other fellow Pharm Prac colleagues and S114 Residents, thank you for your help and support, and for sharing the journey with me.

To Dad, Mom, Tim and Rowena, thank you very much for your love, support and for constantly keeping me in your prayers.

Lastly, but by no means least, to my husband Ian, thank you for *everything*- thank you for standing by me.

Michelle

PREFACE

In this thesis, the term *written medicine information (WMI)* is used to refer to any form of printed information leaflet about medications intended for consumers and unless otherwise specified, excludes package labels and internet-based information. Although synonymous with WMI, the term *written drug information (WDI)* has not been used in this thesis to prevent confusion; however, it has been used in previous publications. In addition to WMI, the term *Consumer Medicine Information (CMI)* has also been used in this thesis. CMI refers to brand-specific, manufacturer-produced written information about medicines intended for consumers in Australia (Dowling, 1996).

In the literature, different terms have been used to refer to individuals who utilise healthcare, ranging from patient to consumer to client. Preferences seemed to vary between groups of individuals [e.g. preference for *patient* by attendees of a back-pain clinic (Wing, 1997) and *client* by attendees of a mental health service (Lloyd, King, Bassett *et al.*, 2001)]. In this thesis, the term *patient* will be used specifically to refer to individuals who are unwell and receiving medical treatment (Zanni and Wick, 2001). On the other hand, the term *consumer* will be used more broadly to refer to all who use goods or services (Zanni and Wick, 2001), in this case provided by health professionals. Thus, *patients* who are unwell and receiving medical treatment are also considered as *consumers*.

The CMI Study formed part of a larger study funded by the Commonwealth Department of Health and Aged Care and a report has previously been submitted to the funding body (Aslani, Koo and Krass, 2001). This study was approved by the Human Research Ethics Committee of the University of Sydney.

The WMI Study Phase 1 and WMI Study Phase 2 were approved by the Human Research Ethics Committees of the University of Sydney, St George Hospital, Concord Hospital and St Vincent's Hospital.

ABSTRACT

Background and aims

Written medicine information (WMI) has been available in various forms since the 1960s. Over the past few decades, spurred on by consumer needs and demands, WMI has evolved to form an important tool in consumer education. A plethora of studies have been dedicated to examining the readership, use and impact of WMI on consumers. In Australia, Consumer Medicine Information (CMI), a brand-specific, standardised form of WMI for consumers produced by the manufacturer, was introduced in the early 1990s. Despite the extensive research on the readership, use and impact of WMI internationally, there is a noticeable lack of contribution from Australia hence research was needed to determine the use and impact of CMI on Australian consumers. Such research will also advance the current understanding of consumers' needs and thus may inform the development of measures that will ensure optimal use of medicines to improve health outcomes for consumers.

In contrast to the wealth of literature on the use and impact of WMI on consumers, little is known about the steps that precede a consumer using WMI, that is, the factors which influence a consumer's use of WMI, including the way they evaluate, read and seek WMI. Research in this area is worthwhile as research focussing on consumers' perceptions has the potential to inform and shape the future direction of health practice. Moreover, there is evidence that health information which is tailored to the patient is more effective than non-tailored information; however, for WMI to be tailored optimally, health professionals and researchers first need to understand the factors which influence the way a consumer uses information.

To address these gaps in the literature, this research aimed to investigate the:

- use of CMI and WMI by consumers
- influence of consumer factors on consumers' reading and seeking of WMI
- influence of consumer characteristics on consumers' evaluation and future use of CMI.

Methods

The research consisted of three studies. In the first study (CMI Study), a structured questionnaire was administered to 226 eligible consenting consumers from 17

randomly selected community pharmacies in metropolitan Sydney. The questionnaire consisting of five sections examined consumer's knowledge of CMI, current and past receipt of CMI, experiences when receiving CMI, readership and action taken after reading CMI, attitudes towards CMI and demographic characteristics. Most questions in the questionnaire consisted of multiple-choice closed-ended questions. Frequency distributions were examined for responses to all these questions. The items that were used to measure consumer attitudes towards CMI were developed to represent five constructs which appeared to be related to the use of CMI by consumers, based on data from an earlier focus group study. These were: readability and presentation (six items), perception of disease/condition (five items), role of carer (five items), health locus of control (six items) and experience of problems with medications in the past (five items). The construct validity and reliability of the "attitude toward CMI" scales were tested using exploratory factor analysis and Cronbach's alpha, respectively.

The findings from the CMI Study informed the development of the questionnaire for the second study, the WMI Study Phase 1. The questionnaire consisted of six sections used to gather the following patient-related information: interest and likelihood in reading and seeking WMI and general use of CMI/WMI, perceptions of CMI (comprehension, perceived usefulness and design rating) and likelihood of using CMI in the future, health locus of control, coping style, health literacy, demographics and disease state. The questionnaire was administered to 479 patients from three rheumatology/pain clinics in teaching hospitals (n=217) and 40 community pharmacies (n=262). Logistic regression was used to examine the relationships between patient factors and interest in reading and seeking WMI. Multiple regression and path analysis were used to examine associations between patient characteristics and their evaluation and intended future use of CMI.

The final study, the WMI Study Phase 2, comprised a series of follow-up semi-structured telephone interviews with 39 respondents from the WMI Study Phase 1 to triangulate the data from the WMI Study Phase 1. Content thematic analysis was conducted on these data.

Results

In the CMI Study, consumers (n=226) had variable understanding of CMI and most commonly associated CMI with written information leaflets inside the medication box (n=142, 62.8%), a reflection of the main form of CMI available at the time of the study.

The majority reported receiving a CMI on the day of the interview (n=132, 58.4%) or in the past (n=184, 81.4%), mainly as a package insert, and without the involvement of a health professional. Consumers (n=214) also expressed preferences to receive CMI mainly from the doctor (n= 82, 41.4%), pharmacist (n=66, 33.3%) or both (n=48, 24.2%) and mainly at the doctor's surgery before the prescription was finalised (n=65, 32.8%) or at the pharmacy after the prescription is dispensed (n=60, 30.3%). Of those who responded to the question on past readership of CMI (n=153), 64% (n=98) reported reading the CMI to different extents. These resulted mainly in positive outcomes, nonetheless, some consumers reported that they had concerns or queries and the majority of these reported contacting a health professional. Factor analysis of the "attitude to CMI" section yielded 4 factors explaining 52.8% of the total variance. These were interpreted as: perception of disease condition [5 items, factor loadings 0.63-0.82, Cronbach's alpha (α)=0.86], role of carer (4 items, factor loadings 0.50-0.85, α=0.85), health locus of control (3 items, factor loadings 0.58-0.78, α=0.67) and readability and presentation (3 items, factor loadings 0.51-0.68, α=0.59).

In the WMI Study Phase 1 (n=479), the majority of patients expressed interest in reading WMI (n=336, 70.1%) but were not interested in seeking WMI (n=328, 68.5%). Most (n=398, 83.1%) were unaware of the definition of 'Consumer Medicine Information'. However, after a description of CMI was given, most participants (n=377, 78.7%) reported having read a CMI for their own medication(s) and approximately a third (n=143, 29.9%) also read CMI for someone in their care. In terms of interest in reading WMI, patients who coped by taking in information [odds ratio (OR)= 2.23, 95% confidence interval (CI) 1.18-4.20] and patients who had adequate health literacy levels (OR=4.09, CI 1.53-10.91) were more likely to be interested in reading WMI than their counterparts while blue-collar workers were less likely to be interested in reading WMI when compared to homemakers (OR 0.26, CI 0.08-0.82). When it came to seeking WMI, those with a symptomatic condition (pain/rheumatology conditions) were more likely to be interested in seeking WMI compared to those with an asymptomatic condition (hypertension) (OR 1.83, CI 1.10-3.04), those with adequate health literacy levels were more likely to be interested in seeking WMI than those with inadequate health literacy levels (OR 4.22, CI 1.49-11.98) and an increase in powerful other health locus of control scores predicted a decreased likelihood in seeking WMI (OR 0.94, CI 0.90-0.99).

In terms of evaluation of CMI, compared to their counterparts, patients who spoke mainly English at home [beta coefficient (B)=0.30, CI 0.08-0.52], those with at least

secondary education (B=0.24, CI 0.02-0.46) and those with adequate health literacy levels (B=0.59, CI 0.35-0.84) had a better comprehension of CMI. Patients who were older (B=0.25, CI 0.02-0.48) and those on greater number of medications (B=0.04, CI 0.00-0.07) found CMI more useful. Compared to younger patients, older patients also scored the design aspects of CMI more favourably (B=0.09, CI 0.04-0.14). Finally, patients with adequate health literacy levels expressed greater intention to use CMI in the future compared to those with inadequate health literacy levels (B=0.46, CI 0.07-0.85). In addition to health literacy levels, increasing comprehension (B=0.41, CI 0.25-0.58) and increasing perceived usefulness of CMI (B=0.32, CI 0.17-0.46) also positively influenced intended use of CMI.

The majority of consumers in the WMI Study Phase 2 expressed interest in obtaining information about their prescription medications but varied in their proactiveness in seeking information, sources of information used and preference for verbal or written information. Most participants felt that health professionals played a crucial role in the provision of information to consumers and should be more proactive in offering information to consumers. In addition to providing more in-depth information on issues surrounding consumer use of WMI, the results from this study also served to triangulate the results obtained in the WMI Study Phase 1. The general level of interest in reading and seeking WMI exhibited by patients in both phases of the studies were found to be similar. The interview data also directly supported some of the factors influencing use of WMI identified in Phase 1 but not others. For the latter, the findings provided some insight into the complexities of some of these associations.

Conclusions

This research contributes to the current understanding in the area of WMI from the perspective of the consumer. Findings revealed that many consumers are interested in WMI, do read CMI and benefit from it. However, there are issues that still need to be addressed in order to optimise the use of CMI by consumers. The research has also identified several consumer factors which may influence the way consumers read, seek or evaluate WMI. These findings have highlighted the need to consider individual consumer factors to ensure that information about medicines is tailored to meet individual needs and preferences. The overall findings from this research have provided useful insights which may be utilised to inform the development of strategies to enhance consumers' medicines use and thus improve consumer health outcomes.

OUTLINE OF CHAPTERS

Chapter 1

This chapter provides an overview of the implementation of WMI in the United States, Europe and Australia, the rationale for WMI, the readership and use of WMI and its impact on consumers. Next, the chapter reviews the international literature that highlights potential factors which may influence the use of WMI by consumers. The chapter concludes with a summary of the research needs identified from the literature.

Chapter 2

Based on the findings in Chapter 1, this chapter provides the rationale, aims and objectives of the research project. It then provides an overview of the quantitative and qualitative research methods used in the studies.

Chapter 3

This chapter focuses on the CMI Study, a pilot questionnaire administered to a sample of consumers of prescription medicines recruited from community pharmacies. The objectives of this study were to determine consumers' awareness, knowledge, receipt and experience of CMI, to examine readership and impact of reading CMI and to explore consumer attitudes towards CMI. Following a description of the methods, the descriptive statistics for all sections are presented. The construct validity and reliability of the attitudinal items are assessed using factor analysis and Cronbach's alpha, respectively. The study results are then discussed.

Chapter 4

Informed by the findings from the CMI Study, this chapter focuses on the development and implementation of the WMI Study Phase 1, involving the administration of a questionnaire to patients with rheumatology/pain conditions from hospital clinics and patients with hypertension from community pharmacies. The objectives of this study were to determine patient's interest and likelihood in reading and seeking WMI, to determine patients' awareness, readership and use of CMI, and to investigate the influence of consumer factors on the way consumers read, seek and evaluate WMI. Logistic regression is used to examine the relationships between consumer factors and

interest in reading and seeking WMI. Multiple regression and path analysis are used to examine associations between consumer characteristics and their evaluation and intended future use of CMI. These findings are discussed at the end of the chapter.

Chapter 5

This chapter focuses on the WMI Study Phase 2, a follow-up telephone interview study with a sub-sample of respondents from the WMI Study Phase 1. The themes identified from the interviews are described, discussed and compared to the findings from the WMI Study Phase 1. This study also provides a further opportunity to gain in-depth information on the factors influencing patients' reading and seeking of WMI as well as to explore further issues surrounding the use of CMI and WMI in general.

Chapter 6

This chapter concludes the thesis by bringing together the three studies in the research project. The findings from these studies provide insights which may be used to inform the development of strategies to enhance consumers' medicines use. These insights and recommendations are discussed in terms of their potential implications on the development, dissemination and use of WMI. Following that, suggestions for future directions are raised, including research which targets both health professionals and consumers.

PUBLICATIONS AND COMMUNICATIONS

Peer-reviewed journal articles

Koo MM, Krass I and Aslani P (2003). Factors influencing consumer use of written drug information. *Annals of Pharmacotherapy*, 37(2), 259-267.

Koo MM, Krass I and Aslani P (2005). Consumer use of Consumer Medicine Information. *Journal of Pharmacy Practice and Research*, 35(2), 94-98.

Koo MM, Krass I and Aslani P (2005). Patient characteristics influencing evaluation of written medicine information: lessons for patient education. *Annals of Pharmacotherapy*, 39(9), 1434-1440.

Koo MM, Krass I and Aslani P (2005). Enhancing patient education about medicines: factors influencing reading and seeking of written medicine information. *Health Expectations* (accepted).

Peer-reviewed published abstracts

Koo M, Krass I and Aslani P (2002). Development of a tool to measure factors influencing the use of written drug information by consumers [abstract]. *Journal of Social and Administrative Pharmacy*, 19(6), 214-215.
-podium presentation at the 12th International Social Pharmacy Workshop (Sydney, Australia).

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-podium presentation at the 13th International Social Pharmacy Workshop (ISPW) 2004 (Malta).

Other research-related articles

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External conference presentations

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-podium presentation at the University of Sydney 3rd College of Health Sciences and Medical Research Conference 2002 "From Cell to Society" (Leura, Australia).

Koo M, Krass I and Aslani P. Consumer Medicine Information (CMI): what do consumers do with them?
-podium presentation at the Australasian Pharmaceutical Science Association (APSA) Annual Conference 2002 (Melbourne, Australia).

Koo M, Krass I and Aslani P. Health literacy, the patient and written medicine information: exploring the connections.

-podium presentation at the University of Sydney 4th College of Health Sciences and Medical Research Conference 2004 "From Cell to Society" (Leura, Australia).

Koo M, Krass I and Aslani P. Consumers and CMI: friends or foes?
-poster presentation at the 3rd National Medicines Symposium 2004 (Brisbane, Australia).

Internal faculty presentations

Koo M, Krass I and Aslani P. Factors affecting the use of written drug information- a literature review.
-podium presentation at the Faculty of Pharmacy Postgraduate Work-in-Progress (2002).

Koo M, Krass I and Aslani P. The use of written medicines information by consumers- preliminary results.
-podium presentation at the Faculty of Pharmacy Postgraduate Conference (2003).

Koo M, Krass I and Aslani P. To read or not to read: that is the question.
-poster presentation at the Faculty of Pharmacy Research Day (2003).

Koo M, Krass I and Aslani P. The influence of consumer characteristics on the evaluation of CMI.
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Koo M, Krass I and Aslani P. Consumers and CMI: friends or foes?
-poster presentation at the Faculty of Pharmacy Research Day (2004).

Koo M. Consumer use of written medicine information.
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GLOSSARY OF TERMS AND ACRONYMS

ABS	Australian Bureau of Statistics
CIRF	Consumer Information Rating Form
CMI	Consumer Medicine Information
FDA	Food and Drug Administration
HBM	Health Belief Model
HLC	Health locus of control
MBSS	Miller Behavioural Style Scale
MHLC	Multidimensional Health Locus of Control
MHRA	Medicines and Healthcare products Regulatory Agency
MIC	Medicines Information to Consumer
MIP	Medicines Information Project
MIDAS	Medication Information Design Assessment Scale
NSAID	Non-steroidal anti-inflammatory drug
PHARM	Pharmaceutical Health and Rational Use of Medicines
PI	Product information
PIL	Patient Information Leaflet
PPI	Patient package insert
QARG	Quality Assurance Reference Group
REALM	Rapid Estimate of Adult Literacy in Medicine
Rx	Prescription
SAM	Suitability Assessment of Material
SORT-R	Slosson Oral Reading Test- Revised
SPSS	Statistical Package for the Social Sciences
SSD	Statistical subdivision
TOFHLA	Test of Functional Health Literacy in Adults
UK	United Kingdom
US	United States
WHO	World Health Organisation
WMI	Written medicine information
WRAT-R	Wide Range Achievement Test- Revised

1 BACKGROUND AND LITERATURE REVIEW

Written medicine information (WMI) intended for consumers of prescription medications has been a topic of international interest and debate since the 1960s. WMI refers to any form of printed information leaflet about medications intended for consumers. These range from simple one-page leaflets to more extensive brochures or texts (Buck, 1998).

In recent times, another source of 'virtual' written information about medicines has arisen through the birth of the internet. Internet-based medicine information is rapidly gaining popularity as it is considered an interactive and time-efficient source of up-to-date information which can be accessed when required, in an anonymous and non-threatening manner (Bessell, Silagy, Anderson *et al.*, 2002; Peterson-Clark, Aslani and Williams, 2004). Nonetheless, there are concerns that the information available on the internet is of variable quality and may be potentially harmful to an undiscerning consumer (Eysenbach, Powell, Kuss *et al.*, 2002). Moreover, despite its popularity, there are still many consumers who do not have ready access to internet-based information, for example, consumers who are older (Cameron, Marquis and Webster, 2001; Tay, 2001), less educated (Taylor, 2002) or from poorer socio-economic backgrounds (Lown, Bukachi and Xavier, 1998; Edejer, 2000; Taylor, 2002).

For these reasons, traditional WMI which is much more tightly regulated and readily accessible will always have a pivotal role to play in educating consumers about their medicines. Notwithstanding, internet-based medicine information, which services a growing proportion of society, is increasing in importance and has attracted much research in recent years. The focus of this thesis and thus this literature review, however, is on traditional forms of WMI. To date, consumer-oriented research in the area of WMI has focussed mainly on the use and impact of WMI on consumers [e.g. Gotsch and Liguori (1982); George, Waters and Nicholas (1983); Johnson, Mitch, Sherwood *et al.* (1986); Gibbs, Waters and George (1987, 1989a, b); Bandesha, Raynor and Teale (1996); Raynor and Knapp (2000)]. Little is known, however, about the steps that precede a consumer using WMI, that is, the factors that influence the way consumers read, seek or evaluate WMI.

In the first part of this chapter, an overview of the introduction of WMI in the United States (US), Europe and Australia will be provided, followed by the rationale for WMI,

an overview of studies examining the readership and use of WMI and its impact on consumers. The second part of this chapter will focus on studies that highlight potential factors which may influence the use of WMI by consumers.

1.1 THE INTERNATIONAL SCENE

1.1.1 The United States

In the late 1960s, in response to consumer demands for more information about prescription medicines, the US Food and Drug Administration (FDA) proposed the introduction of patient package inserts (PPIs) for certain classes of medications (such as oral contraceptives), specific medications (such as isoproterenol, isotretinoin and triazolam) and therapeutic devices (such as intrauterine contraceptive devices) (Johnson, Mitch, Sherwood *et al.*, 1986; Cariski, 1995; Steering Committee, 1996a; Lyons and Rumore, 1997). In 1979, the FDA proposed to extend PPIs to include all prescription medications but this was opposed by health professionals and the pharmaceutical industry who contended that the proposal would:

> *"...encourage self-diagnosis and the transfer of prescription drug products among patients; produce adverse reactions in patients through suggestion; affect adversely the liability of drug manufacturers, physicians, and pharmacists; interfere with the patient-physician relationship; impose unnecessary burdens on manufacturers and pharmacists; and increase the cost of prescription drug products and health care in general"* (p.400-401) (Nightingale, 1995).

After considering these comments, in 1980, the FDA proposed a rule that would have required manufacturers to produce and distribute PPIs for 10 medications or medication classes[1] (Nightingale, 1995; Steering Committee, 1996a).

In 1982, the FDA decided to revoke the PPI program (Nightingale, 1995; Steering Committee, 1996a). This was in part based on assurances by pharmaceutical manufacturers, health professional associations and private-sector providers of WMI

[1] These medications or medication classes were ampicillin, benzodiazepines, cimetidine, clofibrate, digoxin, methoxsalen, propoxyphene, phenytoin, thiazide and warfarin (Nightingale, 1995).

that the goals of providing consumers with information about prescription medications would be met more effectively and efficiently without regulation (Nightingale, 1995; FDA, 2005).

The FDA proceeded to monitor the progress of these voluntary efforts and found that whilst distribution of WMI increased, the usefulness of the information was highly variable (FDA, 2005). Hence, in 1995, the FDA once again put forward another proposal, commonly known as the MedGuide proposal. This proposal set goals for the distribution of useful prescription medicine information to consumers and would have made it mandatory for manufacturers to provide medicine information for consumers (Nordenberg, 1997). Whilst the concept of providing better information about prescription medicines to consumers was supported, there were disagreements with some of the plan's assumptions and opposition to some of the proposed organisational details included in the proposal (Steering Committee, 1996a; Thompson, 1996).

In 1996, in conjunction with the passing of Public Law 104-180, the FDA's MedGuide proposal was put on hold to provide an opportunity for private sectors to develop a plan that would achieve similar goals as set out in the MedGuide proposal but be implemented on a voluntary rather than mandatory basis (Steering Committee, 1996a; Nordenberg, 1997). Public Law 104-180 mandated the formation of a committee of diverse interests to develop a long-range, comprehensive action plan to improve oral and written communication to consumers about their prescription medicines with the goal of distributing useful oral and written prescription information to 75% of individuals receiving new prescriptions by the year 2000 and 95% by the year 2006 (Anonymous, 1996).

Hence, the Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information was formed. The Action Plan was required to address six specific issues: identify plan goals; assess effectiveness of current approaches used to provide oral and written prescription information to consumers; develop guidelines for providing effective oral and written prescription information; contain elements necessary to ensure transmittal of useful information to consumers; develop a mechanism to periodically assess the quality of information and how frequently it is provided to consumers; and provide for compliance with relevant State board regulations on medications (Steering Committee, 1996a). The action plan was accepted in 1997.

'Useful' prescription medicine information has since been referred to as Consumer Medication Information. Ongoing efforts spearheaded by various organisations are currently underway to meet the goals set for 2006. A FDA-commissioned study to assess the receipt and usefulness of Consumer Medication Information revealed that 89% of consumers received written information about their prescription medications, usually in the form of computer-generated printouts. Whilst this figure surpassed the 75% goal set for 2000, the overall usefulness of the information provided (based on the criteria suggested in the Action Plan) was approximately 50% (Svarstad and Mount, 2001). Given this progress, the FDA is continuing to work with the private sector to improve the usefulness of Consumer Medication Information and meet the goal for 2006 (FDA Office of Public Affairs, 2002). In May 2005, the FDA also released a draft document providing guidance for writing 'useful' Consumer Medication Information (FDA, 2005).

Public Law 104-180 prohibited the FDA from taking further regulatory steps if private sector initiatives met the goals of the Action Plan within the specified time frames. Whilst the production of 'useful' Consumer Medication Information remained a voluntary initiative, Public Law 104- 180 did not preclude the FDA from using its existing authority to implement a mandatory program for a small number of medications which posed a *"serious and significant public health concern requiring immediate distribution of FDA-approved patient medication information"* (p.66378) (FDA, 1998). This FDA-approved patient medication information is known as Medication Guides. It exists for medications such as isotretinoin, serotonin selective reuptake inhibitors and non-steroidal anti-inflammatory drugs (NSAIDs).

1.1.2 Europe

In Europe, WMI has been available for consumers since 1977 (Whittet, 1977; White, 1988). However, due to the considerable variation in content and format (Wilkes, 1992), the European Economic Community published Council Directive 92/27/EEC (Council Directive, 1992) which required all medicines to be accompanied by a comprehensive information leaflet produced by the manufacturer of the medication (Blattmann, 1992; Vander Stichele and Bogaert, 1995; Dickinson, Raynor and Duman, 2001). The main purpose of this Directive was to provide consumers of medications with full and comprehensible information so that medicines could be used safely and effectively (Patient Information Working Group, 2005). The content of the leaflets are

closely defined by regulations (Raynor, Savage, Knapp *et al.*, 2004). More specifically, these information leaflets must contain all the information in the Summary of Product Characteristics, but be written in language suitable for consumers (Dickinson, Raynor and Duman, 2001). In January 1999, the Directive came into full effect across the European Union including the UK following a five-year phasing-in period (Dickinson, Raynor and Duman, 2001).

In conjunction with Council Directive 92/27/EEC, the European Commission published a set of guidelines on the readability of the leaflets (European Commission, 1998). For the first time, these guidelines also made recommendations on consumer testing of the leaflets based on the concept of diagnostic testing from Australia (see Section 1.1.3). In 2004, changes to the European legislation introduced a new legal obligation to ensure that all PILs reflected the results of consultations with consumers who are the intended users of the information (Patient Information Working Group, 2005). This legislation was to be implemented across Europe by October 2005; the UK decided to implement it from 1 July 2005.

In the UK, in 2004, the Committee on Safety of Medicines of the Medicines and Healthcare products Regulatory Agency (MHRA) established a Patient Information Working Group to provide advice on a strategy to improve the quality of PIL, propose criteria for assessing the quality of patient information and the process by the which the criteria will be monitored (Patient Information Working Group, 2005). In addition to this committee which focussed on the mandatory PIL, another collaboration was also set up. The Medicines Information Project (MIP), a collaborative partnership between various organisations including private and government bodies, aimed to provide information that will encourage and enable consumers to *"make informed decisions about their own health, be more involved in treatment choices and make best use of their medicines"* (Anonymous, 2003). This was to be achieved through the production of Medicine Guides which are intended to complement PIL and are designed to be available to the consumer before a medicine is prescribed (currently available online) (Anonymous, 2004). The MIP is an ongoing project and to date, Medicine Guides are available for three different conditions: epilepsy, influenza and cholesterol.

1.1.3 Australia

In 1991, a standardised format of WMI (known as Consumer Medicine Information or CMI[2]) resulted from two recommendations of a report on drug evaluation in Australia (Baume, 1991). The incorporation of these recommendations into the Australian legislation (Therapeutic Goods Regulations 9A) led to a mandatory requirement for all new prescription medicines and existing prescription medicines with changes to their Product Information (PI) approved after 1 January 1993 to be accompanied by CMI (Therapeutic Goods Regulations, 1993a; Therapeutic Goods Regulations Amendment No. 364, 1994). It was intended that as of January 2002, all existing prescription medications would have a CMI (Baker, 1994). This date was subsequently revised to January 2003 (Wilmington, 2002). The requirements were further extended to require 'pharmacist only' medications which were approved on or after 1 July 2005 to be accompanied by written information (Therapeutic Goods Regulations Amendment No. 208, 1995). However, the focus of this thesis will be on CMI for prescription medications.

The required content of CMI for prescription medicines is specified by Schedule 12 of the Therapeutic Goods Regulations (Therapeutic Goods Regulations, 1993b). The CMI is required to be consistent with the medication's PI but be written in English and in language that is easily understood by consumers. It can be produced in three formats: computer printout, package insert or loose leaflet (Therapeutic Goods Regulations Amendment No. 364, 1994; Dowling, 1996). Computer printout CMI is usually available in prescribing/dispensing software or electronic drug references. It is printed by health professionals at the time of prescribing or dispensing and is currently the main form of CMI used. With the advent of the internet as a popular source of medicine information, computer printout CMI for many medicines is now also available via several different websites. The second format of CMI, package insert CMI, is located inside or around the medication box/bottle. This is currently being phased out and replaced by computer printout CMI as the latter is considered easier to update (D. Monk, personal communication, 2 November 2004). Lastly, loose leaflet CMI consists of a booklet, tear-off pad or loose leaflet supplied directly to health professionals for distribution by the manufacturers; this form of CMI is rarely used.

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[2] Consumer Medicine Information (CMI) was originally known as Consumer Product Information (CPI). In 1997, the term CPI was changed to CMI to *"promote better consumer awareness of CPI, as well as harmonising with New Zealand nomenclature"* (p.445) (Anonymous, 1997). In this thesis, only the term CMI will be used.

Although the content of CMI is specified in the legislation, its design and presentation is not. In 1994, the Commonwealth Department of Health and Family Services funded the development of usability guidelines by the Communication Research Institute of Australia to assist producers of CMI to communicate information about medicines effectively in the CMI and also provided a method of testing CMI with consumers known as diagnostic testing (Dowden, Clear, Fogg *et al.*, 1996; Sless and Wiseman, 1997). Diagnostic testing involves finding out what is wrong with a CMI through observing a consumer as he/she uses the CMI and asking questions to ascertain if the consumer can appropriately interpret and apply the information they have read (Sless and Wiseman, 1997).

The Australian Pharmaceutical Manufacturers Association (now Medicines Australia) also established CMI consistency working groups to encourage consistency between CMI (Dowden, Clear, Fogg *et al.*, 1996). These working groups consisted of CMI writers from different pharmaceutical companies who collaborated to prepare a core CMI for a given therapeutic area (Shenfield and Tasker, 1997).

In addition, in 1995, a Quality Assurance Reference Group (QARG) was established by the Pharmaceutical Health and Rational Use of Medicines (PHARM)[3] committee. The main role of QARG is to promote high quality and useful CMI, to oversee the work of the CMI consistency working groups and to consider matters related to the content and quality of CMI (Dowden, Clear, Fogg *et al.*, 1996).

In 2001, the Medicines Information to Consumer (MIC) Program was implemented by the Pharmacy Guild of Australia as part of the Third Community Pharmacy Agreement (Benton, Snow and Parr, 2004). The MIC Program is a voluntary program that provides participating pharmacies with financial incentives to encourage them to use CMI in their daily practice (Koo and Aslani, 2004). In 2001, the first incentive consisted of a once-off payment to pharmacies wishing to be part of the program to assist pharmacies in upgrading their resources (e.g. purchasing printers) to enable them to provide CMI (Benton, Snow and Parr, 2004). From 2002 onwards, pharmacies were required to register in order to participate in the second phase of the program. This phase of the program provided an ongoing participation allowance for providing CMI. The ongoing

[3] PHARM is a multidisciplinary committee that provides expert advice to the Minister for Health and Ageing and the Department of Health and Ageing on strategies for quality use of medicines.

allowance is dependent on prescription volume[4] and is paid bi-monthly in arrears (Benton, Snow and Parr, 2004).

1.1.4 Comparison of WMI between regions

Overall, while there are some similarities in the history of WMI implementation between US, Europe and Australia, there are also distinct differences. A summary comparing WMI in these three regions is presented in Table 1.1 Comparison of current written medicine information for prescription medicines in US, Europe and Australia. Although there are differences in the way WMI has been implemented, a comparison of the contents of the resulting WMI revealed a high degree of similarity between the regions (Table 1.2).

[4] The ongoing allowance is calculated based on the number of claimable prescriptions dispensed by the pharmacy (10 cents per claimable prescription) in a two-month cycle (Benton, Snow and Parr, 2004).

Table 1.1 Comparison of current written medicine information for prescription medicines in US, Europe and Australia

	US	Europe	Australia
Name	'Useful' prescription medicine information (recently Consumer Medication Information)*	Patient information leaflet (PIL)	Consumer Medicine Information (CMI)
Associated legislation (year)	Public Law 104-180 (1996)	Council Directive 92/27/EEC (1992)	Therapeutic Goods Regulations 9A (1993)
Implementation	Voluntary but subject to evaluation in 2006	Compulsory by January 1999	Compulsory by January 2003
Form	Not specified but usually computer printout	Package insert	Computer printout, package insert or loose leaflet
Producer	Private organisations	Manufacturer	Manufacturer/sponsor
Legislation/ guidelines specifying content	Action Plan for the Provision of Useful Prescription Medicine Information	Council Directive 92/27/EEC	Schedule 12 and 13 of Therapeutic Goods Regulations

* This refers to the main form of WMI available in the US. As mentioned in Section 1.1.1, mandatory FDA-approved Medication Guides exist for a small number of medications (not covered in the table).

Table 1.2 Comparison of specified contents for WMI in US, Europe and Australia

Content*	US	Europe	Australia
Identification (trade name, generic name, ingredients and excipients)	Yes	Yes	Yes
Indication(s) and how it works	Indications only	Yes	Yes
Precautions before using medicine (contraindications, precautions, interactions, special warnings)	Yes (includes the FDA black box warning and risk of tolerance/ dependence)	Yes (includes risk of withdrawal)	Yes (includes habit forming potential)
How to use medication properly	Yes	Yes	Yes
Unwanted effects	Yes	Yes	Yes
Overdose and missed doses	Yes	Yes	Yes
Storage	Yes	Special storage only	Yes
Reference to expiry date	Yes	Yes	Yes
Sponsor/producer	Yes	Yes	Yes
Date of last revision	Yes	Yes	Yes
Statement encouraging discussion with health professional/ where to go for further information	Yes	Only in relation to unwanted effects	Yes

* Content based on Steering Committee (1996a); Council Directive (1992); Therapeutic Goods Regulations (1993b).
NB: Categories of information may not be listed in the same order in actual WMI.

1.2 RATIONALE FOR WMI

The existing literature suggests several reasons for the provision of WMI. Firstly, there is a burgeoning desire and demand for information by consumers (Ley and Morris, 1984), ranging from information about their conditions [e.g. Kay and Punchak (1988); Beisecker and Beisecker (1990); Trewin and Veitch (2003)] to their medicines [e.g. Baksaas and Helgeland (1980); Kay and Punchak (1988); Gibbs, Waters and George

(1989a); Livingstone, Pugh, Winn *et al.* (1996)] and general health matters (Lam and Krass, 1995). Furthermore, some consumers have expressed a specific preference for written information as it could be read at their own pace and referred to when necessary (Kay and Punchak, 1988).

Secondly, in line with the increasing demand for information by consumers, in the past few decades, there has been a gradual shift from a paternalistic approach by health professionals to a growing recognition of consumer autonomy with respect to their health care (Graham and Kwok, 1995; Mills and Sullivan, 1999). Hence, there has been an emphasis on consumer rights to evidence-based, consumer-centred, accurate and balanced information to empower consumers to actively participate in their own health care (Coulter, 1998; Dixon-Woods, 2001; Benton, Snow and Parr, 2004) and to ensure that consumers are equipped to use their medications correctly and optimally (Anonymous, 1993; Benton, Snow and Parr, 2004).

Thirdly, written information serves to reinforce verbal information (Schommer and Wiederholt, 1994) as consumers may simply forget the verbal information they have been given (Ley and Morris, 1984; Weinman, 1990; Wilson, Robinson, Blenkinsopp *et al.*, 1992) or struggle to understand what they are being told (Ley and Morris, 1984; Weinman, 1990). These situations could be further aggravated by possible anxiety at the time of the consultation or the use of medical jargon by health professionals (Katz, 1991; Benton, Snow and Parr, 2004). In other cases, written information serves to supplement inadequate verbal information provided by health professionals (Coulter, 1998) due to insufficient time, lack of knowledge or an underestimation of consumers' desire and ability to cope with information (Coulter, Entwistle and Gilbert, 1999; Benton, Snow and Parr, 2004).

Last but by no means least, the rationale for the provision of WMI lies in its positive impact on consumers' medication-taking behaviours (Section 1.4).

1.3 READERSHIP AND USE OF WMI

1.3.1 Readership and use of WMI in Europe and the United States

The majority of studies reporting the readership and use of WMI have originated from Europe and the US and involved specific classes of medications [e.g. Morris, Mazis and Gordon (1977); Van haecht, Vander Stichele, De Backer *et al.* (1991); Sleath and Wurst (2002)] or prescription medicines in general [e.g. Bandesha, Raynor and Teale (1996); Raynor and Knapp (2000)].

Despite the apparent demand for drug information by consumers, the readership[5] of WMI varies considerably. Studies examining the readership of package insert WMI without any prompting or encouragement from health professionals reported readership ranging from 40% (Raynor and Knapp, 2000) to 89% (Vander Stichele, Van haecht, Braem *et al.*, 1991). When a health professional was involved in handing out WMI, readership as high as 81% (consumer's attention not drawn to WMI) (Gibbs, Waters and George, 1989a) and 94% (consumer's attention drawn to PPI and encouraged to read it) (Gotsch and Liguori, 1982) have been reported.

Within this range, some consumers read the information thoroughly or partially and others have delegated the task to a relative (Vander Stichele, Van haecht, Braem *et al.*, 1991; Bandesha, Raynor and Teale, 1996; Knapp and Raynor, 1999). Sections of particular interest or deemed the most useful included information on the indication, potential side effects, dosage and administration of the drug (Dodds and King, 1989; Amery and Van Winkel, 1995; Graham and Kwok, 1995; Berry, Michas, Gillie *et al.*, 1997; Dickinson, Raynor and Duman, 2001; Raynor, Savage, Knapp *et al.*, 2004). The impact of reading WMI on consumers is reported in Section 1.4.

[5] Some studies in the literature have reported readership as the proportion of consumers who reported reading WMI out of the total number of consumers who were *aware* of the presence of WMI. As this artificially inflates readership in most cases, in this review, readership is defined as the proportion of consumers who reported reading WMI out of the total study population.

1.3.2 Readership and use of CMI in Australia

The introduction of WMI occurred much later in Australia compared to Europe and the US. Nonetheless, more than a decade after its introduction in 1993, very few published studies have examined the readership and use of CMI by Australian consumers.

A qualitative study in late 1993 found that consumers favoured the concept of CMI and reported that they were likely to read the information in detail (Emjay Research Consultants Pty Ltd, 1994). Several impacts were also observed as a result of consumers reading CMI (Section 1.4). Although informative, the study involved only a small sample, only three different prescription medications and was not conducted in a natural setting.

Another qualitative study focusing on older people conducted in 1998 found that the majority of consumers had previously received some form of WMI together with the medication (Lawrence and Fogg, 1998). Most consumers believed CMI would be useful to them but expressed a preference to receive WMI in their own language. Once again, due to the qualitative nature of the study and the inclusion of only older consumers, the results cannot be generalised.

In addition to these qualitative studies, a report on quality use of medicines noted that approximately 36% in 1996 and 57% in 1999 of consumers reported reading WMI. However, not all of these consumers received CMI specifically (Quality Use of Medicines and Pharmacy Research Centre- University of South Australia, 2001).

More recently, in 2003 and 2004, two surveys[6] examining the readership and use of CMI by consumers were conducted as part of a larger study to evaluate the MIC Program (Benton, Snow and Parr, 2004) (see Section 1.1.3). The first survey was a self-completion questionnaire distributed by pharmacists in July to October 2003 to 30 consecutive consumers to whom they provided a CMI (total n=200) (Benton, Snow and Parr, 2004). From this survey, 94% of consumers (total n=200) reported receiving a computer printout CMI from the pharmacist. This high rate is most likely attributed to the fact that the provision of CMI was part of the inclusion criteria. In light of this, it is

[6] It is important to note that these surveys were conducted after the completion of CMI Study described in this research project (see Chapter 3).

interesting to note that not all consumers who were given a CMI by the pharmacist were actually aware of it.

The second survey consisted of two telephone surveys to a representative sample of 1000 Australian consumers (in July 2003 and April 2004) (Benton, Snow and Parr, 2004). This survey may provide a more realistic receipt rate with 24% (July 2003) and 29% (April 2004) of consumers remembering receiving a computer printout CMI from their pharmacist some time in the past. However, as some consumers may have forgotten that they had been given a computer printout in the past, this rate may be an underestimation of the actual number of consumers who received a computer printout. Moreover, as the study only took into account computer printout CMI printed by the pharmacist, these receipt rates are also likely to be an underestimation of the actual number of consumers who have access to CMI in its different forms.

In the self-completion questionnaire, 78% of consumers read CMI in detail and 13% read it briefly (Benton, Snow and Parr, 2004). This level of readership falls within the range observed in the international literature. However, several factors may have influenced this result. Firstly, it is important to bear in mind that this study only examined the readership of computer printout CMI and not package insert CMI (which was excluded from the study). Secondly, it is not sure whether pharmacists encouraged consumers to read CMI when handing it to them. Lastly, the response rate for the self-completion questionnaire was only 16% which may have biased the results.

Nonetheless, several impacts were observed from this study. These are discussed in Section 1.4 along with the international literature.

1.4 IMPACT OF WMI

A plethora of studies conducted mainly in the US and Europe have examined the impact of various types of WMI on consumers' knowledge, understanding, satisfaction and compliance with their medications as well as their experience of side effects following exposure to WMI. This area has also been covered in several reviews [e.g. Morris and Halperin (1979); Ley and Morris (1984); Arthur (1995); Raynor (1998a)]. Hence, the aim of the following sections is to provide a summary of some of the observed impacts of WMI from the literature.

1.4.1 Knowledge and understanding of medications

In many studies, provision of WMI has been associated with an increase in consumers' knowledge and understanding in some aspects of their medications (Gotsch and Liguori, 1982; George, Waters and Nicholas, 1983; Wiederholt and Kotzan, 1983; Johnson, Mitch, Sherwood *et al.*, 1986; Punchak and Kay, 1988; Gibbs, Waters and George, 1989a, b, 1990; Jones, Clarbour and Erskine, 1990; Baker, Roberts, Newcombe *et al.*, 1991; Connolly and McGlynn, 1992; Peura, Klaukka, Hannula *et al.*, 1993; Emjay Research Consultants Pty Ltd, 1994; Smith and Whitfield, 1995; Bandesha, Raynor and Teale, 1996; Little, Griffin, Kelly *et al.*, 1998; Benton, Snow and Parr, 2004; Al-Saffar, Deshmukh, Carter *et al.*, 2005). Although most of these studies measured short-term changes in knowledge post-exposure to WMI {in the order of days [e.g. Johnson, Mitch, Sherwood *et al.* (1986); Peura, Klaukka, Hannula *et al.* (1993)], or weeks [e.g. Punchak and Kay (1988); Baker, Roberts, Newcombe *et al.* (1991)]}, in other studies, the increased knowledge of consumers who received WMI compared to those who did not was still evident several months to a year later [e.g. Gibbs, Waters and George (1989a); Little, Griffin, Kelly *et al.* (1998)].

It is noteworthy, however, that improvement in knowledge was not obtained on all measures but only on specific aspects [e.g. name of medication (George, Waters and Nicholas, 1983), how to take the medication (Gibbs, Waters and George, 1989a, b) and side effects (George, Waters and Nicholas, 1983; Gibbs, Waters and George, 1989a, b)]. Furthermore, Morris (1989) expressed scepticism about the generalisability of some of these studies as they frequently occurred in settings where consumers were aware that they would be questioned about the WMI that they had received.

1.4.2 Consumer satisfaction

In terms of consumer satisfaction, the results to date are mixed. In some studies, consumers who received WMI expressed greater satisfaction with the amount of information that they had received (Gotsch and Liguori, 1982; Baker, Roberts, Newcombe *et al.*, 1991) and with the efforts of the pharmacist (Benton, Snow and Parr, 2004) compared to those who did not receive WMI. According to Ley and Llewelyn (1995), this finding is not surprising as most consumers want to know as much as possible hence informed consumers are more satisfied consumers.

In other studies, satisfaction seemed to be influenced by different factors, such as the class of medication being studied or the way satisfaction was defined. As an example, in a series of related studies (George, Waters and Nicholas, 1983; Gibbs, Waters and George, 1989a, b, 1990), consumers who received WMI were found to be consistently more satisfied with the amount of information received (compared to those who did not receive WMI) for most classes of medications (NSAIDs, diuretics, benzodiazepines, β-blockers, bronchodilators) except penicillin. For the latter, increased satisfaction was observed in two studies (George, Waters and Nicholas, 1983; Gibbs, Waters and George, 1990) but not in another (Gibbs, Waters and George, 1989b). Furthermore, as illustrated by one of these studies (George, Waters and Nicholas, 1983), greater satisfaction with the amount of information received did not equate to a significant increase in satisfaction with the treatment as a whole.

A study investigating consumer satisfaction with pharmacist consultation found that consumers who received longer consultations and were provided with more types of information about their medication were more likely to report that their expectations were exceeded and were more satisfied with the service (Schommer, 1995). Hence, the author suggested that a key to consumer satisfaction may be exceeding consumer expectations (Schommer, 1995). To this end, WMI may serve as a tool to be used during counselling to improve consumer satisfaction.

1.4.3 Adherence to therapy

A study undertaken to compare the views of pharmacists, general practitioners and consumers on the value of WMI indicated that most participants believed that the medication was more likely to be taken as directed as a result of reading the WMI (Mottram and Reed, 1997). However, that particular scenario was hypothetical and to date, results from studies examining the impact of WMI on actual adherence to therapies are somewhat mixed.

For example, one study reported a significant increase in compliance among consumers receiving WMI for an antidepressant compared to those who did not (Myers and Calvert, 1984). However, the authors postulated that it was the attention given to the consumer whilst providing WMI rather than the nature of the information (negative information about side effects or positive information about benefits of therapy) which positively influenced compliance. Recently, another study involving antidepressant

WMI concluded that consumers receiving a PIL were more likely to be adherent to their medication regimen, especially when the PIL was accompanied by verbal counselling by the pharmacist (Al-Saffar, Deshmukh, Carter *et al.*, 2005). On the other hand, another study demonstrated that antidepressant WMI had no effect on adherence, either on its own or in combination with counselling (Peveler, George, Kinmonth *et al.*, 1999).

The contrasting findings of the above studies mirror general findings in the literature whereby provision of WMI improved compliance in some studies but not in others (Morris and Halperin, 1979; Ley and Morris, 1984; Haynes, McKibbon and Kanani, 1996). Morris and Halperin (1979) observed that WMI can be effective in improving adherence to short-term therapies but has not been shown to be sufficient on its own to improve adherence to long-term therapies.

As WMI is only one of many factors which could influence consumer adherence (Stockwell Morris and Schulz, 1993), the results of these studies suggest that WMI may be best used in conjunction with other strategies to promote adherence. Moreover, health professionals need to be mindful that non-adherence is not necessarily the fault of the consumer and in some cases can serve the interest of the consumer (Raynor, 1992a).

1.4.4 Perception and experience of side effects

Traditionally, some health professionals have been opposed to the provision of WMI to consumers, claiming that they cause anxiety or side effects by suggestion, and thus decrease adherence to therapy (Vander Stichele, De Potter, Vyncke *et al.*, 1996; Morris, 1989; Vander Stichele, Van haecht, Braem *et al.*, 1991). In more recent studies, some health professionals, including pharmacists, doctors and nurses still subscribed to this view (Bowles, 1996; Aslani, 1999; Krag, Nielsen, Norup *et al.*, 2004).

Some studies have shown that WMI caused anxiety in some consumers [e.g. Dodds and King (1989); Gibbs, Waters and George (1989a); Bandesha, Raynor and Teale (1996); Livingstone, Pugh, Winn *et al.* (1996); Benton, Snow and Parr (2004)] and in some cases led to increased reporting of side effects (Gibbs, Waters and George, 1989a, b; Van haecht, Vander Stichele, De Backer *et al.*, 1991) and cessation of therapy (some in consultation with health professionals) (Gibbs, Waters and George,

1989a; Bandesha, Raynor and Teale, 1996; Benton, Snow and Parr, 2004). However, other studies have observed that the provision of WMI increased knowledge and awareness of potential side effects [e.g. Morris and Kanouse (1982); Gibbs, Waters and George (1989b); Baker, Roberts, Newcombe *et al.* (1991); Peura, Klaukka, Hannula *et al.* (1993); Emjay Research Consultants Pty Ltd (1994)], did not cause increased anxiety (Quaid, Faden, Vining *et al.*, 1990; Oldman, Moore and Collins, 2004) or did not cause spurious reporting of side effects (George, Waters and Nicholas, 1983; Myers and Calvert, 1984). In fact, one study reported that those who read WMI were less worried about side effects (Baker, Roberts, Newcombe *et al.*, 1991).

A study by Morris and Kanouse (1982) demonstrated that informing consumers about side effects did not significantly increase reporting of these side effects but informed consumers were more likely to attribute any experienced effect to the medication. Thus, WMI seemed to increase the saliency of the medication as a possible cause of bothersome experiences (Morris, 1989).

Even if the provision of WMI did increase spontaneous reporting of side effects, several authors argue that this is not necessarily a bad outcome (Van haecht, Vander Stichele, De Backer *et al.*, 1991; Harada, Yamazaki and Fujimura, 1999). Some consumers may have been spuriously alarmed but for others, the concern may well be justified hence educating consumers about side effects through WMI can lead to early detection of medication-related adverse events.

1.5 FACTORS INFLUENCING USE OF WMI

Potential factors influencing the use of WMI by consumers were identified from studies published in English since the late 1970s. Due to the lack of design consistency and the heterogeneity of the studies, subjective assessment rather than criteria-based objective review was used. Moreover, due to the paucity of literature directly investigating the factors influencing the use of WMI, related literature on written information for various disease states was also considered. The quality, relevance and limitations of each study were taken into consideration prior to its inclusion in the following sections.

Although it is reasonable to assume that some factors overlap, that is, are inter-related, for ease of discussion, these factors have been arbitrarily divided into three broad areas: written information document factors, environmental factors and consumer factors. Written information document factors refer to the properties of the actual physical printed document. Environmental factors are associated with the context in which WMI is given or used and consumer factors relate to factors associated with the user of the WMI. These factors are discussed in turn below.

1.5.1 Written information document factors

Of the three areas, written information factors, which refer to factors associated with the actual written information document, has attracted the most attention in the past decades. These include the readability and presentation of the documents.

1.5.1.1 Readability

The readability of written information for general health information or disease states (Meade and Byrd, 1989; Davis, Crouch, Wills *et al.*, 1990; Sarma, Alpers, Prideaux *et al.*, 1995; Beaver and Luker, 1997; Smith, Gooding, Brown *et al.*, 1998; Fitzmaurice and Adams, 2000; Payne, Large, Jarrett *et al.*, 2000; Foster and Rhoney, 2002; Wallace and Lennon, 2004) as well as medications (Basara and Juergens, 1994; Bradley, Singleton and Po, 1994; Baker, 1997; Buck, 1998; Kenny, Wilson, Purves *et al.*, 1998; Wong, 1999; Estrada, Martin Hryniewicz, Barnes Higgs *et al.*, 2000; Rolland, 2000; Buchbinder, Hall, Grant *et al.*, 2001; Foster and Rhoney, 2002; Rees, Ford and Sheard, 2003; Kirksey, Harper, Thompson *et al.*, 2004) has been extensively studied.

Readability assessment usually involves the use of readability formulae. The use of these formulae in the health care setting has previously been reviewed (Ley and Florio, 1996) and commonly used readability formulae include Flesch Reading Ease Formula, Simplified Measure of Gobbledygook (SMOG) Grading, Fry Readability Graph, Gunning's Fog Index and Flesch-Kincaid Formula (Arthur, 1995; Ley and Florio, 1996; Buck, 1998).

Although most formulae have acceptable validity and reliability (Ley, 1998), they are still criticised for their limitations. They take into account sentence length, syllable count

or vocabulary index (Kenny, Wilson, Purves *et al.*, 1998) but are insensitive to word order or grammatical complexity (Kitching, 1990; Dickinson, Raynor and Duman, 2001). Moreover, they fail to consider a consumer's personal interest, motivation, background or circumstance and can overestimate the difficulty of a passage (Kitching, 1990; Bradley, Singleton and Po, 1994; Mayberry and Mayberry, 1996; Kenny, Wilson, Purves *et al.*, 1998). Variation in readability estimates for the same text using different formulae has also been reported (Krass, Svarstad and Bultman, 2002).

Despite these limitations, readability formulae have their place in the evaluation of written information for consumers. Focussing on WMI in particular, WMI in general has been criticised for being written at a level beyond the comprehension of most of the population (Basara and Juergens, 1994; Bradley, Singleton and Po, 1994; Baker, 1997; Estrada, Martin Hryniewicz, Barnes Higgs *et al.*, 2000; Buchbinder, Hall, Grant *et al.*, 2001; Foster and Rhoney, 2002) although exceptions do exist (Wong, 1999). Ideally, written information should aim for a reading level of Grade 5 or 6 (Griffin, McKenna and Tooth, 2003).

Whilst many studies have explored the readability of WMI and found it to be too high, far fewer studies have actually explored the relationship between high reading levels and consumer's use of WMI. However, a study involving warfarin WMI found that consumers receiving fifth-grade WMI exhibited significantly better comprehension and had more favourable perceptions of the material than those receiving tenth-grade WMI (Eaton and Holloway, 1980). Hence, the readability of WMI may potentially influence a consumer's use of it.

Although the concerns with readability of WMI is warranted, WMI which is too simple can also be problematic in that it could be perceived as dull, patronising, or lacking in authority (Kenny, Wilson, Purves *et al.*, 1998; Coulter, 1998). Hence, in the production of WMI, the needs of the audience as well as the aims of the educators should be considered and balanced (Mayberry and Mayberry, 1996).

1.5.1.2 Presentation

In addition to their poor readability, consumers have also reported that WMI are unattractive (Koo, Krass and Aslani, 2002), difficult to read due to small print (Vander Stichele, Van haecht, Braem *et al.*, 1991; Bandesha, Raynor and Teale, 1996; Bernardini, Ambrogi, Fardella *et al.*, 2001; Koo, Krass and Aslani, 2002) and are

printed on paper with poor quality (Bandesha, Raynor and Teale, 1996). In line with these consumer complaints, Raynor and Knapp (2000) observed that *"multi-folded leaflets on thin paper which contain large amounts of information, in small type and inserted in the pack may not invest the importance in the leaflet that professionals assume"* (p.269).

In an attempt to improve the presentation of WMI, guidelines to facilitate the production of well-presented WMI have been produced. These include government-initiated guidelines (Steering Committee, 1996b; Sless and Wiseman, 1997; Patient Information Working Group, 2005) as well as guidelines developed by individual groups of researchers (Kitching, 1990; Raynor, 1992b; Bandesha, Raynor and Teale, 1996; Doak, Doak and Root, 1996; Baker, 1997). Favourable design characteristics from these guidelines are summarised in Table 1.3.

Table 1.3 Features of well-presented written medicine information

Characteristic		**Desirable features***
Font	Typeface	Serif
	Style	No italics
		Bold for emphasis
		Mix of upper and lower cases
	Size	10-point (equivalent to "x" height of 1.5mm)
		12-point (equivalent to "x" height of 2mm) if for older persons (some authors recommend this as the norm)
Numerals		Arabic (e.g. 1, 2, 3) rather than Roman (e.g. I, II, III)
Colour		Increase appeal and enhance text but NOT distract from it
Illustrations/pictograms		(See text)
Paper	Contrast	Good contrast between text and paper
	Quality	75-90 g/m^2
Format	Bullets	Use encouraged
	Heading	Clear and outstanding with a mix of upper and lower cases
	Justification	Justified on left but not right
	Line length	30-50 characters and spaces
	Paragraph	Indent first line
	White space	Ample (so leaflet does not appear over-crowded with text)

*based on Ley and Morris (1984); Kitching (1990); Raynor (1992b); Bandesha *et al.* (1996); Doak *et al.* (1996); Mayeaux *et al.* (1996); Steering Committee (1996b); Baker (1997); Ley (1997); Giorgianni (1998); Raynor (1998a); Hartley (2000); Andrus and Roth (2002); Krass *et al.* (2002); Griffin *et al.* (2003); Patient Information Working Group (2005).

Although in most respects there is strong agreement on what constitutes favourable design characteristics, there is still some uncertainty surrounding the use of illustrations or pictograms in WMI. They have been used to increase understanding, to increase the appeal of written materials (Ley, 1997) and to help consumers in finding the information needed (Bernardini, Ambrogi, Perioli *et al.*, 2000). However, there are concerns that illustrations may distract from the text (Ley and Morris, 1984), interfere with processing of the text (Dolinsky, Gross, Deutsch *et al.*, 1983) or that pictograms may be misinterpreted (Amery and Van Winkel, 1995; Hanson and Hartzema, 1995). In relation to the latter, age (Knapp, Raynor, Jebar *et al.*, 2005), educational level (Dowse and Ehlers, 2003; Knapp, Raynor, Jebar *et al.*, 2005), cultural background (Kassam, Vaillancourt and Collins, 2004), repeated exposure to pictograms (Dowse and Ehlers, 2001; Knapp, Raynor, Jebar *et al.*, 2005) and size of pictograms (Knapp, Raynor, Jebar *et al.*, 2005) have been shown to be factors that influenced interpretation of pictograms. Hence, illustrations or pictograms should be used only if the meaning of the symbol is unambiguous as perceived by the intended users (Patient Information Working Group, 2005), when it is relevant to the text (Dolinsky, Gross, Deutsch *et al.*, 1983; Ley and Morris, 1984) and when it can save on the amount of text (Ley and Morris, 1984).

Several authors have incorporated the guidelines presented in Table 1.3 in the development of instruments (partly or wholly) to evaluate the design characteristics of written information in general or WMI specifically. These include the 'User-Friendliness Index' (Basara and Juergens, 1994), 'Suitability Assessment of Material' (SAM) (Doak, Doak and Root, 1996), 'Baker Able Leaflet Design' (Baker, 1997), 'Readability Assessment Instrument' [described by Kirkpatrick and Mohler (1999) and Singh (2000)], 'Medication Information Design Assessment Scale' (MIDAS) (Krass, Svarstad and Bultman, 2002) and a 'checklist' developed by Paul *et al.* (1997). Although all were based on recommended guidelines and have been through some form of testing, with the exception of SAM, MIDAS and the 'checklist' (Doak, Doak and Root, 1996; Paul, Redman and Sanson-Fisher, 1997; Krass, Svarstad and Bultman, 2002), the rest of these instruments do not appear to be validated. Moreover, some of the tools only examine one aspect of WMI [e.g. Readability Assessment Instrument (Kirkpatrick and Mohler, 1999)] or lack consumer involvement [e.g. Baker Able Leaflet Design (Baker, 1997)].

It is striking, however, that research on improving the usability of WMI, using various methods listed above, has involved limited input from consumers. The Communication

Research Institute of Australia pioneered the concept of diagnostic testing in the preparation of CMI in 1994 (Sless and Wiseman, 1997). This concept involved testing the usability of CMI as perceived by its intended audience, the consumer. According to Sless and Wiseman (1997), this is crucial:

> *"CMIs are complex documents and each one is different. Consumers are also complex and highly varied. Put CMI and consumers together and the resulting dialogue can at times be surprising and unpredictable. No known principles of good writing or design, nor any readability scores or measures of reading age have been found which can predict how successfully a document will be used"* (p.73).

The involvement of consumers in the development and evaluation of written information has also been advocated by other researchers (Bernier, 1993; Blenkinsopp, Bashford, Dickinson *et al.*, 1998; Coulter, Entwistle and Gilbert, 1999; Griffin, McKenna and Tooth, 2003) with the hope of improving the usefulness of WMI from the consumer's perspective. In March 2004, the European Union was one of the first to officially mandate consumer involvement in the development of WMI. Changes to the legislation introduced a new legal obligation to ensure that all PILs reflected the results of consultations with consumers who are the intended users of the information (Patient Information Working Group, 2005).

In conjunction with this push for consumer involvement, the Consumer Information Rating Scale (CIRF) (Krass, Svarstad and Bultman, 2002) was developed and validated as a direct method for evaluating consumer's perceptions of WMI, including its comprehensibility, utility and design quality. Compared to existing leaflets, leaflets that were specifically designed to meet favourable design criteria were rated more positively by consumers not only in terms of design quality but also in terms of perceived usefulness and comprehensibility, thus highlighting the potential influence and importance of design quality in affecting consumer's perception of the information (Krass, Svarstad and Bultman, 2002).

The value of consumer testing as a convenient and powerful tool to identify potential problems with WMI and improve consumers' ability to use the information has similarly been demonstrated in other studies (Dickinson, Raynor and Duman, 2001). Interestingly though, in a study by Gustafsson *et al.* (2003), expert and consumer evaluations of WMI were found to concur hence the authors conceded that the expert evaluations alone would suffice.

Overall, it is acknowledged that the presentation of WMI is an important aspect of WMI and much effort has been put into improving this aspect of WMI. Whilst some studies have shown that improved presentation improved the perceived usability (Krass, Svarstad and Bultman, 2002) or perceived effectiveness of the material (Paul, Redman and Sanson-Fisher, 1997), other studies have shown that improving design characteristics of written information did not increase its effectiveness (Davis, Fredrickson, Arnold *et al.*, 1998; Paul, Redman and Sanson-Fisher, 2003). Thus, more research is required to explore the associations between improved presentation of WMI and consumers' use.

1.5.2 Environmental factors

Environmental factors are associated with the context in which WMI is given or used, and includes timing and delivery of information as well as the consumer's experience of the whole encounter. Lenz (1984) proposed that the physical and interpersonal environment may facilitate or impede a consumer's search for information. For example, privacy and comfortable familiar surroundings can facilitate information exchange between consumer and health professional whilst a cooperative and supportive atmosphere can facilitate a consumer's search for information from health professionals (Lenz, 1984).

1.5.2.1 Timing of information

No study has considered timing of information, be it verbal or written, as an independent variable affecting the use of disease state or medicine information. However, several studies suggest that timing can play a crucial role in the use of this information. For example, patients with arthritis were noted to go through a phase of 'desperation' where any information given about the disease seemed to further revolt and depress patients (Donovan, Blake and Fleming, 1989). Similarly, in another study, it was mentioned that consumers could often be physically or emotionally incapacitated or exhausted at the time they are prescribed or when they are collecting a prescription medication hence are unable to fully take in the verbal information provided by health professionals at that stage (Benton, Snow and Parr, 2004).

Several other studies have looked at consumer preference in terms of timing of information. In one study, cancer patients preferred to receive general information about chemotherapy around the time of the treatment decision and specific information just prior to treatment (Butow, Brindle, McConnell *et al.*, 1998). In another study, some patients preferred to receive colposcopy information leaflets at the time they were informed of their abnormal smear results rather than with the colposcopy clinic letter that was received later (Byrom, Dunn, Hughes *et al.*, 2003). The authors postulated that the greatest fear for women awaiting colposcopy was the fear of cancer; hence to reduce anxiety, this fear had to be alleviated at the earliest possible stage, that is, when the patient was first informed of the abnormal smear results (Byrom, Dunn, Hughes *et al.*, 2003).

More recently, D'haese *et al.* (2000) examined the importance of the time sequence of information provision on the anxiety and satisfaction of patients undergoing radiotherapy. Two types of information were given. The first was a booklet describing radiotherapy procedures and the sensations that the patients would experience; the second was selected teaching sheets with specific information related to side effects of the treatment site. The group who received the information stepwise (booklet at first appointment; teaching sheets three to four days into treatment) were found to be significantly less anxious and more satisfied with their treatment compared to the group who received both kinds of information at the first appointment. Two possible explanations were given for the greater anxiety observed in the latter group: firstly, they received information about side effects four to fourteen days before treatment but had no opportunity to verify the information with a health professional prior to treatment; secondly, knowledge of side effects prior to treatment may actually increase anxiety (D'haese, Vinh-Hung, Bijdekerke *et al.*, 2000).

In a preliminary qualitative study to investigate the factors affecting the use of CMI in Australia, some consumers commented that CMI could be redundant if given when they were feeling physically unwell or emotionally upset (Koo, Krass and Aslani, 2002). In addition to this psychological consideration, some consumers wanted to receive CMI from their doctor during their consultation time so that they could make informed decisions about whether or not to take certain medications. Others wanted to receive it in the pharmacy before they paid for their medications to prevent wasting money on ineffective or unsuitable medications.

The above studies highlight the importance of correct timing in imparting information to consumers. Providing information when the consumer is preoccupied with other issues may be counterproductive (Donovan, Blake and Fleming, 1989) and may reflect insensitivity on the health professional's part. Moreover, consumers may want information at specific times to facilitate their own decision-making process or prevent unnecessary expenditure (Koo, Krass and Aslani, 2002).

1.5.2.2 Experience

Consumer's experience can potentially influence their future actions. According to different models of health behaviour (e.g. Leventhal's self-regulatory model), after implementing a certain behaviour, consumers carry out an appraisal in which they evaluate how effective their behaviour has been, leading to a possible change in future action (James and Horne, 2000).

Health professionals are reminded that the healthcare consumer is not a *"blank sheet"* (p.58) (Donovan, Blake and Fleming, 1989). Rather, they have complex sets of beliefs, drawn from their own and their families' experiences, which can influence their use of WMI. Consequently, a consumer who has a positive experience of using WMI is more likely to respond positively in the future when provided with WMI. This positive experience can be directly related to the usefulness of previous WMI (Stewart, Erikson, McHardy *et al.*, 2000) or the worthwhile interaction with a health professional whilst receiving WMI.

1.5.3 Consumer factors

Notwithstanding the influence of written information factors and environmental factors, consumer factors arguably exert the most influence on the use of WMI by the individual consumer. Consumer factors can be divided into non-psychological factors which are relatively independent of the individual's personality (health literacy, disease state, role of caregiver and demographics) and psychological factors which are intrinsically related to the individual's psyche and disposition (health locus of control, coping style and Health Belief Model).

1.5.3.1 Health literacy

According to the World Health Organisation (WHO), health literacy:

> *"represents the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health"* (p.10) (Nutbeam, 1998).

In contrast to this broad and all encompassing definition, in the literature on health information, a narrower and simpler definition has usually been adopted whereby health literacy has largely been examined as 'functional health literacy'. Functional health literacy has been defined as *"the ability to read, understand, and act on health information"* (p.282) (Andrus and Roth, 2002). This is considered one of the most fundamental types of health literacy (Nutbeam, 2000).

Thus, health literacy focuses on the reader of the information. This is in contrast to readability tests which focus on the reading material. The assumption underpinning the use of the latter is that the reader will have adequate functional health literacy to read and understand the information presented to them; however, it is known that this is not necessarily the case (Williams, Parker, Baker *et al.*, 1995). Hence, in recent years, there has been a shift in interest from the reading material to the reader (Rudd, Moeykens and Colton, 2000).

In conjunction with the rising interest in health literacy, various tools have been developed to assess the health literacy of consumers. These can be divided into word recognition tests and comprehension tests (Doak, Doak and Root, 1996; Davis, Michielutte, Askov *et al.*, 1998). The more commonly used word recognition tests in health care include the 'Rapid Estimate of Adult Literacy in Medicine' (REALM), the 'Wide Range Achievement Test-Revised' (WRAT-R) and the 'Slosson Oral Reading Test-Revised' (SORT-R) (Davis, Michielutte, Askov *et al.*, 1998; Andrus and Roth, 2002). The main limitation of these tests is that they do not test comprehension of written information (Andrus and Roth, 2002) and it is known that the ability to read does not imply the ability to understand what is being read (Doak, Doak and Root, 1996). Comprehension tests used in the health care setting include the 'Test of Functional Health Literacy in Adults' (TOFHLA) (Parker, Baker, Williams *et al.*, 1995; Baker, Williams, Parker *et al.*, 1999) and the Cloze technique (Taylor, 1953). The main features of these commonly used literacy tests are summarised in Table 1.4.

Table 1.4 Common literacy and health literacy tests

Variable	WRAT-R*	SORT-R*	REALM*	TOFHLA*	Cloze Test
Description	Word recognition test	Word recognition test	Medical word recognition test	Functional health literacy test	Passage with every fifth deleted word to be replaced exactly
Administration time (min)	3-5 (includes scoring time)	5-10	2-7 (<2 for short version) (includes scoring time)	22 (7 for short version)	10-20 suggested
Scoring	Raw score of 1-57, converted to grade equivalent	Results converted to age and grade equivalents	Approximated grade level: 3rd and below, 4th-6th, 7th-8th, or 9th and above	Results interpreted as inadequate, marginal or functional health literacy	Results interpreted as material understood, material can be used but requires supplemental teaching or material unsuitable
Advantages	Quick	Quick	Quick; uses medical terminology; available in shortened form	Measures functional health literacy; available in a shortened form and in Spanish	Measures reading ability and comprehension; can be adapted for any passage
Limitations	Difficult test; does not test comprehension	Does not test comprehension; small print and many items intimidating, not recommended for poor readers	Does not test comprehension; assigns only grade-range equivalents	Long version is time consuming; timed test can be frustrating	Test needs to be constructed each time; time consuming; not recommended for consumers with WRAT/REALM score below sixth grade

NB: Table adapted from Andrus and Roth (2002) based on Taylor (1953); Davis *et al.* (1993); Murphy *et al.* (1993); Parker *et al.* (1995); Davis *et al.* (1998); Baker *et al.* (1999); Bass *et al.* (2003).
*REALM = Rapid Estimate of Adult Literacy in Medicine; SORT-R = Slosson Oral Reading Test-Revised; TOFHLA = Test of Functional Health Literacy in Adults; WRAT = Wide Range Achievement Test; WRAT-R = Wide Range Achievement Test-Revised

Utilising these tools, a myriad of studies in the area of health literacy have been conducted and there is consensus that there is a link between poor literacy and poorer health in general. However, this link is unlikely to be directly causal in nature and the underlying mechanisms are yet to be fully elucidated (Weiss, Coyne, Michielutte *et al.*, 1998). Nonetheless, poor health literacy levels have been shown to result in decreased use of preventive health services (Scott, Gazmararian, Williams *et al.*, 2002), decreased knowledge of chronic conditions (Williams, Baker, Honig *et al.*, 1998; Williams, Baker, Parker *et al.*, 1998; Gazmararian, Williams, Peel *et al.*, 2003), increased hospital visits (Gordon, Hampson and Capell, 2002) or hospitalization (Baker, Parker, Williams *et al.*, 1997), poorer patient-provider communication (Williams, Davis, Parker *et al.*, 2002; Schillinger, Bindman, Wang *et al.*, 2004), poorer physical health (Weiss, Hart, McGee *et al.*, 1992; Baker, Parker, Williams *et al.*, 1997) and poorer health outcomes (Schillinger, Grumbach, Piette *et al.*, 2002). In addition to these studies, there is a growing number of reviews on health literacy [e.g. Weiss, Hart and Pust (1991); Weiss, Coyne, Michielutte *et al.* (1998); Parker, Williams, Weiss *et al.* (1999); Rudd, Moeykens and Colton (2000); Tooth, Clark and McKenna (2000); Andrus and Roth (2002); Bernhardt and Cameron (2003)].

Based on what is known in the literature thus far, it is clear that the ability to identify consumers with potential health literacy problems is crucial if health professionals are to attempt to overcome the impact of poor health literacy. However, given that illiteracy is often associated with social stigma (Doak, Doak and Root, 1996; Brez and Taylor, 1997) and shame (Baker, Parker, Williams *et al.*, 1996; Parikh, Parker, Nurss *et al.*, 1996), poor health literacy is not always easily identifiable and many consumers with literacy problems may attempt to conceal this with excuses such as 'I forgot my glasses' (Doak, Doak and Root, 1996). Some health professionals also seem to have limited awareness of potential health literacy problems in some consumers (Praska, Kripalani, Seright *et al.*, 2005).

Moreover, the administration of a literacy test in practice is not often practical or feasible. It is also known that the highest level of education is not a reliable indication of a consumer's actual reading abilities (Meade and Byrd, 1989; French and Larrabee, 1999; Wilson, Racine, Tekieli *et al.*, 2003). Recently, several practical methods for identifying poor literacy have been advocated. Chew *et al.* (2004) developed some screening questions and Praska *et al.* (2005) suggested several consumer behaviours which may serve as clinical red flags for identifying consumers with poor literacy. Whilst

these methods offer an important advancement towards identifying poor literacy in practice, their use in a large population remains to be tested.

Despite the plethora of research in the area of health literacy, there are limited studies examining the relationship between health literacy and use of written information, thus the implications of poor literacy on the use of written information by consumers are largely unknown. A positive relationship between reading ability and perceived usefulness of an educational pamphlet has previously been demonstrated (French and Larrabee, 1999). However, in another study, the majority of consumers, regardless of their reading ability, expressed a desire for information on their condition (Foltz and Sullivan, 1996) but the mode of desired information (verbal or written) was not explored.

In addition, it is important to bear in mind that most of the current research on health information focuses only on functional health literacy, the most fundamental type of health literacy. Beyond this, there are two more sophisticated types of health literacy, namely interactive[7] and critical[8] health literacy (Nutbeam, 2000). Notwithstanding, studies on functional health literacy form an essential foundation for understanding the implications of health literacy in consumer health care. Indeed, in the relatively unexplored area of WMI, further research using this fundamental concept of health literacy is required to elucidate the relationship between health literacy and use of WMI. Hence, this thesis will focus on functional health literacy. Once this is established, future research can then focus on more sophisticated types of health literacy.

1.5.3.2 Disease state

Many different aspects of symptoms including factors influencing perception of symptoms, response to symptoms and role of symptoms in health, disease and illness have been explored [e.g. Smith, Sharpe and Banahan III (1981); Harding and Taylor

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[7] Interactive literacy is defined as *"more advanced cognitive and literacy skills which, together with social skills, can be used to actively participate in everyday activities, to extract information and derive meaning from different forms of communication, and to apply new information to changing circumstances"* (p.263-264) (Nutbeam, 2000).

[8] Critical literacy is defined as *"more advanced cognitive skills which, together with social skills, can be applied to critically analyse information, and to use this information to exert greater control over life events and situation"* (p.264) (Nutbeam, 2000).

(2002); Martin, Rothrock, Leventhal *et al.* (2003); Cameron and Moss-Morris (2004)]. Notwithstanding, there is a paucity of studies comparing the differences in health behaviour between consumers who do and do not experience symptoms as part of their disease or illness. However, studies examining the impact of symptoms (or lack there of) in certain diseases suggest that there may be differences in health behaviours between these two groups of consumers. These differences are further explored using the examples of rheumatology conditions which are symptomatic and hypertension which is asymptomatic.

Rheumatology conditions such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and fibromyalgia are characterised by pain and stiffness which can lead to various degrees of functional disability and incapacitation (Taal, Seydel, Rasker *et al.*, 1993). These physical symptoms have been shown to greatly impact on patients' ability to perform daily tasks (Woolf, Zeidler, Haglund *et al.*, 2004), even in the early stages of disease (Griffith and Carr, 2001). In addition, the persistence of symptoms as well as pain and functional impairment were cited as an important impetus for seeking medical help (Sakalys, 1997).

In contrast to rheumatology conditions, hypertension is primarily an asymptomatic disease (Galton, 1973; Grueninger, 1995)[9]. According to the WHO, *"two of the most important factors contributing to poor adherence are undoubtedly the asymptomatic and lifelong nature of [hypertension]"* (p.109) (World Health Organisation, 2003). The absence of symptoms (Viswanathan and Lambert, 2005) in conjunction with a lack of readily apparent perceived benefit of treatment (Feldman, Bacher, Campbell *et al.*, 1998), potential side effects associated with treatment (Krousel-Wood, Thomas, Muntner *et al.*, 2004) and/or lack of symptoms on discontinuation of therapy (Hussar, 1995) have resulted in the absence of a compelling reason for patients to persistently take their prescribed medications.

Indeed, in one study, the main reason given by respondents for discontinuing their antihypertensive medications was that they felt fine without the medications (Cummings, Kirscht, Binder *et al.*, 1982). The same reason was cited by some as their

[9] Although some patients assert that symptoms were associated with changes in blood pressure (Meyer, Leventhal and Guttman, 1985), results from other studies revealed that blood pressure was not reliably related to symptom reports or patient's predictions of blood pressure (Baumann and Leventhal, 1985).

reason for missing some doses of their antihypertensive medication(s). In another study, under a quarter of participants took their antihypertensive medications only when they were having symptoms, a worrying finding given that hypertension is primarily asymptomatic (Ogedegbe, Mancuso and Allegrante, 2004). In yet another study, the majority of patients on antihypertensive therapy were found to have a careless attitude towards hypertension, difficulties in accepting the diagnosis of hypertension and lack motivation for follow-up of hypertension (Jokisalo, Kumpusalo, Enlund *et al.*, 2001). The former was attributed to the common and asymptomatic nature of the disease, but the latter two observations could potentially be attributed to the same factors.

Although no studies have investigated the impact of the presence or absence of symptoms on a consumer's interest and use of WMI, given the contrasting nature and thus contrasting patient reactions to the two different disease states, it is plausible that patients experiencing a symptomatic condition would be more interested in seeking and reading WMI compared to those with an asymptomatic condition. Such studies are important as they assist in understanding the information needs and attitudes towards information of consumers with different diseases.

1.5.3.3 Role of caregiver

Studies examining the information needs of caregivers as well as the medication-related activities of caregivers provide some insight into the role of caregiver as a potential factor which may influence the use of WMI.

In a study investigating the perceptions and knowledge of stroke among surviving patients and their caregivers, compared to patients, caregivers were more likely to want to know all the details about the patient's condition and treatment, to discuss the risk of recurrence, to receive written information and to join information groups (Wellwood, Dennis and Warlow, 1994). Also, where there was no receipt of information, significantly higher proportion of caregivers than patients would have liked to receive some information.

Similarly, studies investigating the information needs of caregivers have consistently reported that caregivers have a desire for information, although the type of information desired varied depending on the type and stage of the care-recipient's illness (Fortinsky and Hathaway, 1990; Iconomou, Vagenakis and Kalofonos, 2001; Fukui, 2002; Kendall, Thompson and Couldridge, 2004). In one of these studies, caregivers

felt that their need for information was not recognised, and most had inadequate information at the time of diagnosis and had to seek ways of finding information themselves (Kendall, Thompson and Couldridge, 2004).

When it came to medication-related activities, studies have noted that caregivers undertake a wide range of activities and responsibilities including providing advice on medicines (Gupta, Smith and Francis, 2002), gathering information from health professionals and relaying information, selectively in some cases, to care recipients (Francis, Smith, Gray *et al.*, 2002). Some of these studies highlight that caregivers do not receive adequate information regarding their care recipient's medications (Mallet and King, 1993; Ranelli and Aversa, 1994; Goldstein and Rivers, 1996), with the majority of caregivers in one study stating that they personally purchased reference books to obtain information regarding medications (Mallet and King, 1993). Interestingly, in contrast to this general observed need for information, Gray *et al.* (2000) found that the majority of caregivers who did not receive any medicine information from the pharmacist perceived no need for any information despite experiencing problems with the medication-related activities. However, the reasons for this were not reported.

With regards to WMI in particular, Koo *et al.* (2002) observed that being a caregiver motivated some consumers to read CMI. Caregivers not only read CMI for their care recipient's medications to assist them in caring for their care recipient, but also for their own medications in order to be well and able to resume their duties as caregivers.

From these studies, it is fair to postulate that caregivers are interested in obtaining information because they perceive a need for information in order to properly discharge their roles as caregivers. However, the relationship between a caregiver role and the use of WMI has yet to be clearly defined.

1.5.3.4 Demographics

Consumer demographic characteristics potentially influence many aspects of health care, ranging from preferences for participation in clinical decision making to attitude towards medications and information-seeking behaviour. Examples of the influence of some demographic variables on different aspects of health care are provided in Table 1.5.

Table 1.5 Influence of demographic variables on aspects of health care

Aspect of health care	Demographic predictors
Preference for passive role in clinical decision making	Lower level of education, minority ethnic group, male and older age (Benbassat, Pilpel and Tidhar, 1998)
Involvement in health-enhancing behaviours	Younger age, higher socio-economic status and higher level of education (Conner and Norman, 1998)
Information needs	Age, gender and education influential in some studies but not in others (Mills and Sullivan, 1999)
Negative attitude towards medications	Younger age and female gender (Isacson and Bingefors, 2002)
Propensity for seeking health-related information	Younger age (Cassileth, Zupkis, Sutton-Smith *et al.*, 1980; Lenz, 1984; Hibbard and Weeks, 1987; Czaja, Manfredi and Price, 2003), higher socio-economic status (Lenz, 1984), higher level of education (Cassileth, Zupkis, Sutton-Smith *et al.*, 1980; Hibbard and Weeks, 1987), female gender (Lenz, 1984; Hibbard and Weeks, 1987; Rakowski, Assaf, Lefebvre *et al.*, 1990)
Awareness of health leaflets	Younger age (Jesson, Pocock, Jepson *et al.*, 1994)
Use of health leaflets	Older age, female gender and higher level of education (Jesson, Pocock, Jepson *et al.*, 1994)

In the area of WMI, observations regarding consumer demographics are inconclusive. Whilst no studies have directly investigated the relationship between consumer demographics and use of WMI, several observations have been made. Van haecht *et al.* (1991) observed a positive relationship between education level and readership of both technical inserts and PPIs but found no association between gender and readership. However, in a related study, the reverse was true; women were shown to read the inserts more often than men but no associations were found between education level and readership (Vander Stichele, Van haecht, Braem *et al.*, 1991).

Several observations have also been made linking consumer demographics to preference for written or verbal medicine information. In one study, it was found that females and younger consumers were significantly more interested in receiving WMI

compared to males and older consumers (Dodds and King, 1989). In contrast, Harvey and Plumridge (1991) found no significant age or gender differences in terms of preference for written or verbal medicine information. In two other studies, consumers with lower levels of education expressed a preference for verbal instead of written medicine information (Culbertson, Arthur, Rhodes *et al.*, 1988; Sleath and Wurst, 2002).

Hence it seems that consumer demographics may be associated with use of WMI but the exact nature of the associations is yet to be clarified.

1.5.3.5 Health locus of control

One of the most widely explored concepts spanning many areas of psychology is the locus of control concept introduced by Rotter in 1966 (Furnham and Steele, 1993). Since its introduction, a myriad of locus of control scales have been developed by different researchers, however, the most well-researched and widely used health-specific locus of control scale is the Multidimensional Health Locus of Control (MHLC) (Furnham and Steele, 1993). The MHLC scales relate the degree to which individuals attribute their personal health outcomes to themselves [internal health locus of control (HLC)], to others (powerful other HLC) or to chance, luck or fate (chance HLC) (Wallston and Wallston, 1978b).

In the literature, HLC theory has mainly been used to predict preventive health behaviours where it is postulated that individuals with internal HLC are more likely to engage in health promoting activities (Shaw, 1999). In general, to date, the overall results from these studies have been inconclusive (McClelland and Rees, 2000; Shaw, 1999) and the predictive relationship is still weak. Internal HLC has been found to positively influence health behaviours including cancer screening and adherence to medical treatment in some studies (Bundek, Marks and Richardson, 1993; Molassiotis, Nahas-Lopez, Chung *et al.*, 2002; Norman, Bennett, Smith *et al.*, 1998; Stanton, 1987) but not in others (Abbott, Dodd and Webb, 1996; Holm, Frank and Curtin, 1999).

Similarly, when it comes to the use of information, the results are mixed. There is some evidence to suggest that consumers with internal HLC had better knowledge of their conditions, were more inquisitive and less easily satisfied with the information given and were more active in their pursuit for information (Wallston and Wallston, 1978a;

Wallston and Wallston, 1982; Lenz, 1984), however, other studies failed to replicate these positive results (Wallston and Wallston, 1982).

Given this, the role of HLC in the use of WMI is still undefined. One study found that some consumers felt that they should be personally in control of their own well being, suggesting that they may have had internal HLC. Conversely, others were happy to trust their doctors or pharmacists and expressed no desire to read WMI (Koo, Krass and Aslani, 2002). These findings may suggest a relationship between HLC and the use of WMI.

1.5.3.6 Coping style

Coping is described as one of the stages in Leventhal's self-regulatory model of illness behaviour whereby a patient decides on a coping procedure based on his/her perception of the problem (James and Horne, 2000). The use of information has been shown to have positive effects on the psychological coping outcomes of the consumers, as exemplified in a study examining the effect of preparatory information prior to hip replacement surgery (Gammon and Mulholland, 1996).

However, whilst some consumers cope by becoming actively involved in their treatment and avidly seek information, others cope by actively avoiding information (Humphrey, Littlewood and Kamps, 1992; van der Molen, 1999). Hence, the former would welcome information but the latter may find it distressing (Weinman, 1990). This is supported by the findings from a series of in-depth interviews with cancer patients where it was found that maintaining hope was an indispensable part of coping with cancer (Leydon, Boulton, Moynihan *et al.*, 2000). To maintain hope, some patients avidly searched for information, but others consciously limited their search for information, avoided new information, or enlisted the help of others to screen new information for them.

When threatened with an aversive event such as illness, Miller *et al.* (1988) proposed that individuals coped with the information available by either 'monitoring' or 'blunting'. Monitors actively seek out information and are more vigilant about cues in their surrounding where as blunters prefer to avoid information and signals from their surroundings (Elf and Wikblad, 2001). A study involving patient consultation with a physician found that high monitors desired more information about the cause of their medical problem, how healthy they were generally, how they could prevent future health problems and possible side effects of medication (Miller, Brody and Summerton,

1988). However, when it came to making a decision about their own care, high monitors desired a less active role than low monitors. Hence, information-seeking was initiated not for decision-making purposes but for coping purposes. Similarly, in a review, cancer patients characterised by a monitoring coping style desired more voluminous information which is thought to help them attach appropriate meaning to their experience and enable them to 'work through' their conditions (Miller, 1995).

If coping by means of information can be extended to the use of WMI, it is likely that consumers who cope by seeking information would welcome it but the converse may also be true. It is therefore important to cater for both types of consumers, providing information at a level and depth appropriate for each consumer and ensuring that their information needs are addressed.

1.5.3.7 Health Belief Model

According to the Health Belief Model (HBM), health behaviour is adopted if individuals regard themselves as susceptible to a condition which they perceive to be serious, if they believe their actions will reduce either the susceptibility to or severity of the condition, and if the perceived benefits of their actions outweigh the perceived barriers to performing the action (Rosenstock, 1991).

The HBM has been utilised in studies looking at various health behaviours, from immunisation and practice of breast self examinations to compliance with medication regimens (Rosenstock, 1991). To date, the literature yields mixed results in terms of the usefulness of the HBM in predicting health behaviours. For example, in one study on osteoporosis, HBM appeared to provide a plausible model for the decision to use newer antiresorptive medications but not hormone therapies for the treatment of osteoporosis (Cline, Farley, Hansen *et al.*, 2005). In other studies, HBM was successful in predicting non-compliance to prescription medications (Fincham and Wertheimer, 1985), complication prevention behaviours in Type 2 diabetes (Tan, 2004) and partially successful in predicting mammography behaviour (Holm, Frank and Curtin, 1999), but failed in predicting skin cancer prevention practices (Marlenga, 1995) or folic acid consumption to prevent neural tube defects (Quillin, Silberg, Board *et al.*, 2000)

Although not a health behaviour per se, the use of information may be potentially influenced by the different variables described in the HBM. No studies have been conducted in this particular area, however, in a qualitative study examining the use of

CMI by consumers (Koo, Krass and Aslani, 2002), many participants agreed that they were more likely to read CMI if the medication was for a condition that was perceived (by the consumer) to be severe such as glaucoma as opposed to a less serious condition such as a common infection.

However, in another study examining information-seeking behaviour in breast cancer chemotherapy patients, information-seeking was found to be negatively related to the severity of the cancer (Hopkins, 1986). A review by Benbassat *et al.* (1998) reported a similar trend, whereby patients with more severe disease (hypothetical, cancer and non-cancer) preferred a more passive role in their doctor-patient relationship. The contradiction between these results and the observations by Koo *et al.* (2002) warrants further investigation. Nonetheless, it is valid to postulate that severity of disease can affect an individual's information use.

Besides perceived severity, perceived benefits and perceived barriers as described in the HBM can also potentially influence the use of WMI. Benefits of reading WMI can range from better understanding of therapy to better awareness of potential side effects; barriers can range from comprehension difficulties to lack of access or relevance of WMI and is covered in other sections of this review. Other potential barriers such as poor provider-consumer relationship, education level and consumer attitudes have also been identified from the literature (Melnyk, 1988).

1.6 SUMMARY AND CONCLUSION

Over the past few decades, spurred on by consumer needs and demands, WMI has evolved to form an important tool in consumer education. A plethora of studies have been dedicated to examining the readership, use and impact of WMI on consumers. From these efforts, it is known that consumers do read WMI. Moreover, WMI has been shown to have both positive and negative impacts.

Despite this wealth of literature, most of these studies have originated from Europe and the US and there is a noticeable lack of contribution to the literature from Australia. As mentioned in Section 1.3.2, to date, the few studies examining the use of CMI in Australia have been small-scale (Emjay Research Consultants Pty Ltd, 1994; Lawrence and Fogg, 1998), not conducted in a natural setting (Emjay Research

Consultants Pty Ltd, 1994), focussed only on certain medications (Emjay Research Consultants Pty Ltd, 1994) or certain groups in the population (Lawrence and Fogg, 1998); in some cases, there was also ambiguity as to whether the document being studied was actually CMI or some other form of WMI (Lawrence and Fogg, 1998; Quality Use of Medicines and Pharmacy Research Centre- University of South Australia, 2001).

From this, it is clear that there is a need for further research to examine the use and impact of CMI on consumers. In order to provide a realistic view on what is going on in practice, this research also needs to be conducted in a natural setting, include different groups in the population and have a broad coverage of all prescription medications that are available.

The recent study by Benton *et al.* (2004) offered an improvement from the previous studies in terms of sample size and sampling frame. Nonetheless, several limitations were evident in the study, some of which may be associated with the fact that this study was designed with the aim of evaluating the MIC Program and not to examine the use of CMI by consumers per se. The main limitations with the self-completion questionnaire study conducted as part of the main study were its poor response rate, its exclusion of all forms of CMI except computer printout CMI and lastly, its inflated CMI receipt and readership rate that is not reflective of a real-life scenario as the provision of a computer printout CMI was a prerequisite to handing out a questionnaire. Notwithstanding the insights provided by this recent study, there remains a need for research which focuses on the use of CMI by consumers.

In addition to filling a research gap, more importantly, research which focuses on the use of CMI by consumers has wider implications. As part of the National Strategy for quality use of medicines, CMI has been emphasised as a means to facilitate dissemination and uptake of objective information about medications (Commonwealth of Australia, 2002b). As users of medications, consumers are considered one of the key partners in developing and implementing initiatives to achieve quality use of medicines (Commonwealth of Australia, 2002a). Hence, research focussing on consumer perspectives of CMI will serve to advance current understanding of consumers' needs. This can then inform the development of measures that will ensure optimal use of medicines to improve health outcomes for consumers.

Along with the need to know how consumers use WMI, there is the need to understand the factors which may influence the way consumers use WMI. This is worthwhile for several reasons. Firstly, as mentioned above, consumers' perceptions are crucial and valuable as they have the potential to inform and shape future direction of health practice.

Secondly, there is evidence in the general health information literature to show that health information which is tailored to the consumer is more effective than non-tailored information (Skinner, Siegfried, Kegler *et al.*, 1993; Bental, Cawsey and Jones, 1999; Dijkstra and De Vries, 1999). This health information was tailored according to different consumer characteristics including health beliefs, stages of change and current health practices (e.g. dietary intake, smoking status) (Campbell, DeVellis, Strecher *et al.*, 1994; Skinner, Strecher and Hospers, 1994; Strecher, Kreuter, Den Boer *et al.*, 1994; Kreuter and Strecher, 1996). Based on these observations, understanding consumers' perceptions and tailoring WMI to suit consumer needs may serve to enhance consumers' experience of information use and allow them to gain maximum benefit from their WMI. By doing so, consumers will be well-informed and empowered to make decisions regarding their medicines. However, to date, the level of sophistication alluded to above has yet to be attained in the arena of WMI. There is some evidence of attempts at personalising computer-generated WMI based on basic consumer information such as demographics and medication history (Raynor, 1998b; Davidse and Nieuwhof, 2003). Nonetheless, by and large, the standardised forms of WMI are not amenable to such individualisation partly due to the stringent legal requirements dictating the contents of these documents. Moreover, for WMI to be tailored optimally, health professionals and researchers first need an appreciation for the factors which influence the way a consumer uses information.

Internationally, there is a paucity of research that has been conducted to examine the factors which potentially influence consumer's use of WMI. This is in stark contrast to the area examining consumer's use of WMI which is relatively well-established internationally, perhaps with the exception of Australia.

By comparison, the written information factors, namely readability and presentation, are probably the most well-researched factors. Nonetheless, as mentioned in the literature review (Section 1.5.1.1), many studies have critiqued the readability of WMI but few have actually explored the relationship between high reading levels and a consumer's use of WMI. Similarly, in terms of presentation (Section 1.5.1.2), not many studies have

examined the relationship between this factor and consumer's use of WMI, and those that have done so have yielded conflicting results. Moreover, consumer involvement in the design and evaluation is now recognised as an important part of the development process of WMI, but once again, no studies have been conducted to determine any factors which may affect a consumer's evaluation of the material.

No studies have been conducted in the area of WMI to examine the environmental or consumer factors potentially influencing the use of WMI. Several relationships have been suggested or observed in some studies; however, these have been exploratory in nature and are yet to be properly tested [e.g. timing, role of caregiver, HLC, HBM by Koo *et al.* (2002)] or have not taken into account possible confounding variables [e.g. demographics in Culbertson, Arthur, Rhodes *et al.* (1988); Dodds and King (1989); Harvey and Plumridge (1991); Van haecht, Vander Stichele, De Backer *et al.* (1991); Vander Stichele, Van haecht, Braem *et al.* (1991); Sleath and Wurst (2002)].

As described in the literature review, the wider literature offers some insight into these potential factors and provides a good background for future research. However, the applicability of these findings to the area of WMI is unknown. For example, many of the studies were from the cancer setting, and it is likely that there will be differences in the approach towards cancer-related information versus WMI in general. In light of this, research which specifically examines the influence of different factors on the use of WMI will make an important contribution to the development of strategies to improve the use of medicines and thus health outcomes.

2 AIMS AND GENERAL METHODS

2.1 INTRODUCTION

A review of the research in the area of WMI has revealed several important issues for further research. Firstly, there was a need for Australian research which examines consumer's readership and use of CMI as well as its impact on consumers. Secondly, the review highlights the lack of research examining the influence of different factors on consumers' use of WMI.

In light of these needs, a research project consisting of three studies was designed to address some of the gaps observed in the literature. The aims of the overall research project are presented in Section 2.2.1 and the objectives for each of the studies are presented in Section 2.2.2.

Although many potential factors were identified from the literature, patient factors arguably exert the most influence on a consumer's use of WMI, hence the project focussed on some of the patient factors covered in the review (Section 1.5.3). Furthermore, a decision was also made to explore specific aspects of consumers' 'use' of WMI, namely their readership of WMI, their search for WMI and their evaluation of WMI.

2.2 RESEARCH PROJECT AIMS AND STUDY OBJECTIVES

2.2.1 Research project aims

In light of the issues identified in the literature, the aims of the research project were:

- To investigate the use of CMI and WMI by consumers
- To investigate the influence of consumer characteristics on consumers' evaluation and future use of CMI
- To investigate the influence of consumer factors on consumers' reading and seeking of WMI

In order to achieve these aims, the research project consisted of three studies:

- Use of Consumer Medicine Information- pilot study (CMI Study)

- Factors influencing use of written medicine information- Phase 1 survey (WMI Study Phase 1)
- Factors influencing use of written medicine information- Phase 2 follow-up interviews (WMI Study Phase 2)

The objectives corresponding to each of these studies are listed below.

2.2.2 Study objectives

2.2.2.1 CMI Study

The objectives of the CMI Study were:

- To determine consumers' awareness and knowledge of CMI
- To determine consumers' receipt and experience when receiving CMI
- To examine consumers' readership and impact of reading CMI
- To explore consumers' attitudes and opinions towards CMI

2.2.2.2 WMI Study Phase 1

The objectives of the WMI Study Phase 1 were:

- To determine patients' interest and likelihood in reading and seeking WMI
- To determine awareness, readership and use of CMI
- To investigate the relationship between patient factors and patients' reading and seeking of WMI
- To investigate the influence of patient characteristics on patients' evaluation and intended use of CMI
- To determine the impact of patient CMI evaluation on their intended use of CMI

2.2.2.3 WMI Study Phase 2

The objectives of the WMI Study Phase 2 were:

- To triangulate the results of the WMI Study Phase 1 by comparing patient responses from the WMI Study Phase 1 and Phase 2
- To gain more in-depth information on factors influencing patients' reading and seeking of WMI
- To explore further issues surrounding the use of CMI and WMI in general

2.3 OVERVIEW OF THE RESEARCH METHODS

2.3.1 Quantitative and qualitative approaches

In this research, both quantitative and qualitative methods have been used. Quantitative approaches are typically associated with enumeration and the establishment of relationship between variables whilst qualitative approaches focus on concepts and categories, but not their incidence or frequency (Brannen, 1995). Despite the ongoing debate over the relative merits of quantitative and qualitative methods, researchers have endeavoured to combine both approaches in an attempt to gain the advantages of both methods without compromising their differences (Grbich, 1999). Combining these approaches is an example of methodological triangulation, which refers to the use of a variety of methods to collect and interpret the same data (Arksey and Knight, 1999; Neuman, 2003). In this context, triangulation serves to provide confirmation and/or completeness of data (Arksey and Knight, 1999).

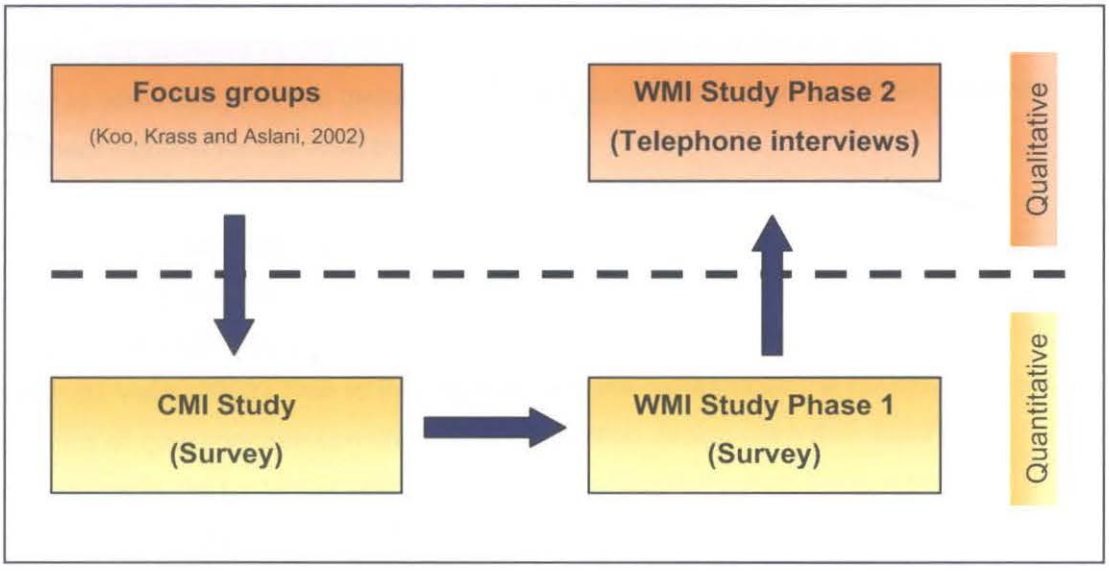
More specifically, quantitative research conducted before qualitative research allows for suitable participants to be selected for the latter phase (Bryman, 2004). Conducted before a quantitative study, qualitative research facilitates quantitative research by generating hypotheses that could be tested in a systematic way (Bryman, 2004). It also assists in the planning of the content of the questionnaire and the design of the questions (Morton-Williams, 1985). On the other hand, conducted after a quantitative study, qualitative research provides an opportunity for verification and broader exploration of the issues covered in the quantitative phase; it may also facilitate interpretation of observed relationships between variables (Morton-Williams, 1985; Aldridge and Levine, 2001; Bryman, 2004).

An earlier qualitative study on CMI involving patients in focus groups (Koo, Krass and Aslani, 2002)[10] was the first in a series of studies involving patients and CMI. The results from the qualitative focus groups provided insight into issues which were then incorporated as part of a qualitative pilot survey (CMI Study) to investigate the use of CMI by patients (Chapter 3). The results from both the focus groups and the CMI Study informed the development of a larger quantitative survey (WMI Study Phase 1) examining not only the use of CMI and WMI by patients, but also factors that influence

[10] This study was conducted as an honours project in 2000 during the researcher's undergraduate degree and does not form part of this thesis.

this (Chapter 4). Finally, qualitative follow-up interviews (WMI Study Phase 2) followed the WMI Study Phase 1 to confirm and explore the obtained results (Chapter 5). These series of qualitative and quantitative studies are summarised in Figure 2.1.

Figure 2.1 Combination of quantitative and qualitative methods



2.3.2 Quantitative method

A survey was chosen as the most appropriate method for addressing the study objectives in the CMI Study and WMI Study Phase 1. In health care research, surveys are commonly used to investigate attitudes, opinions or beliefs of participants concerning health-related issues, to study characteristics of samples or populations on health-related variables, to establish the proportion of participants who hold particular views, to describe association between variables and to collect information about the demographic characteristics of samples or populations (Polgar and Thomas, 2000; Smith, 2002). Moreover, interesting patterns may arise from data collected from a survey; these can form the basis for hypotheses testing (Polgar and Thomas, 2000).

A structured questionnaire is commonly used to conduct large-scale surveys as it allows the researcher to achieve uniformity by asking set questions and recording the answers hence maximising reliability of the survey (Quine, 1998). The three main methods of collecting data using a structured questionnaire are self-completion questionnaire, face-to-face interview and telephone interview (Aldridge and Levine, 2001). Face-to-face interviews were chosen for the studies in this research project primarily because they are not restricted by the participant's literacy level as the

questionnaire is administered by the researcher (Hawe, Degeling and Hall, 1990). This allowed a wider sample of patients to be interviewed.

Moreover, in the WMI Study Phase 1, patient health literacy was assessed as a potential factor which influenced use of WMI (Section 4.2.1.2.5). Self-completion questionnaires would exclude participants with inadequate literacy levels whereas telephone interviews would not allow the administration of a literacy test. Hence in order to allow this potential factor to be tested, face-to-face interviews were deemed the most suitable for the WMI Study Phase 1.

Face-to-face interviews also have the advantage of allowing the researcher to answer participant's questions, clarify misunderstandings, probe answers to open-ended questions and observe participant's non-verbal behaviour (Hawe, Degeling and Hall, 1990; de Vaus, 2002). Due to this, face-to-face interviews pose the fewest constraints in terms of questionnaire construction and question design (de Vaus, 2002). There is also the potential for higher response rates especially for surveys of general populations (Czaja and Blair, 1996; de Vaus, 2002) as the researcher will have the opportunity to explain the importance of the survey and assure the participant of the confidentiality of his/her responses (Salant and Dillman, 1994). A researcher who is successful at establishing rapport with the participant will also encourage better quality answers from the respondents (Aldridge and Levine, 2001).

Despite these advantages, face-to-face interviews are associated with several limitations. Firstly, compared to self-completion questionnaires and telephone interviews, face-to-face interviews incur the greatest cost per questionnaire in terms of money, time and personnel (Hawe, Degeling and Hall, 1990; Aldridge and Levine, 2001). Secondly, although rapport with the participant can possibly elicit better quality responses from participants, the mere presence of a researcher can also cause participants to give socially desirable answers rather than true answers (Aldridge and Levine, 2001; de Vaus, 2002; Hoyle, Harris and Judd, 2002) or to feel inhibited to give truthful answers to sensitive questions (Hawe, Degeling and Hall, 1990). Thirdly, there is the possibility that the researcher may introduce bias by offering comments that may lead the participant in a particular direction (Aldridge and Levine, 2001). The training and experience of the researcher is crucial to minimise this disadvantage.

2.3.2.1 Survey design

As mentioned earlier, two questionnaires were used as part of this research. The CMI Study consisted of questions constructed by the researchers (Chapter 3) based on the responses provided by participants from the focus group study (Koo, Krass and Aslani, 2002). The WMI Study Phase 1 consisted of a compilation of previously validated measures as well as questions constructed by the researchers (Chapter 4).

In the WMI Study Phase 1, where possible, existing validated measures were incorporated (with permission) into the study. As these questions have already been through extensive testing, they can save a great amount of time and effort (Czaja and Blair, 1996). Reliability and validity testing has been conducted, hence the researcher will be aware of the quality of the questions (Bryman, 2004). Moreover, using previously validated questions allows comparisons to be drawn with other research (Bryman, 2004). Where previously validated questions did not exist or were not considered suitable, the survey questions were constructed by the researchers.

For both the CMI Study and WMI Study Phase 1, the following survey design principles were taken into consideration when constructing the survey questions. One of the main considerations was the use of open-ended or closed-ended questions. Open questions allow respondents to express themselves freely and can provide valuable insight into a respondent's perception as well as indicate what is salient in a respondent's mind (Foddy, 1993; Jackson and Furnham, 2000; Aldridge and Levine, 2001; Bryman, 2004). However, closed-questions are typically preferable for a survey (Czaja and Blair, 1996; Jackson and Furnham, 2000; Bryman, 2004) as they are easier to complete for the respondents, and easier to code, analyse and compare for the researcher (Frazer and Lawley, 2000; de Vaus, 2002; Bryman, 2004).

Nevertheless, in constructing the survey questions in the CMI Study and WMI Study Phase 1, some open-ended questions were used especially where it was not possible to provide an exhaustive list of responses, where the researcher wanted to elicit the salient issues for the respondents and for any other comments pertaining to the subject that the respondents may have volunteered, that were not directly examined in the survey.

The rest of the survey consisted of closed-ended questions. These included simple yes or no questions and multiple-choice questions (with one answer or multiple answers allowed) (Hawe, Degeling and Hall, 1990) which were used to ask about respondent

behaviour and attributes (Salant and Dillman, 1994). For some of the multiple-choice questions, an "other" option was also included to allow respondents the opportunity of providing their own response if none of the choices given were considered applicable to them (Salant and Dillman, 1994).

Another variant of the close-ended question used were rating scales (Salant and Dillman, 1994; McQueen and Knussen, 2002; de Vaus, 2002). In this research project, both Likert scales[11] and horizontal rating scales[12] were used. The Likert scale is one of the most frequently encountered formats for measuring attitudes (Foddy, 1993; Bryman, 2004) and was used in the CMI Study to measure participants' attitudes toward CMI. As it is difficult and inaccurate to measure attitudes using a single question, researchers employ a scaling technique, that is, a series of questions usually measured along a rating scale to improve measurement. Compared to other types of closed-ended questions, rating scales are considered a better method of measuring attitudes and beliefs (Salant and Dillman, 1994).

However, in designing these scales, there is controversy surrounding the use of a middle ground (that is, where respondent neither agrees nor disagrees with the statement or question) and/or a 'don't know' or 'no opinion' option. The inclusion of these options means that respondents are not forced to express a view that they do not necessarily hold. However it is also argued that they may be too attractive an option for respondents who are not interested in thinking about the issue (Aldridge and Levine, 2001; de Vaus, 2002; Bryman, 2004). In this research, both Likert scales (Section 4 in the CMI Study- Section 3.2.1.1.4) and horizontal rating scales (Section A in the WMI Study Phase 1- Section 4.2.1.2.1) constructed by the researchers included a middle ground to prevent respondents from being forced into creating an artificial opinion.

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[11] Likert scale refers to a scale with several points (usually 5) ranging from "strongly disagree" to "strongly agree" where the respondent is asked to indicate their level of agreement or disagreement with the statement (de Vaus, 2002).

[12] Horizontal rating scale refers to a scale with opposite attitude positions where the respondent is asked to indicate with a number where his/her view falls (de Vaus, 2002).

An additional consideration in the construction of survey questions was the use of filter questions[13]. Filter questions were incorporated in the questionnaires where necessary to prevent asking questions that were irrelevant or not applicable to some participants (Neuman, 2003). In such cases, clear directions were written next to each response category of the filter question (e.g. go to Question 9) (Jackson and Furnham, 2000). One of the advantages of face-to-face surveys is that the interviewer has to do the skipping, not the participant; hence it is not a source of confusion for the participant (Aldridge and Levine, 2001).

Effort was also made to ensure that the questions were concise, clear, uncomplicated and written in easy to understand language (Czaja and Blair, 1996; Jackson and Furnham, 2000; de Vaus, 2002; Bryman, 2004). Negatively worded questions (with the exception of attitude statements), leading questions and double-barrelled questions were avoided (Polgar and Thomas, 2000; Aldridge and Levine, 2001; de Vaus, 2002; Bryman, 2004).

In addition to question construction, attention was also paid to other aspects of the survey. Questions were strategically and logically ordered to encourage completion by respondents. Relatively straightforward, non-sensitive and simple questions applicable and answerable by most if not all respondents were presented at the beginning of the surveys to capture interest and encourage cooperation (Czaja and Blair, 1996; Frazer and Lawley, 2000; Aldridge and Levine, 2001). Sensitive and more complicated questions were placed in the middle and towards the end of the survey (Hawe, Degeling and Hall, 1990; Jackson and Furnham, 2000). Some authors recommend that demographic questions be placed at the beginning of the survey as they are simple to answer (Jackson and Furnham, 2000; Polgar and Thomas, 2000). However, other authors argue that although simple to answer, demographic questions should be placed at the end of the questionnaire due to their personal and potentially sensitive nature (Czaja and Blair, 1996; Frazer and Lawley, 2000; Aldridge and Levine, 2001). In this research, the latter approach was adopted.

[13] Filter questions are questions whereby depending on the response to the previous question, the participant is required to proceed to the next question, or skip to a later one (Aldridge and Levine, 2001).

Transition statements were used between sections in the survey so that the respondent was aware of where the interview was heading (Hawe, Degeling and Hall, 1990; Salant and Dillman, 1994).

Last but not least, the design and layout aspects of the survey were considered. These aspects are considered less critical for face-to-face interviews (used for both surveys in this research project) (Frazer and Lawley, 2000). Nonetheless, special attention was paid to the CMI Study as it was administered by multiple interviewers and to the WMI Study Phase 1 due to the presence of a self-completion section. These are discussed in Chapters 3 and 4, respectively.

2.3.2.2 Survey reliability and validity

Reliability and validity are two important qualities that help establish the credibility of findings measured by an instrument (Neuman, 2003). Reliability refers to the dependability or consistency of an instrument, that is, it is a measure of the extent to which the results of a particular test, question or instrument are consistent over time (Aldridge and Levine, 2001; Neuman, 2003). There are several different ways of establishing the reliability of a particular instrument:

- Stability (or test-retest reliability): refers to reliability over time, and is usually examined using the test-retest method, where the instrument is retested on the same group of people to see if the same results are obtained (Polgar and Thomas, 2000; Neuman, 2003; Bryman, 2004).
- Internal reliability: applies to consistency across different items that are used to measure the same constructs or concepts (Bryman, 2004). A commonly used test for measuring the internal consistency of an instrument is Cronbach's alpha[14] (Punch, 1999).
- Inter-observer reliability: applies only when more than one observer is involved in a study which requires a high degree of subjective judgement (Bryman, 2004).

[14] Cronbach's alpha is a statistic that reflects the homogeneity of the scale, that is, *"how well the different items complement each other in their measurement of different aspects of the same variable or quality"* (p.22) (Litwin, 2003). The rule of thumb for an acceptable Cronbach's alpha is 0.70 or greater (Hair, Anderson, Tatham *et al.*, 1998; Jackson and Furnham, 2000). However, in exploratory research, 0.60 is considered acceptable (Hair, Anderson, Tatham *et al.*, 1998).

Validity on the other hand refers to the 'truthfulness' of an instrument, that is, it is a measure of the extent to which an instrument measures what it is claimed to measure (Punch, 1999; Neuman, 2003). There are four types of validity:

- Face validity: concerned with whether the questionnaire appears to be measuring what it says it does (Jackson and Furnham, 2000). In other words, *"do the questions appear to be relevant, reasonable, unambiguous and clear?"* (p.133) (Bowling, 2000)
- Content validity: concerned with the extent to which the content of the instrument appears to *"examine and comprehensively include, in a balanced way, the full scope of the characteristic or domain it is intended to measure"* (p.133) (Bowling, 2000). It is usually achieved following an evaluation and critique of the instrument by individuals with expertise in the field (Jackson and Furnham, 2000).
- Criterion validity: involves comparing the instrument with another instrument which is accepted as the gold standard, and is only possible if the latter exists in the literature (Bowling, 2000).
- Construct validity: refers to the extent to which the instrument tests the hypothesis or theory it is measuring (Bowling, 2000). It is achieved when the proposed hypotheses are supported by the results of the survey (Jackson and Furnham, 2000). There are two parts to construct validity: convergent validity (item to correlate with related variables) and discriminant validity (item not to correlate with unrelated variables) (Bowling, 2000).

The reliability and validity of the CMI Study and WMI Study Phase 1 questionnaires as research instruments are discussed in more detail in Chapter 3 (Section 3.2.1.2) and Chapter 4 (Section 4.2.1.3), respectively.

2.3.2.3 Survey pre-testing and piloting

The credibility of a questionnaire as discussed above can be improved by pre-testing and piloting[15] the questionnaire. Pre-testing is an essential stage in survey studies as it

[15] Some authors use the term pre-testing and piloting interchangeably to refer to the evaluation of the questionnaire before its final administration (de Vaus, 2002). Other authors further distinguish between the two in terms of size: pre-testing involves a smaller number of individuals and is a preliminary stage to piloting; piloting involves a larger number of individuals (Czaja and Blair, 1996). In this research study, the term pre-testing will mainly be used unless a large sample is involved in which case the term piloting will be used.

provides an opportunity to test if the questionnaire works in the manner intended by the researcher (Czaja and Blair, 1996), and to identify and eliminate any potential problems in the questionnaire before its final administration (Frazer and Lawley, 2000).

At the individual question level, pre-testing serves to establish how the participants interpret the question's meaning, to establish participants' ability to respond to the questions, to check if the range of response choices is sufficient, and to detect potential problems like non-response, acquiescence[16] or response set[17] (Czaja and Blair, 1996; Bowling, 2000).

At the questionnaire level, pre-testing serves to establish whether the whole questionnaire can be administered smoothly, that is, if it flows well, the amount of time required to complete the questionnaire, if the participants' attention and interest can be maintained for that duration of time, and if more complicated questioning patterns (e.g. question skips) work.

In this research, all studies were subjected to pre-testing and this will be further discussed in the individual chapters. The CMI Study was actually designed to be a pilot study.

2.3.3 Qualitative methods

In this research, a qualitative method, namely interview, was chosen to complement the data obtained from the WMI Study Phase 1. Used following a quantitative method, interviews have the potential to yield rich data that complement the generalisable but relatively thin data from a questionnaire. It also provides the opportunity to clarify any puzzling responses or unexpected findings (Aldridge and Levine, 2001).

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[16] Acquiescence is the tendency for some respondents to agree with a statement on a questionnaire, irrespective of its content (McBurney and White, 2004). It is an example of response set.

[17] Response set is the tendency for respondents to consistently respond in the same way to a set of statements or questions (Bryman, 2004). For example, for attitude statements, this can mean consistently agreeing, consistently disagreeing or consistently making moderate responses.

An interview is defined as a *"verbal exchange in which the interviewer attempts to elicit information and/or opinion on a topic from another person or persons"* (p.522) (Quine, 1998) and is the most common technique used to gather research information (Grbich, 1999).

Although there are many ways of interviewing, semi-structured[18], open-ended one-to-one telephone interviews were deemed the most appropriate to meet the objectives for this part of the research.

The semi-structured nature of the interview ensured that all areas of interest to the researcher were able to be covered and thus allowed some degree of comparability (Arksey and Knight, 1999); this was particularly important as one of the objectives of this part of the research project was to verify responses provided in the WMI Study Phase 1. Moreover, in order to meet the other objectives set out for this study, the semi-structured nature of the interview also allowed the interviewer to probe responses, follow up ideas and ask for clarification (Arksey and Knight, 1999).

Telephone interviews were chosen for this part of the research project mainly because it was a series of follow-up interviews from the WMI Study Phase 1. Hence, the researcher already had the opportunity to have a face-to-face encounter with the participant and was able to establish rapport at that time (Grbich, 1999). Hence, the lack of face-to-face contact and therefore the difficulty of establishing rapport, a common disadvantage associated with telephone interviews, was not an issue (Quine, 1998). As a relationship with the participant had already been established, compared to face-to-face interviews, telephone interviews also presented a more convenient, cost-effective and time-efficient option (Aldridge and Levine, 2001).

[18] Different authors advocate different definitions for the term 'semi-structured' [e.g. Grbich (1999); Arksey and Knight (1999)]. For the purposes of this research project, 'semi-structured' interviews refer to interviews whereby the main questions are fixed, but the interviewer is able to improvise follow-up questions to further explore responses and/or interesting issues that arise (Arksey and Knight, 1999).

3 USE OF CONSUMER MEDICINE INFORMATION- PILOT STUDY

The CMI Study was a pilot study conducted in 2001 involving a structured questionnaire administered by trained interviewers to a sample of consumers of prescription medicines recruited from a random sample of community pharmacies in metropolitan Sydney[19].

3.1 OBJECTIVES

The overall objectives of this study were:

- 1. To determine consumers' awareness and knowledge of CMI
- 2. To determine consumers' receipt and experience when receiving CMI
- 3. To examine consumers' readership and impact of reading CMI
- 4. To explore consumers' attitudes and opinions towards CMI

3.2 METHODS

3.2.1 Study questionnaire

3.2.1.1 Content

The questionnaire (Appendix A) consisted of five sections, Section 1 to Section 5. The development of the questionnaire was informed by the results of a qualitative study involving focus groups (Koo, Krass and Aslani, 2002) (Section 2.3.1). Table 3.1 summarises the purpose of each section and the related objective(s).

[19] CMI Study formed the second phase of a larger study which was funded by the Commonwealth Department of Health and Aged Care. A report has previously been submitted to the funding body (Aslani, Koo and Krass, 2001).

Table 3.1 Summary of sections of the CMI Study questionnaire

Section	Purpose	To address objective
1	Examine awareness of CMI and its content	1
	Assess consumer's receipt of CMI	2
2	Determine consumer's experience when receiving CMI	2
3	Determine readership of CMI and impact of reading CMI	3
4	Explore consumer's attitude towards CMI	4
5	Collect demographic details and provide opportunity for further comments	All

Each section is described below in order of appearance in the questionnaire. The general survey design principles discussed in Section 2.3.2.1 were applied to all questions in the questionnaire. Some are elaborated with examples from the questionnaire.

3.2.1.1.1 Section 1

Section 1 consisted of questions assessing the consumer's knowledge of CMI and the current and past[20] receipt of CMI. The information requested included the name and status[21] of the prescription medication(s) for which a CMI was received. Consumers who had not received a CMI before were asked if they were interested in receiving a CMI for his/her prescription medication(s) in the future (Question 9 to 11).

Most questions in Section 1 were multiple-choice close-ended questions (some with an "other" option) as described in Section 2.3.2.1. An open-ended question was used to gauge participant's knowledge and understanding of the content of a CMI (Question 2). It also allowed the researcher to validate whether the consumer was referring to CMI or

[20] CMI received in the 'past' included any CMI received prior to the day of the interview.

[21] 'Status' of the prescriptions refer to whether they were new, repeat or received in the past. New prescriptions are those that the consumer had never taken before and may be acute or chronic medications. Repeat prescriptions refer to medications that the consumer takes continuously on a regular basis (e.g. oral contraceptive pill, anti-cholesterol medication). These are usually collected on a monthly basis. Prescriptions received in the past refer to medications that the consumer had taken previously but not on a regular basis (e.g. antibiotics, analgesics).

not. Open-ended questions were also used when requesting for names of medications for which CMI was received as it was not possible to include a comprehensive list of all prescription medicines.

3.2.1.1.2 Section 2

Section 2 examined the consumer's experience when receiving a CMI in the community pharmacy either on the day of the interview or in the past. Questions addressed the provider of the CMI (Question 12), whether the CMI was given or requested (Question 13), the type of CMI given/received (Question 14) and the interaction that occurred when the CMI was given/received (Questions 15 and 16). Section 2 concluded with several questions ascertaining the consumer's preference regarding when to receive a CMI (Question 17), the preferred provider of CMI (Questions 18 and 19) and the preferred interval for receiving CMI for repeat prescriptions (Question 20).

All questions in Section 2 were multiple-choice questions with an "other" option. For some questions, the responses were not mutually exclusive and consumers were allowed to select more than one option.

3.2.1.1.3 Section 3

Section 3 examined the readership and action taken after reading a CMI, hence was only applicable to consumers who had received a CMI in the past. Consumers were requested to recall the most recent time they last received a CMI, and to base their responses on this incident.

Questions asked of the consumer included the last time a CMI was received (Question 21), whether they read the CMI and if so, the extent of readership (Questions 22 and 23), and reasons for reading or not reading CMI (Questions 24 and 25, respectively). Consumers who read the CMI were asked to mention specific items they focused on when reading the CMI (Question 26). The questions which followed focused on the impact of reading a CMI (Questions 27 to 29) and the action taken after reading a CMI (Question 30 to 32).

Section 3 concluded with two questions on reading CMI for a third party (e.g. child, parent or partner) (Questions 33 and 34).

Similar to Section 2, the questions in Section 3 were mainly multiple-choice questions with an "other" response and the responses were not mutually exclusive. However, open-ended questions were used when asking consumers what information from the CMI they focused on (Question 26) and what they learnt from reading CMI (Question 27).

3.2.1.1.4 Section 4

This section focussed on consumer's attitude towards CMI. From the focus group data (Koo, Krass and Aslani, 2002), five constructs which appeared to be related to the use of CMI by consumers were identified. These five constructs formed the basis of the items in Section 4. These were: readability and presentation (six items), perception of disease/condition (five items), role of carer (five items), health locus of control (six items) and experience of problems with medications in the past (five items). Multiple items were used to measure each construct to improve its accuracy and reliability (Hoyle, Harris and Judd, 2002).

General principles for question design previously discussed (Section 2.3.2.1) were taken into consideration when developing the attitudinal items. In addition, the items were worded both positively (in this case conveying a positive attitude towards CMI) and negatively (in this case conveying a negative attitude towards CMI). This was done to avoid acquiescence or response set (Hoyle, Harris and Judd, 2002; DeVellis, 2003).

Consumer's responses were measured along a Likert scale ranging from "strongly disagree" (1) to "strongly agree" (5). A middle (third) point ("neither agree nor disagree") was present and a sixth point ("not applicable") was also included following feedback from pre-testing (Section 3.2.1.4). The advantages and disadvantages of including a middle point and a "not applicable" point had been discussed earlier (Section 2.3.2.1).

3.2.1.1.5 Section 5

The final section in the questionnaire collected demographic details from the participants. This was done in order to define the characteristics of the recruited sample and to identify possible trends associating a demographic variable to the use of CMI. Hence, standard demographic details were requested including gender, age, country of birth, main language spoken at home, marital status, number of children,

highest level of education, occupation, employment status and residential postcode. In addition, details about medical conditions and current prescription medications were collected to verify some of the responses provided in the preceding sections of the questionnaire.

Finally, participants were given an opportunity to make any further comments regarding CMI or any related matter.

3.2.1.2 Reliability and validity

As this was a pilot study, the credibility of the whole questionnaire was established through the actual process of conducting the study. Nonetheless, specific reliability and validity assessments were still conducted.

In general, of the three approaches to establishing the reliability of an instrument (Section 2.3.2.2), internal reliability was the main method used in this study. The internal reliability of the participant's responses was assessed by cross-checking responses provided in different sections of the questionnaire. For example, participants who did not report receiving a CMI in the past should not have responded to questions about the action taken after reading a CMI. Although filter questions (Section 2.3.2.1) should have prevented this from occurring in the first instance, extra checks such as these helped to ensure that the recorded responses were reliable. Cronbach's alpha was used to assess the internal reliability of the attitudinal items (Section 2.3.2.2).

Criterion validity was not able to be established as no gold standard was available for comparison. In order to establish face validity, pre-testing of the questionnaire (Section 3.2.1.4) was conducted on a convenience sample of individuals. All individuals considered the questions in the pre-test to be relevant to the research topic, however some changes had to be made to clarify certain ambiguities. Content validity was also established based on the comments and feedback from two other researchers associated with the study. Lastly, construct validity of the attitudinal items in Section 4 was tested using exploratory factor analysis (Section 3.2.6).

3.2.1.3 Layout and appearance

The questionnaire consisted of 12 printed pages (double-sided) of white A4 paper. Although the layout is generally considered less critical for personally administered questionnaires (Frazer and Lawley, 2000), in this case, as the questionnaire was to be administered by multiple interviewers, special attention was paid to the clarity of the questions and instructions on the questionnaire. The questionnaire was mainly typed in Arial font size 11. Questions were typed in bold, and where necessary, instructions to the interviewers were also highlighted in bold. Line spacing was set at one and a half to ensure that the questionnaire was clear and easy to read, and did not appear congested.

3.2.1.4 Questionnaire pre-test

The questionnaire was pre-tested with a convenience sample of 20 individuals to establish face validity and ensure the smooth administration of the questionnaire. There were two differences between the pre-test and the actual study. Firstly, pre-test individuals were not collecting a medication for themselves on the day of the interview, but had previously taken or were currently taking prescription medications. Secondly, pre-test individuals were informed of the nature and aim of the pre-test and were requested to provide feedback to the researcher; this helped to establish the validity of the survey.

Based on the feedback received during pre-testing, several changes were made to the questionnaire (see Appendix A for questionnaire). The changes are summarised below:

- Some of the offered choices for multiple-choice questions were not mutually exclusive, hence the phrase "you may tick more than one box" was added to clarify that participants were allowed to choose more than one response (e.g. Questions 1 and 19).
- For a more comprehensive list of choices, an additional option ("only when I ask for it") was added to Question 20.
- Minor word changes were made to simplify and/or clarify questions and attitudinal items. For example, in Section 4, the item, "The print in CMI is too small" was changed to "I find the print in CMI too small to read" to clarify that the statement referred to the participant's own experience and not anyone else's.
- Some instructions for the interviewer had to be clarified. This included the addition of instructions for question skips that were accidentally omitted (e.g. "Go to Section

4" following the "Don't know" option), and highlighting certain instructions for interviewers by using bold print (e.g. instructions for Section 2).

- Tick boxes were added for the response choices in Question 19 to prevent any ambiguity when responses were ticked.
- A "not applicable" option was added to the attitudinal items in Section 4 to prevent forcing participants to give a response to items that did not apply to them (e.g. if they do not have someone in their care) (see also Section 3.2.1.1.4).
- Several typographical errors were corrected.

3.2.2 Sampling frame and sample size

3.2.2.1 Sampling frame

As this pilot study was conducted to investigate the use of CMI by ambulatory consumers in the community setting, the sampling frame for this study consisted of all consumers collecting prescription medications in the randomly selected community pharmacies.

3.2.2.2 Sample size

The sample size was calculated using the standard error of proportions equation (Kalton, 1983), which determines the sample size required to detect a certain population proportion (Figure 3.1).

Figure 3.1 Standard error of proportions equation

$$SE(p) = \sqrt{(PQ/ n')}$$

where:	p	= sample percentage
	SE(p)	= standard error of p
	P	= population percentage
	Q	= 100 – P
	n′	= initial estimate of sample size
also:	1.96 SE(p)	= degree of precision

To calculate the sample size, the population proportion was taken as the proportion of consumers receiving computer printout and loose leaflet CMI from community pharmacists in a previous study, which was 7.3% (Aslani, 1999). At a 3% degree of precision, a total of approximately 300 consumers were required.

3.2.3 Interviewer recruitment and training

In face-to-face surveys, the interviewer is critical to data quality as he/she is the person who actually administers the questionnaire (Salant and Dillman, 1994). In this study, the questionnaires were administered by 12 interviewers with experience in market research. These interviewers were recruited by snowballing[22].

Based on their availability, the interviewers recruited consumers from one or more pharmacies. The interviewers were instructed to visit each pharmacy consecutively for three days. Interviewers reported directly to the researcher who conducted the training session. They were remunerated AUD$20 per questionnaire completed.

All interviewers were trained prior to the data collection period to ensure that interviewer behaviours did not compromise the quality of the collected data especially since multiple interviewers were involved (Czaja and Blair, 1996). The training which lasted for two hours covered various aspects of the study (Appendix B) and was conducted at the Faculty of Pharmacy.

3.2.4 Consumer recruitment

The rationale for consumer recruitment was to capture a broad sample of consumers of prescription medications. Hence, community pharmacy was considered the strategic recruitment site for these consumers. A list of community pharmacies from the Health Insurance Commission was obtained and stratified to include only community pharmacies in the Sydney metropolitan area. Assuming a maximum response rate of approximately 30% as previously observed (Aslani, 1999), a random sample of 75 community pharmacies were selected to enable a broad cross-section of the population

[22] Snowballing is a form of convenience sampling where the researcher makes initial contact with known individuals and then uses these to establish contacts with others (Bryman, 2004).

to be reached. A sample of consumers was consecutively recruited from each of these pharmacies.

One of the interviewers was responsible for contacting and inviting the pharmacist-in-charge of each community pharmacy to participate in the study. Consenting pharmacies were informed that an interviewer would be contacting them to arrange a convenient time to recruit the consumers. After the list of consenting pharmacies was established, the names of consenting pharmacies were distributed amongst the interviewers. The interviewer was responsible for contacting the pharmacy to arrange a suitable time for him/her to visit the pharmacy and conduct the interviews. At the pharmacy, a Participant Information Sheet (Appendix C) was given to the pharmacist-in-charge, and a consent form (Appendix C) was signed if he/she was willing to participate.

With the assistance of the pharmacist-in-charge, the interviewer located a quiet area in the pharmacy where the interviews could be conducted. The interviewer also came to an agreement with the pharmacist whether the consumers would be approached directly by the interviewer as they were leaving the dispensary area or whether they would be referred to the interviewer by the pharmacist.

Using either approach, the interviewer introduced himself/herself to the consumer and invited him/her to participate in the study. A brief explanation of the study was provided and the eligibility criteria were checked. Consumers were eligible to participate in the study if they were:

- at least 18 years of age
- able to take part in the study without the help of a translator
- collecting a prescription medication for themselves on the day of the study.

Eligible and consenting consumers were given a Participant Information Sheet (Appendix C) and requested to sign a consent form (Appendix C). The interview was then conducted.

3.2.5 Administration of questionnaire

After written consent had been obtained from the participant, the interviewer commenced the interview using the structured questionnaire in a quiet area of the pharmacy. The questionnaire took approximately 15 minutes to administer.

3.2.6 Data analysis

All data were coded and entered into a database in SPSS (1999). The data were checked for incorrect entries and missing values using frequency distributions. Frequency distributions were compiled for categorical variables. Summary statistics were generated for continuous variables. The means and standard deviations were reported for normally distributed continuous variables. For non-normally distributed continuous variables, the medians and interquartile ranges (IQRs) were reported.

As mentioned earlier, the construct validity of the attitudinal items in Section 4 were tested using exploratory factor analysis. Factor analysis is a class of multivariate statistical methods which are applied to a single set of variables to *"discover which variables in the set form coherent subsets that are relatively independent of one another"* (p.582) (Tabachnick and Fidell, 2001). In other words, factor analysis reduces a set of variables to a smaller number of factors (Graetz, 2003) and these factors are thought to reflect the underlying processes that have created the correlations among variables (Tabachnick and Fidell, 2001).

Principal axis factoring, a commonly used technique, was chosen as the extraction technique (Tabachnick and Fidell, 2001; Pett, Lackey and Sullivan, 2003). The number of factors was determined by selecting only factors with eigenvalue > 1.0 (Pett, Lackey and Sullivan, 2003). Oblique rotation was considered most suitable as preliminary analysis showed the correlations among factors exceeded 0.3 (Tabachnick and Fidell, 2001). The Promax solution gave the most interpretable solution[23]. Individual items were retained if they had loadings greater than 0.30, had minimal or no cross-loading and aided interpretation of the factor (Comrey and Lee, 1992; Pett, Lackey and Sullivan, 2003).

[23] Two oblique rotations were available in SPSS: Oblimin and Promax. Both were trialled but the Promax rotation gave the most interpretable solution hence is presented here.

Weighted factor-based scales were computed for the final factor solution to allow the identified factors to be used in subsequent analysis (de Vaus, 2002). These scales were chosen as they took into account the factor loadings of each item, so that items with a high factor loading contributed more to the weighted factor-based scales than an item with low factor loading (Comrey and Lee, 1992; de Vaus, 2002). By reversing the scoring of negatively-worded items and calculating the weighted factor-based scales, the original Likert scales ranging "strongly disagree" (1) to "strongly agree" (5) were converted to different scales unique to each factor. Descriptive statistics for the new scales were also computed, including a mid-point for each scale. Scores above the mid-point indicated agreement with the factor, and vice-versa.

Following factor analysis, reliability tests using Cronbach's alpha were conducted to determine the internal consistency of the factors. Before conducting the tests, scoring of the negatively-worded items was reversed (Pett, Lackey and Sullivan, 2003).

3.2.7 Response rates

Of the 75 randomly selected community pharmacies, 18 (24%) agreed to participate in the study.

A total of 241 consumers were recruited and completed the questionnaires. Of these, four questionnaires were discarded as the consumer was not actually eligible for the study. A further 11 questionnaires were discarded due to contradictory responses in different sections of the questionnaire. Hence, the final number of useable questionnaires was 226. The number of questionnaires administered and the number of useable questionnaires from each pharmacy is presented in Appendix D Table A1.1.

3.3 RESULTS

This section presents the results for the CMI Study. As mentioned in Section 3.2.7, a total of 226 useable questionnaires were collected. However, not all questions were answered by all participants, hence in the following sections, the number of respondents may vary for different questions.

3.3.1 Sample demographics

3.3.1.1 Gender

Of the 226 participants who completed the CMI Study, 87 (38.5%) were male, 138 (61.1%) were female, and one participant was transgender (0.4%).

3.3.1.2 Age

Ages ranged from 18 to 92 years, with a median value of 56.5 years (IQR 36-73 years). Table 3.2 shows the distribution of the participants' age broken down into decades.

Table 3.2 Frequency distribution of participant age by groups

Age groups	n	%
20 and below	8	3.5
21-30	33	14.6
31-40	23	10.2
41-50	29	12.8
51-60	35	15.5
61-70	34	15.0
71-80	48	21.2
81-90	15	6.6
91 and above	1	0.4
Total	226	100.0

3.3.1.3 Country of birth and language spoken

The majority of participants were born in Australia (n=165, 73.0%) and the remainder were born overseas. At home most of the participants spoke only English (n=191, 84.5%) whilst the remainder spoke a language other than English. The main non-English languages spoken were Greek, Spanish, Italian and German.

3.3.1.4 Marital status and number of children

The majority of participants were married (Table 3.3). Of these, 66 (n=29.2%) stated that they did not have any children. The remaining had one child or more [range 1-5, median 2 (IQR 2-3)].

Table 3.3 Frequency distribution of participants' marital status

Marital status	n	%	Valid %
Never married	45	19.9	20.2
Married	109	48.2	48.9
De facto	10	4.4	4.5
Separated	6	2.7	2.7
Divorced	29	12.8	13.0
Widowed	24	10.6	10.8
Missing	3	1.3	
Total	226	100.0	100.0

3.3.1.5 Highest level of education

Highest level of education varied across the sample (Table 3.4). Although most respondents had attained at least some level of secondary education, approximately a third of the participants did not complete secondary education.

Table 3.4 Frequency distribution of participants' highest level of education

Highest level of education	n	%	Valid %
None	9	4.0	4.0
Primary School	1	0.4	0.4
School Certificate	71	31.4	31.8
Higher School Certificate	52	23.0	23.3
Associate Diploma	21	9.3	9.4
Undergraduate Diploma	24	10.6	10.8
Bachelor Degree	29	12.8	13.0
Postgraduate Diploma	7	3.1	3.1
Higher Degree	9	4.0	4.0
Missing	3	1.3	
Total	226	100.0	100.0

3.3.1.6 Occupation and work status

Participants' occupations are shown below[24] (Table 3.5). Some participants only mentioned that they were "retired" "or "unemployed" without stipulating their main occupation/training prior to retirement/unemployment hence the presence of two additional categories in Table 3.5.

Table 3.5 Frequency distribution of participants' occupation

Occupation	n	%	Valid %
Managers and administrators	9	4.0	4.2
Professionals and associate professionals	66	29.2	31.0
Tradesperson and related workers	21	9.3	9.9
Clerical workers	23	10.2	10.8
Production and transport workers	4	1.8	1.9
Sales and service workers	24	10.6	11.3
Labourers and related workers	1	0.4	0.5
Homemaker	24	10.6	11.3
Student	12	5.3	5.6
"Retired"	28	12.4	13.1
"Unemployed"	1	0.4	0.5
Missing	13	5.8	
Total	226	100.0	100.0

In terms of work status, 43 (19.0%) were working full time and 54 (23.9%) were working part time. The rest (n=124, 54.9%) were not working mainly due to retirement as reflected by the age distribution of the sample. There were five missing responses.

3.3.1.7 Current medical conditions and prescribed medications

Sixty eight consumers reported that they did not have any current medical conditions. Of the 150 consumers who did, the most common medical conditions were hypertension (n=47, 29.7%), arthritis (various forms) (n=27, 17.1%),

[24] An open ended question was used to collect information on participant's occupation. For purposes of data analysis, these occupations were categorised according to the Australian Standard Classification of Occupations (Australian Bureau of Statistics, 1997a).

hypercholesterolemia (n=20, 12.7%), and diabetes (n=15, 9.5%). There were eight missing responses.

In terms of current prescription medications taken by the consumers, 28 consumers reported that they were not taking any medications. This seemingly contradicted the eligibility criteria (Section 3.2.4) however as these consumers were collecting new medications, they did not consider themselves as currently taking the medication.

The prescription medications currently taken by 194 consumers are shown in Table 3.6. Four consumers did not answer the question.

Table 3.6 Current prescription medications (by therapeutic classes) taken by participants (n=194)

Current medication by therapeutic class	n medications	%
Cardiovascular system	171	37.7
Endocrine and metabolic disorders	64	14.1
Central nervous system	49	10.8
Musculoskeletal system	40	8.8
Respiratory systems	26	5.7
Alimentary system	24	5.3
Infections and infestations	18	4.0
Analgesia	15	3.3
Contraceptive agents	10	2.2
Skin	8	1.8
Nutrition	8	1.8
Eye	7	1.5
Other	14	3.1
Total number of medications	454	100.0

3.3.2 Awareness and knowledge of CMI

Consumers had variable understanding of CMI (Table 3.7). They most commonly associated CMI with written information leaflets inside the medication box (n=142, 62.8%), a reflection of the main form of CMI available during the time of the study. Despite the majority having some awareness of CMI, others held inaccurate views (n=8, 3.4%) or were unaware of CMI (n=26, 11.5%).

Table 3.7 Consumers' definition of CMI (n=226)

Definition of CMI	n	%
Written information about prescription medications	107	47.3
Written information printed by the pharmacist	79	35.0
Written information leaflets or brochures	73	32.3
Written information leaflets inside the medication box	142	62.8
I don't know	26	11.5
Other (including internet material, verbal information and advertising material)	8	3.4

NB: Responses are not mutually exclusive.

Participants who claimed to know what a CMI was (n=200) were then asked what kind of medicine information a CMI contained. Nineteen consumers (9.5%) stated that it contained information about the medication. Most respondents, however, named specific items, with side effects, dosage, precautions, ingredients and indication being the most commonly mentioned items (Appendix D Table A1.2).

3.3.3 Receipt of CMI

A total of 132 respondents (58.4%) reported receiving one or more CMI on the day of the interview (Appendix D Table A1.3) and 184 (81.4%) reported receiving one or more CMI in the past (Appendix D Table A1.4). In total, 195 CMI were received on the day of the interview and 290 in the past. In both cases, these medications were mainly repeat medications (Appendix D Table A1.5) for a range of therapeutic classes (Appendix D Table A1.6).

Forty-one consumers (18.1%) (Appendix D Table A1.4) had not or were unsure if they had received a CMI in the past. However, when asked if they would like to receive a CMI for their prescription medications in the future, eight consumers did not respond (19.5%) and only 17 (41.5%) expressed a desire to do so. The latter further expressed their preference to receive CMI for new medications (n=8, 47.1%), repeat medications (n=3, 17.6%) or medications that were taken in the past (n=5, 29.4%). One consumer did not give a preference.

3.3.4 Experience of receiving CMI

These questions were directed to consumers who had received CMI on the day of the interview and/or in the past (n=206). Of these, only 179 (86.9%) identified the provider of CMI for specific medications that they were prescribed (Table 3.8). The primary provider appeared to be the pharmacist followed by the manufacturer, the latter referring to package insert CMI found inside medication boxes.

Table 3.8 Provider of CMI for medications received (n=179 consumers)

Provider of CMI	n medication	%
Pharmacist	110	35.0
Manufacturer	82	26.1
Doctor	69	22.0
Both doctor and pharmacist	49	15.6
Other	4	1.2
Total number of medications	314	100.0

When asked if the CMI was offered or requested, less than half the participants reported that it was given to them by a health professional and interestingly, very few consumers actually requested a CMI from their health professional (Table 3.9). For the rest, CMI was neither given nor requested, but mainly found inside the medication boxes (n=84, 40.8%).

Table 3.9 Mode of receipt of CMI

How CMI was received	n	%	Valid %
Given	78	37.9	43.6
Requested	6	2.9	3.4
Found inside medication box	84	40.8	46.9
Other (combination of above)	11	5.4	6.1
Missing	27	13.1	
Total	206	100.0	100.0

Package insert CMI was by far the most common form of CMI received (Table 3.10).

Table 3.10 Type of CMI for medications received

Type of CMI	n medication	%	Valid %
Package insert	257	81.8	82.1
Computer printout	13	4.1	4.2
Loose leaflet	11	3.5	3.5
Other (including combinations of above)	32	10.2	10.3
Missing	1	0.3	
Total number of medications	314	100.0	100.0

Although the pharmacist was cited as the primary provider, in the majority of cases the CMI was just found inside the medication boxes without the involvement of a health professional (Table 3.11). Hence, it seems that some consumers considered a package insert CMI as being provided by the pharmacist simply because they received their medications which contained the CMI from the pharmacy.

Table 3.11 Consumer's experience during receipt of CMI (n=206)

Experience when receiving CMI	n	%	Valid %
It was inside the medication box	154	74.8	86.0
It was simply handed out with no further discussion	24	11.7	13.4
My attention was drawn to the CMI document only	8	3.9	4.5
My attention was drawn to specific sections of the CMI	19	9.2	10.6
I was asked to read the CMI	10	4.9	5.6
I was asked to read the CMI and come back if I had questions	12	5.8	6.7
The content of CMI was discussed in detail	7	3.4	3.9
The content of CMI was discussed in detail when requested	1	0.5	0.6
Missing	27	13.1	

NB: Responses are not mutually exclusive.

For the small proportion of consumers for whom the content of CMI was discussed in detail, the sections that were discussed by the health professionals are presented in Appendix D Table A1.7.

3.3.5 Preferred timing and provider of CMI

These questions were directed to participants who had received CMI on the day of the interview or in the past as well as participants who expressed interest in receiving CMI in the future. Of the 198 consumers who responded to these questions, the most common preference was to receive a CMI at the doctor's surgery after the doctor had decided what medication to prescribe but before the actual prescription was written, at the pharmacy after the prescription was dispensed or a combination of the two (Table 3.12).

Table 3.12 Consumer's preferred time to receive CMI

Preferred time to receive CMI	n	%	Valid %
At the doctor's surgery before the doctor writes the Rx (1)	65	30.4	32.8
At the doctor's surgery after the doctor writes the Rx (2)	14	6.5	7.1
At the pharmacy before the Rx is dispensed (3)	17	7.9	8.6
At the pharmacy after the Rx is dispensed (4)	60	28.0	30.3
(1) and (4)	20	9.3	10.1
(1) and (3)	11	5.1	5.6
Miscellaneous combinations of the above	11	5.1	5.6
Missing	16	7.5	
Total	214	100.0	100.0

Rx = prescription

In terms of preferred provider of CMI, the doctor was nominated as the primary preferred provider, followed by the pharmacist, and both doctor and pharmacist (Table 3.13). The common cited reasons for nominating the doctor were that the doctor is aware of the consumer's medications and medical history (Appendix D Table A1.8). The main reason for nominating a pharmacist was the perception that the pharmacist is an expert on medications (Appendix D Table A1.8).

Table 3.13 Consumer's preferred provider of CMI

Preferred CMI provider	n	%	Valid %
Doctor	82	38.3	41.4
Pharmacist	66	30.8	33.3
Both doctor and pharmacist	48	22.4	24.2
Drug manufacturer	2	0.9	1.0
Missing	16	7.5	
Total	214	100.0	100.0

Finally, consumers were also asked how often they would like to receive CMI for their repeat prescriptions (Appendix D Table A1.9). Most consumers either preferred to receive CMI the first time they collected a prescription (41.6%) or every time they collected a repeat prescription (43.9%). A variety of other preferences were also noted.

3.3.6 Readership of CMI

This section of the questionnaire was only applicable to consumers who had received a CMI in the past. A total of 184 consumers reported receiving a CMI in the past, however, only 153 consumers responded to this section. According to 148 of these consumers, the last CMI was received between 1 day to 2 years ago (median 1.5 months, IQR 0.8-6.0 months).

Ninety eight participants (53.3% of 184 participants) stated that they had read the CMI. A large proportion of these consumers (n=60, 61.2%) reported reading all sections of the CMI, while the others read only selected sections (n=16, 16.3%) or scanned the CMI (n=21, 21.4%). Consumers gave a variety of responses when asked for their focus while reading CMI but the main ones were side effects and dosage (Appendix D Table A1.10).

The main reasons for reading a CMI reported by the respondents were to learn about the medication and related to their concerns about the medication's side effects (Appendix D Table A1.11). The main reasons given for not reading the CMI were having taken the medication in the past or on a continuing basis (Appendix D Table A1.12).

Of those who read a CMI for themselves, approximately 60% (n=57) reported reading CMI for someone in their care, at varying frequencies and to different extents (Appendix D Table A1.13), mainly for partners, children, and elderly parents or relatives (Appendix D Table A1.14).

3.3.7 Impact of reading CMI

Becoming better informed about medications was the most commonly cited impact of reading CMI (Table 3.14). This was followed by greater confidence in taking medications and greater awareness of the importance of taking medications as prescribed. More than a third of consumers reported that they had not changed their medication-taking behaviour after reading CMI, but other consumers reported stopping their medications due to fear of possible side effects or drug interactions.

Table 3.14 Impact of reading CMI (n=98)

Impact of reading CMI	n	%	Valid %
I am more informed about my medication	72	73.5	75.8
I am more confident about taking my medication	55	56.1	57.9
I am more aware of the importance of taking my medication as prescribed	53	54.1	55.8
I have made no changes to the way I take my medication	36	36.7	37.9
I have changed the way I take my medication	15	15.3	15.8
I have stopped taking my medication because I did not want to suffer any side effects	11	11.2	11.6
I have stopped taking my medication because of interactions with other medications	9	9.2	9.5
I have not learnt anything new about my medication	8	8.2	8.4
I have thought about the medication when side effect occurred	1	1.0	1.1
Missing	3	3.1	

NB: Responses are not mutually exclusive.

Twenty consumers (20.4%) reported that they had concerns or queries after reading the CMI and the majority of these reported contacting a health professional (Appendix D Table A1.15). After consultation with a health professional (n=16), no changes

occurred for about half the participants. The other half reported changing dosage, medication or ceasing it altogether (Appendix D Table A1.16).

3.3.8 Use of CMI after reading

After reading CMI, many participants kept it for a short time, that is, until they finished their medication (Table 3.15). Others threw it away, filed it for future reference or shared it with others on the same medication.

Table 3.15 Use of CMI after reading

Use of CMI after reading	n	%	Valid %
Kept the CMI in the medication box until I finished the medication (1)	55	56.1	57.9
Threw the CMI away (2)	20	20.4	21.1
Filed the CMI away for future reference (3)	13	13.3	13.7
Shared the CMI with friends/relatives who were also on the same medication (4)	2	2.0	2.1
(1) and (4)	4	4.1	4.2
(1) and (3)	1	1.0	1.1
Missing	3	3.1	
Total	98	100.0	100.0

3.3.9 Attitudes towards CMI

Using the methods outlined in Section 3.2.6, factor analysis was conducted on the attitudinal items (Section 4 of questionnaire) using principal axis factoring with Promax rotation. Initial factor analysis of the 27 attitudinal items yielded seven factors explaining 52.1% of the total variance (Appendix D Table A1.17). However, several problems were observed from the pattern matrix for this solution: two items cross-loaded significantly (>0.3) (Pett, Lackey and Sullivan, 2003) on multiple factors, Factors 5 and 7 only had two items loading on each factor and overall, the factor solution did not provide a meaningful interpretation.

Hence, the analysis was further refined. Based on the process mentioned in Section 3.2.6, items that had significant cross-loading, had weak loadings on all items and/or

did not aid interpretation of a factor were removed one at a time. Factor analysis was repeated after each removal and the factor solution was inspected.

The final factor solution contained four factors (15 items). This was considered the most satisfactory and interpretable solution. The Kaiser-Meyer-Olkin (KMO) test of sampling adequacy was 0.81 and Bartlett's test of sphericity was significant (χ^2=617.72, p<0.01), both confirming that there were sufficient numbers of significant correlations among the items to justify undertaking factor analysis in the first place (Pett, Lackey and Sullivan, 2003).

The factors in the final solution were interpreted as: 1) perception of disease/condition, 2) role of carer, 3) health locus of control, and 4) readability and presentation. The loadings of the individual items are shown in Table 3.16. With the exception of two items (in 'role of carer' and 'readability and presentation'), all items had good to excellent loading[25] (Comrey and Lee, 1992) on the respective factors.

[25] As a guideline, factor loadings > 0.71 is considered as excellent, > 0.63 as very good, > 0.55 as good, > 0.45 as fair and < 0.32 as poor (Comrey and Lee, 1992).

Table 3.16 Factor loadings of the items in the "attitude to CMI" scale

Items	Factor			
	1	2	3	4
Factor 1: Perception of disease/condition				
1. I will only read the CMI if I think that my illness is serious.	0.82			
2. I don't read the CMI for medications prescribed for minor ailments.	0.74			
3. I only read the CMI for a medication which is for a serious medical condition.	0.74			
4. CMI is useful only for medications used in severe diseases.	0.73			
5. CMI should not be given out for medications used in minor illnesses.	0.63			
Factor 2: Role of carer				
1. It is important to read the CMI for the medications taken by someone in my care.		0.85		
2. As a carer, I would like to know what medication the person in my care is taking.		0.77		
3. The CMI is an important source of information for the medication taken by someone in my care.		0.77		
4. I don't believe that I should know about the medications taken by someone in my care.		-0.50		
Factor 3: Health locus of control				
1. I leave all the decision making about my medications to my doctor.			0.78	
2. I would like to be involved with my doctor in deciding what medications I should take.			-0.65	
3. I trust the doctor to prescribe medications that are suitable for me.			0.58	
Factor 4: Readability and presentation				
1. The CMI is set out well, so I can always find the information I want.				0.68
2. CMI contains all the medication information I need.				0.61
3. CMI is written in a language that is easy to understand.				0.51

NB: Only factor loadings ≥ 0.30 have been included in the table.

The final factor solution explained 52.8% of the total variance. The contribution of each factor is shown in Table 3.17.

Table 3.17 Eigenvalue and percentage variance explained by each factor in the "attitude to CMI" scale

Factor		Initial		After extraction	
		Eigenvalue	% total variance	Eigenvalue	% total variance
1	Perception of disease/condition	4.71	31.38	4.28	28.53
2	Role of carer	1.90	12.66	1.44	9.62
3	Health locus of control	1.75	11.66	1.26	8.39
4	Readability and presentation	1.43	9.56	0.94	6.26

The correlation between factors is presented in Table 3.18. The presence of correlations >0.3 between certain factors justified the use of oblique rotations in factor analysis (Pett, Lackey and Sullivan, 2003). These correlations were also below 0.5, indicating that the constructs measured by each of these factors were still distinct enough to be considered as separate factors (Pett, Lackey and Sullivan, 2003).

Table 3.18 Correlation between factors

	Factor 1	Factor 2	Factor 3	Factor 4
Factor 1 Perception of disease/condition	1.000	-0.448	0.430	-0.081
Factor 2 Role of carer	-0.448	1.000	-0.211	0.019
Factor 3 Health locus of control	0.430	-0.211	1.000	0.105
Factor 4 Readability and presentation	-0.081	0.019	0.105	1.000

The reliability of each of these factors is shown in Table 3.19. With the exception of the 'readability and presentation' factor, all other factors demonstrated acceptable reliability.

Table 3.19 Factor reliability of the "attitude to CMI" scale

Factor		n	Number of items	Cronbach's alpha
1	Perception of disease/condition	206	5	0.86
2	Role of carer	110	4	0.85
3	Health locus of control	220	3	0.67
4	Readability and presentation	220	3	0.59

As discussed in Section 3.2.6, weighted factor-based scale statistics for the factors were computed (Table 3.20). Median scores for factors 'role of carer' and 'readability and presentation' were above the mid-point, indicating that at least half or more of participants agreed with the items. Hence, most believed that CMI was an important document to aid carers in looking after their care-recipients and slightly over half agreed that CMI was understandable and presented in a user-friendly manner.

Conversely, median weighted factor-based scores for 'perception of disease/ condition' and 'health locus of control' were below the mid-point, indicating that at least half or more of participants disagreed with the items. This meant that most consumers disagreed that their use of CMI was dependent on the severity of their condition and slightly more than half disagreed that decisions about their health should be left solely to the doctor.

Table 3.20 Weighted factor-based scale statistics for the "attitude to CMI" scale

Factor	Range	Mid-point	Median	IQR
1. Perception of disease/condition	0.73 – 3.66	2.20	1.46	1.46 – 2.00
2. Role of carer	1.57 – 3.61	2.59	3.01	2.89 – 3.42
3. Health locus of control	0.67 – 3.16	1.91	1.78	1.34 – 2.29
4. Readability and presentation	1.17 – 2.83	2.00	2.20	1.86 – 2.40

3.3.10 Additional comments

At the end of the questionnaire, participants were given the opportunity to provide further comments relevant to the topic area. Thirty four participants (15.0%) provided

comments. Several themes were identified from the comments and are summarised below.

3.3.10.1 Study concept and survey design

Positive comments were made regarding the study. Some respondents commented that they enjoyed being part of the study, and were happy to know that researchers were taking an active interest in consumers' views on CMI and related issues.

3.3.10.2 Readability and presentation of CMI

Most of the comments relating to the readability and presentation of CMI were negative. In terms of readability, participants commented that CMI was too complex and confusing, and felt that there was a need to simplify and summarise the information contained in the CMI.

In terms of its presentation, participants requested for CMI to be printed in larger, darker print, and for certain sections such as the side effects to be printed in bold.

3.3.10.3 Content of CMI

Besides comments on the readability and presentation of CMI, several comments were also made regarding the content of CMI. There were suggestions to expand the list of interactions with other medications and food, and to include a contact number that consumers can use to obtain further information as well as a date indicating when the CMI was last updated. Some of this information was already contained in the CMI but may have escaped the consumers' attention when they were reading it.

One participant also commented that the indications listed in CMI did not include the indication for which he/she was taking the medication, and another participant cynically commented that the information contained in CMI was intended to promote the product.

3.3.10.4 Availability of CMI

There were suggestions for CMI to be made available in other languages for people who did not speak English, and in other forms such as tape recordings for people with reading difficulties. There was also a request for CMI to be available as package inserts in all medications.

3.3.10.5 Role of health professionals

Comments involving health professionals highlighted that participants viewed doctors and pharmacists as good sources of information about their prescription medications. In some cases, CMI was seen as an adjunct to advice from health professionals, in another case, information from health professional replaced the need for reading CMI.

One participant's description of his/her ideal experience of CMI also highlighted the role of the health professional.

> *"The ideal CMI is computer-generated and handed to me by the pharmacist- this makes me take more note of the warnings and prompts me to ask questions."* (P18008[26])

3.3.10.6 Importance of medicine information

CMI was viewed as a source of medicine information and participants commented on the importance of being aware of and reading medicine information such as CMI.

Participants also commented on other sources of medicine information that they have used in the past. This included information from manufacturers, health professionals, libraries and the internet.

3.3.10.7 Ambivalence towards CMI

Two comments reflected the nonchalant attitude of some participants towards CMI.

> *"When you take so many medications, you become blasé and stop reading these things."* (P02014)

Another participant commented that when he did read a CMI, he only scanned it and then discarded the CMI.

> *"[CMI gets] in the way when I open the box."* (P02004)

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[26] Each participant is assigned a participant code. The alphabet 'P' and the following two digits refer to the particular community pharmacy in order of recruitment and the final three digits refer to the participant number. Hence, participant code P18008 refers to the eighth participant recruited in the eighteenth community pharmacy.

3.4 DISCUSSION

3.4.1 Consumers' awareness and knowledge of CMI

The results of this study indicate that most consumers had some understanding that CMI referred to written information about medicines, however others were unaware of it or held inaccurate views. In keeping with the main form of CMI available at the time of the study, CMI was most commonly associated with written information leaflets inside the medication box. While several previous studies have examined consumer awareness of the presence of package insert WMI (see Section 3.4.2) there seemed to be no published studies which have examined consumer awareness of the concept of WMI.

Although the level of awareness of CMI was generally encouraging, there remained the possibility that consumers were influenced by the available choices read out by the interviewer. However, responses to the subsequent open-ended question on consumer knowledge of CMI indicated that this may not be the case as most consumers who were aware of CMI were also able to correctly name some of the specific information contained in a CMI.

3.4.2 Consumers' receipt and experience when receiving CMI

In this study, 58% of respondents reported receiving a CMI on the day of the interview and 81% reported receiving it in the past. It is not known, however, if the respondents were able to spontaneously answer the question, or if they had to look for the CMI before responding. Previous studies involving package insert WMI have reported that these inserts were noticed by approximately 80% of consumers without health professionals drawing their attention to it (Gotsch and Liguori, 1982; Raynor and Knapp, 2000). Hence, some consumers may not have actually realised that they received a CMI, especially if it was in the form of a package insert CMI.

Other researchers have reported varying receipt rates for various kinds of WMI. Internationally, in a UK study, 78% of consumers said that they had received a patient information leaflet (PIL) (Bandesha, Raynor and Teale, 1996). In the US, over a twelve-year period from 1982 to 1994, receipt of WMI by pharmacy consumers increased from 16% to 59% (Morris, Tabak and Gondek, 1997). In a more recent study involving eight

states in the US, 87% of pseudo-consumers who presented with prescriptions at community pharmacies received a computer-generated WMI leaflet (Svarstad, Bultman, Mount *et al.*, 2003).

In earlier studies conducted in Australia, consumers have reported WMI (not necessarily CMI) receipt rates of 36% in 1996 and 57% in 1999 (Quality Use of Medicines and Pharmacy Research Centre- University of South Australia, 2001). Due to the different WMI investigated, comparison with the current results is not possible. More recently, an Australian study documented receipt rates of 24% (2003) and 29% (2004) for computer printout CMI from pharmacists. Although still low, these receipt rates are an improvement compared to the 14% computer printout CMI receipt rate observed in the current study (conducted in 2001).

Hence, overall, there is a common trend of increased receipt of WMI both internationally and in Australia over the past few decades (Gotsch and Liguori, 1982; Morris, Tabak and Gondek, 1997; Raynor and Knapp, 2000; Quality Use of Medicines and Pharmacy Research Centre- University of South Australia, 2001). A more detailed comparison is difficult due to differences in format as well as country-specific requirements surrounding the provision of WMI.

In earlier questions in the survey, many consumers claimed that CMI were given to them by a pharmacist. However, later questions revealed that consumers attributed all CMI received while in the pharmacy to be provided by the pharmacist, including CMI which were placed in the medication box by the manufacturer. In fact, response to a subsequent question indicated that most respondents received CMI in the form of a package insert, largely without the involvement of a health professional, which reflects the findings from an earlier English study on package inserts (Bandesha, Raynor and Teale, 1996). Other studies have not reported whether health professionals were actively involved in the distribution and use of package inserts (Vander Stichele, Van haecht, Braem *et al.*, 1991; Van haecht, Vander Stichele, De Backer *et al.*, 1991; Raynor and Knapp, 2000).

This passive provision of CMI is a cause for concern as having package inserts in boxes of medication does not guarantee that the consumer will be aware of its presence (Raynor and Knapp, 2000). Moreover, WMI alone is considered less effective than WMI provided in conjunction with verbal counselling (Gotsch and Liguori, 1982; Myers and Calvert, 1984). Hence, passive CMI provision without accompanying verbal

information may not be as beneficial for consumers. To compound this issue, since 2001 when this study was conducted, there has been a steady decline in package insert CMI and a growing trend for manufacturers to make CMI available electronically (D. Monk, personal communication, 2 November 2004), generally via dispensing and prescribing software packages.

Indeed, in a recent study, consumers reported that they resorted to the internet for medicine information because of the decline in package insert CMI but were unaware that their pharmacist could supply CMI in other formats (Peterson-Clark, Aslani and Williams, 2004). Given this trend, without the active involvement of health professionals, CMI would become more inaccessible to consumers. Although programs such as the MIC Program (see Section 1.3.2) have been instigated to address these issues, the low receipt rates of computer printout CMI in the recent MIC Program evaluation study (Benton, Snow and Parr, 2004) indicate that much work is still needed to improve the situation.

The results of the current study, CMI Study, also indicated that individual consumers have distinct preferences when it comes to the provider and timing of CMI. The main preferred providers were doctors, pharmacists or a combination of the two. Other studies have similarly identified medical practitioners as the primary source of information for prescription medicines, followed by pharmacists, but these findings were not related specifically to the provision of WMI (Stergachis, Maine and Brown, 2002; Trewin and Veitch, 2003). This finding has interesting implications. The doctor was preferred as he/she was aware of the medication and medical history, however it is not known if these consumers were also unfamiliar with the extended role of the pharmacists in information provision. Currently, in Australia, through the MIC Program, the government is encouraging the dissemination of CMI via pharmacists as it is considered feasible to provide CMI together with the medicine at the time of dispensing. Given that some consumers have other preferences, new avenues for providing CMI may have to be explored.

Consumers also had different preferences for when they would like to receive CMI. The traditional time of receiving CMI at the pharmacy after the prescription was dispensed was still one of the favoured options. Interestingly, the other favoured option was to receive CMI at the doctor's before the prescription is written. The latter option reflects the increasing desire for consumers to be actively involved in their health care. Whilst receiving CMI at this stage of the consultation would greatly empower the consumer

and promote concordance, the practicalities of doing so remain to be explored. Thus, while there are still many issues surrounding these consumer preferences that have to be addressed, ultimately, efforts to address these preferences will result in consumers having greater access to CMI in a way that best meets their needs and preferences.

3.4.3 Consumers' readership and impact of reading CMI

Despite issues surrounding the receipt of CMI, CMI was read fully or partially by 64% of consumers which concords with the average rate reported in the literature (Koo, Krass and Aslani, 2003). Most consumers reported increased knowledge about their medications, which is a commonly reported impact of reading WMI [e.g. Gibbs, Waters and George (1989a); Peura, Klaukka, Hannula *et al.* (1993); Bandesha, Raynor and Teale (1996)]. A small proportion reported stopping their medications due to fear of potential side effects or drug interactions, which echoes the findings of several previous studies (Sands, Robinson and Orlando, 1984; Gibbs, Waters and George, 1989a; Bandesha, Raynor and Teale, 1996). However, other studies have found no relationship between readership of WMI and cessation of therapy due to fear of potential side effects (George, Waters and Nicholas, 1983; Myers and Calvert, 1984; Gibbs, Waters and George, 1989b).

The low proportion of consumers ceasing their medications demonstrates that the reluctance of some health professionals to provide WMI to consumers for fear that they will not take their medications is unjustified. The challenge is for health professionals to ensure that consumers are equipped to understand the potential risk of a side effect or drug interaction by accompanying the provision of a CMI with verbal explanation. Most consumers in this study did not receive any guidance from health professionals when using CMI, and it would have been interesting to know if health professional input would have made a difference to the proportion of consumers who decided to cease their medications.

3.4.4 Consumers' attitudes and opinions towards CMI

The factor analysis conducted in this study was exploratory in nature and explained just over half of the observed variance. This is not surprising as there are other factors that may influence the way consumers use CMI which were not able to be covered in the

current study. There is the possibility that certain issues may not have been elicited in the focus group discussions from which the attitude statements used in this study were derived (Koo, Krass and Aslani, 2002) or have arisen since then. It is also possible that some of the issues that arose from the focus groups were not conducive to being explored using a survey. Further work is required to refine the items in the attitude scale to arrive at a more robust solution and to produce a more reliable and valid tool to measure consumers' attitudes toward CMI. Nevertheless, some lessons may be drawn from the current findings.

The finding that consumers used CMI regardless of the severity of their condition is in contrast to previous findings (Koo, Krass and Aslani, 2002). It is worth noting that severity of condition involves very subjective assessment, hence further complicating research in the area. It is unclear if the observed discrepancy reflects true differences between the two groups or if it is due to the way the attitude statements were worded in this study.

The finding that carers considered CMI a valuable information source for someone in their care is relatively new in relation to WMI, but is an established finding when it comes to carers and information in general (Fortinsky and Hathaway, 1990; Mallet and King, 1993; Ranelli and Aversa, 1994; Wellwood, Dennis and Warlow, 1994; Goldstein and Rivers, 1996; Iconomou, Vagenakis and Kalofonos, 2001; Fukui, 2002; Kendall, Thompson and Couldridge, 2004). Carers are involved in a range of activities, from collecting and administering medicines to obtaining and relaying medicine information to their care-recipients (Francis, Smith, Gray *et al.*, 2002; Gupta, Smith and Francis, 2002). Hence, health professionals should be proactive in promoting and assisting carers with their information needs.

Over half of the respondents were interested in being involved in making decisions that influenced their health. Although unclear from this study, an earlier study found that interested respondents found CMI to be a useful tool in aiding decision making (Koo, Krass and Aslani, 2002). In a related area, consumers with breast cancer who desired an active role in treatment decision also desired detailed information about their condition (Hack, Degner and Dyck, 1994).

Lastly, consumers differed in their opinion regarding the comprehensibility and presentation of CMI. This was an expected finding as the user-friendliness of WMI has been under scrutiny for the past few decades, both by consumers and researchers

(Koo, Krass and Aslani, 2003). The positive opinions of more than half of the consumers attest to the efforts involved in the development of CMI and indicate that these efforts are headed in the right direction. However, it is worth noting that the free comments provided by consumers on this aspect of CMI were largely negative. Hence, there is definitely still room for improvement, and whilst it is important to continually improve CMI, what is more pertinent is whether negative attitudes towards the way a CMI is presented actually translate into negative behaviours when using CMI, as suggested by earlier research (Koo, Krass and Aslani, 2002). This remains to be explored.

3.4.5 Study limitations

As with all studies, the current study was associated with several limitations. The main limitation of the study arose due to the errors made by some interviewers. Despite the training session conducted prior to the commencement of the interviews, when entering the data, it was discovered that some interviewers had administered the questionnaire to consumers who were not eligible for the study and some interviewers had used the question skips incorrectly. Ideally, these errors should have been identified early on and feedback provided to the respective interviewers. However, the errors were not identified until the data collection process was completed. Nonetheless, these errors did not affect the final study results as the invalid questionnaires were discarded. Despite this, there were still pockets of missing data. From this experience, in the WMI Study Phase 1, a single data collector was used.

Secondly, non-responders may have presented a systematic bias in the study. However, neither the number of non-respondents nor the reason for non-response was documented in this study. This limitation was noted and addressed in the WMI Study Phase 1.

Lastly, despite the attempt to reach a broad cross-section of the population, the consumer sample was self-selected hence caution is required in generalising the results.

3.5 CONCLUSIONS

This pilot study is one of the first studies in Australia to examine some of the issues surrounding the provision and use of CMI by consumers. The results indicate that most consumers had some awareness of CMI, and many had received CMI in the past, albeit without the active involvement of health professionals. Many consumers also read CMI. Most found it useful and beneficial but some had concerns about taking their medications after reading it.

The results from this pilot study have to be confirmed in a larger study and further work is required to refine some of the questions used in this study. The attitudinal scales need to be refined in order to arrive at a more robust solution and to produce a more reliable and valid tool to measure consumers' attitudes toward CMI. In addition, whilst the attitudinal items suggest some potential factors which may influence consumers' attitude towards CMI and subsequently their use of CMI, there remains a need for research which focuses specifically on delineating the role of these factors.

In conclusion, the results from this study form the foundation for further research in the area of consumer's use of CMI as well as the factors which may influence this process. Some of the ideas and questions from this study were incorporated in a subsequent study, the WMI Study Phase 1, which is reported in Chapter 4.

4 FACTORS INFLUENCING USE OF WRITTEN MEDICINE INFORMATION- PHASE 1 SURVEY

The WMI Study Phase 1 was conducted in 2003. It consisted of the administration of a structured questionnaire by the researcher to patients with pain/rheumatology conditions recruited from Rheumatology Clinics of three major teaching hospitals in Sydney and patients with hypertension recruited from a random sample of community pharmacies in metropolitan Sydney.

4.1 OBJECTIVES

The overall objectives of this study were:

- 1. To determine patients' interest and likelihood in reading and seeking WMI
- 2. To determine patients' awareness, readership and use of CMI
- 3. To investigate the relationship between patient factors[27] and patients' reading and seeking of WMI
- 4. To investigate the influence of patient characteristics[28] on patients' evaluation and intended use of CMI
- 5. To determine the impact of patient CMI evaluation on their intended use of CMI

[27] Patient factors investigated in this study included disease state, health locus of control, coping style and various patient characteristics (demographics and health literacy).

[28] Patient characteristics investigated in this study included health literacy and various patient demographics (gender, age, main language spoken at home, highest level of education, occupation, duration of disease and number of medications).

4.2 METHODS

4.2.1 Study questionnaire

4.2.1.1 Incorporation of questions and ideas from the CMI Study

The development of the current study, the WMI Study Phase 1 was informed by the results of an earlier focus group study (Koo, Krass and Aslani, 2002) and the CMI Study (Chapter 3). A number of the questions piloted in the CMI Study (mainly on the use of CMI and demographics) were incorporated into the WMI Study Phase 1. Several, however, needed refinement on the basis of the insight and experience gained from the CMI Study. The modifications are summarised in Appendix E Table A1.18.

Other additions to the current survey included measures of patient's rating of WMI and health locus of control. The CMI Study results suggested that patients had differing attitudes and opinions with respect to the readability and presentation of CMI (Section 3.4.4) hence the Consumer Information Rating Form (CIRF) was included to examine how patients evaluate the various aspects of CMI and how this in turn may influence their intended use of CMI (Section 4.2.1.2.2).

Similarly, from the CMI Study (Section 3.4.4) and an earlier focus group study (Koo, Krass and Aslani, 2002), health locus of control (HLC) was identified as a possible influence on patients' use of CMI. Hence, patients' HLC was measured using the Multidimensional Health Locus of Control (MHLC) Scales (Section 4.2.1.2.3).

4.2.1.2 Content

The questionnaire (Appendix F) comprised six sections, Section A to Section F. Table 4.1 presents a summary of the purpose of each section and the related objective(s).

Table 4.1 Summary of sections of the WMI Study Phase 1 questionnaire

Section	Purpose	To address objective
A	Examine interest in reading and seeking WMI Examine patient's awareness, readership and use of CMI and other sources of WMI	1 and 3 2
B	Examine patient's perception of the comprehensibility, intended use, usefulness and design quality of CMI	4 and 5
C	Determine health locus of control	3
D	Determine coping style	3
E	Determine health literacy level	3 and 4
F	Collect demographic details and provide opportunity for further comments	3 and 4

Each section of the questionnaire is described below in order of appearance in the survey form. As mentioned in Section 2.3.2, all sections in the questionnaire were administered by the researcher with the exception of Section E which was a self-completion section. The questions in the questionnaire reflect the use of the general survey design principles discussed in Section 2.3.2.1. Some of these are elaborated with examples from the questionnaire.

4.2.1.2.1 Section A

Section A consisted of new questions constructed by the researchers and existing questions from the CMI Study (Section 4.2.1.1).

Question 1, consisting of four horizontal rating scales (1a to 1d) examined the participant's interest and likelihood in reading and seeking WMI. The five-point horizontal rating scales ranged from 1 ('not at all') to 5 ('very').

The concept of CMI as a specific form of WMI was introduced in Question 2. Questions 2 to 12 examined the participant's use of CMI including awareness and readership of CMI and reasons for reading or not reading CMI. Several questions also served to explore the influence of duration of therapy (long term or short term), status of the prescription (new versus repeat prescription) (Questions 4 and 5) as well as the role of the participant as a carer (Questions 9 and 10) on readership of CMI. Section A

concluded with two questions on other sources of WMI used apart from CMI (Questions 13 and 14).

Most questions in Section A were variants of the close-ended question described in Section 2.3.2.1, including simple yes or no questions, multiple choice questions (some with an "other" option and/or with multiple answers allowed) and rating scales. The exceptions to this were Questions 11 and 12 (reasons for reading or not reading CMI respectively) which consisted of open-ended questions followed by multiple-choice closed-ended questions. As previously mentioned, the questionnaire was administered by the researcher hence it was not viewed by the participants. This allowed participants to express what was salient in their own minds first without being influenced by the available alternatives (Foddy, 1993).

4.2.1.2.2 Section B

Section B was included to explore patients' perceptions (that is, their evaluation) of various aspects of CMI and how this in turn influenced their intended use of CMI.

Although many tools for the evaluation of WMI exist, they are associated with various limitations (Section 1.5.1.2). The Consumer Information Rating Form (CIRF), designed to provide a more direct method of quantifying patients' perceptions of different aspects of a patient information leaflet (Krass, Svarstad and Bultman, 2002) was chosen for the following reasons: it was designed to gain the patient's (and not the researcher's) perception of WMI, it covered multiple aspects of WMI and its validity and reliability had been previously established.

An adapted form of the CIRF was included in Section B. An extra question on intended future use of CMI was added (see below) to examine the effect of CMI evaluation on intended use of CMI. Other minor changes were made to make the rating form specific for CMI. These consisted of changing the generic term "patient information leaflet" to "CMI", and adapting the different sections (Question 3 below) of a leaflet to that of a CMI[29]. As only minor word changes were made, these changes were not expected to affect the validity and reliability of the instrument.

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[29] The content of most WMI is separated into different sections, such as instructions for taking the medication, precautions and side effects. In order to make the form applicable to CMI, the sections in the original CIRF were adapted to reflect the content of a standard CMI.

Section B consisted of five questions. The first four questions consisted of the adapted CIRF. Question 1, the comprehensibility subscale, explored perceived comprehensibility of CMI (five items on how easy/hard the CMI was to read, understand, remember, locate information and keep for future reference). Question 2 (not in the original CIRF), the future use subscale, explored intended future use of CMI (three items on how likely the patient is to read, use or keep CMI). Question 3, the utility subscale, explored the perceived usefulness of CMI (eight items on the quantity and usefulness of information in different sections of the CMI). Question 4, the design quality subscale, measured the perceived design quality of the CMI (seven items on design aspects: organization, attractiveness, print size, tone, helpfulness, bias and spacing between lines).

Responses to all questions of the adapted CIRF were scored using rating scales. All items in Questions 1 and 2 were scored from 1 (very hard or very unlikely respectively) to 5 (very easy or very likely, respectively). Items in Question 3 were scored 0 (none, too little or too much) or 1 (about right) for information quantity and 1 (not so useful) to 3 (very useful) for information usefulness. Finally, items in Question 4 were scored from 1 (negative adjective) to 5 (positive adjective).

The last question in Section B was an open-ended question which allowed the participant to provide further comments on any aspect of the CMI they have read.

4.2.1.2.3 Section C

Section C measured patient's health locus of control (HLC) using the Multidimensional Health Locus of Control (MHLC) Scales; the validity and reliability of these scales had previously been established (Wallston and Wallston, 1978b).

The MHLC Scales tap beliefs that an individual's health and therefore health-related behaviours is primarily influenced by themselves (internal HLC), by other influential people in their lives (powerful other HLC) or by fate and chance (chance HLC) (Wallston and Wallston, 1978b).

Two equivalent forms of the MHLC, Forms A and B, were developed to cater for studies which may require repeated administrations. Where only a single administration is required (as in the current study), the authors suggested choosing either form in its entirety rather than choosing only some items from a given form (Wallston and

Wallston, 1978b). Based on this suggestion, Form A was arbitrarily chosen for this study.

Six items relating to each of the three dimensions of control constituted the 18 items in the MHLC Scales. These dimensions of control were internal HLC, powerful others HLC and chance HLC. For example, agreement with the statement "If I get sick, it is my own behaviour which determines how soon I get well again" reflects an internal HLC. All items utilised a six-point Likert scale, ranging from "Strongly Disagree" (scored as one) to "Strongly Agree" (scored as six) (Wallston and Wallston, 1978b). As per the original instrument, no middle ground was provided to guard against respondents using an acquiescent response mode (Polgar and Thomas, 2000).

Where there were missing items, a coin toss determined whether an item was scored "Slightly Disagree" (scored as three) or "Slightly Agree" (scored as four) (Wallston and Wallston, 1978b).

4.2.1.2.4 Section D

Section D was included to examine how patients coped with stressful situations in order to examine whether their coping style was related to the way they used WMI.

A shortened version of a validated instrument known as the Miller Behavioural Style Scale (MBSS) designed to assess an individual's coping disposition (Miller, 1987) was chosen as this instrument had been widely used in the health literature (Miller, 1996) and coping styles had been shown to influence patient behaviour including their need for information (Miller, 1995).

The MBSS consists of hypothetical, relatively uncontrollable scenes that are stress-evoking. Following each scene, there are eight descriptions of ways of coping with the situation, half of which involve monitoring (taking in and scanning for threat-relevant information) and half of which provide blunting options (ignoring or avoiding threat-relevant information) (Miller, Brody and Summerton, 1988; Miller, 1996). The MBSS has been shown to possess good predictive validity, good discriminant validity and modest convergent validity (Rees and Bath, 2000). The monitoring subscale of the MBSS has also been found to have acceptable reliability (Rees and Bath, 2000).

The shortened version chosen for inclusion in the questionnaire (comprising two out of the four original scenarios, namely dental visit and possible retrenchment) had previously been validated in a separate study (Steptoe, 1989). The participant was required to tick all the responses that would best describe how he/she would have responded if the hypothetical scenario did arise. This version was chosen in the interest of time. Moreover, the other two scenarios in the MBSS (being held hostage and being on a turbulent flight) were considered by some critics as being too far removed from the everyday experience of many people, making it difficult for participants to hypothetically place themselves in such situations (Steptoe, 1989; Muris, Van Zuuren, De Jong *et al.*, 1994; Bijttebier, Vertommen and Vander Steene, 2001).

4.2.1.2.5 Section E

Section E aimed to assess patient's health literacy level and hence was a self-completion section. Many tools have been developed to assess patient's health literacy levels, however many of these are word recognition tests that do not actually test comprehension of written material (Koo, Krass and Aslani, 2003) and it is known that the ability to read does not imply the ability to understand what is being read (Doak, Doak and Root, 1996). Hence, the short-form Test of Functional Health Literacy for Adults (S-TOFHLA), a validated test which tests both reading and comprehension skills was chosen (Baker, Williams, Parker *et al.*, 1999).

In the interest of time, the abbreviated version of S-TOFHLA was used (Nurss, Parker, Williams *et al.*, 2001). This consisted of a timed reading comprehension test comprising two passages from the health care setting, namely instructions for preparation for an upper gastrointestinal examination and the patient rights and responsibilities section of a US Medicaid application form (Baker, Williams, Parker *et al.*, 1999). These passages consisted of a total of 36 items using a modified Cloze procedure[30] (Taylor, 1953). In S-TOFHLA, four options are given for each omitted word. As per the S-TOFHLA administration instructions, participants were given seven minutes to complete the test (Nurss, Parker, Williams *et al.*, 2001). One point was given for each correct item.

[30] The Cloze procedure refers to *"a test of readability or comprehension in which a person is required to supply words which have been deliberately omitted from a passage"* (Oxford University Press, 1992).

The passages in S-TOFHLA were set in the American health care context. Hence, for the purposes of this study, in order to make the passages applicable to the Australian health care context, minor word changes were made. In the first passage, the 7-digit telephone number was changed to an 8-digit number. In the second passage, the term 'Medicaid' was changed to 'health benefits' and the term 'county' was changed to 'government'.

As Section E was a self-completion section, particular attention was paid to the way this section was laid out (see Section 4.2.1.4).

4.2.1.2.6 Section F

In Section F, demographic details were requested from participants to define the characteristics of the sample and to identify possible trends associating a demographic variable to use of WMI. Standard demographic details and other demographic details which were possibly associated with the use of WMI were collected: gender, age, country of birth, languages spoken at home, highest level of education, occupation, employment status, current medical conditions, duration of condition (for which participant was recruited into the study), current medications prescribed by the participant's doctor and residential postcode. The demographic details collected were similar to those collected for the CMI Study; however, there were some modifications (Appendix E Table A1.18).

Following the request for demographic details, participants were given an opportunity to express any further thoughts or comments they had regarding CMI or WMI in general.

4.2.1.3 Reliability and validity

As mentioned in the preceding section (Section 4.2.1.2), the questionnaire utilised several validated instruments, namely the CIRF (Section B) (Krass, Svarstad and Bultman, 2002), MHLC Scales (Section C) (Wallston and Wallston, 1978b), MBSS (Section D) (Miller, 1987) and S-TOFHLA (Section E) (Baker, Williams, Parker *et al.*, 1999).

The use of previously validated questions can save time and effort as the questions have already been through extensive tests. Nevertheless, certain differences in the

design and execution of a study can affect the validity of the validated instruments (Czaja and Blair, 1996). The first of these is the use of different audiences; this was not an issue as both the validation studies and current study utilised members of the general public. However, consideration had to be given to the fact these 'members of the general public' resided in different countries.

The second of these related to the different modes of administration. This was a potential problem as the validated instruments were originally designed for self-completion but were administered by the researcher (except Section E) in the current study. However, this difference was minimised with the use of show cards (Section 4.2.4) that allowed participants to visualise the questions (as in a self-completion questionnaire).

Despite the use of validated instruments, to ensure the overall credibility of the survey results, reliability and validity of the questionnaire were assessed in the analyses.

Two different types of reliability were assessed in this study (Section 2.3.2.2). The stability of the questionnaire was indirectly tested using a series of follow-up telephone interviews involving a sample of patients from the current study (Chapter 5). This allowed the responses provided in the WMI Study Phase 1 to be checked against the responses provided in the telephone interview. In addition, in Section A, the reliability of the rating scale used in Question 1 was determined using Cronbach's alpha.

In terms of validity testing, all of the validity tests outlined in Section 2.3.2.2 were conducted with the exception of criterion validity as there was no gold standard available for comparison.

To establish face validity, the entire questionnaire was pre-tested with a convenience sample (see Section 4.2.1.5). All individuals in the pre-test considered the questions to be clear as well as relevant to the research topic. In addition to face validity, content validity was also established based on the comments and feedback from two other researchers involved with the study.

Construct validity tests were conducted for different sections of the questionnaire. In general, convergent validity was established by ascertaining if the predicted associations between different variables were fulfilled. This is illustrated with examples from different sections. In Section A, a high self-reported interest in seeking WMI was

expected to be correlated with the use of other sources of WMI. In Section B, computer printout CMI was expected to be rated better than package insert CMI in terms design quality. In Section E, patients with adequate levels of functional health literacy are expected to have better comprehension of CMI than patients with inadequate functional health literacy. Convergent validity was demonstrated if the expected associations were observed from the results.

4.2.1.4 Layout and appearance

The questionnaire consisted of 14 printed pages of white A4 paper. The layout of questionnaires personally administered by the researcher is considered less crucial than for self-completion surveys (Frazer and Lawley, 2000), however, care was still taken to ensure that the instructions and questions were clear for the interviewer. All pages were printed double-sided with the exception of Section E. Most questions and instructions to be read out to the participant were printed in bold using Arial font size 11 whilst most responses were printed in Arial font size 10 or 11. Certain instructions for the researcher were printed in font size 8.

As Section E was to be completed by the participant, special attention was paid to the way this section was set out. The questions were printed single-sided and the back page contained the sentence 'this page has been left intentionally blank' to prevent any confusion. Arial font size 12 was used and care was taken to ensure that each page appeared uncluttered and contained adequate white space.

4.2.1.5 Questionnaire pre-test

The rationale for pre-testing has been discussed in Section 2.3.2.3. For this study, most of the sections have essentially been pre-tested in one form or another: the previously validated instruments, Sections B to E were pre-tested in other studies. Sections A and F were based on the CMI Study hence had been pre-tested and piloted at that stage (Chapter 3). Notwithstanding, some questions in the CMI Study were modified and improved before being incorporated into Sections A and F of the current study. Several new questions were also added.

The entire questionnaire was pre-tested on a convenience sample of five individuals consisting of a research officer, a medical student and patients. To help establish the

face validity of the survey, pre-test individuals were informed of the nature and aim of the pre-test and were requested to provide any feedback to the researcher.

The only issue identified was the occasional difficulty in remembering the questions as well as all the possible answers read out by the researcher. This difficulty was associated mainly with the previously validated instruments which were all designed for self-completion by the patient. The introduction of show cards ameliorated the difficulty. This is discussed in Section 4.2.4.

As no other problems were encountered, no further pre-testing was considered necessary.

4.2.2 Sampling frame and sample size

4.2.2.1 Sampling frame

The sampling frame for this study consisted of patients with rheumatology/pain conditions and patients with hypertension. This section describes the primary rationale for this sampling frame.

As there is some evidence to suggest that symptoms such as pain are an important impetus for patients to seek medical help (Griffith and Carr, 2001), it was postulated that patients experiencing a symptomatic condition will regard and therefore manage their condition differently compared to patients with an asymptomatic condition. This difference may also extend to their use of WMI which led to the research hypothesis that a patient's disease state will influence their reading and seeking of WMI.

Hence, to examine this, patients with rheumatology/pain conditions (Group 1) and patients with hypertension (Group 2) were chosen for inclusion in this study. Group 1 comprised patients with a chronic condition which is usually accompanied by symptoms including pain, tenderness, inflammation and/or stiffness (Anonymous, 1999b). Group 2 which comprised patients with an asymptomatic but chronic condition (Galton, 1973; World Health Organisation, 2003) was chosen for comparison.

4.2.2.2 Sample size

As no similar studies had previously been conducted, a decision was made to base the sample size on the population of patients who reported reading WMI from the literature (40% to 89%) (Koo, Krass and Aslani, 2003) and CMI from the CMI Study (64.1%). Taking an approximate value of 60% readership at a 5% degree of precision, and using the standard error of proportions equation (Figure 3.1) (Kalton, 1983), a total of approximately 400 patients was required.

This sample size also accounted for the number of patients required in order for the regression models to be generalisable to the studied population. Approximately 15-20 subjects per variable is recommended (Stevens, 1996; Hair, Anderson, Tatham *et al.*, 1998). Since the maximum number of independent variables in a particular regression model for this study is 15, with 20 subjects per variable, a minimum of 300 patients was required.

Hence, the proposed sample size of 400 was considered adequate (200 per group).

4.2.3 Site recruitment and patient recruitment

Participants in Group 1 were recruited from Rheumatology/Pain Clinics and participants in Group 2 were recruited from community pharmacies.

In order to be eligible for the study, participants had to be:

- over the age of 18 years
- able to take part in the study without the help of a translator
- currently taking at least one prescription medication for rheumatology/pain (Group 1) (Appendix F) or hypertension (Group 2) (Appendix F).

Although attention was paid to ensure that the sample was drawn from as wide a population as possible, the recruited sample from both groups was essentially a convenience sample. The recruitment process is described in more detail below.

4.2.3.1 Group 1 recruitment

4.2.3.1.1 Group 1 site recruitment

Rheumatology/Pain Clinics operated in most principal referral hospitals in Sydney and these hospitals serviced a high volume of outpatients as they were the main tertiary referral sites for specialist consultations. Hence, a decision was made to recruit Group 1 participants from these specialist clinics as they offered a convenient yet large number of potential participants.

The rheumatologist-in-charge of six of these principal referral hospitals in Sydney were approached via telephone and invited to take part in the study. St George Hospital, Concord Hospital and St Vincent's Hospital were the first three hospitals to grant verbal and written consent hence were recruited into the study. Responses from the other teaching hospitals were not pursued as recruitment from these three hospitals was deemed sufficient to meet the required sample size of 200 patients. In addition, these three hospitals were located geographically apart from one another and belonged to different area health services in Sydney, hence allowing the sample to be drawn from different parts of the population.

Recruitment could only be conducted when the clinics were in session and the clinics were usually run as half-day clinics several times each week (depending on the hospital). As there were inevitable clashes between clinic times for the different hospitals, it was not possible to attend every single clinic in all hospitals in any given week. Generally, each week during the recruitment period, the researcher visited approximately four to six clinics at two different hospitals.

4.2.3.1.2 Group 1 patient recruitment

All patients waiting for their specialist appointments were approached (with the exception of those who were identified on the clinic list as requiring a translator and thus were not eligible). Patients were approached by the researcher, occasionally with the assistance of the nursing staff. After determining eligibility, patients were given a participant information sheet (Appendix G) and a brief explanation of the study. Patients were then requested to sign a consent form (Appendix G) if they agreed to participate in the study.

The interview was conducted in a quiet private area, usually a spare consultation or meeting room. The administration of the questionnaire is discussed below (Section 4.2.4).

From the sample size calculation (Section 4.2.2.2), a total of 200 patients were required for Group 1, hence the researcher aimed to recruit approximately 70 patients from each of the three hospitals.

4.2.3.2 Group 2 recruitment

4.2.3.2.1 Group 2 site recruitment

Despite the high prevalence of hypertension in the community[31], there were not many specialist clinics in the principal referral hospitals which catered specifically for patients with hypertension. Even if there were, many hypertensive patients become symptomatic by the time tertiary referral is required, which placed patients outside the required sampling frame for this study. Therefore, community pharmacies were considered the most suitable site to recruit Group 2 patients as patients with hypertension who were on antihypertensive medications visited community pharmacies regularly to collect their medications.

For logistical reasons, the Sydney metropolitan area was used as the sampling frame for Group 2 and a list of community pharmacies in the area was obtained from the Pharmacy Board of New South Wales.

Assuming a maximum response rate of approximately 24%, as observed in the CMI Study, a random sample of 100 community pharmacies were selected. As the names of individual pharmacy owners were not available, an information sheet addressed to the pharmacist-in-charge was sent to each pharmacy (Appendix G). Three copies of information sheet were also included for distribution to pharmacists-on-duty so that they were aware of the study (Appendix G). The pharmacist-in-charge was contacted approximately a week after mailing to determine receipt of the information sheet and to gauge interest in the study.

[31] In Australia, in 1999 to 2000, 30% of people aged 25 years and over had hypertension (Australian Institute of Health and Welfare, 2004).

During the course of recruitment, it became apparent that some areas of metropolitan Sydney were not represented in the sample of consenting pharmacies. Hence, the previously obtained list from the Pharmacy Board was further stratified to include only pharmacies in each of the under-represented 'Statistical Subdivisions (SSD)'[32] (excluding the previously approached pharmacies). From the remaining list, a random sample of 10 pharmacies was drawn for each under-represented SSD. The same protocol was followed in mailing and contacting the pharmacies. When the total number of participants recruited from the consenting pharmacies from each SSD was deemed sufficient to make up for the under-representation, the remaining pharmacies were considered lost to follow-up or informed that their assistance was no longer required.

Consenting pharmacies were visited at an agreed time which was convenient for the pharmacies. On the first visit, the pharmacist-in-charge was requested to sign a consent form (Appendix G). During the recruitment period, approximately four to six pharmacies were visited each week. Generally, the researcher spent a full day (approximately six to seven hours) in each pharmacy. This was to prevent selection bias which can be introduced by visiting the pharmacy only during certain hours (e.g. capturing mainly business people during the lunch hour).

4.2.3.2.2 Group 2 patient recruitment

Pharmacists were requested to identify consecutive patients who were on at least one antihypertensive medication (based on their dispensing history) and refer them to the researcher. This was done for two reasons: firstly, it assisted the researcher in identifying eligible patients for the study; secondly, it was thought that patients would be more comfortable with the researcher following a referral from a pharmacist with whom they were familiar.

However, this approach did not prove feasible in all pharmacies as in some pharmacies the pharmacist was too busy and/or neglected to refer patients to the researcher. Hence, the researcher requested permission from the pharmacist to personally approach patients while they were waiting to collect their prescriptions.

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[32] *"The Statistical Subdivision (SSD) is an Australian Standard Geographical Classification (ASGC) defined area which represents an intermediate level, general purpose, regional type geographic unit"* (p.256) (Australian Bureau of Statistics, 2001a). Metropolitan Sydney is divided into 12 such areas.

As the latter approach proved to be efficient and no less effective for recruitment, with subsequent visits to the pharmacies, both approaches were offered as options to the pharmacist. In most cases, the pharmacist was happy to relinquish the responsibility of recruitment to the researcher.

All eligible patients were then given a participant information sheet (Appendix G) and a brief explanation of the study, and then requested to sign a consent form (Appendix G) if they agreed to participate in the study. The interview was conducted in a low-traffic, quieter area of the pharmacy. The administration of the questionnaire is discussed below (Section 4.2.4).

A total of 200 patients were required for Group 2 and 40 pharmacies were involved, hence the researcher attempted to recruit a minimum of five patients from each pharmacy.

4.2.4 Administration of the questionnaire

After the participant had completed the consent form, the researcher commenced interviewing the patient using the structured questionnaire. In response to the feedback provided in the pre-testing stage (Section 4.2.1.5), show cards were prepared to assist participants in answering the questions (Frazer and Lawley, 2000) (Appendix F). Generally, show cards were used for all questions except those that were relatively simple (e.g. yes or no questions and short multiple-choice questions).

Each section was printed on different colour A4 paper which acted as a visual representation to distinguish between sections. For clarity, the questions were typed in bold using Arial font size 16 whilst the possible answers were presented in font size 14 or 16. All cards were individually laminated and converted into a flip chart using ring binders. This ensured that the cards were always presented in the correct order (Frazer and Lawley, 2000).

Each participant was also shown a CMI for a particular medication that he/she was currently taking and was given approximately 10 minutes to read the CMI before completing Section B. Patients were shown a computer printout CMI unless a package insert CMI was also available for their specific medication. In these instances,

participants were alternately shown a package insert or a computer printout CMI[33] to ensure even numbers of each were used.

The questionnaire took approximately 30 minutes to complete. Where possible, the whole questionnaire was administered to the participant by the researcher face-to-face in the hospital clinic or community pharmacy. However, in some cases, due to patient time constraints, this was not always feasible. In these instances, patients were asked if they would be happy for the interview to be conducted or completed by telephone. If so, a copy of the questionnaire was given to the patient to take home (in place of show cards), but the patient was requested not to look at the questionnaire until the time of the arranged telephone interview. If patients declined, only certain sections of the questionnaire were administered in the available time. The implications of these are discussed in Section 4.4.5.

4.2.5 Data analysis

All data were coded and entered into a database in SPSS (1999). The data were checked for incorrect entries and missing values using frequency distributions.

4.2.5.1 Variables used in data analysis

Besides data that were directly collected during the survey, further variables were created for use in later analyses. The main ones are outlined below according to sections in the questionnaire.

In Section A, two scales were derived from the four items measured on a horizontal rating scale (Section 4.2.1.2.1). Questions 1a and 1d (which measured the participant's interest and likelihood of *reading* WMI) were summed to form the "reading" scale, while Questions 1b and 1c (which measured the participant's interest and likelihood of *seeking* WMI) were summed to form the "seeking" scale. For multivariate analysis (Section 4.2.5.2), the "reading" and "seeking" scales were dichotomised based on the

[33] Both types of CMI contain the same information presented in the same order but differ in their presentation. In order to fit inside medication boxes or around medication bottles, package insert CMI is typically printed double sided on lightweight paper of varying sizes, with relatively smaller print and limited white space. Computer printout CMI is typically printed on A4-size printing paper (normally in three columns), with larger print and more white space.

midpoint of the scale. Patients scoring above the midpoint were classified as interested in reading and seeking information, respectively. The remainder of patients were classified as not interested.

In Section B, the individual scores assigned to the different parts in each of the four subscales of the adapted CIRF (Section 4.2.1.2.2) were summed. The maximum possible score for each subscale was 25 (comprehension), 15 (future use), 32 (utility) and 35 (design quality). The utility subscale score is the sum of two scores: the quantity of the information and the usefulness of the information (see Section 4.2.1.2.2 for scoring details). In order for each subscale to have equal weighting during data analysis, all possible maximum subscale scores were standardised to a maximum score out of five. Patient scores were then standardised accordingly.

In Section C, scores corresponding to each dimension of the MHLC Scales (Section 4.2.1.2.3) were summed. The maximum possible score for each dimension of the MHLC Scales was 36.

For Section D, the number of monitoring and blunting responses provided by the patient was summated separately (Section 4.2.1.2.4). The median score for each scale was calculated for the total sample. A decision was made to focus on the monitoring scale as it has been found to be more reliable (Rees and Bath, 2000) and more useful in predicting health behaviour (M. Rodoletz, personal communication, 14 October 2002) than the blunting scale. Thus, based on their responses to the monitoring scale, participants were classified as a 'high monitor' (coped by taking in information; score ≥ median of the total monitoring score) or 'low monitor' (coped by avoiding information; score < median of the total monitoring score) (M. Rodoletz, personal communication, 14 October 2002).

For Section E, as mentioned in Section 4.2.1.2.5, one score was given for each correct item (maximum score of 36) in the S-TOFHLA. Based on their scores, patients were classified as having different levels of health literacy (Nurss, Parker, Williams *et al.*, 2001). These are summarised in Table 4.2.

Table 4.2 S-TOFHLA functional health literacy levels

S-TOFHLA score	Functional health literacy level	Interpretation
0-16	Inadequate	Unable to read and interpret most health texts
17-22	Marginal	Has difficulty reading and interpreting health texts
23-36	Adequate	Can read and interpret most health texts

From Nurss *et al.* (2001)

In Section F, for demographic characteristics where more than two categories existed, some categories were combined to facilitate data analysis. The combination was based on the results of analysis of variance for age groups and highest level of education, and existing classification for occupation (Australian Bureau of Statistics, 1997a).

Lastly, as mentioned earlier, disease state was used to examine whether or not patients living with chronic symptoms (in this case pain) used WMI differently from those with a chronic asymptomatic disease. The two different settings presented feasible options for recruitment; however, it was not possible to recruit only patients with hypertension without any symptomatic co-morbidities (especially pain). Hence, to further confirm that the observed results supported the proposed theory, the groups were reclassified based on the presence of pain as a symptom. This was defined as any participant who reported taking analgesics and/or medication for musculoskeletal conditions. The results based on this classification were compared with the initial analysis.

4.2.5.2 Statistical analysis

Frequency distributions were compiled for categorical variables. Summary statistics were generated for continuous variables. The medians and IQRs were reported for non-normally distributed continuous variables (all continuous variables in this study were non-normally distributed).

Univariate analyses were conducted to determine the relationships between the variables using non-parametric tests; these included Chi-square test (with continuity correction where required), Mann-Whitney U test, Kruskal-Wallis test and Spearman's

correlation. Variables that were significant at the $p<0.1$ level[34] were included as predictors in multivariate analyses.

Multiple regression analysis is a multivariate statistical technique that is used to analyse the relationship between a single dependent variable and several independent variables (Hair, Anderson, Tatham *et al.*, 1998). As the independent variables used in this study were potentially inter-related, multiple regression analysis was considered an appropriate statistical technique to evaluate the contribution of specific variables whilst controlling for other possible confounding factors (Gow, 2003).

Standard multiple regression was performed, that is, all independent variables were simultaneously entered into the regression equation (Tabachnick and Fidell, 2001). This was considered the most appropriate type of multiple regression analysis to avoid prematurely assigning hierarchy to the independent variables (Tabachnick and Fidell, 2001). The resulting regression models and the residuals were evaluated to ensure that they met the assumptions for multiple regression, namely normality, linearity and homoscedasticity[35], and the absence of multicollinearity[36] and outliers[37].

Where the assumptions for multiple regression were not met despite attempts at transforming the variables, the continuous dependent variables were dichotomised and logistic regression was conducted. Logistic regression is a special form of regression in which the dependent variable is a dichotomous variable (Hair, Anderson, Tatham *et al.*, 1998). It is similar to multiple regression but is considered a more flexible and robust technique which is unrestricted by the strict assumptions of multiple regression (Hair, Anderson, Tatham *et al.*, 1998; Tabachnick and Fidell, 2001).

As with standard multiple regression, direct logistic regression was performed by entering all predictors into the equation simultaneously (Tabachnick and Fidell, 2001).

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[34] For interest in reading and seeking WMI, variables were included if they reached statistical significance for each individual scale. For the adapted CIRF, variables were included if they reached statistical significance for any of the subscales.

[35] Normality, linearity and homoscedasticity were assessed using visual inspection of the normal probability plot and residuals scatterplot (Hair, Anderson, Tatham *et al.*, 1998).

[36] Tolerance values <0.2 is indicative of a problem with multicollinearity (Garson, 2005b).

[37] Outliers are defined as those with standardised residuals in excess of ±3.3 (for a sample $n<1000$ at the $p=0.001$ level) (Tabachnick and Fidell, 2001).

This is considered the method of choice when there are no specific hypotheses about the importance or order of the independent variables (Tabachnick and Fidell, 2001).

Despite the robustness of logistic regression, cross-tabulation was performed at the univariate level to ensure sampling adequacy[38], the resulting models were checked for potential multicollinearity[39] and several diagnostic statistics[40] were evaluated to identify potential outliers or influential cases.

In addition to multiple regression, the relationships amongst the study variables of the adapted CIRF was also tested using path analysis.

4.2.6 Response rates

There is no universally acceptable patient response rate[41] as it is dependent on many factors (Bowling, 2000; Jackson and Furnham, 2000). However, patient response rates of 65% and above (Hawe, Degeling and Hall, 1990) or 75% and above (Bowling, 2000) are considered to provide a relatively good representation of the population. In this study, the overall patient response rate for both groups was 77% (n=479). The patient response rate for each group is discussed below.

4.2.6.1 Group 1 response rate

As mentioned earlier (Section 4.2.3.1.1), three hospitals were used as recruitment sites for Group 1. These were St George Hospital (coded H01), Concord Hospital (H02) and St Vincent's Hospital (H03). The overall patient response rate for Group 1 was 81% (n=217). The response rates for each of these hospitals are presented in Table 4.3.

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[38] To ensure sampling adequacy, when cross-tabulation is performed, all cell frequencies are ≥ 1 and no more than 20% of cells are <5 (Garson, 2005a).

[39] Potential multicollinearity is indicated when the correlation between two independent variables in a model is >0.70 (Tabachnick and Fidell, 2001).

[40] By convention, standardised residuals >2.58 are defined as outliers at the p=0.01 level (Garson, 2005a). The leverage statistic identifies cases which influence the model more than others; leverage >0.5 is indicative of a problem (Garson, 2005b).

[41] In this study, patient response rate is defined as the number of eligible patients who participated in the study and provided useable data divided by the total number of eligible patients who were approached.

Table 4.3 Patient response rate for Group 1

Hospital	Patient		
	Yes (n)	No (n)	Response rate (%)
St George Hospital (H01)	76	23	78
Concord Hospital (H02)	70	13	84
St Vincent's Hospital (H03)	71	15	83
Group 1	217	51	81

The reasons given by patients in Group 1 for not participating in the study is presented in Appendix E Table A1.19. Time constraint (e.g. due to parking, other appointments and transportation) was cited as the main reason for not participating.

4.2.6.2 Group 2 response rate

Group 2 participants were recruited from a random sample of consenting community pharmacies. As such, there were two response rates, pharmacy response rate and patient response rate.

A total of 160 community pharmacies were invited to participate in the study. Forty three pharmacies agreed to participate, yielding an overall pharmacy response rate[42] of 27% (Appendix E Table A1.20). However, three of these pharmacies were eventually not required; hence only 40 pharmacies were used as recruitment sites. The reasons given by the pharmacies for not participating are presented in Appendix E Table A1.21.

The overall patient response rate for Group 2 was 73% (Appendix E Table A1.20). The reasons given by patients in Group 2 for not participating in the study are presented in Appendix E Table A1.19. As with Group 1, time constraint was the main reason cited for non-participation.

The composition of the sample was compared to the latest Australian census data (Australian Bureau of Statistics, 2001b) to ensure that the proportion of recruited

[42] In this study, pharmacy response rate refers to the number of pharmacies who consented to participate in the study divided by the total number of pharmacies who were approached. Pharmacies that were lost to follow-up were considered as non-responders.

patients from each SSD were reflective of the actual proportion of residents residing in a particular SSD in the Sydney metropolitan area (Appendix E Table A1.22).

The proportion of patients in the sample recruited from each SSD did not differ to the proportion of the total population residing in each SSD; however, there were several exceptions. In SSD12, a relatively high proportion of pharmacies in the random sample coupled with a relatively high response rate from the pharmacies (Appendix E Table A1.20) led to overrepresentation in the recruited sample. In SSD02 and SSD06, the lower proportion in the recruited sample may be attributed to language barriers (Australian Bureau of Statistics, 2001b). In support of this, some pharmacies in these areas cited this as the reason for their non-participation. The poor pharmacy response rate in these SSD (Appendix E Table A1.20) in turn led to reduced patient numbers in the study.

4.3 RESULTS

4.3.1 Degree and mode of completion

Although the overall response rate was high, as previously mentioned (Section 4.2.4), due to time constraints, not all questionnaires were fully completed (Appendix E Table A1.23) and not all interviews were able to be completed face-to-face (Appendix E Table A1.24). With the patient's consent, some of the interviews were conducted or completed by telephone. In other cases, only certain sections of the questionnaire could be completed in the time that the patient had available.

To ensure that there were no demographic differences between the different modes of data collection (face-to-face and involving telephone) and different levels of completion (fully complete and partially complete), Chi-square statistics were computed. With the exception of occupation, no statistically significant differences were observed between the different modes of data collection (Appendix E Table A1.25 to Table A1.31). Similarly, no statistically significant differences were observed between the different levels of completion for any of the demographic variables (Appendix E Table A1.32 to Table A1.38).

4.3.2 Sample demographics

This section reports on the demographics of the whole study sample. A summary of patient demographics by recruitment groups (Group 1 and Group 2) is included in Appendix E Table A1.39. The patient demographics of both groups were similar except for gender, age and employment status. The higher proportion of females in Group 1 may be attributed to the higher prevalence of rheumatology conditions in females compared to males (Anonymous, 1999b). The higher proportion of older patients in Group 2 is most likely due to the rising prevalence of hypertension with increasing age (Anonymous, 1999a) whereas the onset of rheumatology condition can occur at any age (Anonymous, 1999b). As patients in Group 2 were generally older, it is therefore not surprising to observe that a greater proportion of patients in this group were retired compared to Group 1.

4.3.2.1 Gender

Of the 479 participants who completed the survey, 279 (58.2%) were female and 200 (41.8%) were male.

4.3.2.2 Age

The age of the participants in the sample ranged from 19 to 90 with a median of 67 years (IQR 54-76). The age distribution by decades is shown in Table 4.4.

Table 4.4 Frequency distribution of participants' age by groups

Age groups	n	%
20 and below	1	0.2
21-30	8	1.7
31-40	22	4.6
41-50	46	9.6
51-60	103	21.5
61-70	116	24.2
71-80	126	26.3
81-90	57	11.9
Total	479	100.0

4.3.2.3 Country of birth and language spoken

In the sample, 307 patients (64.1%) were born in Australia. The other participants were born overseas in 54 different countries, the common ones being England, New Zealand, Egypt, China and Malta. Reflective of the countries of birth, English was the main language spoken at home by 391 participants (81.6%); other main languages spoken at home included Italian, Greek, Spanish and Cantonese. A quarter of the sample (n=118; 24.6%) also spoke a second or third language at home; English was by far the most common second language (n=64).

4.3.2.4 Highest level of education

Highest level of education varied across the sample (Table 4.5) but most respondents had attained at least secondary education.

Table 4.5 Frequency distribution of participants' highest level of education

Highest level of education	n	%
None	6	1.3
Primary School	81	16.9
School Certificate (Year 10)	145	30.3
Higher School Certificate (Year 12)	106	22.1
Trade or other Certificate	37	7.7
Tertiary (Diploma, Bachelor or higher)	103	21.5
Missing	1	0.2
Total	479	100.0

4.3.2.5 Occupation and employment status

Participants' occupations are listed in Table 4.6. For data analysis purposes, the occupations were also reclassified into white- and blue-collar occupations[43]: 291

[43] This classification was based on the Australian Bureau of Statistics, whereby white-collar occupations (managers and administrators, professionals and associate professionals, clerical workers, sales and service workers) are *"predominantly associated with higher education and specific skills or with lower-skilled jobs that are mainly social rather than physical"* and blue-collar occupations (tradesperson, production and transport workers, labourers and related workers) are *"predominantly associated with trades and lower-skilled jobs that are often physical"* (Australian Bureau of Statistics, 1997b).

(60.8%) participants held white-collar occupations and 108 (22.5%) held blue-collar occupations (the remainder were homemakers, student, or never worked before as shown on Table 4.6).

Table 4.6 Frequency distribution of participants' occupation

Occupation	n	%
Managers and administrators	48	10.0
Professionals and associate professionals	105	21.9
Tradesperson and related workers	59	12.3
Clerical workers	76	15.9
Production and transport workers	28	5.8
Sales and service workers	62	12.9
Labourers and related workers	21	4.4
Homemaker	75	15.7
Student	1	0.2
"Never worked before"	3	0.6
Missing	1	0.2
Total	479	100.0

In terms of employment status, approximately half of the patients were retired, approximately a quarter were in full or part time employment and the rest were not working due to various reasons (Table 4.7).

Table 4.7 Frequency distribution of participants' employment status

Employment status	n	%
Full time	65	13.6
Part time	41	8.6
Retired	251	52.4
Unable to work due to health reasons	37	7.7
Unemployed	9	1.9
Homemaker	75	15.7
Missing	1	0.2
Total	479	100.0

4.3.2.6 Current medical conditions and prescribed medications

The most commonly reported medical conditions were hypertension (n=324, 67.6%), hypercholesterolemia (n=140, 29.2%), rheumatoid arthritis (n=87, 18.2%), osteoarthritis (n=80, 16.7%) and diabetes (n=69, 14.4%).

The main presenting medical conditions (for which the patients were recruited into the study) are presented in Appendix E Table A1.40. As expected, this comprised a range of rheumatology/pain conditions for Group 1 participants and hypertension for Group 2 participants. The duration since diagnosis of the presenting condition ranged from 1 month to 58 years with a median of 10 years (IQR 3-20 years) (41 missing data).

The current medications taken by patients in the sample are shown in Table 4.8. The two main classes of medications taken were cardiovascular and musculoskeletal system, which reflects the eligibility criteria used in the study. The median number of medications taken by the patients was four (range 1-32, IQR 3-6 medications).

Table 4.8 Current prescription medications (by therapeutic class) taken by participants (n=479)

Current medication by therapeutic class	n medications	%
Cardiovascular system	915	40.4
Musculoskeletal system	315	13.9
Endocrine and metabolic disorders	287	12.7
Analgesia	166	7.3
Alimentary system	139	6.1
Central nervous system	137	6.0
Vitamins and minerals	98	4.3
Respiratory systems	88	3.9
Eye	39	1.7
Infections and infestations	25	1.1
Other	57	2.5
Total (for medications)	2266	100.0

4.3.3 Interest and use of medicine information

4.3.3.1 Interest and likelihood in reading and seeking WMI

Four items were used to measure patients' interest and likelihood in using WMI. As mentioned in Section 4.2.5, two scales, namely "reading" and "seeking" scales were derived from these four items. The descriptive statistics for the four individual items and the two scales are shown in Table 4.9. The majority of patients were interested (item 1a) and very likely to read (item 1d) WMI about their prescription medications, however, the reverse was true for their likelihood (item 1b) and frequency (item 1c) of seeking WMI. The distribution of the "reading" and "seeking" scales mirrored this pattern, hence the "reading" scale had a very high median and the "seeking" scale had a very low median.

Cronbach's alpha for the "reading" and "seeking" scale was 0.90 and 0.94, respectively, indicating very high internal consistency.

Table 4.9 Interest and likelihood in reading and seeking WMI (n=479)

Item		Range	Median	IQR
1a	How interested would you say you are in reading written information about your prescription medicines?	1-5	4	3-5
1b	How likely are you to seek written information about your prescription medicines?	1-5	1	1-5
1c	Typically, how often would you seek written information about your prescription medicines?	1-5	1	1-3
1d	How likely are you to read written information about your prescription medicines?	1-5	5	3-5
"Reading" scale = 1a + 1d		2-10	9	6-10
"Seeking" scale = 1b + 1c		2-10	2	2-8

When the "reading" and "seeking" scales were dichotomised (Section 4.2.5.1), a similar trend was observed. Hence, the majority of patients were classified as interested in reading WMI (n=336, 70.1%) but not interested in seeking WMI (n=328, 68.5%).

4.3.3.2 Awareness, readership and use of CMI

The majority of participants (n=398, 83.1%) were not aware of the definition of 'Consumer Medicine Information'. However, after a description of CMI was given by the

researcher, most participants (n=377, 78.7%) reported having read a CMI for their own medication(s). Of these, most participants reported always reading a CMI for a new medication, be it a short or long term medication, however, the converse was true when it came to repeat medications (Appendix E Table A1.41). Seventy percent (n=264) of participants who read a CMI reported reading all sections of the CMI, while the rest read most (n=39, 10.3%) or some (n=74, 19.6%) sections only. For the latter groups, the most popular sections were side effects, indication and how to take the medication (Appendix E Table A1.42).

After reading CMI, approximately a third of participants (n=140, 37.1%) kept it for a short time until they finished their medication and another third (n=139, 36.9%) threw it away immediately. Only 52 participants (13.8%) reported filing away the CMI for future reference. The remainder reported a combination of the above.

Approximately a third (n=143, 29.9%) reported reading a CMI for someone in their care, mainly for partners, elderly parents or relatives and children (Appendix E Table A1.43). Interestingly, one of these participants reported reading a CMI for her husband's medications but not her own.

In response to an open-ended question about reasons for reading a CMI, the top three reasons given by participants were to find out about side effects (n=188, 49.7%), about the medication in general (n=135, 35.7%) and to be reassured that the medication is safe and suitable (n=70, 18.5%). A variety of other reasons were also volunteered (Table 4.10). When this question was followed by a multiple-choice close-ended question listing possible reasons for reading CMI, once again, side effects was the top reason (n=305, 80.7%) (Appendix E Table A1.44).

Table 4.10 Reasons for reading CMI (open-ended question) (n=378)

Reason	n*	%
To find out about side effects	188	49.7
To find out general information about medication	135	35.7
For reassurance that medication is safe and suitable	70	18.5
To find out about interactions (drug, disease, food)	54	14.3
Feel personally responsible for own health	47	12.4
To know the effects of medication	45	11.9
To find out the purpose of medication	24	6.3
To find out about allergies	21	5.6
To find out specific information (miscellaneous)	17	4.5
To know how to take medication	15	4.0
Information from health professional inadequate	8	2.1
Due to serious/complex nature of disease condition	5	1.3
Health professional asked to read CMI	2	0.5
Other	11	2.9

NB: Responses are not mutually exclusive.
*total n=378 as the question was directed to all participants who read a CMI (for themselves and/or someone in their care, n=377 and for someone in their care only, n=1)

Questions of the same style were also posed to participants who did not read CMI, but this time requesting their reasons for not reading CMI. In response to the open-ended question, trust and reliance in the doctor and/or pharmacist was by far the most common reason given for not reading CMI (n=63, 62.4%) (Table 4.11). In response to the close-ended question that followed, trusting the doctor and receiving adequate information from the doctor were the main reasons for not reading a CMI. These were followed by trust in the pharmacist and adequate information from the pharmacist (Appendix E Table A1.45).

Table 4.11 Reasons for not reading a CMI (open-ended question) (n=101)

Reason	n*	%
Trust in/ rely on doctor and pharmacist	63	62.4
Indifference or lack of interest or need	30	29.7
Receives or asks for verbal information	24	23.8
Difficulty in reading or understanding information	18	17.8
Eyesight problems	10	9.9
Unable to access information	6	5.9
Medication taken for a long time	6	5.9
Other (preferred) source of information	3	3.0
Other	13	12.9

NB: Responses are not mutually exclusive.
*total n=101 as the question was directed only to participants who did not read a CMI for themselves nor for someone in their care

4.3.3.3 Other sources of WMI

Three quarters of the participants (n=353, 73.7%) reported not using any other sources of WMI other than CMI. The remaining quarter (n=126, 26.3%) reported consulting various sources of WMI, with reference books (e.g. annual medication guides for lay people) and internet being the most popular sources (Appendix E Table A1.46).

Despite the use of other sources of WMI, CMI was still considered by many as their most frequently used (n=66, 52.4%) and most useful (n=54, 43.9%) source of WMI.

4.3.3.4 Relationship between interest and likelihood in reading and seeking WMI and reported use of medicine information

As part of the validation process of the "reading" and "seeking" scales, the relationship between the scales and various aspects of CMI and WMI use were explored. Statistically significant differences in both "reading" and "seeking" scores were observed between patients who did and did not do the following: read CMI for their own medications, read CMI for medications of someone in their care, and use other sources of WMI (Appendix E Table A1.47). Patients who engaged in the above-mentioned activities had significantly higher median "reading" and "seeking" scores than those who did not. Hence, the "reading" and "seeking" scales demonstrated convergent validity.

Similarly, when the scales were dichotomised, there were statistically significant differences between patients with different levels of interest in reading and seeking WMI, and the behaviours reported above (Appendix E Table A1.48).

4.3.4 Health locus of control

The descriptive statistics for each dimension of the health locus of control (HLC) scales are presented in Table 4.12. Given that the possible minimum and maximum summed scores were 6 and 36 respectively, the ranges indicate that the scores were widely distributed. Nonetheless, they were negatively skewed as reflected by the median and IQR. Overall, patients appeared to have greater tendencies towards the internal and powerful other dimensions of HLC compared to chance HLC.

Table 4.12 Descriptive statistics for dimensions of the HLC scales

Scale	Range	Median	IQR
Internal HLC	12 – 33	26	22 – 28
Chance HLC	7 – 31	19	15 – 24
Powerful other HLC	10 – 35	24	20 – 27

4.3.5 Coping style

Useable data were collected from 286 respondents[44]. The median score for the monitoring items was 5 (range 0-8, IQR 4-6). As explained in Section 4.2.5, the sample was split into high and low monitors based on this score. As a result, 167 participants were classified as monitors (score ≥ median) and 119 participants were classified as blunters (score < median).

[44] Although this section was attempted by 324 participants, there were missing data as some participants found themselves unable to relate to the presented scenarios (dental visit scenario, n=67; possible retrenchment scenario, n=50).

4.3.6 Health literacy

Health literacy scores ranged from 0 to 36 with a median of 33 (IQR 26-35). Based on their scores, participants were classified into three different levels of health literacy (Section 4.2.5) as shown in Table 4.13 Patients' health literacy level . The majority of participants who had completed S-TOFHLA had adequate levels of health literacy.

Table 4.13 Patients' health literacy level

Health literacy level (S-TOFHLA score)	n	%
Inadequate (0-16)	58	12.1
Marginal (17-22)	13	2.7
Adequate (23-36)	291	60.8
Missing*	117	24.4
Total	479	100.0

*Not all participants completed this section due to time constraint.

4.3.7 Patient factors in relation to reading and seeking of WMI

4.3.7.1 Relationship between patient factors and interest in reading and seeking WMI

The univariate analyses on relationships between interest in reading and seeking WMI and the various patient factors (disease state, health locus of control, coping style and health literacy) are summarised in Appendix E Table A1.49. Variables that were significant at the $p<0.1$ level were included as predictors in multivariate analyses. For interest in reading WMI, qualifying predictors were disease state, coping style, health literacy, chance HLC and powerful other HLC (Section 4.3.7.2). For interest in seeking WMI, disease state, coping style, health literacy, chance HLC and powerful other HLC qualified as predictors (Section 4.3.7.3).

In addition, to confirm the hypothesis regarding asymptomatic and symptomatic conditions (Section 4.2.5), univariate analysis was also conducted using presence or absence of pain as the independent variable. Statistically significant associations were found between pain as a symptom (pain present or pain absent) and interest in seeking WMI, but not interest in reading WMI (Appendix E Table A1.50).

Lastly, the relationships between patient demographics and interest in reading and seeking WMI at the univariate level are summarised in Appendix E Table A1.51. Variables that were significant at the $p<0.1$ level were included as predictors in multivariate analyses. These included age, main language spoken at home, highest level of education and occupation for both interest in reading and seeking WMI. At the same significance level, gender and country of birth was significant only for interest in reading WMI whilst employment status was significant only for interest in seeking WMI.

4.3.7.2 Modelling predictions for interest in reading WMI

Logistic regression was performed to determine patient variables which predicted interest in reading WMI (Table 4.14). The variables demonstrated sampling adequacy. No significant outliers were detected and no cases exerted undue influence on the model. Multicollinearity was not evident (all bivariate correlations were <0.51).

Overall, as indicated by the model Chi-square, the model was statistically reliable indicating that the predictors, as a whole, reliably distinguished between patients who were interested in reading WMI and those who were not. The model accounted for a fifth of the observed variance as reflected by the Nagelkerke R^2.

The Hosmer and Lemeshow test statistic indicated that the model's estimates fitted the data at an acceptable level. The model performed poorly in predicting patients who were not interested in reading WMI (26.5% correct predictions) but performed well in predicting patients who were interested in reading WMI (95.3%) (Table 4.15). Overall, the model successfully predicted 78.7% of the cases.

From the Wald statistics (Table 4.14), coping style, health literacy and occupation reliably predicted patients who were interested in reading WMI. Patients who coped by taking in information (monitors) were twice more likely to be interested in reading WMI than their counterparts. Patients with adequate health literacy levels were four times more likely to be interested in reading WMI than those with inadequate health literacy levels. Finally, patients with blue-collar occupations were approximately four times less likely than homemakers to be interested in reading WMI.

Although presence of pain did not qualify as a predictor in logistic regression (Section 4.3.7.1), to confirm the hypothesis regarding asymptomatic and symptomatic conditions, a separate logistic regression model for interest in reading WMI was

generated substituting disease state with presence of pain as one of the independent variables. Factors predicting interest in reading WMI were found to be identical (Appendix E Table A1.52).

Table 4.14 Logistic regression for interest in reading WMI

Independent variables		Regression coefficient	Wald test (z-ratio)	p	Odds ratio	95% confidence interval
Disease state	- hypertension, pain/rheumatology (ind)	0.448	1.725	0.189	1.565	0.802 – 3.053
Chance HLC		-0.021	0.435	0.510	0.979	0.919 – 1.043
Powerful other HLC		-0.039	1.426	0.232	0.962	0.902 – 1.025
Coping style	- blunter, monitor (ind)	0.801	6.137	0.013	2.228	1.182 – 4.200
Health literacy	- inadequate, marginal (ind)	1.708	3.277	0.070	5.518	0.868 – 35.073
	- inadequate, adequate (ind)	1.409	7.918	0.005	4.091	1.533 – 10.913
Gender	- male, female (ind)	0.446	1.691	0.194	1.562	0.798 – 3.058
Age (years)	- ≤ 60, ≥ 61 (ind)	0.139	0.162	0.687	1.149	0.584 – 2.261
Country of birth	- other, Australia (ind)	0.462	1.371	0.242	1.587	0.733 – 3.439
Main language spoken at home	- other, English (ind)	-0.495	0.949	0.330	0.609	0.225 – 1.651
Highest level of education	- ≤ primary, ≥ secondary (ind)	0.145	0.093	0.760	1.156	0.456 – 2.932
Occupation	- homemaker, white (ind)	-0.801	2.203	0.138	0.449	0.156 – 1.293
	- homemaker, blue (ind)	-1.363	5.286	0.021	0.256	0.080 – 0.818
n		282				
Model χ^2 test		χ^2=40.519, df=13, p<0.001				
Hosmer & Lemeshow test		χ^2=13.052, df=8, p=0.110				
Nagelkerke R^2		0.200				

(ind) = indicator category

Table 4.15 Logistic regression classification table for interest in reading WMI

		Predicted		% correct
		Not interested	Interested	
Observed	Not interested	18	50	26.5
	Interested	10	204	95.3
Overall %				78.7

4.3.7.3 Modelling predictions for interest in seeking WMI

Logistic regression was performed to determine patient variables which predicted interest in seeking WMI (Table 4.16). As with the previous model, the variables demonstrated sampling adequacy. No significant outliers were detected and no cases exerted undue influence on the model. Multicollinearity was not evident (all bivariate correlations were <0.61).

Overall, the model was statistically reliable and accounted for approximately a fifth of the observed variance. The Hosmer and Lemeshow test statistic indicated that the model's estimates fitted the data at an acceptable level. The model performed relatively well in predicting patients who were not interested in seeking WMI (88.4% correct predictions) but performed poorly in predicting patients who were interested in seeking WMI (27.6%) (Table 4.17). The predictive success of the entire model was 67.4%.

From the Wald statistics (Table 4.16), disease state, powerful other health locus of control and health literacy predicted patients who were interested in seeking WMI. Patients with rheumatology/pain conditions were approximately two times more likely to be interested in seeking WMI than patients with hypertension. Increasing scores on the powerful other HLC scale predicted a decreasing interest in seeking WMI. Lastly, as for interest in reading WMI, patients with adequate health literacy levels were four times more likely to be interested in seeking WMI compared to those with inadequate health literacy levels.

Following the substitution of disease state by presence of pain, factors predicting interest in seeking WMI were similar (Appendix E Table A1.53). Powerful other HLC and health literacy remained reliable predictors. Presence of pain displayed trends towards being a predictor but was not significant at the $p<0.05$ level.

Table 4.16 Logistic regression for interest in seeking WMI

Independent variables		Regression coefficient	Wald test (z-ratio)	p	Odds ratio	95% confidence interval
Disease state	- hypertension, pain/rheumatology (ind)	0.605	5.464	0.019	1.832	1.103 – 3.044
Chance HLC		0.010	0.174	0.677	1.010	0.962 – 1.061
Powerful other HLC		-0.057	5.185	0.023	0.944	0.899 – 0.992
Health literacy	- inadequate, marginal (ind)	1.503	3.749	0.053	4.495	0.982 – 20.578
	- inadequate, adequate (ind)	1.441	7.338	0.007	4.224	1.489 – 11.979
Age (years)	- ≤ 60, ≥ 61 (ind)	-0.302	1.090	0.297	0.739	0.419 – 1.304
Main language spoken at home	- other, English (ind)	0.053	0.019	0.891	1.054	0.496 – 2.242
Highest level of education	- ≤ primary, ≥ secondary (ind)	0.378	1.012	0.314	1.459	0.699 – 3.044
Occupation	- homemaker, white (ind)	0.072	0.043	0.835	1.075	0.544 – 2.122
	- homemaker, blue (ind)	-0.357	0.733	0.392	0.699	0.309 – 1.586
Employment status	- retired/not working, working (ind)	-0.007	0.000	0.984	0.993	0.506 – 1.950
n		356				
Model χ^2 test		χ^2=45.253, df=11, p<0.001				
Hosmer & Lemeshow test		χ^2=8.279, df=8, p=0.407				
Nagelkerke R^2		0.165				

(ind) = indicator category

Table 4.17 Logistic regression classification table for interest in seeking WMI

		Predicted		% correct
		Not interested	Interested	
Observed	Not interested	206	27	88.4
	Interested	89	304	27.6
Overall %				67.4

4.3.8 Patient evaluation of Consumer Medicine Information

The distribution of scores for each item of the four subscales is shown in Appendix E Table A1.54 to Table A1.57). Overall, participants rated CMI very well in all aspects.

For the comprehension subscale, many participants agreed that CMI was easy to read, understand and to locate important information (Appendix E Table A1.54). However, when it came to remembering the information in CMI and keeping CMI for future reference, there was more variation in responses.

Similarly, in the future use subscale, most participants expressed strong intentions of reading a CMI if the medication was a new medication (Appendix E Table A1.55) but less so when it came to using or referring to CMI and keeping CMI. This indicated that some participants viewed CMI as a source of information for new medications, but not as an ongoing source of reference.

The utility subscale was divided into the quantity and usefulness of information contained in CMI. Although CMI contained the right quantity of information in each section for most participants, it is noteworthy that up to approximately a fifth of participants felt that this was not the case (Appendix E Table A1.56). Nonetheless, generally, most participants agreed that the information contained in CMI was useful.

All items in the design quality subscale were also rated well by participants (Appendix E Table A1.57). Comparatively, attractiveness and tone were rated less positively than the other items.

When the individual items in each subscale were summed and weighted, the weighted subscale scores show a similar distribution to its constituent items (Table 4.18).

Despite the wide range, scores were negatively skewed indicating that generally, patients found CMI easy to understand, useful and well designed, and expressed intentions to use it in the future.

Table 4.18 Weighted subscale scores for CIRF

Subscale	n	Range	Median	IQR
Comprehension	305	1.0 - 5.0	4.0	3.6 – 4.6
Future Use	307	1.0 - 5.0	4.3	3.3 – 4.7
Utility	281	1.3 - 5.0	4.4	3.4 – 5.0
Design Quality	289	1.9 - 5.0	4.4	3.6 – 4.4

4.3.8.1 Association of patient characteristics with evaluation of CMI

The results of the univariate analyses for the various patient characteristics examined are shown in Appendix E Table A1.58. Variables that were significant at the $p<0.1$ level for any of the subscales were included as predictors in multivariate analyses. These included gender, age, main language spoken at home, highest level of education, health literacy, occupation and number of current medications. CMI type[45] and patient group were included to control for potential confounding effect.

The resulting regression models met the assumptions for the absence of multicollinearity (tolerance values listed in individual regression tables) and outliers (Appendix E Table A1.59), and did not show marked evidence of heteroscedasticity (Appendix E Figure A1.1 to Figure A1.5). However, the evaluation of the residuals normal probability plot led to reflect inverse transformation of the weighted design quality subscale to reduce skewness and improve the linearity and normality of the residuals (Appendix E Figure A1.6 to Figure A1.11).

4.3.8.1.1 Patient characteristics and perceived comprehension of CMI

Overall, the regression model is significant as reflected by the F test of significance. The model explained approximately a quarter of the observed variance and was associated with a standard error of 0.66.

[45] Due to the decline of package inserts, only 34 (7.1%) participants evaluated a package insert CMI. All other participants evaluated a computer printout CMI.

After adjusting for patient group and CMI type, main language spoken at home, highest level of education and health literacy were independently associated with weighted comprehension scores (Table 4.19). More specifically, patients who spoke mainly English at home, who had achieved at least secondary education and who had adequate health literacy levels had higher weighted comprehension scores than their counterparts.

Table 4.19 Relationship between patient characteristics and comprehension subscale

Predictor	B	95% CI		p	Tolerance
		Lower	Upper		
Group					
- Community (ref), hospital	0.015	-0.153	0.182	0.864	0.822
CMI type					
- Package insert (ref), computer printout	0.051	-0.259	0.361	0.747	0.897
Gender					
- Male (ref), female	-0.020	-0.191	0.150	0.814	0.800
Age group					
- ≤ 60 (ref), ≥ 61	-0.021	-0.190	0.148	0.808	0.846
Main language spoken at home					
- Other (ref), English	0.297	0.077	0.518	0.008	0.778
Education					
- ≤ Primary (ref), ≥ secondary	0.238	0.016	0.459	0.036	0.773
Health literacy					
- Inadequate (ref), marginal	0.165	-0.280	0.609	0.467	0.830
- Inadequate (ref), adequate	0.592	0.347	0.837	<0.001	0.601
Occupation					
- Homemaker (ref), white-collar	0.080	-0.144	0.303	0.483	0.478
- Homemaker (ref), blue-collar	0.012	-0.258	0.281	0.931	0.448
Number of medications	-0.015	-0.041	0.010	0.247	0.911
n	301				
R^2	0.230				
SEE	0.664				
F	7.852 (p<0.001)				

(ref) = reference category

4.3.8.1.2 Patient characteristics and perceived future use of CMI

Health literacy level was the only patient characteristic independently associated with the future use of CMI (Table 4.20), whereby patients with adequate health literacy levels scored significantly better than those with inadequate health literacy skills. Nonetheless, this finding needs to be interpreted with care as the overall model was not statistically significant (p=0.067) and explained less than 10% of the observed variance.

Table 4.20 Relationship between patient characteristics and future use subscale

Predictor	B	95% CI		p	Tolerance
		Lower	Upper		
Group					
- Community (ref), hospital	0.116	-0.150	0.382	0.392	0.822
CMI type					
- Package insert (ref), computer printout	0.283	-0.210	0.777	0.259	0.897
Gender					
- Male (ref), female	0.160	-0.112	0.432	0.249	0.800
Age group					
- ≤ 60 (ref), ≥ 61	0.074	-0.195	0.343	0.590	0.846
Main language spoken at home					
- Other (ref), English	0.131	-0.220	0.482	0.464	0.778
Education					
- ≤ Primary (ref), ≥ secondary	0.036	-0.318	0.389	0.843	0.773
Health literacy					
- Inadequate (ref), marginal	0.004	-0.704	0.712	0.991	0.830
- Inadequate (ref), adequate	0.455	0.065	0.845	0.022	0.601
Occupation					
- Homemaker (ref), white-collar	-0.181	-0.537	0.174	0.316	0.478
- Homemaker (ref), blue-collar	-0.172	-0.601	0.257	0.431	0.448
Number of medications	0.018	-0.023	0.059	0.386	0.911
n	303				
R^2	0.061				
SEE	1.061				
F	1.726 (p=0.067)				

(ref) = reference category

4.3.8.1.3 Patient characteristics and perceived utility of CMI

Weighted utility scores were associated with age whereby scores increased for older (61 years and over) compared to younger (60 years and under) patients (Table 4.21). The scores also increased with number of medications indicating patients on more medications considered the information more useful. Although the overall model was significant, it only explained approximately 10% of the observed variance.

Table 4.21 Relationship between patient characteristics and utility subscale

Predictor	B	95% CI		p	Tolerance
		Lower	Upper		
Group					
- Community (ref), hospital	0.156	-0.068	0.380	0.171	0.822
CMI type					
- Package insert (ref), computer printout	0.314	-0.101	0.729	0.138	0.897
Gender					
- Male (ref), female	0.144	-0.085	0.373	0.216	0.800
Age group					
- ≤ 60 (ref), ≥ 61	0.249	0.022	0.475	0.032	0.846
Main language spoken at home					
- Other (ref), English	0.227	-0.069	0.523	0.132	0.778
Education					
- ≤ Primary (ref), ≥ secondary	-0.016	-0.313	0.281	0.914	0.773
Health literacy					
- Inadequate (ref), marginal	-0.161	-0.757	0.434	0.594	0.830
- Inadequate (ref), adequate	0.144	-0.184	0.472	0.387	0.601
Occupation					
- Homemaker (ref), white-collar	-0.100	-0.399	0.199	0.511	0.478
- Homemaker (ref), blue-collar	-0.154	-0.515	0.207	0.400	0.448
Number of medications	0.036	0.001	0.070	0.042	0.911
n	278				
R^2	0.090				
SEE	0.855				
F	2.393 (p=0.008)				

(ref) = reference category

4.3.8.1.4 Patient characteristics and perceived design quality of CMI

Although not a patient characteristic, type of CMI was strongly associated with weighted total design, with computer printout CMI scoring significantly higher than package insert CMI (Table 4.22). When the individual attributes that comprised the design subscale were compared for these two different formats of CMI, computer printouts were rated more favourably by patients in terms of overall attractiveness, print size, helpfulness and spacing (Table 4.23).

Table 4.22 Relationship between patient characteristics and design quality subscale

Predictor	B	95% CI		p	Tolerance
		Lower	Upper		
Group					
- Community (ref), hospital	-0.016	-0.065	0.033	0.516	0.822
CMI type					
- Package insert (ref), computer printout	0.193	0.101	0.284	<0.001	0.897
Gender					
- Male (ref), female	0.043	-0.007	0.093	0.091	0.800
Age group					
- ≤ 60 (ref), ≥ 61	0.089	0.039	0.139	0.001	0.846
Main language spoken at home					
- Other (ref), English	-0.011	-0.076	0.054	0.730	0.778
Education					
- ≤ Primary (ref), ≥ secondary	-0.063	-0.128	0.002	0.058	0.773
Health literacy					
- Inadequate (ref), marginal	0.101	-0.030	0.232	0.129	0.830
- Inadequate (ref), adequate	0.063	-0.009	0.135	0.085	0.601
Occupation					
- Homemaker (ref), white-collar	-0.015	-0.081	0.050	0.647	0.478
- Homemaker (ref), blue-collar	-0.016	-0.095	0.063	0.690	0.448
Number of medications	0.001	-0.007	0.008	0.842	0.911
n	285				
R^2	0.162				
SEE	0.190				
F	4.791 (p<0.001)				

NB: The dependent variable, weighted design quality scores, was reflected and inverse transformed; (ref) = reference category

Table 4.23 Median scores for design quality subscale by CMI type

Attribute	Package inserts			Computer printouts		
	n	Median	IQR	n	Median	IQR
Organisation	33	4	3.5 – 5.0	264	5	4.0 – 5.0
Attractiveness*	33	3	3.0 – 4.0	264	4	3.0 – 5.0
Print size*	34	3	1.8 – 4.0	264	5	4.0 – 5.0
Tone	33	3	3.0 – 5.0	262	4	3.0 – 5.0
Helpfulness*	33	5	3.0 – 5.0	264	5	5.0 – 5.0
Bias	33	5	4.0 – 5.0	256	5	4.0 – 5.0
Spacing between lines*	33	4	2.5 – 5.0	264	5	5.0 – 5.0

*Mann-Whitney U test $p<0.001$

Even after controlling for the difference arising from the two types of CMI, age was still independently associated with weighted design scores with the older age group giving more favourable scores than the younger age group.

4.3.8.2 Association of weighted CIRF subscales with future use of CMI

In addition to the influence of individual patient characteristics, the association between the original CIRF subscales (comprehension, utility and design quality subscales) and the future use of CMI were explored. After adjusting for patient group and CMI type, weighted comprehension scores and weighted utility scores were independently associated with future use of CMI (Table 4.24). In other words, as patients' understanding of CMI and their perceived usefulness of it increased, they expressed greater intentions to use it in the future. Interestingly, weighted design quality scores did not have any impact on patients' likelihood of using CMI in the future. The overall model was statistically significant and explained 17% of the observed variance.

Table 4.24 Relationship between original CIRF subscales and future use subscale

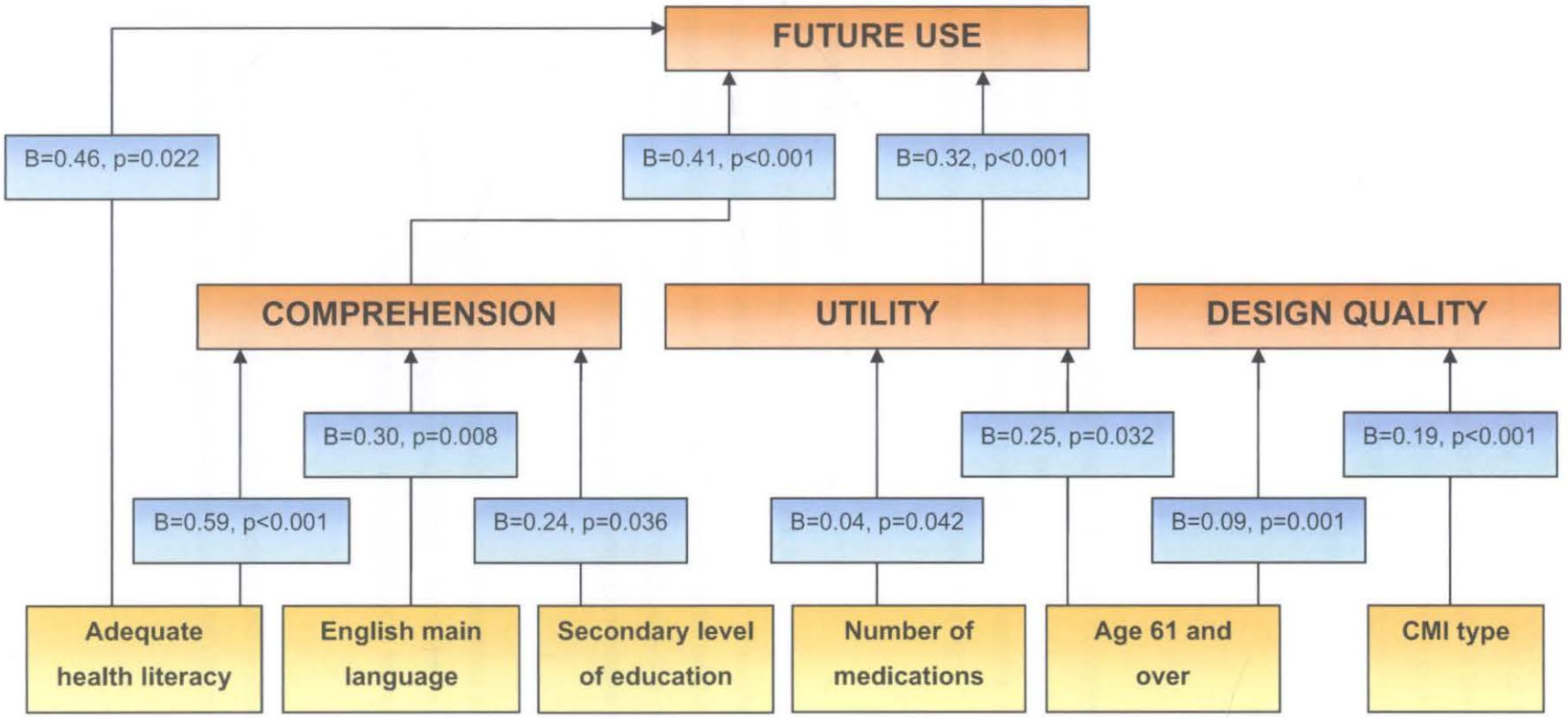
Predictor	B	95% CI		p	Tolerance
		Lower	Upper		
Group					
- Community (ref), hospital	0.106	-0.143	0.356	0.403	0.891
CMI type					
- Package insert (ref), computer printout	0.261	-0.236	0.757	0.302	0.847
Weighted comprehension score	0.414	0.247	0.581	<0.001	0.895
Weighted utility score	0.317	0.171	0.463	<0.001	0.840
Weighted design quality score*	-0.379	-1.041	0.283	0.261	0.760
n	275				
R^2	0.172				
SEE	0.987				
F	11.151 (p<0.001)				

*reflected and inverse transformed; (ref) = reference category

4.3.8.3 Path analysis of associations between patient characteristics and adapted CIRF

Following multiple regression, the relationships amongst the variables in the preceding sections (Section 4.3.8.1 and Section 4.3.8.2) were tested using path analysis (Figure 4.1). Only relationships reaching statistical significance are shown. As shown, various patient characteristics (age, main language spoken at home, highest level of education, health literacy and number of medications) and CMI type at the base of the figure influenced the scores of each subscale of the adapted CIRF (comprehension, utility, design quality and future use). The original CIRF (comprehension, utility, and design quality) subscale scores in turn also influenced intended future use of CMI.

Figure 4.1 Path analysis of associations between patient characteristics and evaluation of CMI



4.3.9 Additional comments

Participants were given the opportunity to make further comments in relation to the CMI they evaluated (Section B) and in relation to the whole study (at the end of the questionnaire). Other unsolicited comments were also made throughout the administration of the questionnaire. Themes were identified from these comments. These are reported under two separate headings, comments specifically relating to the actual CMI document (Section 4.3.9.1) and general comments (Section 4.3.9.2).

4.3.9.1 Comments on CMI document

4.3.9.1.1 Satisfaction with CMI

Many patients were *"pleased"* and *"impressed"* with the information contained in CMI and described the information as *"very informative"*, *"valuable"*, *"good to read"*, *"very useful"* and *"very helpful"*. On the whole, CMI was viewed as an essential document although some participants doubted if *"other people will bother reading it."*

4.3.9.1.2 Presentation of CMI

Not surprisingly, participants commented that the print in package insert CMI was too small although this was considered acceptable by some in order to fit everything in a small piece of paper. Interestingly, several participants commented that the print size in computer printout CMI can and should be reduced, partly to decrease the number of pages. However, one participant realistically pointed out, *"[you] can't make everyone happy regardless what is done"*.

Participants appreciated the use of bold print to highlight certain sections of the CMI especially the different headings. Several others requested for more information in bold print, with description of the tablet (for methotrexate) and side effects stated as examples.

There were also requests for CMI to be printed on white background (instead of the occasional dark grey background used on some package insert CMI) to improve its clarity.

4.3.9.1.3 Structure of CMI

In general, patients felt that CMI was *"well laid out"* and followed a *"logical sequence"*. Participants also applauded the use of headings which were thought to be very clear and made it very easy to navigate through the CMI.

There were several requests for important points to be placed at the start of CMI, partly so that patients who did not have time to read through the whole CMI can at least read through the important points. However, there were obvious differences in what were considered as important points, with how to take the medication, precautions, side effects, what to do if you forget to take the tablet and storage being cited by different participants.

4.3.9.1.4 Content of CMI

The length of CMI attracted numerous comments from participants. Whilst many participants considered CMI a very comprehensive document which covered *"everything"*, equally as many complained that the length was *"intimidating"* and *"ridiculous"*.

> *"Goes on and on... no wonder I don't read them!"* (H02055[46])

In conjunction with that, many felt that CMI could be summarised as some of the information contained in CMI was common sense and *"goes without saying"*. In addition, CMI was considered repetitive, contained *"generic"* information that were similar in all CMI and lacked personal relevance in some sections.

Other participants, however, wanted more information, partly to explain and clarify some of the points already contained in CMI.

Besides length, a few participants commented that CMI was written in *"nice simple language"*. Many more, however, were critical on the use of technical terms

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[46] Each participant is assigned a participant code. The first alphabet 'C' or 'H' denotes the recruitment group that is, 'community' or 'hospital', respectively. The following two digits refer to the particular community pharmacy or hospital in order of recruitment and the final three digits refer to the participant number. Hence, participant code H02055 refers to the fifty fifth participant recruited in the second hospital.

(interestingly with the ingredients list cited several times as an example) which were considered *"bit over the top"* for some patients, not necessarily the participants themselves. For a small minority, the difficulty with understanding CMI extended beyond the use of technical terms to the use of English language itself.

Several comments were directed at particular sections of CMI. These included indications and side effects. In relation to indications, a few patients commented that they were taking the medication for indications that were not listed or not given emphasis in the CMI. For example, one patient commented that CMI for Salazopyrin™ (sulfasalazine) was biased towards bowel cancer rather than the condition he had which was ankylosing spondylitis. More explanation in CMI was considered necessary for situations such as these.

In terms of side effects, although recognising that the information could be *"potentially scary"* or *"alarming"*, with the exception of a few participants who preferred to be unaware of the potential side effects, most participants who commented on this issue felt that it was necessary to be informed of the side effects so that any actual side effects that occurred could be appropriately attributed to the medication. A few participants even went to the extent of saying that it was necessary for the information in CMI to be slightly alarming to deter people from treating the medication lightly.

It was also interesting to note that several participants read their CMI because they were experiencing an actual side effect.

4.3.9.1.5 Comparison between package insert CMI and computer printout CMI

Several participants commented on the differences between the two formats of CMI. Of note was the perception by several participants that computer printout CMI contained more information than package insert CMI although these two different formats contained identical information for the same medication. Whilst some found the former more favourable, there were others who expressed preference for the latter for its perceived brevity.

The other main comparison made by participants related to the size of the two documents and how this impacted on ease of keeping the document for future reference. Some felt that the A4 computer printout CMI was a better-sized document to

keep but others considered the compact nature of package insert CMI as an incentive to keep it.

4.3.9.2 General comments

4.3.9.2.1 Access to CMI

The absence of CMI from the medication box or bottle was by far the most common unsolicited comment made during the survey. Many participants questioned the absence of package insert CMI and some expressed that they were *"not impressed"* and *"not happy"*.

Some patients proceeded to ask the manufacturer or the pharmacist for CMI. In some cases, these were provided but in other cases, patients were informed that CMI was not available. One participant asked the doctor for verbal information.

Other patients however only read a CMI if it came with the medication box or bottle, but otherwise *"don't bother"*.

> *"If I've had it, I would've read it."* (H02066)

4.3.9.2.2 Importance of emphasis on CMI document

Some participants commented that CMI document was inadequately emphasised and promoted to patients. There were suggestions that more emphasis could come on the CMI itself (for example, *"something in red that says 'Please read this document'"*) or from a health professional.

> *"Perhaps doctor should encourage patient to read more."* (H03060)

Independent of the above comments but nonetheless reinforcing the importance of emphasising the CMI document, several other participants mentioned that they would read a CMI if given one or asked to by their health professionals.

4.3.9.2.3 Patient proactiveness

Some patients were active in seeking WMI. This was illustrated by the actions taken when no package insert CMI was found (Section 4.3.9.2.1). Further examples included calling the manufacturer to query a side effect or obtaining information to help the support group they were leading, and asking questions of health professionals.

4.3.9.2.4 Reliance on health professionals

Contrary to the proactivity displayed by some patients, many participants expressed a heavy reliance on their doctors and pharmacists in whom they placed great trust and confidence. Hence, some considered reading CMI a *"peripheral"* activity although CMI was still considered a useful document.

> *"The boss tells me to do it [take the medication], I do it!"* (H01073)

Others considered CMI an unnecessary document, with some patients expressing that patients nowadays had access to too much information and asked too many questions of their health professionals.

> *"Don't give patients too much information to allow them to become their own doctors."* (H03007)

4.4 DISCUSSION

4.4.1 Patients' interest and likelihood in reading and seeking WMI

The items constituting the "reading" and "seeking" scales were used to describe patients' use of WMI and subsequently to form the dependent variables for other analyses. These scales were found to demonstrate high reliability and convergent validity.

From these scales, reading and seeking WMI were two distinct activities associated with the use of WMI by patients. The majority of patients were interested and likely to read WMI but most were not prepared to actively search for it. In seeking to explain a lack of proactivity in information seeking, it may be that patients perceived no need to engage in information search because they could acquire the information passively, had sufficient information or that the effort involved in conducting a search outweighed the expected benefits (Lenz, 1984). It could also be that patients had been diagnosed with their conditions for a considerable length of time hence the information-seeking stage often associated with new diagnoses had passed.

4.4.2 Awareness, readership and use of CMI

The interest expressed by most patients for reading WMI was supported by the finding that the majority (78.7%) had read a CMI for their own medication(s). It is noteworthy, however, that the majority of patients were not aware of the term 'Consumer Medicine Information'. Even after an explanation was provided, most patients only recognised package insert CMIs and were not familiar with computer printout CMI. Interestingly, at the time of the study, the former were being phased out and the latter were to become the main form of CMI available.

Most patients in this study were familiar with package insert CMI and many had noted its disappearance in recent times, notwithstanding concerns previously expressed that package insert WMI would go unnoticed by patients (Raynor and Knapp, 2000). Such awareness represents progress in the effort to inform patients about their medications. In contrast, the limited awareness regarding computer printout CMI, purportedly the main form of CMI available, is a sign that much work remains in the implementation of this alternate form of CMI. This notion is further supported by findings from another Australian study conducted at the same time which reported that less than half of consumers who had had a prescription filled in the past six months were aware that pharmacists could provide consumers with computer printout CMI (Benton, Snow and Parr, 2004).

Whilst the majority of participants had read a CMI, in agreement with a previous study (Knapp and Raynor, 1999), not all participants read all the information in CMI. Information on side effects, indication and how to take the medication were the most popular amongst those who only read CMI partially, another finding which is consistent with the literature [e.g. Dodds and King (1989); Berry, Michas, Gillie *et al.* (1997); Dickinson, Raynor and Duman (2001); Raynor, Savage, Knapp *et al.* (2004)]. In addition, it was clear from the findings that information on side effects was not only a popular section, but also the main reason for many to read the CMI. Given this, health professionals should move away from the debate about whether the provision of WMI and specifically side effects does more harm than good; rather, they should concentrate on ensuring that patients are properly equipped with the necessary skills and knowledge to interpret and apply such information in a beneficial way.

Furthermore, where reading CMI was concerned, most patients read CMI for their medication if it was new, regardless of whether it was a long or short term medication. CMI for repeat medications were rarely read. After reading, CMI was generally

discarded immediately or kept for a short period of time. These observations may mean that there is a potential medication safety issue whereby patients on chronic therapy may not have a readily accessible CMI when there is a need to identify potential medication-related problems which may occur after the initiation of therapy. This situation is further exacerbated by the decline in package insert CMI which at least ensured CMI delivery with every box of medication.

4.4.3 Relationship between patient factors and patients' reading and seeking of WMI

In addition to providing some insight into the use of WMI by Australian consumers, this study is also one of the first to focus specifically on potential patient factors that may influence the way patients read and seek WMI. Besides making a distinction between the reading and seeking of WMI, the study results identified several patient factors which influenced one or both of these activities.

In this study, monitors expressed greater interest and likelihood only in terms of reading WMI, but not seeking WMI. This suggests that they do want more information than blunters but are unprepared to actively find it for themselves. Compared to previous studies, such passivity is uncharacteristic of monitors (Miller, 1995; Miller, 1996). A possible explanation for this may be that these respondents had been diagnosed with their conditions for a considerable length of time hence the information-seeking stage often associated with new diagnoses had passed.

In addition to coping style, occupation was another patient factor associated with reading WMI in that patients with blue-collar occupations were found to be less interested and less likely to read WMI compared to homemakers. The reason for this is unclear but is likely to be an interaction between several factors. A previous study identified blue-collar occupation as one of the characteristics associated with higher rates of inadequate health literacy (Gazmararian, Baker, Williams *et al.*, 1999); this may be one contributing factor which explains the decreased interest and likelihood in reading WMI. Another contributing factor could be that homemakers are predominantly females, and according to Walker (Walker, 2001), *"the female head of household views herself as the family's caretaker, "owning" the well-being of her children and/or spouse"* (p.12). Given this role of the family's carer, as suggested in the literature review

(Chapter 1), homemakers may be more interested and likely to use medicine information.

Health literacy levels were found to influence both reading and seeking of WMI. There is a plethora of evidence to substantiate the pervasive nature of inadequate health literacy levels on a patient's health (Weiss, Hart and Pust, 1991; Weiss, Coyne, Michielutte *et al.*, 1998; Parker, Williams, Weiss *et al.*, 1999; Rudd, Moeykens and Colton, 2000; Tooth, Clark and McKenna, 2000; Andrus and Roth, 2002; Bernhardt and Cameron, 2003). However, this is one of the first studies to show, albeit not surprisingly, that patients with inadequate health literacy levels are less interested and less likely to read as well as seek WMI. This lack of motivation is most likely the direct result of poor literacy itself but undoubtedly, the prevalence of written material pitched beyond the literacy level of the general population (Weiss, Hart and Pust, 1991) further complicates the matter.

Patients with rheumatology/pain conditions recruited from the hospital clinics were more likely to seek WMI than patients with hypertension recruited from community pharmacies. Similar results were observed when disease state was reclassified by the absence or presence of pain. Although this has not been previously reported in the literature, there is evidence to suggest that symptoms play a key role in the initiation of seeking medical care (Cameron, Leventhal and Leventhal, 1993). Moreover, it is well-established that patients with rheumatology/pain conditions experience considerable physical symptoms that impinge on their ability to perform everyday tasks (Sakalys, 1997; Griffith and Carr, 2001; Woolf, Zeidler, Haglund *et al.*, 2004). Hence, it is plausible that the presence of symptoms encouraged these patients not only to seek medical care but also to seek medicine information, which enabled them to understand their condition and participate in their care (Ryan, Hassell, Dawes *et al.*, 2003).

Conversely, the asymptomatic nature of hypertension (Galton, 1973; Grueninger, 1995) has been cited as a major reason for non-compliance or discontinuation of therapy among patients with hypertension (Cummings, Kirscht, Binder *et al.*, 1982; Jokisalo, Kumpusalo, Enlund *et al.*, 2001; World Health Organisation, 2003). Hence, compared to patients with rheumatology/pain conditions, patients with hypertension may have found that reading WMI sufficed, and were not as motivated or perhaps did not find it necessary to actively search for WMI.

Lastly, health locus of control was also found to influence the search for WMI. As scores on the powerful other HLC increased (indicating a higher reliance on powerful others), the interest and likelihood of seeking WMI decreased. This finding is partially supported by another finding in this study whereby trust and reliance in health professionals was stated as the most common reason for not reading CMI. Whilst it is not surprising that trust and reliance on health professionals mitigates the need to seek information, the underlying reasons for this observation seem more complicated. These patients seem to perceive no need to search for information due to their *"belief in the maxim that 'doctor knows best'"* (p.910) (Leydon, Boulton, Moynihan *et al.*, 2000) or because the health professional had provided sufficient verbal information (Nicholas, Huntington and Williams, 2004). However, the literature also suggests that some patients were concerned that health professionals might view patients' information seeking behaviour as violating their role as patients (Leydon, Boulton, Moynihan *et al.*, 2000).

4.4.4 Influence of patient characteristics on patient evaluation and future use of CMI

Despite the wide range of responses to each section of the adapted Consumer Information Rating Form (CIRF), on the whole, patients found CMI easy to understand, useful and well designed. Most patients expressed strong intentions to use CMI if they were commencing a new medication. However, consistent with earlier results which have already been discussed (Section 4.4.2), patients expressed less intention to refer back to CMI or keep it for future reference.

Overall, the results of this section of the study highlight the need to consider patients' characteristics, opinions and perceptions in designing WMI. The study showed that the way patients evaluate WMI, and in turn, their likelihood of using the information in the future was associated with individual patient characteristics. This differs from previous findings whereby leaflet evaluation was found to be unrelated to the consumer's gender, age, education or current use of medication, and race only affected evaluation of one of the four study medications (Svarstad and Mount, 2001, 2002). A possible explanation for the observed difference may be that in this current study, patients evaluated WMI for their own medication rather than general WMI.

From the results, the self-reported ability of patients to comprehend CMI was related to their health literacy level, the main language spoken at home and their level of education. Adequate level of health literacy as measured by S-TOFHLA was associated with increasing levels of comprehension; this result was anticipated and provides further confirmation of the validity of the S-TOFHLA as a literacy tool that measures not only reading abilities but comprehension skills as well (Baker, Williams, Parker *et al.*, 1999). More importantly, the study also shows that patients with adequate health literacy are also more likely to use CMI in the future. Whilst this makes sense, the converse of this finding is a sober reminder that those with inadequate health literacy levels are less likely to do so. For the latter, alternative methods of patient education such as simplified leaflets or verbal communication may prove more beneficial (Davis, Meldrum, Tippy *et al.*, 1996; Mayeaux, Murphy, Arnold *et al.*, 1996; Weiss, Coyne, Michielutte *et al.*, 1998).

Several studies have previously demonstrated the influence of main language spoken at home as well as highest level of education on a patient's literacy level and hence ability to comprehend information. In a US study, it was observed that English-speaking patients scored higher in TOFHLA than their Spanish counterparts (Williams, Parker, Baker *et al.*, 1995). This trend was also reflected in the International Adult Literacy Study worldwide where non-English language status was shown to be a significant determinant of literacy proficiency especially in English-speaking nations including Australia (OECD and Statistics Canada, 2000).

Similarly, the role of highest level of education in influencing literacy or comprehension skill is well documented in the literature (Williams, Parker, Baker *et al.*, 1995; Parikh, Parker, Nurss *et al.*, 1996; Gazmararian, Baker, Williams *et al.*, 1999; OECD and Statistics Canada, 2000; Benson and Forman, 2002). However, highest level of education alone is not a reliable predictor of a patient's ability to comprehend information (Meade and Byrd, 1989; French and Larrabee, 1999; Wilson, Racine, Tekieli *et al.*, 2003) and the data collected in this study are consistent with previous findings. Hence, there will be some patients who have achieved high levels of education yet still have problems understanding WMI, and the converse may also be true.

From the results, perceived usefulness and design quality of CMI was observed to increase with age. The reasons for this are unknown. It may be that older patients have more co-morbidities and hence are more dependent on medications and medicine

information. Another explanation could be that the younger age group, having grown up in an environment of increased interest in health-related issues and increased recognition of individuals' rights to information, have come to be more demanding and discriminatory with respect to information on medicines (Dodds and King, 1989; van der Molen, 1999). This was demonstrated in a study of information sources for patients with cancer whereby compared to older patients, younger patients used a wider variety of information sources more frequently but rated the quality of the information less favourably (Mills and Davidson, 2002). Older patients, who seem to prefer a passive role in their relationship with health professionals (Benbassat, Pilpel and Tidhar, 1998) and who tend to place greater faith in health professionals (Mills and Davidson, 2002) may be accustomed to the 'traditional' ways of receiving information verbally prior to the increasing availability of WMI. Thus, they may have had lower expectations and access to information. Hence, they perceived the information contained in the CMI to be more useful and better designed than younger patients.

Perceived usefulness of CMI also increased with increasing number of medications. High number of medications may be a reflection of increased severity or complexity of the conditions experienced by patients. For such patients, as verbal information can be easily forgotten or confused, CMI may serve as an important reference source and a permanent record to refresh their memories and clarify any misconceptions they may have regarding their many medications (Mills and Sullivan, 1999).

In terms of design quality, it is not surprising that the presentation of CMI, whether as a package insert or a computer printout influenced the design rating, with computer printouts scoring significantly better in terms of overall attractiveness, print size and spacing between lines. However, computer printout CMI also rated better than package inserts in terms of helpfulness, thus emphasising the role of design aspects in assisting patients as they read a document. These design aspects continue to be a challenging area that is attracting much discussion and research in the literature (Koo, Krass and Aslani, 2003).

Finally, just as individual patient characteristics can influence their evaluation of CMI, their evaluation of CMI in turn can affect the likelihood of using it again in the future. Patients who found CMI understandable and useful were also more likely to use CMI in the future. These findings are expected, and further highlight the importance of taking account of patient characteristics not only in patient evaluation of WMI, but also in educating patients about the utility of WMI not only for immediate safe and effective

use but also for future identification of potential medication-related problems. Moreover, a closer examination of the path analysis in Figure 4.1 reveals that the association between comprehension of CMI and intended use of CMI may be attributed to the direct influence of health literacy levels on intended use of CMI; this further emphasises the importance of health literacy as a predictor of CMI use in the future.

In contrast, the observation that design quality did not influence the intended future use of CMI is unexpected and seems to contradict the findings with regard to design aspects of CMI mentioned earlier. A plausible explanation could be that patients were not given a choice between the two CMI types they were asked to evaluate (package insert or computer printout), thus having any type of CMI albeit poorly designed may have been deemed better than having no CMI at all. Moreover, despite being recognised by a patient, poor design although frustrating may still be deemed "acceptable" if the patient has the motivation and desire to read CMI. Hence, it does not prevent a patient from reading it as long as the information is comprehensible and useful as discussed earlier.

Finally, the results from this study serve as further validation for the original CIRF as an instrument for measuring patient perceptions of information comprehensibility, utility and design quality (Krass, Svarstad and Bultman, 2002). The relationship between patients' self-reported comprehension and their literacy levels confirms that the comprehension subscale of the CIRF is able to distinguish between patients of different literacy levels. The different design quality rating given to package inserts and computer printouts also reflects the subscale's ability to identify favourable or less favourable design characteristics as perceived by the patients.

4.4.5 Study limitations

Although all care has been taken to ensure the validity and generalisability of the study results, there are several study limitations. Non-respondents presented a limitation as there are possible differences between respondents and non-respondents (in terms of their demographics, attitudes and behaviours). The reasons for non-participation were able to be documented (Appendix E Table A1.19), however, due to privacy issues, no demographics were requested. Nonetheless, the significance of this potential limitation is somewhat mitigated by the high response rates (81% for Group 1, 73% for Group 2).

The involvement of the pharmacist during Group 2 recruitment also introduced another source of bias. Although pharmacists were requested and reminded to identify and refer consecutive eligible patients to the researcher, due to the busyness of the pharmacy or forgetfulness, this did not always occur. In some cases, the pharmacist consciously made a decision that certain patients, despite fulfilling the eligibility criteria, were 'not suitable' for the study. To overcome this, as mentioned in Section 4.2.3.2.2, the researcher requested for permission to personally approach all patients to determine their eligibility for the study. In most cases, permission was granted. Hence, the limitation was partly overcome.

Despite the care taken to ensure that the quality of the collected data was not compromised, the use of a different mode of collecting the data (that is, via telephone) and completion of only certain sections of the questionnaire were obvious limitations in the study. However, as time was a major constraint for many patients, this was deemed to be a more satisfactory compromise than entirely excluding these patients, which would introduce a selection bias to the recruitment process. As presented in Section 4.3.1, no statistically significant differences were observed between the different modes of data collection and the different levels of completion for the majority of the demographic variables. Despite having missing data, as all of the sections were highly subjective and dependent on the individual patient, it was deemed inappropriate to replace these missing pockets of data. Having said that, the available data set contained more than sufficient numbers to run valid and generalisable multiple regression analyses and produced overall significant regression equations and significant relationships between the dependent variables and some of the predictors.

The last limitation associated with the methods was that the patients in the study were drawn from essentially a convenience sample. Although the researcher attempted to collect a representative sample by sampling from different geographical areas and by systematically recruiting all eligible patients, the generalisability of the data to the main population remains limited. The eligibility criteria also excluded patients with insufficient command of the English language hence the current results are probably an underestimation of the actual extent of the influence of patient literacy levels and primary language spoken at home in the community.

In terms of the study results, all multivariate analyses only managed to explain some of the variance observed in the data. This is not surprising as there are many other potential factors, some of which were mentioned in Chapter 1, which can influence the

way a patient uses WMI. Moreover, although statistically significant results were observed in this study, the magnitude of some of the relationships was small; also, the clinical significance of these results was outside the scope of this study and is largely unknown. Hence, further work is needed to clarify some of the findings in this study as well as to identify other factors that contribute to the way a patient uses WMI.

4.5 CONCLUSIONS

This study revealed that the majority of patients are interested in reading but not seeking WMI. This interest in reading WMI is supported by the finding that the majority of patients have read CMI in the past. Nonetheless, despite a high reported readership, there is still room for improvement in terms of patients' awareness of different forms of CMI and the role of CMI as an ongoing reference source.

This is also one of the first studies to establish the influence of certain patient factors on reading and information-seeking behaviour. More specifically, coping style, health literacy and occupation were predictors of the way patients read WMI whilst disease state, health literacy and health locus of control influenced information-seeking behaviour. Furthermore, reading and seeking WMI were treated as two distinct independent activities that did not necessarily occur in tandem.

Finally, the results provide an additional aspect for consideration when involving patients in the design and evaluation of WMI. Not all patients will evaluate the same information in the same way and certain patient characteristics may influence a patient's preferences and need for medicine information.

In conclusion, further research is needed to confirm the validity and reliability of the current results as well as clarify the findings in this study. Hence, a follow-up qualitative study, the WMI Study Phase 2, was conducted, the results of which are reported in Chapter 5. In addition to this, the results from this study provide other directions for future research. At the forefront of this is the need for studies which determine the clinical significance of some of these observed associations as well as studies to identify other potential factors that may influence the way a patient uses WMI.

5 FACTORS INFLUENCING USE OF WRITTEN MEDICINE INFORMATION- PHASE 2 FOLLOW-UP INTERVIEWS

This study was conducted in 2003 and comprised a series of follow-up semi-structured telephone interviews administered to a sub-sample of respondents from the WMI Study Phase 1 to meet the objectives stated below (Section 5.1).

5.1 OBJECTIVES

The overall objectives of this study were:

- 1. To triangulate the results of the WMI Study Phase 1 by comparing patient responses from the WMI Study Phase 1 and this study
- 2. To gain more in-depth information on factors influencing patients' reading and seeking of WMI
- 3. To explore further issues surrounding the use of CMI and WMI in general.

5.2 METHODS

5.2.1 Interview guide

An interview guide mainly consisting of open-ended questions (some with prompts) was used for the semi-structured interviews (Appendix H). The themes covered in the interview guide and the related objectives are summarised in Table 5.1 .

Table 5.1 Summary of questions in the interview guide

Theme	Purpose	To address objective
1	Explore how patients cope with diagnosis and the role of information in the coping process	1 and 2
	Examine the impact of symptoms (or lack there of) on the coping process	1 and 2
2	Examine interest in medicine information, especially WMI	1 and 3
3	Examine perceived access and perceived role of health professionals in relation to medicine information	3
4	Explore opinion about format and presentation of CMI and its impact on CMI use	2
5	Explore ease of understanding content of CMI	1 and 2
6	Examine perceived HLC and its influence on use of medicine information	1 and 2
7	Provide opportunity for further comments	3

5.2.2 Reliability and validity

In qualitative research, validity refers to the accuracy of findings from the perspective of the researcher, participant or readers (Creswell, 2003). Hence, in order to establish the credibility of the study, the validity of the interviews was assessed in several ways (Maxwell, 1996; Minichiello, Aroni, Timewell *et al.*, 2000; Polgar and Thomas, 2000; Creswell, 2003). Firstly, validity was examined by probing and cross-checking patient responses where applicable during the interview (Minichiello, Aroni, Timewell *et al.*, 2000). This enabled the interviewer to discover any discrepancies in the participant's responses. Secondly, validity was enhanced by identifying and reporting negative or discrepant information that ran counter to the themes (Maxwell, 1996; Creswell, 2003). Perspectives presented in real life do not necessarily concur, hence the discussion of contrary information adds to the credibility of the data (Creswell, 2003). Finally, triangulation of findings from this study with data from the WMI Study Phase 1 was also carried out to support the validity of the study (Maxwell, 1996; Polgar and Thomas, 2000; Creswell, 2003).

To establish the reliability of patient responses in both studies, some of the participant's responses in the interview were compared to his/her responses to the same questions in the WMI Study Phase 1.

5.2.3 Sampling frame and sample size

The sampling frame consisted of all participants in the WMI Study Phase 1 who consented to be contacted for a follow-up telephone interview.

From this sampling frame, a purposive sample was chosen for inclusion in the study. Purposive sampling is considered appropriate when the researcher wishes to select unique cases that are especially informative and to identify particular types of cases for more in-depth investigation (Neuman, 2003).

The sample size in a qualitative study is not considered as critical as a sample size in a quantitative study. Where the qualitative study is conducted to inform the development of a quantitative study, the sample size is usually dependent on the number taken to reach saturation, that is, the study is ceased when no new concepts emerge (Creswell, 1998). However, the current study was conducted mainly for the purposes of triangulation and there were no set guidelines for determining the sample size for such a study. Hence, initially, approximately 40 interviews were conducted. After the initial interviews were conducted, the data were reviewed and judged adequate for the purposes of triangulation, hence no further interviews were considered necessary.

5.2.4 Patient selection

At the end of the WMI Study Phase 1, all patients were informed of the plan for a series of follow-up telephone interviews. Patients were given an information sheet (Appendix I) and a brief explanation of the follow-up interviews. They were informed that the telephone interviews would last approximately 30 to 45 minutes and would be conducted at a convenient time. As not all the WMI Study Phase 1 participants were required for interviews, patients were asked if they would consent to be contacted if necessary. Consenting patients were requested to fill in a consent form which also included a request for telephone contact details and the best time of day for contact (Appendix I).

Of the 479 participants of the WMI Study Phase 1, 112 participants (23.4%) [n=85 from Group 1 (pain/rheumatology) and n=27 from Group 2 (hypertension)] consented to be contacted if necessary for the follow-up telephone interviews.

As one of the objectives was to triangulate patient responses provided in both studies, a heterogeneous group of patients representing a mix of recruitment groups, geographic locations, demographics and reported interest in WMI were selected.

Furthermore, as another objective was to gain more in-depth information and to clarify the factors influencing patient's use of WMI, patients who were observed to be especially informative in terms of their previous experience with WMI (based on their comments in the WMI Study Phase 1) were selected (Neuman, 2003).

Selected patients were then contacted by telephone twice. The first call was made to establish contact and arrange a time for the interview. The second call was the actual telephone interview.

The first call was made at the time specified on the consent form. As this study commenced at the completion of the WMI Study Phase 1, in most cases, approximately one to three months had lapsed between the initial contact for the WMI Study Phase 1 and the follow-up telephone call. Hence, when patients were contacted by telephone, they were reminded about the study and the consent they had given for further contact, and were asked if they were still willing to participate in the follow-up interviews. Patients were also told that with their consent, the interviews would be recorded to ensure accuracy and to ease analysis of the interviews. A suitable time for the actual interview was then arranged with consenting patients.

Of the 112 participants who consented to be contacted for follow-up telephone interviews, 44 were contacted (n=22 from both Group 1 and Group 2) and 39 were interviewed. Of the five patients who did not participate in the interviews, three were uncontactable after several attempts and therefore lost to follow-up (from Group 1) and two changed their minds about participating (one from each group).

5.2.5 Conducting the interview

The telephone interviews were conducted at the Faculty of Pharmacy. With the patient's consent, the interviews were recorded using a digital recorder; a tape recorder was also simultaneously used as a backup. The interview procedure is outlined in Appendix H.

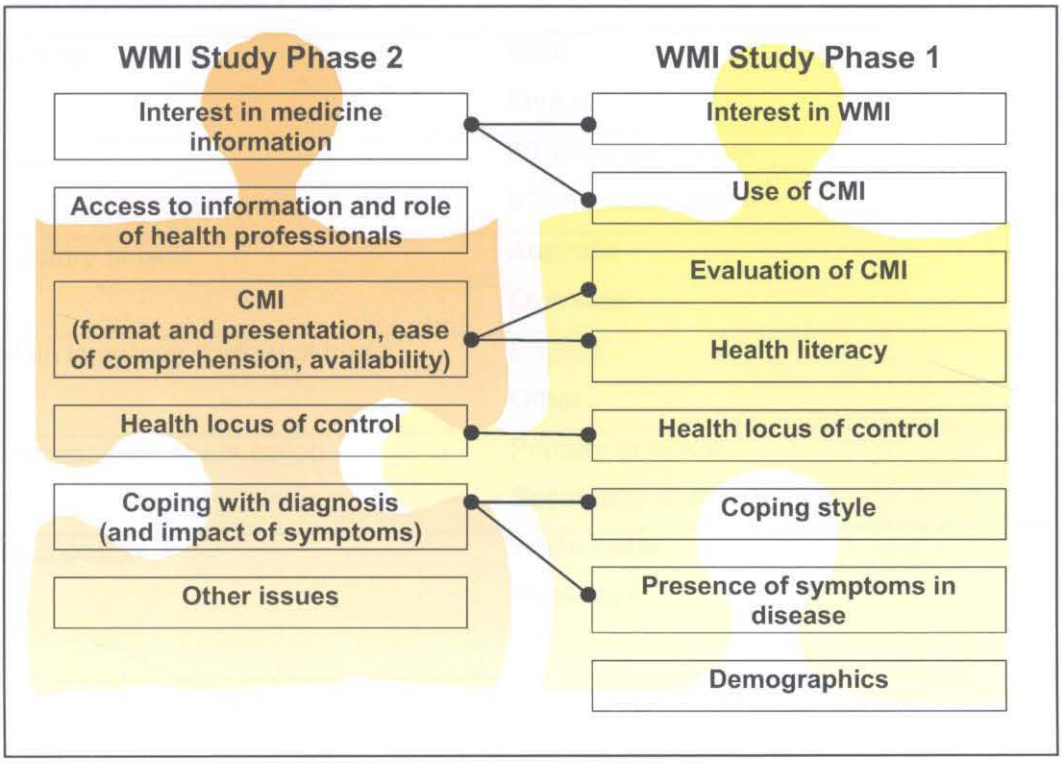
5.2.6 Data analysis

Following verbatim transcription of all interviews, NVivo Version 2.0.161 (QSR, 2002) was used to facilitate content analysis of the data. According to Holsti [in Bauer (2000)], content analysis is defined as *"any technique for making inferences by objectively and systematically identifying specified characteristics of the messages"* (p.133). Thematic content analysis was conducted. The main themes set out in the interview guide formed the basis of the analysis. Other emergent themes were also elucidated and explored.

5.3 RESULTS

The structure of the results section is summarised in Figure 5.1. The left column lists the themes in the current study that are discussed in this results section in order of appearance. The right column lists the different aspects examined in the WMI Study Phase 1 (Chapter 4). The links between the two columns represent the triangulation points between the two studies.

Figure 5.1 Outline of study results and triangulation points with the WMI Study Phase 1



5.3.1 Sample demographics

The demographics of the interviewees are summarised in Table 5.2.

Table 5.2 Demographic characteristics of interviewees (n=39)

Demographic characteristic		n
Gender	Male	19
	Female	20
Age	60 years and below	18
	61 years and above	21
Country of birth	Australia	32
	Overseas	7
Main language spoken at home	English	37
	Other	2
Highest level of education	Primary or below	8
	Secondary or above	31
Occupation	White-collar	28
	Blue-collar	9
	Homemaker	2
Employment status	Working (full- or part-time)	10
	Not working (including retired)	29
Number of medications	Range= 1-32; Median= 5; IQR= 4-7	
Duration of disease (years)	Range= 0.1-40; Median= 7; IQR= 1-13 (1 missing data)	

5.3.2 Interest in medicine information

The majority of participants expressed interest in obtaining information about their prescription medications to find out about particular aspects of the medication (e.g. benefits or side effects) and for their own safety and well-being.

> *"Gives you more information and you know, you feel more relaxed by knowing what you're taking."* (C05004)

> *"I am interested in getting information about my medicines. Yes, I am. I think I have the responsibility these days to really be aware and to look after one self."* (C09002)

> *"Oh yeah… if you don't know what you're taking, you know, you might be taking Fred's tablets instead of my tablets, you know?"* (H02022)

There were several interviewees, however, who were not interested in obtaining information about their medications.

> *"I don't worry about any of those [information], like when I've got cancer, I've never looked into it. I just take the treatment and that's it, you know, and just... I'm alright. As far as I'm concerned I'm good."* (C39005)

> *"Well, I'm not that interested. As I say, I just go along with what [doctors] recommend because I think, well, they know and I don't."* (H03015)

Interestingly, some participants, especially those who were very interested in medicine information also commented on the general public's lack of interest in medicine information.

> *"It's... it's the same as people putting their hands up to help at preschool or school. You'll have some people who do everything and some that would do nothing. And same as the people who are aware, and the people who are unaware. You'll have some that will try to be aware of much information, and others don't care."* (C34004)

Overall, the general level of interest expressed by the majority of interviewees was similar to that expressed in the WMI Study Phase 1 (Section 4.3.3.1).

5.3.2.1 Preference for verbal or written medicine information

Participants were also asked to express preferences for written or verbal information. Written information was favoured by some mainly because verbal information was considered easily forgotten. Moreover, written information was a handy reference for the future and allowed participants to digest the information in their own time.

> *"Well you can refer back to it, cos sometimes you can't remember everything and you can refer back to it."* (C14002)

> *"And sometimes if people are stressed or a little bit shocked if they're being introduced to something, and they're a bit... you know, hard to take everything in, but if it's written, it's something that they can go back and read later on."* (C34004)

Those who preferred verbal information considered it a more user-friendly, clearer, personal and relevant way of obtaining information. Interestingly, in Phase 1, receiving verbal information was one of the reasons cited for not reading WMI (Section 4.3.3.2).

> *"I find it better to have it, something clearly spoken to me, and explained thoroughly, than to try and read all the little bits in all different packages, and you haven't got a clue as to what they're really saying."* (H02008)

> *"It's just because I, I am going to the doctor, having that time put aside. That is just part and parcel of the time put aside to see the doctor. Reading the great long leaflets, one doesn't always have the time or inclination."* (C09002)

> *"I haven't found the information that comes with the medication completely accurate. A lot of it is generalised... Your pharmacist knows you, your doctor knows you, and they are better sources."* (H01040)

Finally, some participants preferred a combination of both written and verbal information.

> *"I actually would like to be told by the doctor, and follow up with brochure on the product... in like inside the packet... I think they're both necessary."* (C30005)

5.3.2.2 Use of written medicine information

The range of different sources of WMI used by the interviewees was similar to that reported in the earlier study (Section 4.3.3.3). Package insert CMI was by far the most common source of WMI. Other sources included the internet, patient medication handbooks/encyclopaedias, computer printout CMI and various other printouts from pharmacies, health professional medical references as well as support group newsletters, magazines and newspaper articles.

Some participants were content to use the information if it happened to be there (e.g. package insert CMI), but would not go out of their way to look for information. This relatively passive use of information was characteristic of the majority of participants in the WMI Study Phase 1 (Section 4.3.3.1). However, as found in Phase 1, there were also those who avidly searched for medicine information, including WMI.

> *"Well, I don't go looking for 'em you know. If they're not in the box, I don't worry about it and I don't, as I've said, I don't very often read them anyway. Now and*

again, if I think I am going to find out anything I'm not sure, I'll read them, but uhm, no, I'm happy with them as it is." (H02066)

"... Again I stress the point if I find the print in the box or the sheet in the box not to my satisfaction I look elsewhere to get the answer." (H01040)

Regardless of their information seeking behaviour, CMI was read by most participants. Some participants reported always reading it whilst others reported reading it only for new medications. Certain sections appeared to be of particular interest, including drug interactions, side effects, benefits and how to take the medication.

A handful of participants claimed that they seldom or never read WMI. Of these, some were aware of the benefit of keeping the information for future reference, but the majority of non-readers reported discarding the CMI.

"No, [I don't normally read it]. I just accept what the doctor tells me. When I get my script, sometimes I'll read the little pamphlets that's inside with the medication, sometimes I don't , if I'm, you know... the only thing that I know there might be information there I can make use of when I need it." (H02066)

"Chuck [CMI] straight in the garbage tin." (C34005)

When interviewees' reported readership of CMI was compared to their response to an identical question in the earlier study (Section 4.3.3.2), the answers were consistent in all cases with the exception of one interviewee. In Phase 1, this interviewee stated that he did not read CMI; the opposite response was provided in Phase 2.

5.3.3 Access to information and role of health professionals

5.3.3.1 Receipt of and access to medicine information

Interviewees reported that they received a mixture of solicited and unsolicited medicine information from their pharmacist, doctor and/or WMI such as package inserts and printouts. Pharmacists more commonly gave a combination of verbal and written information whilst doctors by and large provided only verbal information. Hence in general, many felt they had no trouble accessing information when it was needed,

using a combination of CMI and advice from health professionals plus the occasional extra source.

Although many were satisfied with the information they were able to obtain, several issues were identified with the information provision process, including inadequate information, provision of contradictory information by different health professionals, inappropriate timing of information and lack of proactiveness from health professionals. The latter point is further discussed in Section 5.3.3.3.

> *"It's in and out. So getting information on your pills, they're not prepared to sit down and talk about that."* (C20003)

> *"What I have found in practice though is that sometimes they give you contradictory information... If I get contradictory information from the doctor and the chemist usually it's more to do with what the doctor's left out telling me."* (H01020)

> *"[The pharmacist] will attempt to give me some explanation if I want it, but I actually think that's a bit far down the track... Before you actually go and buy the drug and actually put your prescription in, you should know what you're... why you're getting this particular drug."* (H03043)

> *"Well, health care professionals never seem very... willing to... provide information. I think they're not forward in providing it."* (H02002)

Moreover, where information seeking was concerned, several individuals felt that information was not that easily accessible and that the information seeking process required initiative and perseverance.

> *"Well, it's not, it's not out there looking at you in the face. You have to actually investigate for yourself... It's not what I'd say freely available in... in any shape or form."* (H03043)

5.3.3.2 Perceptions of health professionals

Patients' perceptions of health professionals varied widely. Many had high regard and spoke well of the health professionals. However, a minority also expressed negative

perceptions and comments about doctors and pharmacists. One of the quotes also highlighted the participant's perceptions of the difference between the role of doctors and pharmacists.

> *"If [doctors are] arrogant and big-headed and oh... so... "I'm God and you're nothing, just lie there like a piece of meat on a hook"... no, I have no confidence in that variety at all... the rheumatologist that I go under... an excellent person, because he not only thinks of your complaints, he talks to you. He is understanding of your complaint, and he listens to you when you talk to him."* (H02008)

> *"The pharmacist is very important because the average person relies a great deal on their pharmacist. Quite often they do develop a personal relationship with the pharmacist over a number of years. If you don't have a good pharmacist that you can go to and rely on, then you know, it's quite unfortunate..."* (H01040)

> *"Doctors are alright and chemists are alright if you need them, but if you don't need them, I sort of don't bother with them. I didn't need to go to a doctor for years, and I didn't. And so... I don't... see the need to... have them as a prop in your life sort of thing."* (H02013)

> *"I don't think [doctors] understand that you NEED a bit of information, but the ways surgeries are run today... it's absurd! More business than there ever was, and you only get a time limit!"* (C20003)

> *"I suppose I just see a doctor as a professional, and to me a pharmacist just sells the drug, it's almost like I think, the difference between the bar manager and the barmen. You know, the bar manager sets the rules and everything, the barmen's just there to sell the alcohol."* (H03007)

5.3.3.3 Role of health professional in medicine information provision

Regardless of their perceptions of health professionals, most respondents felt that health professionals played a crucial role in the provision of medicine information and were responsible in educating the public about their medications.

> *"I think it's paramount that they know exactly what they're talking about and they're able to impart that knowledge on to you in a layman's term."* (C15007)

Some felt that the onus should fall on the doctor, the prescriber of the medication.

> *"As soon as he writes that first script, and if he has to write uh three, four... how many medications when you first have... something diagnosed, he should give you a full page covering that medication."* (C20003)

Others argued that the pharmacist should be responsible.

> *"Oh, pharmacists should always give a printout to the patient, and I know that doctors can't always go through all the side effects 'cos they just haven't got enough time."* (C03009)

However, most felt that it should be a shared role between the doctor and the pharmacist.

> *"Because like if the doctor gives me a script, he knows if it's going to muck up with another script that I'm taking... and then I'll go... to the chemist and he'll say, "look, be careful with this one, this one, this one" sort of thing..."* (C30001)

Still others felt that ideally the information should come directly from the drug manufacturer, although some were sceptical of the credibility of such information.

> *"The manufacturer I'd say... well, saves everybody a lot of mucking about. You receive the packet, you got the information there!"* (C14002)

> *"Well anything is better than nothing [referring to information from manufacturers]. But if it came from an independent source I think it'll probably be more trustworthy."* (H01031)

Despite their preferences as to who should provide the information, with the exception of a few individuals, all interviewees agreed that health professionals needed to be proactive in offering medicine information to patients.

> *"I think they should offer information, because some people are a bit reluctant to er, ask- they're you know a little bit apprehensive where as the doctor or the chemist approaches them in a pleasant manner, I think it's better for the patient."* (C05004)

In addition, interviewees were also asked for their suggestions of strategies for patients who were not interested in medicine information and WMI in particular. Participants conceded that patients cannot be forced to read WMI, but emphasised that health

professionals should at least offer the information to patients, and actively ask the patient to read the WMI.

> *"I think when a person gets the medications from the pharmacist, well, if they give the printout as I think our pharmacist would, say, "Now, here's the printout, read it carefully, if there's anything there that's a problem, speak to me, I'll help you, or ring your doctor." People have got to be guided."* (H01040)

In response to a similar suggestion, one participant commented that she would possibly have read the CMI had she been asked to do so by a health professional. Another participant, however, felt that asking a patient to read a CMI implied disinterest on the health professional's part to spend time with the patient and counsel them with verbal information.

Some participants also suggested that WMI should be provided regardless of the patient's interest in the information as it may be a handy resource for family members and carers, as well as for the patients themselves should the need arise to consult WMI in the future.

Despite these suggestions, it was acknowledged that there was no guarantee of WMI being read. Therefore, several participants highlighted the importance for health professionals to provide adequate verbal counselling to all patients.

5.3.4 Consumer Medicine Information

As the main form of available WMI, CMI attracted a lot of discussion during the interviews. CMI was mainly found as a package insert or provided as a printout by the pharmacist. Participants were by far more familiar with the former format than the latter. Many participants first encountered computer printout CMI during the WMI Study Phase 1 when they were asked to evaluate a CMI.

5.3.4.1 Format and presentation of CMI

Overall, the comments on the format and presentation of CMI made by interviewees were very similar in scope to those provided by participants in the WMI Study Phase 1 (Section 4.3.9.1). Nonetheless, some comments made during these interviews were

more detailed and thus served to elaborate some of the points raised in the earlier study.

5.3.4.1.1 Presentation of CMI

Approximately half the participants found package insert CMI acceptable or well set out and presented. These participants understood the need for the print size to be smaller in order to fit into the medication box or around bottles, and to avoid having a leaflet the size of a *"toilet roll"*.

> *"Most of them are pretty good... They sort of... clearly indicate each paragraph, and you could skip to what you want to know..."* (C19003)

> *"Oh well, I think if the box isn't big enough to hold it... so they have to squash it a bit."* (C03009)

By the same token, small print size was by far the biggest complaint of participants who were dissatisfied with the current package insert CMI. Interestingly, several people expressed concern about the small print not for themselves, but for older people and people with impaired vision in general.

> *"Oh, for one thing, the thing inside the boxes gets creased and they're in smaller print... and if the crease mark goes across the actual wording, you know, it can become a bit difficult to read..."* (C15007)

> *"Sometimes the print's very small... you know, sort of older people may find it hard to read."* (C39004)

In contrast, the larger print size of the computer printout CMI was a welcomed change from package insert CMI. Nonetheless, some participants commented that computer printout CMI was unattractive and less user-friendly.

> *"...doesn't necessarily attract the eye to things. It's usually on an A4 sheet of paper, it's big and it's cumbersome..."* (H01020)

> *"...Something that looks like a sort of uh, a medical textbook, where it's fairly bland, and sort of research papery like, you know, isn't that appealing... Needs to be something that is actually manageable to put into your handbag or to carry home... without having to fold it ten times..."* (H03043)

5.3.4.1.2 Comprehensiveness of CMI

In terms of the comprehensiveness of package insert CMI, whilst many were satisfied with the current length of CMI, others were not. Some participants felt it was too lengthy, and wanted something more concise; others felt that it was too brief, and wanted something more detailed.

> *"It's generally very comprehensive, you know, covers a lot of areas..."* (C39004)

> *"Sometimes it can be long winded..."* (H01009)

> *"They are probably a little bit brief I think..."* (C03008)

Interestingly, some participants perceived computer printout CMI to be more comprehensive than package insert CMI although these two formats are identical in terms of content for the same medicine.

> *"[That computer printout CMI] I thought had more information probably than the one I looked at in the box, cos it's very small... but I would like again, even more information or at the bottom of that somewhere that I could get more information..."* (H03028)

There were also comments that CMI was too general and not relevant for a particular individual, or too repetitive. Some interviewees also expressed cynicism that CMI was included to protect manufacturers from litigation than to benefit consumers.

> *"It tends to be a bit stereotype... [the manufacturers] seem to include a lot of information that just sort of covering themselves you know... probably not even relevant to what you're doing or what you're taking... it's not to my benefit..."* (C14002)

5.3.4.1.3 Influence of format and presentation on use of CMI

Despite identifying shortcomings with the presentation of CMI, some participants commented that these did not influence their use of CMI. For example, one participant who complained about the small print size mentioned that he *"[needed] glasses to read it properly, that's all."* This concurs with the findings in the WMI Study Phase 1 whereby design quality did not influence intended future use of CMI (Section 4.3.8.2).

In contrast, there were others who felt that whilst the presentation of CMI did not influence their own use, it may affect its use by the general population.

"As a marketing professional, I find it irritating when I see things that are not well-presented that I know mean that most people will be turned off by it." (H03043)

5.3.4.2 Comprehension of CMI

At least half of the participants found CMI *"very easy to understand"* and *"pretty simple and straightforward"*. A minority, however, commented that there was too much medical jargon and requested *"down-to-earth language that normal people can understand"*. Once again, some participants expressed concern not for themselves, but for others.

"Put it in our lingo... not in the expert's lingo, they KNOW all about it already!" (H02008)

"...You gotta remember when you write this stuff, that you're writing to people that are... don't have any medical knowledge at all, and you're writing to people with various uhm education level, so you've gotta sort of bring it down so that everybody can understand." (H01002)

5.3.4.2.1 Influence of comprehension on use of CMI

Although participants' health literacy levels influenced their interest in reading and seeking WMI in the WMI Study Phase 1 (Sections 4.3.7.2 and 4.3.7.3, respectively), in the current study, it was more difficult to ascertain whether interviewees' health literacy level affected their understanding and hence their use of CMI. All participants who commented on the comprehensibility of CMI, including those who felt CMI was not that easily understood, had adequate health literacy levels (as determined during the WMI Study Phase 1). Moreover, there were no apparent differences in terms of ease of understanding CMI between participants who did not usually read CMI and those who usually read them.

The only interviewee who had inadequate health literacy level was unable to comment on his comprehension of CMI as he had never read it before. However, there was no indication as to whether poor literacy was the reason for not reading CMI. Rather, a preference for being told *"face to face"* and faith in the doctor were the cited reasons.

5.3.4.3 Availability of CMI

As was the case in the WMI Study Phase 1 (Section 4.3.9.2.1), many participants noticed the disappearance of package insert CMI in recent times.

> *"Well, to tell you a fact, in all of the last few months, a lot of the medications I received, not one, but from several chemists... have had no information inside."* (C13005)

Many participants expressed dissatisfaction when they were informed that package insert CMI was being phased out and being replaced by computer printout CMI that could be obtained from their pharmacists. Participants viewed package insert CMI as a convenient and reliable source of WMI. Moreover, some interviewees added that it may be the sole form of WMI available to some patients.

> *"... Most other consumer products the instructions come with it... my new dryer came with an instruction manual. Drugs should come with their, you know, the equivalent, which is the instruction manual. If it's left out then you're less likely to see it."* (H01020)

> *"I don't think that's a good idea to be honest with you... You know, the information in the box is vital because... you won't always think to ask the pharmacist "Can I have information on this tablet?""* (C39004)

> *"For the couple of times that I've actually read the pamphlet, I've only read it cos it was there. If it hadn't been in the packet, I wouldn't have gone out of my way to ask for it... so I find it much better of an idea being in the packet."* (H03007)

Even participants who did not normally read CMI conceded that package insert CMI *"can be helpful to people who do want some knowledge about it."*

Just as many were unaware that package insert CMI was being phased out, many were also unaware of the availability of an alternative version of CMI.

> *"Oh, I thought that was the only way they come, in the box."* (C17009)

Only one participant mentioned that the pharmacist had advertised the availability of computer printout CMI. Other participants felt that it was important for pharmacists to promote this alternative version of CMI.

"Yes, they have a sign up near the counter saying that the information is available." (H02002)

Although some participants felt that it was a good idea for health professionals to be able to provide computer printout CMI, there was some scepticism regarding how well health professionals could maintain this practice in an everyday setting.

"What I worry about when the information isn't [with the medication], is that although in an ideal world, the doctor or pharmacist would tell you that you have this option of getting it or actually give you the information anyway... they're often too busy to do so." (H01020)

5.3.4.4 Suggestions for improvement of CMI

Besides the suggestions that were voiced in the preceding paragraphs, other suggestions were made regarding measures that could be taken to improve the current CMI. These are summarised in Appendix J.

5.3.5 Health locus of control

5.3.5.1 Dimensions of control in relation to health

From their comments, interviewees exhibited traits reflective of one or more of the three dimensions of the MHLC scales: internal HLC, powerful other HLC and chance HLC (Section 4.2.1.2.3). Patients with internal HLC viewed themselves as being personally responsible for decisions that affected their health, with the assistance of health professionals when required.

"I guess the individual. For me it's me... Well... it's up to me to... if I have a... an unusual... Then I go to the doctor. So it's me to take the first move..." (C33005)

"Well, I should be... if the doctor actually makes a comment about a particular aspect of my health... if he said to me "well, look, you really do need to lose 10kg", I mean, I don't need him to tell me that, I know I should lose 10kg, so I suppose I am controlling my health... 'cos like I know my body, so I know when something's not right." (C30005)

> *"I listen to the information and make a decision for myself. And that may well be that I do what [the health professionals] ask me to do... but, because information is not always consistent, sometimes you're forced to make that decision yourself."* (H01020)

On the other hand, patients with powerful other HLC viewed themselves *"as a patient"* and saw their role as just being aware of the symptoms and presenting themselves to the doctor when they were unwell. Although the doctor was deemed as the 'powerful other' individual in most cases, one participant saw her parents in the decision-making role.

> *"I rely on my doctor to explain things to me and he makes the decision what I take and what I do, and I just go and do what he says, you know."* (C28001)

> *"Well, I'm not the sort of person that would go out to seek all I know about the disease you know. I mean, I sort of take the view that the doctors have gone a long time to university to get the qualifications that they have and I couldn't help to match it in... with them as far as knowledge is concerned, so I don't even bother... I sort of just leave it to them... I rely on the doctor."* (H01002)

> *"Well, if I wanted to take a medication... I would obviously speak to my parents first rather than have a doctor give it to me as to what he thinks... and parent's decision would always have [an] overriding effect."* (H01009)

Several participants deemed their health as being jointly controlled by themselves and by powerful other individuals in their lives. Some of them still viewed themselves as the main driver, others viewed the health professional as the main driver, and still others saw it as an equal partnership.

> *"Well, it's not an equal partnership, I have to get a bit pushy... just so that I can function and so that's why I sort my pills out myself and then next time I go to the doctor, I say, "Now, I've done this. Is this OK?"... it's a bit arrogant but I'm the only one who knows how I'm feeling."* (C20003)

> *"Well, of course you've got your own thoughts on the matter, and you've got to... work out your own... capabilities with what you're going to do about it. But my wife's very good, she assists me in lots of ways and of course you go to the chemist and of course the doctor's the... the final say."* (C05004)

"I think it's a joint thing, and I take responsibility for, you know, for actually involving myself and understanding what's best for me. I mean, rheumatoid arthritis to a large extent is self-management. Unless you learn that, you really aren't going to, and you need to be able to monitor your own condition, and therefore it's a partnership." (H03043)

Only one individual held a chance HLC, namely a trust and belief in God, but at the same time acknowledged the role of health professionals.

"I just... accept the advice people give me, uh... but I don't go looking for it, and that's maybe different from other people. Other people might need to know the ifs and buts and... everything else, uhm... by firstly, my trust in God, and secondly, my trust in humans, being doctors or whatever..." (H02013)

5.3.5.2 Influence of health locus of control on use of medicine information

For some participants, there appeared to be an association between HLC and their use of information. As expected, interviewees exhibiting internal HLC were more active in using and seeking medicine information whilst those with powerful other HLC were less inclined to do so, the latter confirming the findings from the WMI Study Phase 1 (Section 4.3.7.3).

"Most other people that I see or talk to don't as much as I do. Yeah, generally, I research everything and find out what I want to do, and then find you know, and then go and get a few opinions." (H03028)

"Yes, I do, because I often will find something... independently... and I will then discuss that with my rheumatologist. I'll take up those issues or thoughts and talk about you know, potential treatments." (H03043)

"I think well, [the doctors are] prescribing and they know what's best and... what's the point of reading what's inside [the boxes]...?" (H03015)

However, for most participants, there seemed to be no apparent link between HLC and use of medicine information. Medicine information was an important means of acquiring knowledge and information, but did not necessarily influence the health decision-making process.

Nonetheless, it is noteworthy that trust and confidence in health professionals seemed to be common to both interviewees with powerful other HLC (current study) and participants who did not read CMI (Section 4.3.3.2).

5.3.6 Coping

5.3.6.1 Reaction and coping with diagnosis

Patients reacted to the diagnosis of their conditions in different ways. For patients with symptomatic conditions (Group 1- patients with rheumatology/pain conditions), many were surprised, frightened or worried.

> *"I was a bit surprised and then when I found out how bad it was I was a bit devastated."* (H01002)

> *"I've been healthy all my life so… it's quite a… disturbing thing. And… I knew nothing about [giant cell arthritis], not even how to spell the name actually! So, it was quite a shock."* (H02013)

> *"The specialist told me that because lupus is difficult to diagnose he wanted to wait for a conclusive diagnosis… before he answered my questions because he didn't want to frighten me, which of course was quite frightening."* (H01020)

However, some others were relieved that the diagnosis *"had a name"* and that it *"wasn't something worse"* whilst others just accepted the diagnosis or were unperturbed.

> *"There's not a great deal you can do about… [osteoarthritis] was in the family … it was just a possibility and it came to be. So I just accept it. I didn't really like the pain that goes with it, all the inconveniences, things you can't do, but… as for actually having it… you just accept it."* (H02008)

A few individuals were unsure or ignorant of what the diagnosis meant, and one patient viewed her osteoarthritis diagnosis as *"just a nuisance"*.

The spectrum of reactions for patients with the asymptomatic condition (Group 2- patients with hypertension) was similar; however, there were several distinct differences. Firstly, the fear and shock expressed by a small number of individuals was

linked to the presence of past family history of cardiovascular complications or diagnosis at a very young age. Secondly, whereas fear or anxiety was the common reaction by Group 1 patients, the majority of Group 2 patients were unperturbed with the diagnosis or accepted it as an inevitable part of ageing.

> *"Well, I didn't really react to it at all. I just got high blood pressure..."* (C39005)

> *"I tend to be the sort of person who accepts these things as inevitable as one gets older... part and parcel of life's great canvas."* (C09002)

Thirdly, a small number of Group 2 patients also expressed denial or shock at the diagnosis possibly due to the absence of symptoms.

> *"Stupidly, because I said to the doctor... before I had any [cardiovascular complications], I said to the doctor, "Well, I'm not sick. I'm still walking about."* (C20003)

> *"It surprised me a bit, because I didn't know. I mean, you had no effects..."* (C17009)

In relation to the absence of symptoms, one participant also commented on the deceptive nature of an asymptomatic condition such as hypertension.

> *"So many people have high blood pressure, but don't relate it so much as how much damage and what damage it can cause the heart."* (C34004)

Following their diagnosis, the coping strategies of each group of patients reflected their general reaction to their diagnosis. Group 2 patients who were largely unperturbed at their diagnosis proceeded to take medications with advice from their health professionals.

> *"Well, I went on the medication that was prescribed for me and just took advice of what to do with it and... follow the procedures."* (C15007)

In contrast, although some Group 1 patients proceeded to follow instructions from health professionals and took medications as prescribed, many patients sought information about their condition from health professionals, family, friends and different sources of written information.

> *"I asked around about... I asked my mom... and my... people I knew, and I looked on the internet, I read things to find out if you know... if I've got... you know what... oh... to find out everything about it."* (H03028)

Others queried the necessity of certain medications, especially *"heavy"* medications like prednisone, whilst others tried to be optimistic and put things into perspective.

> *"... possibly not have it severely, I was hoping that that would be the case. So I set off with sort of a degree of optimism that I wouldn't be in the too-hard basket..."* (H03043)

> *"Probably I realised that there were so many people worse off than me, so... that made it easier I suppose."* (H01002)

5.3.6.2 Role of information in the coping process

Most participants in Group 1 received information from their doctors as well as from family and friends. One patient complained that the doctor refused to provide any information yet another was satisfied with the very basic information she had received.

> *"He didn't want to give me any information, so then I set about finding information for myself and eventually changing doctors."* (H01020)

> *"I'm quite happy with what they've said because I've never been one to sort of... I've never been one for asking a lot of questions because I think "well, they know better than what I do" and you ask a lot of questions and half the time, you don't know what it's about anyway, you know..."* (H03015)

To a lesser extent, a few participants in Group 2 also mentioned that they were given information. In contrast, a few said they did not receive any information.

Overall, although many interviewees felt that the information was useful to help them cope with their condition, others were unsure or felt that the information did not make any difference. Interestingly, one participant in particular felt that she coped best without information.

> *"... Once you realised what you've got and where you're going you're more settled and a bit more probably confident about the treatment you're getting... if you've got some knowledge of it."* (H01017)

> *"Well, I think it helped ME because I'm the sort of person who likes to get to the bottom of everything and I've got a research mind... I've been an academic in the past and... I've obviously got that desire to know as much as possible. So it helped me to understand what was happening to my body and the way in which*

the drugs may or may not help, and to have a realistic appraisal of the situation." (H03043)

"Well, I don't know [if the information would have made a difference], because I think, well, once you get this sort of thing, you just gotta learn to live with it I think, haven't you? (H03015)

"What works or how I got it, it wouldn't make any difference. I will be still none the wiser." (H02023)

"Yes, I can cope very well with the less I know of it, and about it..." (C39005)

When the responses of the interviewees were compared to their coping style determined in the WMI Study Phase 1 (monitor or blunter- Section 4.2.5.1), many of the interviewees who were monitors found medicine information useful in the coping process, thus supporting the definition that monitors were those who coped by taking in information. Moreover, interviewees who were monitors were generally interested in medicine information, thus supporting the finding of the earlier study whereby monitors were more interested in reading WMI (Section 4.3.7.2). Nonetheless, from the interviews, some blunters also found medicine information useful to aid with the coping process.

5.3.6.3 Impact of symptoms

The presence of symptoms affected the way patients perceived and dealt with their condition (Section 5.3.6.1). Although the range of reactions to their diagnoses were similar in both groups, Group 1 patients appeared more negatively affected by their diagnoses and were more interested in seeking information about their conditions. This was not surprising as participants had to learn to cope with symptoms that had a debilitating impact on their daily lives. This also concurred with the findings in the WMI Study Phase 1 whereby patients with symptomatic conditions were more interested in seeking WMI (Section 4.3.7.3).

"I'm still finding there's a part of me fighting it and that's because I've grown up for 28 years with full mobility, and now coming up year and a half without, it's like yeah, just hitting your head against a brick wall." (H03007)

"I'm a very active person... I'm with a few little groups that I'm involved with, uh, and we go on little trips... Well, now I find that I can't get involved in anything!" (H03015)

"Oh well the [pain] certainly annoys you but I mean, you learn to accept these things." (H01002)

5.3.7 Other issues

5.3.7.1 Side effects

The issue of side effects was brought up in several interviews. A few participants expressed alarm over the list of side effects found in CMI. Nonetheless, all except one felt that it was still important to be aware of these. The participant who was the exception to this rule avoided reading CMI due to the side effects.

"I think [medicine information should be given] once you started on the medication... rather than right at the beginning... just so not to freak us out... Yeah you haven't taken it and...then you're like bombarded with all these side effects..." (H01009)

"That's right [I don't want to know], not as far as in the pamphlets. I mean sometimes, it's got that many things that could happen, that it's frightening you know. You think, "oh my god!"" (C39005)

On the contrary to the side effect list causing alarm, several participants found it reassuring to know of the possible side effects so that if it were to occur, they would know that *"it's the drugs and not you going nutty"*.

"I do like to know if something's happening to me... I can put it down to the medication because I've read about the side effects, and not... be worry about... why I'm having that particular side effect." (H02002)

One participant proposed that health professionals' reluctance in providing information may be linked to their fear of *"[scaring] their patients about... side effects"*. Another participant however felt that this was unjustified, and along with several other participants felt that it was the responsibility of health professionals to provide patients with a balanced perspective on potential side effects.

> *"I think worrying about patients getting scared... is garbage. I think that patients are more likely to be scared when they're given no information. And the job of the healthcare professional no matter what the... you know pharmacist, doctor, whatever, is... is to let people know that it's not necessary to be upset about [side effects]."* (H01020)

In addition to the role of health professionals, one participant felt that current CMI was lacking in positive information about the medication and expressed the need for CMI to *"express the benefits as well as the... potential side effects"*.

5.3.7.2 Other factors influencing interest in WMI

Other potential factors influencing interest and use of WMI emerged during the interviews. These included personality, past experience, timing of information and background or career. Quotes illustrating these points are included in Appendix J.

5.4 DISCUSSION

5.4.1 Triangulation with the WMI Study Phase 1 results

The current study provides greater insight into some of the issues examined in the WMI Study Phase 1. On the whole, the interview data supports the reliability of the responses provided by participants and the validity of the findings from the WMI Study Phase 1.

In terms of interest in medicine information, as in Phase 1, most respondents in the current study expressed interest in obtaining information about their prescription medicines. This interest has been evident in previous studies on medicine information conducted both in Australia [e.g. Allen and Alderman (1995); Newby, Hill, Barker *et al.* (2001)] and internationally [e.g. Baksaas and Helgeland (1980); Trewin and Veitch (2003)]. However, in contrast to the active search for information displayed by respondents in the Australian studies, in both phases of the WMI Study, many patients were relatively passive in the way they used information, especially WMI. The factors that may have contributed to this passivity are explored below.

Nonetheless, many participants read WMI. Consistent with the findings in the WMI Study Phase 1, package insert CMI was the most common source of WMI. The interview data also provided confirmation that many participants had noticed the disappearance of package insert CMI in recent times. With the exception of one interviewee, all participants were found to provide reliable responses (compared to Phase 1) when asked if they had read CMI. The reason for the exception was unknown.

Consistent with the findings in WMI Phase 1, patients experiencing symptomatic conditions were more proactive and inclined to search for information. In Phase 1, it was postulated that the physical symptoms experienced by these patients served as an impetus to seek information. The interview data revealed that the inconveniences associated with the symptoms of the disease do play a role. In addition, other factors including anxiety with the diagnosis and lack of familiarity with the disease also motivated these patients to seek information. Conversely, with the exception of the few who had past family history of cardiovascular complications or were diagnosed at a very young age, most of the patients with hypertension were either somewhat surprised at the diagnosis (due to the absence of symptoms) or unperturbed.

Where health locus of control was concerned, the interview data produced mixed observations compared to the WMI Study Phase 1. As predicted in Phase 1, some patients with powerful other HLC were less interested in seeking information and entrusted their health and well-being in the hands of health professionals, especially doctors. However, in the interviews, some patients with internal HLC were also more active in using WMI; this was an expected trend but it was not evident in Phase 1. The discrepancy between these two phases may be explained by the overarching finding that for the majority of interviewees, there seemed to be no apparent link between HLC and use of medicine information. Medicine information served as a means of gaining knowledge and information but an interest in medicine information did not necessarily translate into internal HLC. This is similar to a previous finding by Beisecker and Beisecker (1990). They reported that patients wanted to be well-informed without necessarily wanting to assume responsibility for health-related decisions.

The interview data also confirmed that monitors were generally interested in medicine information and found information useful in the coping process. Whilst this concurs with findings from Phase 1, there were several blunters who also found medicine information useful in aiding the coping process. A plausible suggestion may be that an

individual's coping style may be positioned somewhere along a spectrum between the two opposite polarities, monitors and blunters, rather than distinctly at either end of the polarities. Hence, it is possible that some blunters may still be interested in general and basic information about their medicines.

In terms of health literacy, it was difficult to confirm the associations observed in the WMI Study Phase 1 between health literacy and use of WMI as only one interviewee with inadequate health literacy levels was available for interview. However, many respondents with adequate health literacy levels complained about the use of medical jargon in WMI. This suggests a need to re-evaluate the readability of CMI.

5.4.2 Other issues surrounding use of CMI and WMI

Besides allowing the triangulation of data with the WMI Study Phase 1, the interviews also provided an opportunity to explore participants' opinions on other issues surrounding the use of CMI and WMI.

In addition to clarifying the roles of some of the patient factors that were examined in the WMI Study Phase 1, several other factors which potentially influenced participants' interest in reading and seeking WMI emerged during the interviews. Past experience appeared to be a notable one, with positive experiences in using medicine information as well as negative experiences with the medication or treatment both serving as impetus to seek and use medicine information. This lends support to one of the factors, 'experience', which was identified in the literature review (Section 1.5.2.2). The finding that negative experiences with medication or treatment encouraged use of medicine information also concurred with previous findings (Koo, Krass and Aslani, 2002).

The availability of package insert CMI, or rather, the lack there of, was another issue discussed during the interviews. As mentioned earlier, in both phases of the WMI Study, many participants noticed the recent disappearance of package insert CMI. As reported in the results section, many participants expressed their dissatisfaction when they were informed that there was an intentional move to phase out package insert CMI and make them available as computer printout CMI via pharmacies and other providers. Despite its small font size, package insert CMI was viewed as a convenient and reliable source of WMI, and for some people, the sole source of WMI. This sentiment was echoed in another study whereby concern was expressed that the shift

from package insert to computer printout CMI meant that *"consumers were no longer automatically provided information, but instead were subject to the vagaries of a health professional's approach."* (p.37) (Benton, Snow and Parr, 2004).

Indeed, in the current study, this concern was further compounded with the perceived lack of proactiveness from health professionals. Some participants perceived that health professionals were unwilling to provide information about medicines. Whilst many others had received solicited and unsolicited advice from health professionals, they still agreed that health professionals should be proactive in offering medicine information to patients. The importance of this is underscored by the transition from package insert to computer printout CMI. Although the MIC Program was established as an incentive for pharmacists to provide CMI to patients, based on the responses provided by participants in both phases of the WMI Study, it is clear that there is much room for improvement.

Whilst it is important for health professionals to actively encourage the use of WMI by patients, it is prudent to bear in mind that not all patients have a preference for WMI. As in previous studies (Harvey and Plumridge, 1991), in terms of medicine information, participants expressed preference for verbal information, written information or a combination of the two. Hence, whilst many participants in the current study preferred WMI and extolled its benefits, others perceived verbal information as more user-friendly, clearer and more personal than WMI. The latter had been reported in a previous study (Raynor, Savage, Knapp *et al.*, 2004). Thus, in addition to being sensitive to individual patient preferences, the provision of verbal counselling accompanied by written information may aid health professionals to meet a variety of patient needs.

Last but not least, the issue of side effects was raised. There were comments that the current CMI lacked positive information about the medication and that the list of side effects was slightly alarming, the latter echoing the findings of some studies in the literature (Dodds and King, 1989; Gibbs, Waters and George, 1989a; Bandesha, Raynor and Teale, 1996; Livingstone, Pugh, Winn *et al.*, 1996; Benton, Snow and Parr, 2004). There were also comments that the side effects list was reassuring, a finding which is consistent with another previous study (Baker, Roberts, Newcombe *et al.*, 1991). However, regardless of their comments, most interviewees felt that it was important for them to be aware of potential side effects and felt that the responsibility of providing a balanced perspective on side effects fell on health professionals. This need

for information on side effects has been demonstrated in the literature [e.g. Dodds and King (1989); Berry, Michas, Gillie *et al.* (1997); Dickinson, Raynor and Duman (2001); Raynor, Savage, Knapp *et al.* (2004)]. Hence, in conjunction with the low proportion of consumers observed to cease their medications due to side effects in the CMI Study (Section 3.3.7), the current findings provide further confirmation that health professionals should be actively informing patients about the benefits as well as the potential side effects associated with the medications.

5.4.3 Study limitations

Several limitations were evident in the study. Firstly, the time that had lapsed between the initial meeting and the follow-up interview allowed for the possibility that patients may have forgotten about the study. However, when the researcher contacted patients for the follow-up telephone interviews, most patients remembered and no problems were encountered. Moreover, the consistency of the responses provided by the participants in spite of the lapsed time between the two phases of the study further strengthened the reliability of their responses.

Secondly, only approximately 10% of participants in Group 2 consented to be contacted for this study (as opposed to approximately 40% from Group 1). This is reflective of the issues encountered with Group 2 recruitment outlined in the limitations in Chapter 4. Although this limitation could not be overcome per se, from the consenting list, the researcher attempted to select a heterogeneous group of participants (Section 5.2.4).

Lastly, saturation of responses was reached for some of the topics covered in the interviews but not for others. As generation of new ideas or issues was not the primary aim of this study, forty interviews were considered a feasible number for this study.

5.5 CONCLUSIONS

This study served to confirm the reliability and validity of some of the findings from Phase 1. The general level of interest exhibited by patients in terms of reading and seeking WMI in both phases of the studies was found to be similar. The interview data directly supported some of the factors influencing use of WMI identified in Phase 1 but not others. For the latter, the findings from this study provided some insight into the complexities of some of these associations.

Furthermore, this study provided the opportunity to explore several other issues surrounding the use of CMI and WMI including other potential factors which influence the use of CMI and WMI, availability of CMI, patient preferences for information, role of health professionals and information on side effects. Participants' opinions and perceptions on these issues can inform future practice and are discussed in Chapter 6.

In conclusion, the WMI Study Phase 2 served as a means of triangulating study results and gaining insight into participants' perceptions on issues surrounding the use of WMI. In doing so, it also emphasised the value of complementing quantitative with qualitative research.

6 CONCLUSIONS AND RECOMMENDATIONS

This thesis comprised of three studies which focussed on examining various aspects of WMI from the perspective of medication users, the consumers. The studies provided a description of how Australian consumers use CMI and contributed to the current understanding of consumer factors which may influence the use of WMI by consumers. Overall, consumers are interested in obtaining information about their prescription medications and the results support the ongoing use of WMI in consumer education. However, in order to ensure consumers gain maximum benefits from the use of WMI, much remains to be done.

The recommendations arising from these findings may have implications at various stages associated with WMI as it progresses from development to use by consumers. These stages are the development of WMI, availability and dissemination of WMI, use of WMI during consultation and use of WMI after consultation.

6.1 DEVELOPMENT OF WMI

The findings from this research highlighted that consumers have varying opinions about the content of WMI and the way it is presented. Many consumers expressed satisfaction with the current CMI. However, others indicated preferences for increased font size (for package inserts) and the use of simpler language. In regard to presentation, the results suggested that consumers were capable of discriminating between well designed and poorly designed WMI. Although the way CMI was presented was not found to influence readership and use, it did influence consumers' perceptions of its helpfulness, with better designed CMI considered more helpful. Thus, it is important for developers of WMI to consider the comments from consumers and strive to improve the content and presentation of CMI. However, as there seemed to be no consensus from consumers on what constituted an ideal CMI, predicting a single universal version of CMI that meets all consumers' needs is likely to be impossible.

In addition to improving current CMI based on consumers' comments, the results also revealed another aspect for consideration by developers of WMI. As mentioned in the literature review, the involvement of consumers in the development and evaluation of

written information has been advocated. Findings from this research established that consumer characteristics including age, main language spoken at home, highest level of education and health literacy levels can influence their evaluation of WMI and should be taken into consideration in the design and evaluation of WMI. Hence, when conducting evaluation of WMI, it is crucial to involve consumers who will be representative of the intended users of a particular medication.

Furthermore, from the current research, it was also observed that consumers may have different information needs depending on the stage of their therapy. For example, different information regarding the medication may be required when the consumer is deciding to start on a medication compared to when the consumer has already been taking the medication for a period of time. Whilst standardised WMI such as CMI serves as an important tool in consumer education, its content and presentation are essentially rigid in order to comply with current legislations. As such, in its current form, it is informative but not necessarily consumer-centred. Hence, there is a need for further research which explores the development of WMI which can cater to different consumer needs associated with different stages in the medicine-taking process.

6.2 AVAILABILITY AND DISSEMINATION OF WMI

Once WMI has passed the development stage, the next challenge lies in ensuring that consumers are aware of it and have ready access to it. While this may sound straightforward in principle, awareness and access to WMI was a recurrent issue during this research. Most consumers were able to identify with package insert CMI when a description was provided but the majority were generally unaware of the term 'Consumer Medicine Information', the concept of CMI and other forms of CMI available. This lack of awareness was further accentuated by consumers' ignorance of the current transition from package insert CMI to computer printout CMI. In addition, whilst some consumers had noticed the recent disappearance of package insert CMI from medication boxes, most consumers were not avid seekers of WMI, hence would not necessarily make the effort to seek CMI if it was not in the medication box. Thus, consumers' access to WMI especially CMI may be compromised.

One possible solution to this problem is to re-introduce package insert CMI. Many consumers were in favour of this option. Nonetheless, according to manufacturers, one

of the main reasons for phasing out package insert CMI was that it was not easily updated. Given this, other possible solutions have to be considered.

Programs such as the MIC Program have been instigated to address this issue, but from its recent evaluation, it is clear that there is still much room for improvement (Benton, Snow and Parr, 2004). Recently, the Therapeutics Goods Administration initiated a discussion forum to improve access of prescription medicine information, namely CMI and PI, to consumers (mpconsulting, 2005).

In conjunction with these government policies and programs, at the practice level, much can be done by health professionals. During the evaluation of the MIC program, many pharmacists indicated that the greatest impetus for widespread provision of CMI will be consumer demand (Benton, Snow and Parr, 2004). Ironically, consumers cannot demand for CMI unless they are aware of it and they would not be aware of it unless it is actively promoted. Whilst public awareness campaigns would be desirable, health professionals also need to assume responsibility in educating the public about the availability of CMI. Hence, as suggested by some participants in the study, health professionals can help to increase consumer awareness of the availability of alternate forms of CMI by offering it to them and incorporating it in their counselling.

In addition to the efforts of health professionals, changes can be made to prescribing and dispensing softwares used by doctors and pharmacists to facilitate the process. This can include the appearance of an automatic reminder which prompts the health professional to offer and print a CMI before the health professional is able to complete the prescribing or dispensing process. The system can be set up in such a way that this reminder is automatically triggered for new prescriptions and/or is triggered at a specified interval for repeat prescriptions. There can also be an additional function that allows the health professional to document when a CMI has been offered and/or provided.

6.3 USE OF WMI DURING CONSULTATION

Of all the stages involving consumers and WMI, results from this research have the largest implications for the use of WMI during consumer interaction with health professionals. The results highlight the need for a more holistic and integrated

approach by health professionals when using WMI for consumer education. Rather than viewing consumer education from the perspective of ticking off a 'to do' list (e.g. offered WMI, counselled consumer), consumer education should be approached from a consumer-centred perspective, where meeting the information needs of the consumer is the main priority.

In meeting information needs of consumers, there is evidence in the general health information literature to suggest that tailored information, often with the assistance of computer programs and software, is more effective than non-tailored information (Skinner, Siegfried, Kegler *et al.*, 1993; Bental, Cawsey and Jones, 1999; Dijkstra and De Vries, 1999). For WMI, working towards an information system for providing tailored information would be a worthwhile albeit challenging endeavour, notwithstanding the potential legal ramifications of altering standardised and regulated WMI such as CMI. Meanwhile however, much can be done on a personal level by health professionals. The results from this study reveal some of the issues for consideration and may assist health professionals in understanding consumers' perspectives and needs and thus assist health professionals to tailor information to meet these needs.

It is clear from the study results that not all consumers will utilise WMI in the same way. Hence, it is important to take account of this variation. First and foremost, there is a need to identify the individual's information preferences. This may involve asking appropriate questions, making inferences from existing consumer medication/medical history or being observant during the interaction with the consumer. In addition, as the results suggested that several consumer factors may influence reading and/or information-seeking behaviour, it is also crucial to identify these traits in the individuals.

Once these are identified, health professionals may then tailor the delivery of medicine information to suit the individual. The following paragraphs suggest strategies for health professionals corresponding to each of the influential consumer factors identified from this research.

Consumers with adequate functional health literacy levels, homemakers and monitors may be more interested than their counterparts in reading WMI but may not be prepared to actively look for it. Hence, health professionals can encourage use of WMI in these groups of consumers by actively offering WMI and ensuring access to reliable and appropriate sources of WMI. Adequate health literacy levels and presence of a symptomatic disease may indicate consumers who are interested in seeking WMI.

Health professionals can further assist these consumers by referring them to credible sources of WMI and being prepared to answer potential questions which may arise from their information search.

Consumers who are less motivated in reading and/or seeking WMI pose a greater challenge to health professionals. Understanding the reasons underlying the disinterest in WMI may help health professionals decide the best way to tailor information for these consumers. The disinterest may be due to consumers' own beliefs and perceptions. As an example, some consumers such as those with asymptomatic diseases may view their conditions as innocuous. Hence, health professionals may be able to encourage these consumers to use WMI by providing them with a realistic and balanced appraisal of their condition. Other consumers may perceive the amount of information in WMI to be overwhelming and may benefit from small doses of subtle and initially non-threatening information. Yet others may not perceive a need for or realise the usefulness of WMI. Health professionals may assist these individuals by promoting WMI and taking the time to explain the information and how it may serve as a useful reference for the duration of their medication therapy.

Besides being related to a consumer's own beliefs and perceptions, disinterest in WMI may be related to difficulty in understanding WMI. This is certainly the case for consumers with inadequate health literacy levels. Of all the factors identified from this research, this is arguably the most pervasive. However, it is difficult to identify consumers with inadequate health literacy levels as it is associated with shame and embarrassment hence is often concealed (Parikh, Parker, Nurss *et al.*, 1996; Brez and Taylor, 1997). As mentioned earlier, appropriate questions or astute observation may help health professionals in identifying these consumers. Several questions proposed by Chew *et al.* (2004) including "how often do you have problems learning about your medical condition because of difficulty understanding written information?" were found to be effective in predicting inadequate health literacy. However, these questions need to be used with care as they are very direct and may be considered offensive to some consumers. Praska *et al.* (2005) proposed more indirect methods which involved observing consumer behaviours that may flag a literacy problem such as identifying medications by pill colour and shape rather than by name.

Myriad strategies and tips for identifying and managing poor health literacy in practice suggested in the literature may provide a helpful starting point in addressing this crucial yet challenging issue (Meade, McKinney and Barnas, 1994; Plimpton and Root, 1994;

Davis, Meldrum, Tippy *et al.*, 1996; Mayeaux, Murphy, Arnold *et al.*, 1996; Nichols-English, 2000; Tooth, Clark and McKenna, 2000). It is clear that current CMI will not adequately serve the needs of these consumers. Whilst an emphasis on oral communication seems to be the obvious solution, there is evidence to suggest that consumers with low literacy levels do not only struggle with written information but also have poorer oral communication skills (Williams, Davis, Parker *et al.*, 2002; Schillinger, Bindman, Wang *et al.*, 2004). However, a combination of techniques tailored to suit consumers with poor health literacy such as verbal information, simplified explanations, 'teach-back' and picture-based materials have been shown to improve health outcomes (Rothman, DeWalt, Malone *et al.*, 2004). In addition, on a more general level, it may also be worthwhile to consider educational strategies which engage the interest of these consumers and work interactively with them to improve their health literacy levels.

As mentioned earlier, not all consumers will utilise WMI in the same way and consumer preferences and needs should be taken into consideration when using WMI as an education tool. Some of these preferences were highlighted during the project. Notwithstanding the efficacy of WMI as an effective education tool, some consumers in the study had a preference for verbal information; hence health professionals need to be mindful of this preference when counselling consumers. A combination of verbal and written medicine information, perhaps with an emphasis on the consumer's preferred mode, may be the ideal way to meet a variety of different consumer needs.

Consumers also had individual preferences regarding when (e.g. before prescription is written, after medication is dispensed) and from whom (e.g. doctor, pharmacist) they wanted to receive WMI. While it may not always be feasible to meet consumer preferences due to logistics constraints such as work practice and time, these preferences should be acknowledged and accommodated where possible. However, meeting these preferences may involve changes in work practice and training sessions for health professionals to ensure they are competent in delivering CMI.

Finally, consistent with existing literature, the findings in this research confirmed that consumers particularly want to know what the medicine is for, how to take the medicine properly and the potential side effects. In relation to the latter, despite some participants finding information about side effects alarming, an overwhelming proportion of participants wanted to be informed about these and felt that the onus was on health professionals to provide a balanced perspective.

A series of research studies in the UK have indicated that the way side effects of medications are described and communicated to consumers can influence their perception of the likelihood of the side effects occurring (Berry, Knapp and Raynor, 2002; Berry, Raynor and Knapp, 2003; Berry, Raynor, Knapp *et al.*, 2003; Knapp, Raynor and Berry, 2004). Recently, the MHRA Patient Information Working Group (Patient Information Working Group, 2005) made some recommendations for improvements to the side effects information in existing PILs. Other countries including Australia have yet to evaluate the side effects information in their standard WMI.

Meanwhile, health professionals should embrace the challenge of equipping consumers with the necessary skills to interpret and apply potentially alarming information in a beneficial and positive way. However, this should usually be done in conjunction with the benefits of the medication. Several strategies have been suggested by Paling (2003) to assist health professionals in communicating risks to consumers, especially the numerical likelihood of a certain risk occurring. These include framing the message in both positive and negative forms (and not only the negative form), using absolute numbers rather than relative risks and using standardised vocabulary.

6.4 USE OF WMI AFTER CONSULTATION

Although the majority of participants read CMI, it was observed that most only read it for new medications and generally discarded CMI straight after reading it or kept it for a short duration after commencing a new medication. From this it seemed that most consumers failed to realise the potential benefit of keeping CMI as a source of ready reference for their medications after commencing therapy. Health professionals can thus play an important role in enlightening consumers on the usefulness of CMI beyond the initial stages of therapy and encourage consumers to keep CMI. This is particularly important as CMI is no longer available with each repeat box of medication received by the consumer.

6.5 FUTURE DIRECTIONS

The results from this research provide a myriad of suggestions for ongoing work in the area of WMI. These suggestions focus on CMI as it is the standard form of WMI available in Australia but some of these ideas may be transferable to other forms of WMI internationally.

There is clearly room to improve on the current CMI. Whilst the current study highlights this need, due to wide variations in consumer perceptions of CMI, a wider national consultation may be helpful to clarify consumers' perceptions on CMI. This can then inform a process to develop a more consumer-friendly CMI. In conjunction with this, CMI can be improved by increasing the emphasis on the benefits of the medication to balance against the current list of side effects. Research on consumer's understanding of their perceived risk of experiencing a side effect list in the CMI is also needed to inform the best approach to describing side effects in CMI.

Besides improving the actual CMI document, access to CMI was a pertinent discussion point that was raised throughout the entire research project. Whilst some recommendations have been made in the preceding sections, there may be a need for a study which specifically focuses on delineating the issues surrounding access to CMI and identifying feasible solutions to the problem. All stakeholders including manufacturers, health professionals and most importantly, consumers, will have to be consulted.

As mentioned in the preceding sections, prior to delivering consumer education on WMI, it is important for health professionals to assess a consumer's specific needs and preferences, taking into consideration the influence of consumer factors and characteristics. The effectiveness of these approaches could be evaluated using a randomised controlled trial whereby consumers are provided medicine information by health professionals with or without prior assessments of their preferences and needs. Possible outcome measures would be consumer comprehension of the information provided and consumer satisfaction with the information provision process.

A more in-depth study investigating the preferred timing and provider for CMI will also be beneficial. Some of the preferences expressed in this research were somewhat novel and have the potential to empower consumers to make informed decisions about their medications. In addition to the preferences that were stated during the survey,

there may be other preferences that were not mentioned. Moreover, little is known about the reactions or attitudes of health professionals towards these preferences, for example, it is unknown if doctors are willing or consider it feasible to provide a CMI prior to prescribing a medication. All these unanswered questions present avenues for future research.

If consumers do have distinct preferences in terms of providers of CMI, then it stands to reason that these providers should be well equipped and trained to provide CMI. Hence, educational programs on information delivery targeted at health professionals should also be encouraged. In the pharmacy profession, for example, educational programs are already in place (e.g. CMI training by the Pharmaceutical Society of Australia) but more remains to be done. Whilst this program is beneficial, due to its voluntary nature, in most cases, the uptake remains limited to pharmacists who are already motivated to provide information to consumers. Hence, any programs targeting health professionals developed in the future should aim to reach most of the target audience. The training should focus on increasing health professional awareness of consumer demand for information, educating health professionals to provide consumer-centred information, improving the attitudes of health professionals towards CMI and emphasising the important role of health professionals in providing and informing consumers about their medicines.

There is also great opportunity for some training programs to be incorporated into the university curriculum where future health professionals are trained. While many courses already include general programs on information provision and counselling, there may be a possibility of incorporating specific training programs based on research evidence. For example, a module on health literacy has been trialled at a university to teach students to develop sensitivity to the needs of consumers with low health literacy, assess health literacy levels and counsel consumers with low health literacy levels appropriately (Dolinsky, Dhing, Lonie *et al.*, 2001).

In conjunction with health professional education, educational programs targeted at consumers are also needed. While it is clear that consumers are interested in reading CMI, it is also apparent that many lacked the essential knowledge to use WMI optimally and may not be aware of the full extent of the usefulness of CMI. A public education program which equips consumers with a set of generic skills applicable to all CMI may assist consumers to realise the full benefits of CMI. The content of such programs may include educating consumers about the benefits of CMI, where and how they may

access CMI, the way CMI is set out, the differences between CMI and other forms of WMI, and how to interpret side effects information. These programs may be targeted at all levels of society and conducted in different settings including community centres, schools and recreational settings such as lawn bowling clubs.

Special attention needs to be given to consumers who find it difficult to understand standard WMI such as CMI. These include consumers with poor health literacy levels and those who struggle with the official language of their country of residence. Different strategies for engaging these consumers and helping them to understand information about their medicines should be trialled. However, for these strategies to be integrated in the existing system, it is paramount that they are able to be implemented in everyday practice, and be sustainable.

Lastly, in addition to testing the effectiveness of tailored interventions by health professionals, there is also an opportunity to explore the possibilities of tailoring information for consumers using computer programs and software. As mentioned previously, this strategy has been utilised successfully in the area of general health information. In the area of WMI, this strategy has been used for non-legislated WMI. The main challenge with applying this strategy to standard WMI such as CMI is circumventing the legal ramifications of 'altering' the document. Other issues to consider include the parameters to which the information will be tailored.

In conclusion, the research described in this thesis contributes to the current understanding in the area of WMI from the perspective of the consumer. It has provided a description of Australian consumers' perceptions and use of CMI. In doing so, it has emphasised the importance and value of including consumers as informative stakeholders who have much to contribute to the area. This research has also identified several consumer factors which may influence the way consumers read, seek or evaluate WMI. These findings have highlighted the need to consider individual consumer factors to ensure that information about medicines is tailored to meet individual needs and preferences. The overall findings from this research have provided important insights which may be used to inform the development of strategies to enhance consumers' medicines use and as a consequence, improve consumer health outcomes.

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APPENDIX A

- CMI Study questionnaire

Section 1- Knowledge about and receiving CMI

Interviewer: *To begin, I would like to ask you some general questions about consumer medicine information:*

1. **What do you think consumer medicine information is?** *(you may tick more than one box)*

- ❑ Written information about prescription medications.
- ❑ Written information printed by the pharmacist.
- ❑ Written information leaflets or brochures.
- ❑ Written information leaflets inside the medication box.
- ❑ Other (please specify)

_____

- ❑ I don't know.

> ***Interviewer to provide the following information to consumer:***
>
> *Consumer Medicine information (or CMI as it is called for short), is written information about medications, that comes with most prescription medications.*
>
> *CMI provides you with information about your medications, such as telling you*

2. **What kind of drug information do you think a CMI contains?**

_____

_____

_____

_____

_____

_____

3. **Did you receive a consumer medicine information for any of your prescription medications you collected from the pharmacy today?**

- ❑ Yes **GO TO Q4**
- ❑ No **GO TO Q6**
- ❑ Don't know *(Interviewer to check by writing the name of the medication .....)*

4. **Which medication(s) did you receive the consumer medicine information for?**

_____

_____

_____

5. **Is (are) the medication(s), new, repeat or have you had it (them) sometime in the past?**

Name of medication (please write):	.....	.....	.....	.....
New	❑	❑	❑	❑
Repeat	❑	❑	❑	❑
Had it sometime in the past	❑	❑	❑	❑

Other medications (please specify)

_____

_____

6. **Have you ever received consumer medicine information for any of your prescription medications you have collected from a pharmacy?**

- ❑ Yes **GO TO Q7**
- ❑ No **GO TO Q9**
- ❑ Don't know **GO TO Q9**

7. **Which medication(s) did you receive the consumer medicine information for?**

_____

_____

_____

8. **Was (were) the medication(s), new, repeat or have you had it (them) sometime in the past?**

Name of medication (please write):	.....	.....	.....	.....
New	❑	❑	❑	❑
Repeat	❑	❑	❑	❑
Had it sometime in the past	❑	❑	❑	❑

Other medications (please specify)

_____

_____

GO TO SECTION 2

9. **Would you like to receive consumer medicine information for any of your prescription medications which you have collected from a pharmacy?**

- ❑ Yes **GO TO Q10**
- ❑ No **GO TO SECTION 4**
- ❑ Don't know **GO TO SECTION 4**

10. Which medication(s) would you like to receive the consumer medicine information for?

_____

_____

_____

11. Would you like to receive Consumer Medicine Information for your new or repeat medications?

❒ New

❒ Repeat

Other (please specify)

_____

_____

GO TO QUESTION 17

Section 2- CMI Experience and Provider

Interviewer: *We are now going to look at who gave you a CMI and what happened when you received it.*

Please note that questions 12-16 are applicable to consumers who have received a CMI today or for those who have received a CMI in the past.

12. Who provided you with the consumer medicine information for your prescription medication(s)?

Name of medication (please write):	.....	.....	.....
Doctor	❒	❒	❒
Pharmacist	❒	❒	❒
Other (please specify)	❒	❒	❒

_____

13. Was the consumer medicine information given to you or did you ask for it?

❑ Given

❑ Requested.

❑ Neither, found it inside the medication box

❑ Other (please specify)_____

14. What type of CMI did you receive?

Name of medication (please write):	.....	.....	.....
Package inserts	❒	❒	❒
Computer generated print-outs	❒	❒	❒
Loose leaflets / brochures	❒	❒	❒
Other (please specify)	❒	❒	❒

_____

15. How was the CMI given out to you? *(More than one box may be ticked)*

❑ It was inside the medication box

❑ Simply handed out with no further discussion.

❑ My attention was drawn to the CMI document only.

❑ My attention was drawn to specific sections of the CMI.

❑ I was asked to read the CMI.

❑ I was asked to read the CMI and come back if I had any questions.

❑ The content of the CMI was discussed in detail. → **GO TO Q16**

GO TO Q17

16. Which sections of the consumer medicine information did the pharmacist (or doctor) discuss with you?

	Doctor	Pharmacist	Other
How and when to take the medication	❒	❒	❒
Dosage	❒	❒	❒
Ingredients	❒	❒	❒
When not to take the medication	❒	❒	❒
How the medication works	❒	❒	❒
Drug / food interactions	❒	❒	❒
Side effects	❒	❒	❒
What to do if you take too much medication	❒	❒	❒
What to do if you miss a dose of medication	❒	❒	❒
Storage	❒	❒	❒
Disposal	❒	❒	❒
Manufacturer	❒	❒	❒
Other (please specify)	❒	❒	❒

17. When do you think is the best time to receive a CMI?

- ❑ At the doctor's surgery before the doctor writes the prescription
- ❑ At the doctor's surgery after the doctor has written the prescription
- ❑ At the pharmacy before I get the prescription dispensed
- ❑ At the pharmacy after I get the prescription dispensed (with medication)
- ❑ Other (please specify)_____

18. Who do you feel is the best person to provide you with CMI?

- ❑ Doctor
- ❑ Pharmacist
- ❑ Neither
- ❑ Other (please specify) _____

19. Why do you think a pharmacist (or a doctor) is the best person to provide you with CMI?
(you may tick more than one box)

	Doctor	Pharmacist	Other
Is aware of the medication(s) I am taking	❒	❒	❒
Is an expert on medication(s)	❒	❒	❒
Sees me on a regular basis	❒	❒	❒
Has prescribed my medication(s)	❒	❒	❒
We have a good relationship	❒	❒	❒
Is aware of my medical history	❒	❒	❒
I can decide whether to take the medication(s)	❒	❒	❒
Other (please specify) _____	❒	❒	❒

20. How often do you think you should receive CMI for your repeat prescriptions?

- ❑ The first time I get the prescription
- ❑ Every time I collect a repeat prescription
- ❑ Every ___ repeats
- ❑ Every ___ months

Please fill in blanks

- ❑ When new information about the medication becomes available
- ❑ Only when I ask for it
- ❑ Other (please specify)_____

GO TO SECTION 3

Section 3- Action taken

Interviewer: *Please note that this section is only applicable to the CMI document which has been received in the past (NOT today). Please focus on the most recent experience and only select one prescription medication.*

Now I would like to ask you about what you did with the CMI you have received in the past.

21. If you think back to the last time you received a CMI for your prescription medication(s), how long ago was that? _____

22. Did you read the CMI for your prescription medication(s)?

- ❑ Yes **GO TO Q23**
- ❑ No **GO TO Q24**

23. How much of the CMI did you read?

- ❑ All sections
- ❑ Some sections
- ❑ I scanned the CMI

GO TO Q25

24. Here are some reasons other consumers have provided for not reading CMI. Which of the following applies to you? *(More than one box may be ticked)*

- ❑ I receive all the information I need from my doctor.
- ❑ I receive all the information I need from my pharmacist.
- ❑ I trust my doctor to prescribe a medication that is suitable for me.
- ❑ I trust my pharmacist to provide a suitable medication for me.
- ❑ I find the CMI too difficult to understand.
- ❑ I find the CMI too long to read.
- ❑ The print in the CMI is too small to read.
- ❑ I don't have time to read the CMI.
- ❑ I don't think the CMI is important.
- ❑ My illness is not serious.
- ❑ I have been taking my medication for a long time.
- ❑ I am not interested in the information in the CMI.
- ❑ I have taken this medication in the past.
- ❑ Other (Please specify) _____

GO TO SECTION 4

25. Here are some reasons other consumers have provided for reading CMI. Which of the following applies to you? *(More than one box may be ticked)*

- ❑ I want to know about my medication.
- ❑ I am concerned about the medication's side effects.
- ❑ I have allergies and so like to check that I am not allergic to the medication.
- ❑ I have other disease conditions and would like to know if the medication is suitable for me.
- ❑ I want to check that the doctor didn't forget anything.
- ❑ I want to check that the pharmacist didn't forget anything.
- ❑ My doctor / pharmacist asked me to read the CMI *(circle doctor or pharmacist)*.
- ❑ I have had bad experiences with my medications in the past.
- ❑ Do not trust my doctor / pharmacist *(circle doctor or pharmacist)*.
- ❑ Other (Please specify) _____

26. Which specific items of medication information did you focus on when you read the CMI?

_____

_____

_____

_____

_____

_____

_____

27. What have you learnt from reading your CMI(s)?

_____

_____

_____

_____

_____

_____

_____

GO TO QUESTION 28

28. How has reading the CMI influenced the way you take your medication? *(you may tick more than one box)*

Since reading the CMI:

- ❑ I am more informed about my medication.
- ❑ I am more aware of the importance of taking my medication as prescribed.
- ❑ I am more confident about taking my medication.
- ❑ I have stopped taking my medication, because of interactions with other medications.
- ❑ I have stopped taking my medication, because I did not want to suffer any side effects.
- ❑ I have changed the way I take my medication.
  - ❖ Please specify how _____
- ❑ I have not learnt anything new about my medication.
- ❑ I have made no changes to the way I take my medication.
- ❑ Other (please specify)_____

29. Did you have any concerns or queries with the information you read in the CMI?

- ❑ Yes **GO TO Q30**
- ❑ No **GO TO Q32**

30. What did you do to address your concerns or queries with the information you read in the CMI? *(You may tick more than one box)*

- ❑ I contacted my pharmacist
- ❑ I contacted my doctor
- ❑ I contacted another health care professional (Please specify)_____

} **GO TO Q31**

- ❑ I consulted a friend or relative.
- ❑ I searched for more information (please specify the source _____)
- ❑ I made changes to the way I take the medication (please specify _____)
- ❑ Other (please specify_____)

} **GO TO Q32**

31. What further action was taken after consultation with the pharmacist (or doctor or other health care professional)? *(Please tick one box only)*

- ❑ There was no change in the way I take my medication.
- ❑ My medication was changed.
- ❑ There was a change in the dosage.
- ❑ The medication was stopped altogether.
- ❑ A new medication was given to me.
- ❑ Other (please specify)_____

32. After reading the CMI, what did you do with it?

- ❑ Filed the CMI away for future reference (how long did you keep the CMI for? _____)
- ❑ Kept the CMI in the medication box until I finished the medication
- ❑ Shared the CMI with friends / relatives who were also on the same medication
- ❑ Threw the CMI away
- ❑ Other (Please specify _____)

33. Have you read the CMI for anyone else's medication (eg. your child, parent, partner)?

- ❑ Yes, always
- ❑ Yes, sometimes
- ❑ Yes, I scan the CMI and do not read it in-depth

Go To Q34

- ❑ No

34. Whose CMI have you read?

- ❑ Child
- ❑ Partner
- ❑ Elderly parent / relative
- ❑ Other (please specify)_____

GO TO SECTION 4

Section 4- Attitude statements

Interviewer: *Below are a number of opinions of consumers about consumer medicine information. Please read each statement carefully and show whether you, as a consumer, agree or disagree with these statements. If you strongly disagree please circle SD; if you disagree please circle D; if you neither agree nor disagree please circle U; if you agree please circle A; if you strongly agree please circle SA; if the statement is not applicable to you please circle NA*

- *SD= Strongly Disagree*

D= Disagree
U= Neither agree nor disagree
A= Agree
SA= Strongly agree
NA= Not applicable

• I would like to know all about the medications I am taking	SD	D	U	A	SA	NA
• I only read CMI for a medication which is for a serious medical condition	SD	D	U	A	SA	NA
• I read the CMI because I have experienced problems with my medication(s) in the past	SD	D	U	A	SA	NA
• The CMI is an important source of information for the medication taken by someone in my care	SD	D	U	A	SA	NA
• I am not interested in learning about my medications	SD	D	U	A	SA	NA
• I don't believe that I should know about the medications taken by someone in my care	SD	D	U	A	SA	NA
• CMI contains too much drug information	SD	D	U	A	SA	NA
• CMI is useful only for medications used in severe diseases	SD	D	U	A	SA	NA
• I don't read a CMI beacuse I have never had any problems with my medications in the past	SD	D	U	A	SA	NA
• I would like to be involved with my doctor in deciding what medications I should take	SD	D	U	A	SA	NA
• CMI should not be given out for medications used in minor illnesses	SD	D	U	A	SA	NA
• As a carer, I would like to know what medication the person in my care is taking	SD	D	U	A	SA	NA
• CMI is useful for consumers who experience problems with their medications	SD	D	U	A	SA	NA
• I leave all the decision making about my medications to my doctor.	SD	D	U	A	SA	NA
• CMI contains all the medication information I need.	SD	D	U	A	SA	NA
• I find the print in CMI too small to read	SD	D	U	A	SA	NA
• I will only read the CMI, if I think that my illness is serious	SD	D	U	A	SA	NA
• The CMI is set out well, so I can always find the information I want	SD	D	U	A	SA	NA
• CMI is useful as I can check if I am allergic to the medication and its ingredients	SD	D	U	A	SA	NA
• I do not read the CMI for medications taken by my children or someone under my care	SD	D	U	A	SA	NA
• CMI uses words that I find difficult to understand	SD	D	U	A	SA	NA

• I don't read the CMI for medications prescribed for minor ailments	SD	D	U	A	SA	NA
• I trust the doctor to prescribe medication(s) that is (are) suitable for me	SD	D	U	A	SA	NA
• I read a CMI because I have experienced side effects with my previous medications.	SD	D	U	A	SA	NA
• It is important to read the CMI for the medications taken by someone in my care	SD	D	U	A	SA	NA
• I like to take control of my medication taking	SD	D	U	A	SA	NA
• CMI is written in a language that is easy to understand	SD	D	U	A	SA	NA

Section 5- Demographic Characteristics

Interviewer: ***The following questions collect some demographic details about you. Please answer all questions.***

1. Sex:

- ❒ Male
- ❒ Female

2. How old are you? ..... years

3. In what country were you born?

- ❒ Australia
- ❒ Overseas- please state country of birth .....

4. Do you speak a language other than English at home?

- ❒ No
- ❒ Yes- please state language spoken .....

5. Which of the following best describes your current marital status?

- ❒ Never Married
- ❒ Married
- ❒ De Facto
- ❒ Separated
- ❒ Divorced
- ❒ Widowed

6. Do you have any children?

- ❒ No
- ❒ Yes- please state number of children .....

7. What is the highest educational qualification you have obtained?

- ❒ None
- ❒ School Certificate (Year 10)
- ❒ Higher School Certificate (Year 12)
- ❒ Associate Diploma
- ❒ Undergraduate Diploma
- ❒ Bachelor Degree
- ❒ Postgraduate Diploma
- ❒ Higher Degree

8. What is your **a) occupation?** .....

b) type of business or work? .....

9. Which of the following best describes your current work situation?

- ❒ Not Working
- ❒ Part Time Work
- ❒ Full Time Work

10. What postcode is your residence in? .....

11. Do you have any medical conditions?

- ❒ No
- ❒ Yes- please state your medical conditions .....

.....

.....

.....

.....

.....

12. Do you currently take any medications prescribed by your doctor?

- ❒ No
- ❒ Yes- please state your medications .....

.....

.....

.....

.....

.....

Thank you for participating in this study, your input is highly valued, are there any other comments, relevant to the topic area which you

Comments:_____

_____

_____

_____

_____

APPENDIX B

- Interviewer training protocol

Training protocol

Aim and objectives of the study: The interviewers were informed of what the researchers were trying to achieve.

Introduction and background to CMI: The interviewers were given a brief introduction to CMI, covering aspects such as the definition of CMI, the available formats, its contents and its availability from different health professionals.

CMI and community pharmacy practice: The interviewers were briefed on the differences between a typical dispensing scenario (limited verbal counselling when medication is dispensed) and an ideal dispensing scenario (verbal counselling accompanied by written information). They were also informed of the different ways a CMI could be provided in the community pharmacy (e.g. through package inserts, simply handed out, accompanied by detailed counselling and discussion of CMI content).

Difference between CMI and other WMI: The interviewers were taught the differences between CMI and other forms of WMI so that they were able to double-check whether patients were referring to CMI or not during the administration of the survey. Some examples of CMI were shown.

Recruitment process: The recruitment process and the responsibility of each interviewer were explained (see Section 3.2.4).

Questionnaire administration: Each question in the questionnaire was explained to the interviewers. All the different possible combinations of question skips were explored and explained. The interviewers also had a trial run of administering the questionnaire on one another.

Questions: Interviewers were encouraged to ask questions at any time during the training session.

APPENDIX C

- CMI Study pharmacist information sheet
- CMI Study pharmacist consent form
- CMI Study patient information sheet
- CMI Study patient consent form

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Pharmacist Subject Information Sheet- Phase 2 of the Project

Information for Participants

Title of Research Project: The Use of Consumer Medicine Information by Consumers

The above named research study is being conducted by Dr Parisa Aslani (Tel: 9351 6711) and Dr Ines Krass (Tel: 9351 3507), at the Faculty of Pharmacy, University of Sydney. This study aims to investigate consumers' opinions of Consumer Medicine Information (CMI) and how they use CMIs received with their prescription medications.

The study sample will consist of consumers who have collected a prescription medication for themselves from the participating community pharmacy. A researcher (....., 9351 6711) will visit your community pharmacy for three days to recruit and interview consumers. Consumers will be approached by the researcher on leaving the dispensary and invited to participate in the study. A brief explanation of the research will be provided and the consumer inclusion criteria will be checked. The criteria include: being 18 years of age or over; not requiring a translator to respond to the survey; and collecting a prescription medication for themselves. Eligible and consenting consumers will be requested to sign a consent form. The interviews will be approximately 15 minutes in duration. The questionnaire will focus on awareness of and attitudes to CMI for prescription medications and how CMIs are used by consumers.

All data collected during the research study will be confidential. Only group data will be used in reporting and publishing the results of the research. Participation in the study is voluntary. You and your consumers can withdraw from the study at any time.

Any person with concerns or complaints about the conduct of a research study can contact the Manager of Ethics and Biosafety Administration, University of Sydney, on (02) 9351 4811

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Pharmacist Consent Form- Phase 2 of the Project

Title of Research Project: The Use of Consumer Medicine Information by Consumers

1, ...
(name)

of, ...
(address)

have read and understood the "Information for Participants" on the above named research study and have discussed it with one of the researchers (....., Tel (02) 9351 6711). I am aware of the procedures involved and understand what is expected of me.

I hereby voluntarily consent to participate in the study, and understand that I can withdraw from the study at any time.

I also understand that all data obtained from this study will be treated confidentially and only group data will be used in future research or published. No personal details will be revealed at any time during or after the study.

Signature: .....

Name (please print): .....

Date: .....

Name of Witness: .....

Signature of Witness: .....

Date: .....

Any person with concerns or complaints about the conduct of a research study can contact the Manager of Ethics and Biosafety Administration, University of Sydney, on (02) 9351 4811

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Consumer Subject Information Sheet- Phase 2 of the Project

Information for Participants

Title of Research Project: The Use of Consumer Medicine Information by Consumers

The above named research study is being conducted by Dr Parisa Aslani (Tel: 9351 6711) and Dr Ines Krass (Tel: 9351 3507), at the Faculty of Pharmacy, University of Sydney.

This study aims to investigate consumers' opinions of Consumer Medicine Information (CMI) and how they use CMIs received with their prescription medications.

If you consent to participate in the study, you will be interviewed by the researcher using a structured questionnaire. The interview will be approximately 15 minutes in duration and will be conducted in a quiet area of the pharmacy. The questionnaire will focus on awareness of and attitudes to CMI for prescription medications; experiences when receiving CMI for prescription medications from community pharmacists; and how CMIs are used by consumers.

All data collected during the research study will be confidential. Only group data will be used in reporting and publishing the results of the research. Participation in the study is voluntary and you can withdraw from the study at any time.

Any person with concerns or complaints about the conduct of a research study can contact the Manager of Ethics and Biosafety Administration, University of Sydney, on (02) 9351 4811

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Consumer/ Patient Consent Form- Phase 2 of the Project

Title of Research Project: The Use of Consumer Medicine Information by Consumers

1, ...
(name)

of, ...
(address)

have read and understood the "Information for Participants" on the above named research study and have discussed it with one of the researchers (....., Tel (02) 9351 6711). I am aware of the procedures involved and understand what is expected of me.

I hereby voluntarily consent to participate in the study, and understand that I can withdraw from the study at any time.

I also understand that all data obtained from this study will be treated confidentially and only group data will be used in future research or published. No personal details will be revealed at any time during or after the study.

Signature: .....

Name (please print): .....

Date: .....

Name of Witness: .....

Signature of Witness: .....

Date: .....

Any person with concerns or complaints about the conduct of a research study can contact the Manager of Ethics and Biosafety Administration, University of Sydney, on (02) 9351 4811

APPENDIX D

- Ancillary results to Chapter 3 (CMI Study)

Table A1.1 Number of questionnaires from each pharmacy

Pharmacy code	Questionnaire administered	Useable questionnaire
P01	20	20
P02	20	18
P03	20	18
P04	3	3
P05	2	2
P06	19	16
P07	9	9
P08	20	20
P09	20	19
P10	10	10
P11	20	18
P12	1	1
P13	19	18
P14	7	7
P15	16	13
P16	10	9
P17	5	5
P18	20	20
Total	241	226

Table A1.2 Information contained in CMI as reported by patients (n=200)

Information contained in CMI*	n	%
Side effects	108	54.0
Dosage/ how to take	94	47.0
Warning/ precaution/ contraindication	54	27.0
Content of drug/ ingredients	45	22.5
Indication	35	17.5
Drug interactions	19	9.5
Information about medication	19	9.5
Other	67	33.5

NB: Responses are not mutually exclusive.
*Question was only directed to patients who knew what a CMI was.

Table A1.3 Receipt of CMI on the day of interview

Received CMI on day of interview	n	%
Yes	132	58.4
No	91	40.3
Don't know	3	1.3
Total	226	100.0

Table A1.4 Receipt of CMI in the past

Received CMI in the past	n	%	Valid %
Yes	184	81.4	81.8
No	26	11.5	11.6
Don't know	15	6.6	6.7
Missing	1	0.4	
Total	226	100.0	100.0

Table A1.5 Status of prescription medications for which CMI was received

Status of prescription	Day of interview (n=135 patients)		In the past (n=184 patients)	
	n medications	%	n medications	%
New	43	22.1	39	13.4
Repeat	144	73.8	197	67.9
Had before	8	4.1	39	13.4
Unspecified	0	0.0	15	5.2
Total number of medications	195	100.0	290	100.0

Table A1.6 Medications (by therapeutic classes) for which CMI was received

Medication by therapeutic class	Day of interview (n=135 patients)		In the past (n=184 patients)	
	n medications	%	n medications	%
Cardiovascular system	53	27.2	88	30.3
Central nervous system	31	15.9	36	12.4
Infections and infestations	21	10.8	25	8.6
Endocrine & metabolic disorders	20	10.3	27	9.3
Musculoskeletal system	17	8.7	23	7.9
Analgesia	10	5.1	12	4.1
Respiratory system	10	5.1	10	3.4
Alimentary system	8	4.1	19	6.6
Eye	7	3.6	5	1.7
Skin	6	3.1	6	2.1
Contraceptive agents	5	2.6	4	1.4
"Cannot recall"	0	0.0	19	6.6
Other	7	3.6	16	5.5
Total number of medications	195	100.0	290	100.0

Table A1.7 Sections discussed in detail by doctor and pharmacist

Sections discussed	Doctor (n=8)		Pharmacist (n=6)	
	n	%	n	%
How and when to take the medication	6	75.0	5	83.3
Dosage	8	100.0	3	50.0
Ingredients	4	50.0	0	0.0
When not to take the medication	3	37.5	2	33.3
How the medication works	5	62.5	2	33.3
Drug/food interaction	5	62.5	2	33.3
Side effects	7	87.5	3	50.0
What to do if you take too much medication	2	25.0	1	16.7
What to do if you miss a dose of medication	5	62.5	1	16.7
Storage	1	12.5	1	16.7
Disposal	0	0.0	1	16.7
Manufacturer	0	0.0	1	16.7

NB: Responses are not mutually exclusive.

Table A1.8 Reasons for preferred provider of CMI

Reason for preference	Doctor (n=130)		Pharmacist (n=114)		Manufacturer (n=2)	
	n	%	n	%	n	%
Is aware of the medication(s) I am taking	101	77.7	60	52.6		
Is an expert on medication(s)	81	62.3	87	76.3	2	100
Sees me on a regular basis	89	68.5	40	35.1		
Has prescribed my medication(s)	86	66.2		0.9		
We have a good relationship	77	59.2	44	38.6		
Is aware of my medical history	100	76.9	28	24.6		
I can decide whether to take the medication	31	23.8	15	13.2		
Doctor can outline important relevant points	1	0.8				
Convenience			1	0.9		
Has the time			4	3.5		
Dispenses my medications			4	3.5		
Missing			3	2.6		

NB: Responses are not mutually exclusive.

Table A1.9 Patient's preferred frequency of CMI receipt (n=214)

Preferred frequency of receiving CMI	n	%	Valid %
First time I get the prescription	89	41.6	44.9
Every time I collect a repeat prescription	94	43.9	47.5
When new information about the prescription becomes available	31	14.5	15.7
Only when I ask for it	5	2.3	2.5
Every few repeats	6	2.8	3.0
Every few months	2	0.9	1.0
When there are changes to the dose or the medication	2	0.9	1.0
Never	2	0.9	1.0
Missing	16	7.5	

NB: Responses are not mutually exclusive.

Table A1.10 Items of focus when reading CMI (n=98)

Focus while reading CMI	n	%	Valid %
None in particular	7	7.1	7.4
Side effects	46	46.9	48.4
Dosage	28	28.6	29.5
Warning/contraindication	10	10.2	10.5
Drug interactions	8	8.2	8.4
Ingredients	6	6.1	6.3
Indication	5	5.1	5.3
Diet/food while on medication	5	5.1	5.3
Other	36	36.7	37.9
Missing	3	3.1	

NB: Responses are not mutually exclusive.

Table A1.11 Patient's reasons for reading CMI (n=95)

Reason for reading CMI	n	%	Valid %
I want to know about my medication	78	79.6	82.1
I am concerned about the medication's side effects	76	77.6	80.0
I have other disease conditions and would like to know if the medication is suitable for me	25	25.5	26.3
I want to check that the doctor didn't forget anything	22	22.4	23.2
I have allergies and so like to check that I am not allergic to the medication	21	21.4	22.1
I want to check that the pharmacist didn't forget anything	15	15.3	15.8
I have had bad experiences with my medications in the past	13	13.3	13.7
My doctor asked me to read the CMI	8	8.2	8.4
My pharmacist asked me to read the CMI	8	8.2	8.4
I do not trust my doctor	2	2.0	2.1
Other	3	3.1	3.2
Missing	3	3.1	

NB: Responses are not mutually exclusive.

Table A1.12 Patient's reasons for not reading CMI (n=55)

Reason for not reading CMI	n	%
I have taken this medication in the past	37	67.3
I have been taking my medication for a long time	29	52.7
I trust my doctor to prescribe a medication that is suitable for me	22	40.0
I receive all the information I need from my doctor	18	32.7
I receive all the information I need from my pharmacist	11	20.0
I find the CMI too long to read	8	14.5
I trust my pharmacist to provide a suitable medication for me	7	12.7
The print in the CMI is too small to read	5	9.1
I find the CMI too difficult to understand	2	3.6
I don't have time to read the CMI	2	3.6
My illness in not serious	2	3.6
Other	3	5.5

NB: Responses are not mutually exclusive.

Table A1.13 Third party readership of CMI (n=95)

Read CMI for someone else	n	%	Valid %
Yes, always	34	34.7	35.8
Yes, sometimes	21	21.4	22.1
Yes, I scan the CMI and do not read it in depth	2	2.0	2.1
No	38	38.8	40.0
Missing	3	3.1	
Total	98	100.0	100.0

Table A1.14 Third party for whom CMI was read (n=57)

Third party	n	%
Partner	31	54.4
Child	25	43.9
Elderly parent/relative	18	31.6
Friend	4	7.0
Other (others with same condition, grandchild, neighbour, patient)	6	10.5

NB: Responses are not mutually exclusive.

Table A1.15 Action taken to address concern after reading CMI (n=20)

Action taken to address concern	n	%
I contacted my doctor	14	70
I contacted my pharmacist	5	25
I made changes to the way I take the medication	3	15
I consulted a friend or relative	1	5
I searched for more information	1	5

NB: Responses are not mutually exclusive.

Table A1.16 Further action taken after consultation with health professional to discuss concerns

Action taken after consulting health professional	n	%
There was no change in the way I take my medication	8	50.0
My medication was changed	3	18.8
There was a change in the dosage	2	12.5
The medication was stopped altogether	2	12.5
I was reassured and more confident to take my medication	1	6.3
Total	16	100.0

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Table A1.17 Initial factor analysis

Items	Factor						
	1	2	3	4	5	6	7
The CMI is an important source of information for the medication taken by someone in my care.	0.87						
It is important to read the CMI for the medications taken by someone in my care.	0.81						
As a carer, I would like to know what medication the person in my care is taking.	0.72						
I would like to know all about the medications I am taking.	0.58						
I don't believe that I should know about the medications taken by someone in my care.	-0.56						
CMI is useful for consumers who experience problems with their medications.	0.53			0.31			
I like to take control of my medication taking.	0.46						
I am not interested in learning about my medications.	-0.42						
CMI is useful as I can check if I am allergic to the medication and its ingredients.	0.42						
I don't read the CMI for medications prescribed for minor ailments.		0.81					
I only read CMI for a medication which is for a serious medical condition.		0.75					
I will only read the CMI if I think that my illness is serious.		0.74					
I don't read a CMI because I have never had any problems with my medications in the past.		0.51					
I do not read the CMI for medications taken by my children or someone under my care.	-0.46	0.49				-0.30	
I leave all the decision making about my medications to my doctor.			0.87				
I would like to be involved with my doctor in deciding what medications I should take.			-0.56				
I trust the doctor to prescribe medications that are suitable for me.			0.48				

Items	Factor						
	1	2	3	4	5	6	7
CMI is written in a language that is easy to understand.				-0.77			
CMI uses words that I find difficult to understand				0.62			
I find the print in CMI too small to read				0.33			
I read a CMI because I have experienced side effects with my previous medications.					0.86		
I read the CMI because I have experienced problems with my medication(s) in the past.					0.69		
CMI is useful only for medications used in severe diseases.						0.80	
CMI should not be given out for medications used in minor illnesses.						0.46	
CMI contains too much drug information.						0.39	
The CMI is set out well, so I can always find the information I want.							0.88
CMI contains all the medication information I need.							0.46
Extraction method: Principal Axis Factoring							
Rotation method: Promax with Kaiser Normalisation							

NB: Only factor loadings ≥ 0.30 have been included in the table.

APPENDIX E

- Ancillary results to Chapter 4 (WMI Study Phase 1)

Table A1.18 Changes made to questions from CMI Study before incorporation into WMI Study Phase 1

CMI Study		WMI Study Phase 1		Rationale for change
Question	**Description**	**Question**	**Description**	
Awareness of CMI				
Sect 1, Q1	MCQ listing various definitions of CMI (≥ 1 response allowed)	Sect A, Q2	Simple yes/no question, with interviewer checking understanding of participants who responded 'yes'	Simpler and clearer way of ascertaining awareness of CMI
Focus/ sections of interest when reading CMI				
Sect 3, Q26	Open-ended question examining focus while reading CMI	Sect A, Q7	MCQ on the sections of CMI usually read (options included all sections in CMI; ≥ 1 response allowed)	Simpler and more direct way of ascertaining sections of interest (sections in CMI are standardised hence feasible to include all possible options)
CMI readership for third party				
Sect 3, Q33	MCQ with separate options for different extents of readership	Sect A, Q9	Simple yes/no question	Distinctions between different extents of third party readership did not prove useful, hence question was simplified
Reasons for reading and not reading CMI				
Sect 3, Q24 & 25	MCQ listing reasons for reading or not reading CMI (≥ 1 response allowed)	Sect A, Q11 & 12	Open ended question, followed by MCQ listing various reasons for reading or not reading CMI; some choices from CMI Study were removed	Allowed participants to express what was salient in their own minds first without being influenced by the available alternatives; some choices in CMI Study were found to be not applicable to many participants hence were removed

CMI Study		WMI Study Phase 1		Rationale for change
Question	**Description**	**Question**	**Description**	
Demographics				
Sect 5, Q4	- Patients asked if they spoke a language other than English at home	Sect F, Q4 & 5	- Main language spoken at home was requested, followed by other languages spoken at home	- Original question did not provide indication of participant's main language which could influence their use of WMI
Q5 & Q6	- Marital status and number of children were requested	Nil	- Marital status and number of children were not requested	- Information was not found to be useful
Q7	- Eight options were provided when requesting for highest level of education	Q6	- Only six options were provided when requesting for highest level of education	- The more detailed differentiation between levels did not prove useful, hence categories were condensed
Q8	- Open-ended question requesting for occupation followed by type of business or work	Q7	- MCQ requesting for occupation only*	- Open-ended question produced inaccurate response from participants (e.g. "retired"); request for type of business/work was confusing and therefore removed

*based on ABS ASCO (Australian Bureau of Statistics, 1997a)
Sect= section, Q= question, MCQ= multiple choice question, ABS= Australian Bureau of Statistics, ASCO= Australian Standard Classification of Occupations

Table A1.19 Group 1 and Group 2 patient reasons for not participating

Reason for not participating	Group 1		Group 2	
	n	%	n	%
Time constraints	24	47.1	57	60.0
Not interested	9	17.6	15	15.8
Not feeling well	8	15.7	4	4.2
Not comfortable with English	0	0.0	6	6.3
Other	5	9.8	2	2.1
No reason given	5	9.8	11	11.6
Total	51	100.0	95	100.0

Table A1.20 Pharmacy and patient response rate for Group 2

SSD	Pharmacy			Patient		
	Yes (n)	No (n)	Response rate (%)	Yes (n)	No (n)	Response rate (%)
SSD01	3	8	27	20	4	83
SSD02	2	16	11	12	2	86
SSD03	4	4	50	27	5	84
SSD04	3	11	21	14	9	61
SSD05	4	8	33	19	6	76
SSD06	1	6	14	9	3	75
SSD07	5	16	24	23	10	70
SSD08	2	7	22	11	11	50
SSD09	5	21	19	21	5	81
SSD10	3	5	38	16	6	73
SSD11	2	3	40	17	3	85
SSD12	9	12	43	73	31	70
Overall	43	117	27	262	95	73

Table A1.21 Pharmacy reasons for not participating

Reason	n
No reason provided	33
Not contactable or lost to follow-up	21
Mainly non-English speaking clientele	15
Too busy (e.g. with QCPP accreditation*)	11
Fear of pressurising clients/ deem clients unsuitable/ disinterested	5
Low prescription volume	5
Not interested	5
Low walk-in clientele (mainly deliveries)	4
Space restriction in pharmacy	4
Involved in other research studies	3
Pharmacy undergoing relocation	3
Pharmacy undergoing change of ownership	3
Other	5
Total	117

*Quality Care Pharmacy Program (QCPP) accreditation is a national quality assurance program for community pharmacies; pharmacies receive incentive payments for accreditation before certain deadlines (The Pharmacy Guild of Australia, 1998).

Table A1.22 Chi-square statistics for the comparison between recruited sample and population of metropolitan Sydney

	Sydney (n= 3.4 million)	Sample (n=262)		Chi square statistics		
	%	n	%	χ^2	df	P-value
SSD01	7.6	20	7.6	0.00	1	0.98
SSD02	8.8	12	4.6	5.85	1	0.02
SSD03	11.5	27	10.2	0.36	1	0.55
SSD04	8.5	14	5.3	3.38	1	0.07
SSD05	6.9	19	7.3	0.05	1	0.83
SSD06	10.0	9	3.4	12.55	1	<0.001
SSD07	9.2	23	8.8	0.06	1	0.81
SSD08	4.7	11	4.2	0.14	1	0.70
SSD09	8.3	21	8.0	0.03	1	0.88
SSD10	6.5	16	6.1	0.06	1	0.80
SSD11	5.6	17	6.5	0.38	1	0.54
SSD12	12.3	73	27.9	58.94	1	<0.001
Total	100.0	262	100.0			

Table A1.23 Completion rate by section of questionnaire

Section	Group 1 (n=217)		Group 2 (n=262)		Overall (n=479)	
	n	%	n	%	n	%
A	217	100.0	262	100.0	479	100.0
B	217	100.0	104	39.7	321	67.0
C	217	100.0	251	95.8	468	97.7
D	217	100.0	104	39.7	321	67.0
E	217	100.0	152	58.0	369	77.0
F	217	100.0	262	100.0	479	100.0

NB: These figures indicate the number of participants who attempted each section of the questionnaire.

Table A1.24 Mode of administration of questionnaire

Administration of questionnaire	Group 1		Group 2		Overall	
	n	%	n	%	n	%
Face to face	175	80.6	230	87.8	405	84.6
Completed or conducted by telephone	42	19.4	32	12.2	74	15.4
Total	217	100.0	262	100.0	479	100.0

Table A1.25 Comparison of participants' gender for surveys conducted face-to-face or by telephone

Gender	Face-to-face		Completed or conducted by telephone	
	n	Within column %	n	Within column %
Male	173	42.7	27	36.5
Female	232	57.3	47	63.5
	405	100.0	74	100.0

n=479, χ^2=0.759, df=1, p=0.384

Table A1.26 Comparison of participants' age for surveys conducted face-to-face or by telephone

Age	Face-to-face		Completed or conducted by telephone	
	n	Within column %	n	Within column %
18 to 40	24	5.9	7	9.5
41 to 60	118	29.1	31	41.9
61 to 80	214	52.8	28	37.8
81 and above	49	12.1	8	10.8
	405	100.0	74	100.0

NB: Certain categories with small frequencies were combined to allow meaningful and valid statistical analyses to be conducted.
n=479, χ^2=7.354, df=3, p=0.061

Table A1.27 Comparison of participants' country of birth for surveys conducted face-to-face or by telephone

Country of birth	Face-to-face		Completed or conducted by telephone	
	n	Within column %	n	Within column %
Australia	263	64.9	44	59.5
Overseas	142	35.1	30	40.5
	405	100.0	74	100.0

n=479, χ^2=0.595, df=1, p=0.440

Table A1.28 Comparison of participants' main language spoken at home for surveys conducted face-to-face or by telephone

Main language	Face-to-face		Completed or conducted by telephone	
	n	Within column %	n	Within column %
English	332	82.0	59	79.7
Non-English	73	18.0	15	20.3
	405	100.0	74	100.0

n=479, χ^2=0.087, df=1, p=0.768

Table A1.29 Comparison of participants' highest level of education for surveys conducted face-to-face or by telephone

Highest level of education	Face-to-face		Completed or conducted by telephone	
	n	Within column %	n	Within column %
Primary or below	75	18.6	12	16.2
Secondary	217	53.7	34	45.9
Tertiary	112	27.7	28	37.8
	404	100.0	74	100.0

n=478 (1 missing value), χ^2=3.093, df=2, p=0.213

Table A1.30 Comparison of participants' occupation for surveys conducted face-to-face or by telephone

Occupation	Face-to-face		Completed or conducted by telephone	
	n	Within column %	n	Within column %
White-collar	246	60.7	45	60.8
Blue-collar	98	24.2	10	13.5
Other	61	15.1	19	25.7
	405	100.0	74	100.0

n=479, χ^2=7.388, df=2, p=0.025

Table A1.31 Comparison of participants' current employment status for surveys conducted face-to-face or by telephone

Employment status	Face-to-face		Completed or conducted by telephone	
	n	Within column %	n	Within column %
Working	84	20.8	22	29.7
Retired or not working	320	79.2	52	70.3
	404	100.0	74	100.0

n=478 (1 missing value), χ^2=2.400, df=1, p=0.121

Table A1.32 Comparison of participants' gender for fully and partially completed surveys

Gender	Fully completed		Partially completed	
	n	Within column %	n	Within column %
Male	126	39.3	74	46.8
Female	195	60.7	84	53.2
	321	100.0	158	100.0

n=479, χ^2=2.201, df=1, p=0.138

Table A1.33 Comparison of participants' age for fully and partially completed surveys

Age	Fully completed		Partially completed	
	n	Within column %	n	Within column %
18 to 40	26	8.1	5	3.2
41 to 60	106	33.0	43	27.2
61 to 80	154	48.0	88	55.7
81 and above	35	10.9	22	13.9
	321	100.0	158	100.0

NB: Certain categories with small frequencies were combined to allow meaningful and valid statistical analyses to be conducted.
n=479, χ^2=7.194, df=3, p=0.066

Table A1.34 Comparison of participants' country of birth for fully and partially completed surveys

Country of birth	Fully completed		Partially completed	
	n	Within column %	n	Within column %
Australia	213	66.4	94	59.5
Overseas	108	33.6	64	40.5
	321	100.0	158	100.0

n=479, χ^2=1.878, df=1, p=0.171

Table A1.35 Comparison of participants' main language spoken at home for fully and partially completed surveys

Main language	Fully completed		Partially completed	
	n	Within column %	n	Within column %
English	264	82.2	127	80.4
Non-English	57	17.8	31	19.6
	321	100.0	158	100.0

n=479, χ^2=0.137, df=1, p=0.712

Table A1.36 Comparison of participants' highest level of education for fully and partially completed surveys

Highest level of education	Fully completed		Partially completed	
	n	Within column %	n	Within column %
Primary or below	64	19.9	23	14.6
Secondary	171	53.3	80	51.0
Tertiary	86	26.8	54	34.4
	321	100.0	157	100.0

n=478 (1 missing value), χ^2=3.809, df=2, p=0.149

Table A1.37 Comparison of participants' occupation for fully and partially completed surveys

Occupation	Fully completed		Partially completed	
	n	Within column %	n	Within column %
White-collar	195	60.7	96	60.8
Blue-collar	69	21.5	39	24.7
Other	57	17.8	23	14.6
	321	100.0	158	100.0

n=479, χ^2=1.127, df=2, p=0.569

Table A1.38 Comparison of participants' current employment status for fully and partially completed surveys

Employment status	Fully completed		Partially completed	
	n	Within column %	n	Within column %
Working	78	24.4	28	17.7
Retired or not working	242	75.6	130	82.3
	320	100.0	158	100.0

n=478 (1 missing value), χ^2=2.341, df=1, p=0.126

Table A1.39 Group 1 and Group 2 sample demographics

Patient characteristics		Group 1 (n=217)		Group 2 (n=262)	
		n	%	n	%
Gender	Male	73	33.6	127	48.5
	Female	144	66.4	135	51.5
Age	≤ 60 years	105	48.4	75	28.6
	≥ 61 years	112	51.6	187	71.4
Country of birth	Australia	142	65.4	165	63.0
	Overseas	75	34.6	97	37.0
Main language spoken at home	English	179	82.5	212	80.9
	Other	38	17.5	50	19.1
Highest level of education	≤ Primary	40	18.4	47	17.9
	≥ Secondary	177	81.6	214	81.7
	Missing			1	0.4
Occupation	White-collar	125	57.6	166	63.4
	Blue-collar	47	21.7	61	23.3
	Homemaker	40	18.4	35	13.4
	Miscellaneous	4	1.8		
	Missing	1	0.5		
Employment status	Working	62	28.6	44	16.8
	Not working	154	71.0	218	83.2
	Missing	1	0.5		
Number of medications	median; IQR (n)	5; 3-7 (217)		4; 2-6 (262)	
Duration of disease (years)	median; IQR (n)	10; 3-20 (177)		10; 3-18 (261)	

Table A1.40 Presenting medical conditions

Presenting medical condition	n	%
Hypertension	262	54.7
Rheumatoid arthritis	73	15.2
Musculoskeletal pain (unclassified*)	38	7.9
Osteoarthritis	34	7.1
Arthritis (unclassified*)	20	4.2
Back problems	13	2.7
Systemic lupus erythematosus	7	1.5
Psoriatic arthritis	5	1.0
Polymyalgia rheumatica	5	1.0
Other	22	4.6
Total	479	100.0

*Some patients were unable to specifically name their medical conditions, hence these were put under broad headings.

Table A1.41 Readership by duration of therapy and status of prescription (n=377)

	New				Repeat			
	Short term		Long term		Short term		Long term	
	n	%	n	%	n	%	n	%
Always	271	71.9	338	89.7	7	1.9	16	4.2
Sometimes	48	12.7	39	10.3	7	1.9	84	22.3
Never	54	14.3			357	94.7	276	73.2
Not applicable	4	1.1			6	1.6	1	0.3
Total	377	100.0	377	100.0	377	100.0	377	100.0

Table A1.42 Sections of CMI read (n=113)

Section (in order of appearance in CMI)	n*	%
What is in the leaflet	52	46.0
What the medication is for	86	76.1
Points to note before starting the medication	71	62.8
How to take the medication	82	72.6
Drug interactions	62	54.9
Side effects	103	91.2
Storage	34	30.1
Disposal	16	14.2
Description of medication	17	15.0
Ingredients	22	19.5
Manufacturer	15	13.3

NB: Responses are not mutually exclusive.
*Applicable to participants who reported reading only certain sections of a CMI (1 missing case).

Table A1.43 Third party for whom CMI was read (n=143)

Third party	n	%
Partner	81	56.6
Elderly parent/relative	36	25.2
Child	28	19.6
Friends/colleagues	11	7.7
Other (grandchild, patients, members of support group, neighbours)	12	8.4

NB: Responses are not mutually exclusive.

Table A1.44 Reasons for reading CMI (multiple-choice question) (n=378)

Reason	n*	%
I am concerned about the medication's side effects.	305	80.7
I take other medications and would like to make sure there are no drug interactions.	166	43.9
I have other disease conditions and would like to know if the medication is suitable for me.	132	34.9
I have allergies so I like to check to make sure I am not allergic to the medication.	126	33.3
I want to check that the doctor did not forget anything.	93	24.6
I have had bad experiences with my medications in the past.	85	22.5
I want to check that the pharmacist did not forget anything.	59	15.6

NB: Responses are not mutually exclusive.
*n=378 as the question was directed to all participants who read a CMI (for themselves and/or someone in their care, n=377 and for someone in their care only, n=1).

Table A1.45 Reasons for not reading a CMI (open-ended question) (n=101)

Reason	n*	%
I trust my doctor to prescribe a medication that is suitable for me.	92	91.1
I receive the information I need from my doctor.	89	88.1
I receive the information I need from my pharmacist.	66	65.3
I trust my pharmacist to provide a suitable medication for me.	59	58.4
I have been taking my medication for a long time.	38	37.6
I have taken this medication in the past.	4	4.0

NB: Responses are not mutually exclusive.
*n=101 as the question was directed only to participants who did not read a CMI for themselves nor for someone in their care.

Table A1.46 Other sources of written medicine information (n=126)

WMI sources	n	%
Reference book	76	60.3
Internet	59	46.8
Journal or magazine	20	15.9
Printout	17	13.5
Other	18	14.3

NB: Responses are not mutually exclusive.

Table A1.47 Relationship between "reading" and "seeking" scales and use of CMI

		n	"Reading" scale		"Seeking" scale	
			Median	IQR	Median	IQR
Read CMI (for self)*	Yes	377	10	8 – 10	5	2 – 9
	No	102	2	2 – 4	2	2 – 2
Read CMI (for someone in care)*	Yes	143	10	9 – 10	6	2 – 10
	No	336	8	4 – 10	2	2 – 6
Used other sources of WMI*	Yes	125	10	9 – 10	9	6 – 10
	No	354	8	4 – 10	2	2 – 5

*Mann-Whitney U test $p<0.001$ for all variables.

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Table A1.48 Relationship between interest in reading and seeking WMI and use of CMI

		Read CMI (for self)*				Read CMI (for someone in care)*				Used other sources of WMI*			
		Yes		No		Yes		No		Yes		No	
		n	%	n	%	n	%	n	%	n	%	n	%
Reading	Interested	328	87.0	8	7.8	134	93.7	202	60.1	219	61.9	117	93.6
	Not interested	49	13.0	94	92.2	9	6.3	134	39.9	135	38.1	8	6.4
Total		377	100.0	102	100.0	143	100.0	336	100.0	354	100.0	125	100.0
Seeking	Interested	150	39.8	1	1.0	71	49.7	80	23.8	61	17.2	90	72.0
	Not interested	227	60.2	101	99.0	72	50.3	256	76.2	293	82.8	35	28.0
Total		377	100.0	102	100.0	143	100.0	336	100.0	354	100.0	125	100.0

NB: Percentages refer to within column percentages.
*Chi-square test p<0.001

Table A1.49 Relationship between patient factors and "reading" and "seeking" scales

		Reading					Seeking				
		Interested		Not interested		Statistics	Interested		Not interested		Statistics
		n	%	n	%		n	%	n	%	
Disease state[a]	Hypertension	168	64.1	94	35.9	χ^2=9.40	61	23.3	201	76.7	χ^2=18.20
	Pain/rheumatology	168	77.4	49	22.6	p=0.002	90	41.5	127	58.5	p<0.001
Coping style[a]	Blunter	83	69.7	36	30.3	χ^2=4.12	43	36.1	76	63.9	χ^2=0.44
	Monitor	135	80.8	32	19.2	p=0.042	68	40.7	99	59.3	p=0.509
Health literacy[a]	Inadequate	25	43.1	33	56.9	χ^2=32.74	6	10.3	52	89.7	χ^2=19.05
	Marginal	10	76.9	3	23.1	p<0.001	4	30.8	9	69.2	p<0.001
	Adequate	231	79.4	60	20.6		117	40.2	174	59.8	
Health locus of control[b]	Internal					Z=-0.066					Z=-1.075
						p=0.948					p=0.282
	Chance					Z=-1.940					Z=-2.126
						p=0.052					p=0.033
	Powerful other					Z=-2.589					Z=-3.977
						p=0.010					p<0.001

[a]Chi-square test; [b]Mann-Whitney U test

Table A1.50 Relationship between pain as a symptom and interest in reading and seeking WMI

		Pain as a symptom			
		Absent		Present	
		n	%	n	%
Reading*	Interested	120	67.8	216	71.5
	Not interested	57	32.2	86	28.5
Total		177	100.0	302	100.0
Seeking**	Interested	40	22.6	111	36.8
	Not interested	137	77.4	191	63.2
Total		177	100.0	302	100.0

NB: Percentages refer to within column percentages.
*χ^2=0.573, df=1, p=0.449; **χ^2=9.714, df=1, p=0.002

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Table A1.51 Relationship between patient demographics and "reading" and "seeking" scales

		Reading					Seeking				
		Interested		Not interested		Statistics	Interested		Not interested		Statistics
		n	%	n	%		n	%	n	%	
Gender[a]	Male	122	61.0	78	39.0	χ^2=12.98, p<0.001	56	28.0	144	72.0	χ^2=1.705, p=0.192
	Female	214	76.7	65	23.3		95	34.1	184	65.9	
Age[a]	≤ 60 years	138	76.7	42	23.3	χ^2=5.37, p=0.021	77	42.8	103	57.2	χ^2=16.09, p<0.001
	≥ 61 years	198	66.2	101	33.8		74	24.7	225	75.3	
Country of birth[a]	Australia	228	74.3	79	25.7	χ^2=6.40, p=0.011	103	33.6	204	66.4	χ^2=1.38, p=0.241
	Overseas	108	62.8	64	37.2		48	27.9	124	72.1	
Main language spoken at home[a]	English	285	72.9	106	27.1	χ^2=6.96, p=0.008	132	33.8	259	66.2	χ^2=4.38, p=0.036
	Other	51	58.0	37	42.0		19	21.6	69	78.4	
Highest level of education[a]	≤ Primary	51	58.6	36	41.4	χ^2=5.87, p=0.015	15	17.2	72	82.8	χ^2=8.76, p=0.003
	≥ Secondary	282	72.5	107	27.5		133	34.2	256	65.8	
Occupation[a]	White-collar	213	73.2	78	26.8	χ^2=19.68, p<0.001	103	35.4	188	64.6	χ^2=8.26, p=0.016
	Blue-collar	58	53.7	50	46.3		22	20.4	86	79.6	
	Homemaker	61	81.3	14	18.7		24	32.0	51	68.0	
Employment status[a]	Working	75	71.4	30	28.6	χ^2=0.042, p=0.838	45	42.9	60	57.1	χ^2=7.34, p=0.007
	Not working	261	69.8	113	30.2		106	28.3	268	71.7	
Number of medications[b]						Z=-0.282, p=0.778					Z=-0.860, p=0.390
Duration of disease of interest[b]						Z=-1.279, p=0.201					Z=-1.385, p=0.166

[a]Chi-square test; [b]Mann-Whitney U test

Table A1.52 Logistic regression of interest in reading (using presence of pain)

Independent variables		Regression coefficient	Wald test (z-ratio)	p	Odds ratio	95% confidence interval
Presence of pain	- no, yes (ind)	0.336	0.900	0.343	1.442	0.677 – 3.072
Chance HLC		-0.019	0.362	0.548	0.981	0.921 – 1.045
Powerful other HLC		-0.042	1.617	0.203	0.959	0.899 – 1.023
Coping style	- blunter, monitor (ind)	0.816	6.372	0.012	2.262	1.200 – 4.262
Health literacy	- inadequate, marginal (ind)	1.782	3.559	0.059	5.941	0.933 – 37.827
	- inadequate, adequate (ind)	1.396	7.857	0.005	4.041	1.522 – 10.728
Gender	- male, female (ind)	0.465	1.834	0.176	1.591	0.812 – 3.117
Age (years)	- ≤ 60, ≥ 61 (ind)	0.114	0.110	0.740	1.121	0.570 – 2.205
Country of birth	- other, Australia (ind)	0.435	1.213	0.271	1.544	0.713 – 3.347
Main language spoken at home	- other, English (ind)	-0.518	1.003	0.317	0.596	0.216 – 1.642
Highest level of education	- ≤ primary, ≥ secondary (ind)	0.226	0.231	0.631	1.253	0.499 – 3.146
Occupation	- homemaker, white (ind)	-0.872	2.598	0.107	0.418	0.145 – 1.207
	- homemaker, blue (ind)	-1.408	5.585	0.018	0.245	0.076 – 0.786
n		282				
Model χ^2 test		χ^2=39.697, df=13, p<0.001				
Hosmer & Lemeshow test		χ^2=8.838, df=8, p=0.356				
Nagelkerke R^2		0.196				

(ind) = indicator category

Table A1.53 Logistic regression for interest in seeking WMI (using presence of pain)

Independent variables		Regression coefficient	Wald test (z-ratio)	p	Odds ratio	95% confidence interval
Disease state	- hypertension, pain/rheumatology (ind)	0.503	3.108	0.078	1.653	0.945 – 2.892
Chance HLC		0.010	0.179	0.673	1.011	0.963 – 1.061
Powerful other HLC		-0.058	5.285	0.022	0.944	0.898 – 0.991
Health literacy	- inadequate, marginal (ind)	1.533	3.902	0.048	4.630	1.012 – 21.184
	- inadequate, adequate (ind)	1.504	8.044	0.005	4.499	1.591 – 12.718
Age (years)	- ≤ 60, ≥ 61 (ind)	-0.310	1.149	0.284	0.734	0.416 – 1.293
Main language spoken at home	- other, English (ind)	0.029	0.006	0.940	1.030	0.483 – 2.193
Highest level of education	- ≤ primary, ≥ secondary (ind)	0.381	1.037	0.309	1.463	0.703 – 3.046
Occupation	- homemaker, white (ind)	-0.020	0.003	0.953	0.980	0.501 – 1.917
	- homemaker, blue (ind)	-0.401	0.931	0.335	0.669	0.296 – 1.513
Employment status	- retired/not working, working (ind)	0.090	0.071	0.790	1.094	0.563 – 2.128
n		356				
Model χ^2 test		χ^2=42.869, df=11, p<0.001				
Hosmer & Lemeshow test		χ^2=8.238, df=8, p=0.411				
Nagelkerke R^2		0.157				

(ind) = indicator category

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Table A1.54 Summary of scores for items in the comprehension subscale

How easy or hard the information in CMI is to... ?	n	Median	IQR
Read	309	4	4 – 5
Understand	309	4	4 – 5
Remember	307	4	3 – 4
Locate important information	307	4	4 – 5
Keep for future reference	307	4	3 – 5

Table A1.55 Summary of scores for items in the future use subscale

How likely is it that you would... the CMI?	n	Median	IQR
Read	307	5	5 – 5
Use/refer	307	4	1 – 4
Keep	307	5	2 – 5

Table A1.56 Summary of scores for items in the utility subscale

Opinion on the quantity and usefulness of the information provided on... in the CMI	Quantity[a]				Usefulness		
	Too much/ too little/ none at all		About right		n	Median	IQR
	n	%	n	%			
Benefits of taking the medication	52	18.0	237	82.0	291	3	2 – 3
Who should not use the medication	40	13.9	248	86.1	290	3	2 – 3
Specific directions on how to take the medication	32	11.1	256	88.9	290	3	2 – 3
Precautions while using the medication	32	11.0	258	89.0	291	3	2 – 3
Possible side effects	41	14.1	249	85.9	290	3	2 – 3
What to do about side effects	37	12.8	253	87.2	291	3	2 – 3
How to store the medication	35	12.1	255	87.9	291	3	2 – 3
General information	44	15.3	243	84.7	291	2	2 – 3

[a]Quantity of information was scored 0 (too much/ too little/ none at all) or 1 (about right) hence was summarised in a different format to make it more informative.
NB: The utility subscale score is the sum of the quantity of information score and the usefulness of information score.

Table A1.57 Summary of scores for items in the design quality subscale

Opinion on... of CMI	n	Median	IQR
Organisation	297	5.0	4.0 – 5.0
Attractiveness	297	4.0	3.0 – 5.0
Print size	298	5.0	3.8 – 5.0
Tone	295	4.0	3.0 – 5.0
Helpfulness	297	5.0	4.0 – 5.0
Bias	289	5.0	4.0 – 5.0
Spacing	297	5.0	5.0 – 5.0

Table A1.58 Relationship between patient characteristics and weighted subscale scores

		Comprehension			Future Use			Utility			Design Quality		
		n	Median	IQR	n	Median	IQR	n	Median	IQR	n	Median	IQR
Gender[a]	Male	117	4.0	3.6-4.4	118	4.0**	3.0-4.7	111	4.1*	3.6-5.0	113	4.4*	3.9-4.7
	Female	188	4.0	3.6-4.6	189	4.7	3.3-4.7	170	4.5	3.8-5.0	176	4.4	4.1-4.8
Age[a]	≤ 60	128	4.1	3.8-4.6	130	4.3	3.0-4.8	119	4.1***	3.6-4.8	125	4.3***	3.9-4.6
	≥ 61	177	4.0	3.6-4.4	177	4.3	3.3-4.7	162	4.7	3.8-5.0	164	4.6	4.1-4.9
Main language spoken at home[a]	English	252	4.0***	3.8-4.6	254	4.3**	3.3-4.7	240	4.4**	3.8-5.0	245	4.4	4.0-4.7
	Other	53	3.6	3.0-4.1	53	3.7	2.5-4.7	41	3.8	3.0-5.0	44	4.4	3.8-4.7
Highest level of education[a]	≤ Primary	57	3.8***	3.2-4.2	56	3.8	3.0-4.7	45	4.8	3.8-5.0	47	4.7**	4.1-4.9
	≥ Secondary	248	4.0	3.8-4.6	251	4.3	3.3-4.7	236	4.3	3.8-5.0	242	4.4	4.0-4.7
Health literacy[b]	Inadequate	39	3.6***	2.8-3.8	39	3.7***	2.3-4.7	26	3.8	3.7-5.0	30	4.4	3.9-4.7
	Marginal	6	3.6	3.0-3.8	6	3.5	2.2-4.7	6	4.0	2.6-5.0	5	4.7	3.9-5.0
	Adequate	256	4.0	3.8-4.6	258	4.5	3.3-4.7	246	4.4	3.8-5.0	250	4.4	4.0-4.7
Occupation[b]	White-collar	191	4.0*	3.6-4.6	192	4.3	3.1-4.7	179	4.4	3.8-5.0	186	4.4	4.0-4.7
	Blue-collar	57	4.0	3.4-4.4	58	4.0	3.0-4.7	49	4.1	3.8-5.0	51	4.4	3.7-4.7
	Homemaker	52	4.0	3.6-4.4	52	4.7	3.3-5.0	49	5.0	3.8-5.0	48	4.5	4.1-4.9

	Comprehension		Future Use		Utility		Design Quality	
	n	R	n	R	n	R	n	R
Number of medications[c]	305	-0.03	307	0.03	281	0.13**	289	0.07
Duration of disease of interest[c]	266	0.00	267	0.09	249	-0.05	253	-0.09

[a]Mann-Whitney U test; [b]Kruskal-Wallis test; [c]Spearman's correlation; R = correlation coefficient; ***p<0.01, **p<0.05, *p<0.1

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Table A1.59 Outliers in the adapted CIRF regression models

Regression model	Outlier*	Standardised residual	Observed value	Predicted value
Comprehension	# 1	-3.490	1.80	4.12
Future use (patient characteristics as predictors)	Nil			
Utility	# 1	-3.354	1.25	4.12
	# 2	-3.368	1.25	4.13
	# 3	-3.304	1.25	4.07
	# 4	-3.735	1.25	4.44
Design quality	Nil			
Future use (CIRF subscales as predictors)	#1	-3.34	1.00	4.30

*Outliers are numbered arbitrarily.

Figure A1.1 Scatterplot of the regression standardised residuals for the comprehension subscale

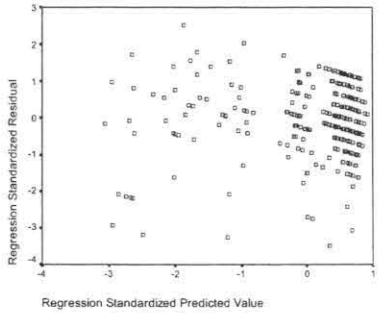


Figure A1.2 Scatterplot of the regression standardised residuals for the future use subscale (with patient characteristics as predictors)

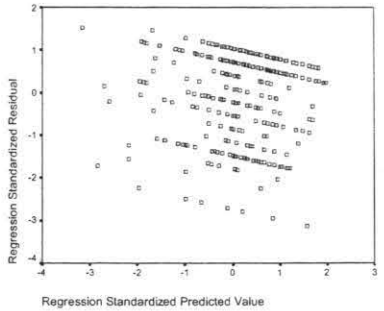


Figure A1.3 Scatterplot of the regression standardised residuals for the utility subscale

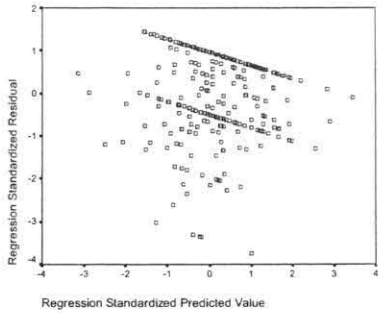


Figure A1.4 Scatterplot of the regression standardised residuals for the design quality subscale

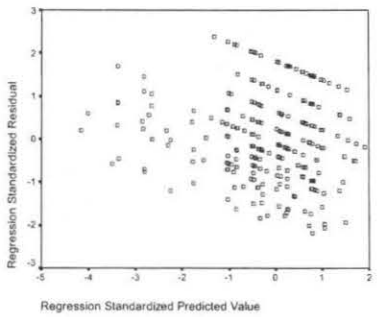


Figure A1.5 Scatterplot of the regression standardised residuals for the future use subscale (with CIRF subscales as predictors)

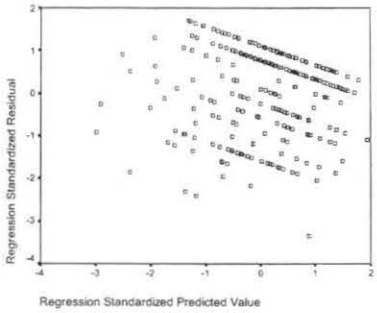


Figure A1.6 Normal probability plot of the regression standardised residuals for the comprehension subscale

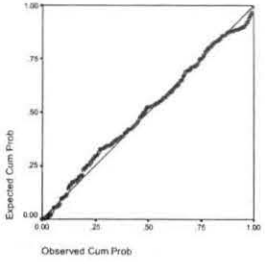


Figure A1.7 Normal probability plot of the regression standardised residuals for the future use subscale (with patient characteristics as predictors)

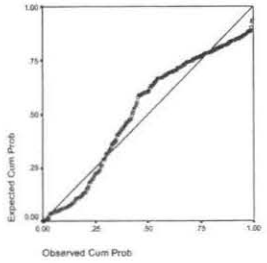


Figure A1.8 Normal probability plot of the regression standardised residuals for the utility subscale

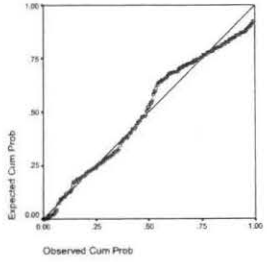


Figure A1.9 Original normal probability plot of the regression standardised residuals for the design quality subscale

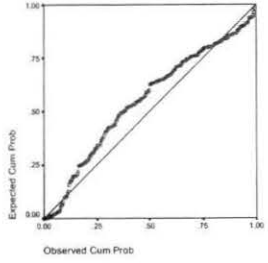


Figure A1.10 Reflect inverse transformed probability plot of the regression standardised residuals for the design quality subscale

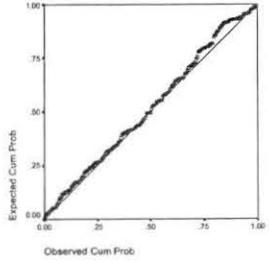
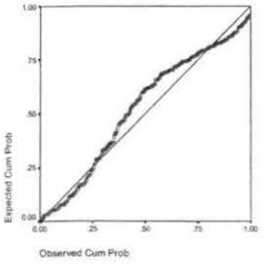


Figure A1.11 Normal probability plot of the regression standardised residuals for the future use subscale (with CIRF subscales as predictors)



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APPENDIX F

- WMI Study Phase 1 questionnaire
- Common medications for arthritis
- Common medications for high blood pressure
- WMI Study Phase 1 show cards

Code:_____ Date: ___/___/___

Consumer Medicine Information (CMI) Questionnaire

Section A

1. (a) How interested would you say you are in reading written information about your prescription medicines?

1 2 3 4 5

Not interested at all — Very interested

(b) How likely are you to seek written information about your prescription medicines?

1 2 3 4 5

Not likely at all — Very likely

(c) Typically, how often would you seek written information about your prescription medicines?

1 2 3 4 5

Not often at all — Very often

(d) How likely are you to read written information about your prescription medicines?

1 2 3 4 5

Not likely at all — Very likely

One form of written information about medicines is known as Consumer Medicine Information. Below are some general questions on Consumer Medicine Information and how you use them.

2. Are you aware of what Consumer Medicine Information (CMI for short) is?

Yes ☐1 go to Q 3
No ☐2 please explain what CMI is, then go to Q 3

> Consumer Medicine Information (or CMI as it is called for short), is written information about medications produced by the manufacturer that comes with prescription medications. CMI provides you with information about your medications, such as how and when to take it, and what to expect after taking it. CMI comes in three different forms: a printed sheet that comes inside your medication box, a loose leaflet given to you with the medication or a computer print out given to you at the pharmacy.

3. Have you ever read CMI for any of <u>your own</u> medications?

Yes ☐1 go to Q 4
No ☐2 go to Q 9

4. Typically, how often would you say you read a CMI for a <u>new</u> medication that was prescribed for ...?

	Always	Sometimes	Never
Short term use (less than 2 weeks)	☐	☐	☐
Long term use (2 weeks or more)	☐	☐	☐

→ go to Q 5

5. Typically, how often would you say you read a CMI for a repeat medication or a medication that you have had in the past that was prescribed for ...?

	Always	Sometimes	Never
Short term use (less than 2 weeks)	☐	☐	☐
Long term use (2 weeks or more)	☐	☐	☐

→ go to Q 6

6. Typically, when you read CMI, how much of the CMI would you read?

All sections ☐1 go to Q 8
Most sections ☐2 go to Q 7
Some sections ☐3 go to Q 7

7. What sections of the CMI would you usually read? *(you may tick more than one box)*

What is in the leaflet ☐1
What the medication is for ☐2
Points to note before starting the medication ☐3
How to take the medication ☐4
Drug interactions ☐5
Side effects ☐6 → go to Q 8
Storage ☐7
Disposal ☐8
Description of medication ☐9
Ingredients ☐10
Manufacturer ☐11
Others (please specify) _____ ☐12

8. What did you do with the CMI after you read it?

- Kept it until I finished the medication ☐1
- Filed it away for future reference ☐2
- Shared it with someone else on the same medication ☐3 → go to Q 9
- Threw it away ☐4
- Other (please specify) _____ ☐5

9. Have you ever read CMI for the medications of someone in your care (e.g. child, elderly parent, partner)?

- Yes ☐1 go to Q 10
- No ☐2 if from Q 8, go to Q 11; if from Q 3, go to Q 12

10. Whose CMI did you read? *(you may tick more than one box)*

- Child ☐1
- Grandchild ☐2
- Partner ☐3 → go to Q 11
- Elderly parent/ relative ☐4
- Other (please specify) _____ ☐5

11. What are your reasons for reading a CMI?

_____

_____

_____

Below are some reasons that other people have given for reading the CMI. Do any of the following apply to you? *(you may tick more than one box)*

- I am concerned about the medication's side effects. ☐1
- I have allergies so I like to check to make sure I am not allergic to the medication. ☐2
- I want to check that the doctor did not forget anything. ☐3
- I want to check that the pharmacist did not forget anything. ☐4 → go to Q 13
- I have had bad experiences with my medications in the past. ☐5
- I have other disease conditions and would like to know if the medication is suitable for me. ☐6
- I take other medications and would like to make sure there are no drug interactions. ☐7

12. What are your reasons for not reading a CMI?

_____

_____

_____

Below are some reasons that other people have given for not reading the CMI. Do any of the following apply to you? *(you may tick more than one box)*

- I receive the information I need from my doctor. ☐1
- I receive the information I need from my pharmacist. ☐2
- I trust my doctor to prescribe a medication that is suitable for me. ☐3 → go to Q13
- I trust my pharmacist to provide a suitable medication for me. ☐4
- I have been taking my medication for a long time. ☐5
- I have taken this medication in the past. ☐6

13. Apart from the CMI, where do you find written information about your prescription medicines? *(you may tick more than one box)*

- Internet ☐1
- Reference books (please specify) _____ ☐2
- Print-outs (from _____) ☐3 → go to Q14
- Journals or magazines (please specify) _____ ☐4
- Other (please specify) _____ ☐5

I don't (because _____) ☐6 go to Section B

14. Consider all the different types of written medicine information that you have used in the past. Please rank your top 3 choices in terms of how often you use them and then in terms of usefulness (with '1' being the most frequently used or the most useful).

	How often you used it?	How useful you found it?
CMI	☐1a	☐1b
Internet	☐2a	☐2b
Reference books	☐3a	☐3b
Print-outs	☐4a	☐4b
Journals or magazines	☐5a	☐5b
Other	☐6a	☐6b

Section B

You will now be shown a CMI for one of your medications and given about 10 minutes to read it. After that, we would appreciate it if you could give us your opinion about this particular CMI by answering the questions below.

1. Overall, how easy or hard would you say the information in the CMI is to .....?

	Very easy	Quite easy	In between	Quite hard	Very hard
♦ Read	❒	❒	❒	❒	❒1
♦ Understand	❒	❒	❒	❒	❒2
♦ Remember	❒	❒	❒	❒	❒3
♦ Locate important information	❒	❒	❒	❒	❒4
♦ Keep for future reference	❒	❒	❒	❒	❒5

2. If you were taking this medication for the first time and found this CMI in the medication box (for package inserts)/ received this CMI from the pharmacist (for computer print out) (delete whichever is not applicable), how likely is it that you would ..... the CMI?

	Very likely	Somewhat likely	Unsure	Somewhat unlikely	Very unlikely
♦ Read	❒	❒	❒	❒	❒1
♦ Use	❒	❒	❒	❒	❒2
♦ Keep	❒	❒	❒	❒	❒3

3. Below is a list of topics. Please indicate your opinion about how much information was provided on each topic and how useful you think this information would be if you were taking this medicine for the first time.

	How much information?				*How useful is the info?*		
	Too much	About right	Too little	None at all	Very useful	Fairly useful	Not so useful
♦ The benefits of taking the medication	❒	❒	❒	❒1a	❒	❒	❒1b
♦ Who should not use the medication	❒	❒	❒	❒2a	❒	❒	❒2b
♦ Specific directions about how to take the medication	❒	❒	❒	❒3a	❒	❒	❒3b
♦ Precautions that need to be taken while using the medication	❒	❒	❒	❒4a	❒	❒	❒4b
♦ Possible side effects	❒	❒	❒	❒5a	❒	❒	❒5b
♦ What to do about side effects	❒	❒	❒	❒6a	❒	❒	❒6b
♦ How to store the medication	❒	❒	❒	❒7a	❒	❒	❒7b
♦ General information (e.g. description of medication)	❒	❒	❒	❒8a	❒	❒	❒8b

4. Below is a list of words on a scale of 1 - 5 describing the design, layout and tone of the CMI. Which best describes your opinion?

	1	2	3	4	5	
poorly organized						well organized
unattractive						attractive
poor print size						ideal print size
alarming in tone						encouraging in tone
unhelpful						helpful
biased						unbiased
poor spacing between lines						ideal spacing between lines

5. Do you have any other comments about this particular CMI?

_____

_____

_____

Section C

Below are a series of statements which describe how people view their health. Please read each statement carefully and show whether you agree or disagree with these statements by ticking the appropriate box.

	Strongly disagree	Disagree	Slightly disagree	Slightly agree	Agree	Strongly agree
♦ If I get sick, it is my own behaviour which determines how soon I get well again.	❒	❒	❒	❒	❒	❒
♦ No matter what I do, if I am going to get sick, I will get sick.	❒	❒	❒	❒	❒	❒
♦ Having regular contact with my physician is the best way for me to avoid illness.	❒	❒	❒	❒	❒	❒
♦ Most things that affect my health happen to me by accident.	❒	❒	❒	❒	❒	❒
♦ Whenever I don't feel well, I should consult a medically trained professional.	❒	❒	❒	❒	❒	❒
♦ I am in control of my health.	❒	❒	❒	❒	❒	❒
♦ My family has a lot to do with my becoming sick or staying healthy.	❒	❒	❒	❒	❒	❒
♦ When I get sick, I am to blame.	❒	❒	❒	❒	❒	❒
♦ Luck plays a big part in determining how soon I recover from illness.	❒	❒	❒	❒	❒	❒
♦ Health professionals control my health.	❒	❒	❒	❒	❒	❒
♦ My good health is largely a matter of good fortune.	❒	❒	❒	❒	❒	❒
♦ The main thing which affects my health is what I myself do.	❒	❒	❒	❒	❒	❒
♦ If I take care of myself, I can avoid illness.	❒	❒	❒	❒	❒	❒
♦ When I recover from an illness, it's usually because other people (for example doctors, nurses, family, friends) have been taking good care of me.	❒	❒	❒	❒	❒	❒
♦ No matter what I do, I'm likely to get sick.	❒	❒	❒	❒	❒	❒
♦ If it's meant to be, I will stay healthy.	❒	❒	❒	❒	❒	❒
♦ If I take the right actions, I can stay healthy.	❒	❒	❒	❒	❒	❒
♦ Regarding my health, I can only do what my doctor tells me to do.	❒	❒	❒	❒	❒	❒

Section D

In the section below, you will be asked to imagine that you find yourself in a particular scene. This is followed by eight responses. Please tick all responses that might apply to you. You can tick more than one response.

1. Vividly imagine that you are <u>afraid</u> of the dentist and have to get some dental work done. Which of the following would you do? Tick <u>all</u> of the statements that might apply to you.

- ♦ I would ask the dentist exactly what work was going to be done. ❒
- ♦ I would take a tranquilizer or have a drink before going. ❒
- ♦ I would try to think about pleasant memories. ❒
- ♦ I would want the dentist to tell me when I would feel pain. ❒
- ♦ I would try to sleep. ❒
- ♦ I would watch all the dentist's movements and listen for the sound of the drill. ❒
- ♦ I would watch the flow of water from my mouth to see if it contained blood. ❒
- ♦ I would do mental puzzles in my mind. ❒

2. Vividly imagine that, due to a large drop in sales, it is rumoured that several people in your department at work will be laid off. Your supervisor has turned in an evaluation of your work for the past year. The decision about lay-offs has been made and will be announced in several days. Tick <u>all</u> of the statements that might apply to you.

- ♦ I would talk to my fellow workers to see if they knew anything about what the supervisor evaluation of me said. ❒
- ♦ I would review the list of duties for my present job and try to figure out if I had fulfilled them all. ❒
- ♦ I would go to the movies to take my mind off things. ❒
- ♦ I would try to remember any arguments or disagreements I might have had that would have resulted in the supervisor having a lower opinion of me. ❒
- ♦ I would push all thoughts of being laid off out of my mind. ❒
- ♦ I would tell my spouse that I'd rather not discuss my chances of being laid off. ❒
- ♦ I would try to think which employees in my department the supervisor might have thought had done the worst job. ❒
- ♦ I would continue doing my work as if nothing special was happening. ❒

Section E

In the section below, there are two passages with a few sentences that have some of the words missing. Where a word is missing, a blank line is drawn, and 4 possible words that could go in the blank appear just below it in the box. *Please fill in the blanks by circling the letter in front of the word which makes the sentence make sense.* You have 7 minutes to complete as much of this as you can.

PASSAGE A

Your doctor has sent you to have a _____ X-ray. You must have an

a. stomach
b. diabetes
c. stitches
d. germs

_____ stomach when you come for _____. The X-ray will _____ from

a. asthma
b. empty
c. incest
d. anaemia

a. is
b. am
c. if
d. it

a. take
b. view
c. talk
d. look

1 to 3 _____ to do.

a. beds
b. brains
c. hours
d. diets

THE DAY BEFORE THE X-RAY.

For supper have only a _____ snack of fruit, _____ and jelly, with coffee

a. little
b. broth
c. attack
d. nausea

a. toes
b. throat
c. toast
d. thigh

or tea. After _____, you must not _____ or drink anything at _____

a. minute
b. midnight
c. during
d. before

a. easy
b. ate
c. drank
d. eat

a. ill
b. all
c. each
d. any

until after you have _____ the X-ray.

a. are
b. has
c. had
d. was

THE DAY OF THE X-RAY.

Do not eat _____. Do not _____, even _____.

a. appointment
b. walk-in
c. breakfast
d. clinic

a. drive
b. drink
c. dress
d. dose

a. heart
b. breath
c. water
d. cancer

If you have any _____, call the X-ray _____ on 9616 4500.

a. answers
b. exercises
c. tracts
d. questions

a. Department
b. Sprain
c. Pharmacy
d. Toothache

PASSAGE B

I agree to give correct information to _____ (a. hair, b. salt, c. see, d. ache) if I can receive health benefits.

I _____ (a. agree, b. probe, c. send, d. gain) to provide the government information to _____ (a. hide, b. risk, c. discharge, d. prove) any statements given in this _____ (a. emphysema, b. application, c. gallbladder, d. relationship) and hereby give permission to the _____ (a. inflammation, b. religion, c. iron, d. government) to get such proof. I _____ (a. investigate, b. entertain, c. understand, d. establish) that for my health benefits, I must report any _____ (a. changes, b. hormones, c. antacids, d. charges) in my circumstances within _____ (a. three, b. one, c. five, d. ten) (10) days of becoming _____ (a. award, b. aware, c. away, d. await) of the change. I understand _____ (a. thus, b. this, c. that, d. than) if I DO NOT like the _____ (a. marital, b. occupation, c. adult, d. decision) made on

my case, I have the _____ (a. bright, b. left, c. wrong, d. right) to a fair hearing. I can _____ (a. request, b. refuse, c. fail, d. mend) a hearing by writing or _____ (a. counting, b. reading, c. calling, d. smelling) the centre where I applied.

If you _____ (a. wash, b. want, c. cover, d. tape) additional benefit for any family _____ (a. member, b. history, c. weight, d. seatbelt), you will have to _____ (a. relax, b. break, c. inhale, d. sign) a different application form. _____ (a. Since, b. Whether, c. However, d. Because) we will use the _____ (a. lung, b. date, c. meal, d. pelvic) on this form to determine your _____ (a. hypoglycaemia, b. eligibility, c. osteoporosis, d. schizophrenia).

Total: _____

0-16	❒1
17-22	❒2
23-36	❒3

Section F

The following questions collect some demographic details about you. Please answer all questions.

1. Sex:
- Male ❒1
- Female ❒2

2. Age: ____ years

3. Country of birth:
- Australia ❒1
- Overseas ❒ please state _____

4. Main language spoken at home:
- English ❒1
- Other ❒ please state _____

5. Other languages spoken at home *(can list more than one)*:
- English ❒1
- None ❒2
- Other ❒ please state _____

6. Highest level of education:
- None ❒1
- Primary school ❒2
- School Certificate (Year 10) ❒3
- Higher School Certificate (Year 12) ❒4
- Trade or other certificate ❒5
- Tertiary (Diploma, Bachelor or higher) ❒6

7. Occupation:
- Managers and administrators ❒1
- Professionals and associate professionals ❒2
- Tradespersons and related workers ❒3
- Clerical workers ❒4
- Production and transport workers ❒5
- Sales and service workers ❒6
- Labourers and related workers ❒7

→ go to Q 8

- Homemaker ❒8 go to Q 9
- Student ❒9 go to Q 9
- Others (please specify) _____ ❒10 go to Q 8

Code:_____ Date: ___/___/___

8. Employment status:
- Full time ❒1
- Part time ❒2
- Retired ❒3
- Unable to work due to health reasons ❒4
- Unemployed ❒5

9. Current medical conditions:

_____
_____
_____

10. Current medications prescribed by doctor:

_____
_____
_____

Thank you for participating in this study. Your time is greatly appreciated and your input is highly valued. Are there any comments relevant to CMIs or written drug information which you would like to make?

_____
_____
_____
_____
_____
_____

GENERIC NAME	COMMON BRAND NAMES
Auranofin	Ridaura®
Azathioprine	Imuran® Thioprine®
Celecoxib	Celebrex®
Chloroquine	Chlorquin®
Codeine	Codeine Phosphate
Codeine/ paracetamol	Panadeine Forte®
Cortisone	Cortate®
Cyclophosphamide	Cycloblastin®
Cyclosporin	Neoral® Sandimmun®
Dexamethasone	Dexmethsone®
Dextropropoxyphene/ paracetamol	Capadex® Di-Gesic® Paradex®
Diclofenac	Fenac® Voltaren®
Diflunisal	Dolobid®
Hydrocortisone	Hysone®
Hydroxychloroquine	Plaquenil®
Ibuprofen	Brufen®
Indomethacin	Arthrexin® Indocid®
Ketoprofen	Orudis® Oruvail®
Leflunomide	Arava®

COMMON MEDICATIONS FOR ARTHRITIS

GENERIC NAME	COMMON BRAND NAMES
Meloxicam	Mobic®
Methotrexate	Ledertrexate® Methoblastin® Methotrexate tablets (Fauldings)
Morphine	Kapanol® MS Contin® MS Mono®
Naproxen	Inza® Naprosyn® Proxen®
Oxycodone	Endone® Oxycontin® Oxynorm®
Paracetamol	Panamax®
Penicillamine	D-Penamine®
Piroxicam	Feldene® Mobilis® Rosig®
Prednisolone	Panafcortelone® Solone®
Prednisone	Panafcort® Sone®
Rofecoxib	Vioxx®
Sulfasalazine	Pyralin® Salazopyrin®
Sulindac	Clinoril®
Tramadol	Tramal®

GENERIC NAME	COMMON BRAND NAMES
Amlodipine	Norvasc®
Atenolol	Noten® Tenormin® Tensig®
Bendrofluazide	Aprinox®
Candesartan	Atacand®
Candesartan/ HCT	Atacand Plus®
Captopril	Acenorm® Capoten®
Clonidine	Catapres®
Diltiazem	Cardizem® Coras® Vasocardol®
Enalapril	Alphapril® Amprace® Auspril® Renitec®
Enalapril/ HCT	Renitec Plus®
Eprosartan	Teveten®
Eprosartan/ HCT	Teveten Plus®
Felodipine	Agon® Felodur® Plendil®
Fosinopril	Monopril®
Fosinopril/ HCT	Monoplus®
Hydralazine	Alphapress®
Hydrochlorothiazide (HCT)	Dichlotride®
HCT/ amiloride	Amizide® Moduretic®
HCT/ triamterene	Hydrene®
Indapamide	Natrilix® Natrilix SR® Dapa-tabs®
Irbesartan	Avapro® Karvea®

COMMON MEDICATIONS FOR HIGH BLOOD PRESSURE

GENERIC NAME	COMMON BRAND NAMES
Irbesartan/ HCT	Avapro HCT® Karvezide®
Lercanidipine	Zanidip®
Lisinopril	Lisodur® Prinivil® Zestril®
Methyldopa	Aldomet®
Metoprolol	Betaloc® Lopresor® Minax®
Nifedipine	Adalat® Adalat Oros® Nifecard®
Perindopril	Coversyl®
Perindopril/ indapamide	Coversyl Plus®
Prazosin	Minipress® Pressin®
Propranolol	Deralin® Inderal®
Quinapril	Accupril® Asig®
Quinapril/ HCT	Accuretic®
Ramipril	Ramace® Tritace®
Telmisartan	Micardis® Pritor®
Telmisartan/ HCT	Micardis Plus®
Trandolapril	Gopten® Odrik®
Verapamil	Anpec® Cordilox® Isoptin® Veracaps®

Section A (Question 1)

(a) How interested would you say you are in reading written information about your prescription medicines?

1	2	3	4	5
Not interested at all				Very interested

(b) How likely are you to seek written information about your prescription medicines?

1	2	3	4	5
Not likely at all				Very likely

(c) Typically, how often would you seek written information about your prescription medicines?

1	2	3	4	5
Not often at all				Very often

(d) How likely are you to read written information about your prescription medicines?

1	2	3	4	5
Not likely at all				Very likely

Section A (Question 14)

Consider all the different types of written medicine information that you have used in the past. Please rank your top 3 choices in terms of how often you use them and then in terms of usefulness (with '1' being the most frequently used or the most useful).

	How often you used it?	How useful you found it?
CMI	❒	❒
Internet	❒	❒
Reference books	❒	❒
Print-outs	❒	❒
Journals or magazines	❒	❒
Other	❒	❒

Section B (1 of 4)

1. Overall, how easy or hard would you say the information in the CMI is to .....?

	Very easy	Quite easy	In between	Quite hard	Very hard
Read	❒	❒	❒	❒	❒
Understand	❒	❒	❒	❒	❒
Remember	❒	❒	❒	❒	❒
Locate important information	❒	❒	❒	❒	❒
Keep for future reference	❒	❒	❒	❒	❒

Section B (Cont'd- 2 of 4)

2. If you were taking this medication for the first time and found this CMI in the medication box (for package inserts)/ received this CMI from the pharmacist (for computer print out), how likely is it that you would ..... the CMI?

	Very likely	Somewhat likely	Unsure	Somewhat unlikely	Very unlikely
Read	❒	❒	❒	❒	❒
Use	❒	❒	❒	❒	❒
Keep	❒	❒	❒	❒	❒

Section B (Cont'd- 3 of 4)

3. Below is a list of topics. Please indicate your opinion about how much information was provided on each topic and how useful you think this information would be if you were taking this medicine for the first time.

	How much information?				How useful is the information?		
	Too much	About right	Too little	None at all	Very useful	Fairly useful	Not so useful
The benefits of taking the medication	❒	❒	❒	❒	❒	❒	❒
Who should not use the medication	❒	❒	❒	❒	❒	❒	❒
Specific directions about how to take the medication	❒	❒	❒	❒	❒	❒	❒
Precautions that need to be taken while using the medication	❒	❒	❒	❒	❒	❒	❒
Possible side effects	❒	❒	❒	❒	❒	❒	❒
What to do about side effects	❒	❒	❒	❒	❒	❒	❒
How to store the medication	❒	❒	❒	❒	❒	❒	❒
General information (e.g. description of medication)	❒	❒	❒	❒	❒	❒	❒

Section B (Cont'd- 4 of 4)

4. Below is a list of words on a scale of 1 - 5 describing the design, layout and tone of the CMI. Which best describes your opinion?

1	2	3	4	5	
poorly organized					well organized
unattractive					attractive
poor print size					ideal print size
alarming in tone					encouraging in tone
unhelpful					helpful
biased					unbiased
poor spacing between lines					ideal spacing between lines

Section C (1 of 3)

	Strongly disagree	Disagree	Slightly disagree	Slightly agree	Agree	Strongly agree
If I get sick, it is my own behaviour which determines how soon I get well again.	❒	❒	❒	❒	❒	❒
No matter what I do, if I am going to get sick, I will get sick.	❒	❒	❒	❒	❒	❒
Having regular contact with my physician is the best way for me to avoid illness.	❒	❒	❒	❒	❒	❒
Most things that affect my health happen to me by accident.	❒	❒	❒	❒	❒	❒
Whenever I don't feel well, I should consult a medically trained professional.	❒	❒	❒	❒	❒	❒
I am in control of my health.	❒	❒	❒	❒	❒	❒

Section C (Cont'd- 2 of 3)

	Strongly disagree	Disagree	Slightly disagree	Slightly agree	Agree	Strongly agree
My family has a lot to do with my becoming sick or staying healthy.	❒	❒	❒	❒	❒	❒
When I get sick, I am to blame.	❒	❒	❒	❒	❒	❒
Luck plays a big part in determining how soon I recover from illness.	❒	❒	❒	❒	❒	❒
Health professionals control my health.	❒	❒	❒	❒	❒	❒
My good health is largely a matter of good fortune.	❒	❒	❒	❒	❒	❒
The main thing which affects my health is what I myself do.	❒	❒	❒	❒	❒	❒

Section C (Cont'd- 3 of 3)

	Strongly disagree	Disagree	Slightly disagree	Slightly agree	Agree	Strongly agree
If I take care of myself, I can avoid illness.	❒	❒	❒	❒	❒	❒
When I recover from an illness, it's usually because other people (for example doctors, nurses, family, friends) have been taking good care of me.	❒	❒	❒	❒	❒	❒
No matter what I do, I'm likely to get sick.	❒	❒	❒	❒	❒	❒
If it's meant to be, I will stay healthy.	❒	❒	❒	❒	❒	❒
If I take the right actions, I can stay healthy.	❒	❒	❒	❒	❒	❒
Regarding my health, I can only do what my doctor tells me to do.	❒	❒	❒	❒	❒	❒

Section D (1 of 2)

1. Vividly imagine that you are <u>afraid</u> of the dentist and have to get some dental work done. Which of the following would you do? Tick <u>all</u> of the statements that might apply to you.

I would ask the dentist exactly what work was going to be done. ❒

I would take a tranquilizer or have a drink before going. ❒

I would try to think about pleasant memories. ❒

I would want the dentist to tell me when I would feel pain. ❒

I would try to sleep. ❒

I would watch all the dentist's movements and listen for the sound of the drill. ❒

I would watch the flow of water from my mouth to see if it contained blood. ❒

I would do mental puzzles in my mind. ❒

Section D (Cont'd- 2 of 2)

2. Vividly imagine that, due to a large drop in sales, it is rumoured that several people in your department at work will be laid off. Your supervisor has turned in an evaluation of your work for the past year. The decision about lay-offs has been made and will be announced in several days. Tick all of the statements that might apply to you.

I would talk to my fellow workers to see if they knew anything about what the supervisor evaluation of me said. ❒

I would review the list of duties for my present job and try to figure out if I had fulfilled them all. ❒

I would go to the movies to take my mind off things. ❒

I would try to remember any arguments or disagreements I might have had that would have resulted in the supervisor having a lower opinion of me. ❒

I would push all thoughts of being laid off out of my mind. ❒

I would tell my spouse that I'd rather not discuss my chances of being laid off. ❒

I would try to think which employees in my department the supervisor might have thought had done the worst job. ❒

I would continue doing my work as if nothing special was happening. ❒

Section E

In the section below, there are two passages with a few sentences that have some of the words missing. Where a word is missing, a blank line is drawn, and 4 possible words that could go in the blank appear just below it in the box. *Please fill in the blanks by circling the letter in front of the word which makes the sentence make sense.* You have 7 minutes to complete as much of this as you can.

Example:

This medication will help you _____
a. eat
b. fire
c. fight
d. drink

your infection. Swallow one _____
a. tablet
b. table
c. stomach
d. food

with a glass of _____
b. lunch
c. water
d. food
e. wafer

twice a day at least half an hour before you eat.

APPENDIX G

- WMI Study Phase 1 patient information sheet (St George Hospital)
- WMI Study Phase 1 patient information sheet (Concord Hospital)
- WMI Study Phase 1 patient information sheet (St Vincent's Hospital)
- WMI Study Phase 1 patient consent form (St George Hospital)
- WMI Study Phase 1 patient consent form (Concord Hospital)
- WMI Study Phase 1 patient consent form (St Vincent's Hospital)
- WMI Study Phase 1 pharmacist-in-charge information sheet
- WMI Study Phase 1 pharmacist on duty information sheet
- WMI Study Phase 1 pharmacist consent form
- WMI Study Phase 1 patient information sheet (community pharmacy)
- WMI Study Phase 1 patient consent form (community pharmacy)

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PARTICIPANT INFORMATION SHEET- PHASE 1

The Use of Written Medicine Information by Consumers

Dear Participant,

You are invited to take part in the above-mentioned study. The study aims to investigate how you use printed information about medications. We are also interested in the factors that influence your use of this information.

This study is being conducted by Ms Michelle Koo as part of the degree of Doctor of Philosophy under the supervision of Dr Parisa Aslani and Dr Ines Krass at the Faculty of Pharmacy, The University of Sydney.

In order to take part in this study, you must be:
1. Over the age of 18 years
2. Able to take part in this study without the help of a translator
3. Currently taking one of the medications specified by the researcher

If you meet the above criteria and agree to participate in the study, you will be interviewed by the researcher using a questionnaire. The interview will last approximately 30 minutes.

All aspects of the study, including results, will be strictly confidential and only the investigators named above will have access to information on participants. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report. Participation in this study is entirely voluntary: you are not obliged to participate and - if you do participate - you can withdraw at any time. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with medical staff.

If you would like to know more at any stage, please feel free to contact Ms Michelle Koo on (02) 9351 3647. This information sheet is for you to keep.

Thank you for your time and participation.

This study has been approved by the Human Research Ethics Committee of the South East Health Southern Section and The University of Sydney Human Ethics Committee.

If you have any concerns or complaints about the conduct of the research study, you may contact the Coordinator of the Human Research Ethics Committee of the South East Health Southern Section, Ms Doukessa Lerias [tel: (02) 9350 2481, fax: (02) 9350 3968, email: LeriasD@sesahs.nsw.GOV.AU] or the Manager of Ethics and Biosafety Administration, University of Sydney, on (02) 9351 4811.

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CONCORD
REPATRIATION GENERAL
HOSPITAL

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Faculty of Pharmacy (Bldg A15),
The University of Sydney,
NSW 2006, AUSTRALIA.

PARTICIPANT INFORMATION SHEET- PHASE 1

The Use of Written Medicine Information by Consumers

Dear Participant,

You are invited to take part in the above-mentioned study. The study aims to investigate how you use printed information about medications. We are also interested in the factors that influence your use of this information. These include your opinions about the current format of written medicine information, how you cope with stressful situations such as medical conditions and how easy it is for you to understand and use general written information that you come across in the health setting.

This study is being conducted by Ms Michelle Koo as part of the degree of Doctor of Philosophy under the supervision of Dr Parisa Aslani and Dr Ines Krass at the Faculty of Pharmacy, The University of Sydney. This study is *not* being conducted by the Rheumatology Department of Concord Hospital and does *not* form part of your normal visit to the clinic, however, Dr Shenstone, one of the specialists has kindly given his support and granted permission for us to recruit and interview patients from this clinic.

In order to take part in this study, you must be:
1. Over the age of 18 years
2. Able to take part in this study without the help of a translator
3. Currently taking one of the medications specified by the researcher

If you meet the above criteria and agree to participate in the study, you will be interviewed by the researcher using a questionnaire. The interview will last approximately 30 minutes. If you are called for your appointment in the middle of the interview, we will put the interview on hold to allow you to see your specialist. We request that you return after your consultation to complete the questionnaire.

If we have your permission, we may also contact you for a separate follow-up telephone interview at a time which is convenient for you. The telephone interview will last approximately 30-45 minutes.

(please turn over)

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Thank you for your time and participation.

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If you have any concerns or complaints about the conduct of the research study, you may contact the Secretary of the Concord Hospital Human Research Ethics Committee, on (02) 9767 6233 or the Manager of Ethics and Biosafety Administration, University of Sydney, on (02) 9351 4811.

Alternatively, if you wish to speak with an independent person within the Hospital about any problems or queries about the way in which the study was conducted, you may contact the Patient Representative on (02) 9767 7488.

ST VINCENT'S
HOSPITAL

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In order to take part in this study, you must be:
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2. Able to take part in this study without the help of a translator
3. Currently taking one of the medications specified by the researcher

If you meet the above criteria and agree to participate in the study, you will be interviewed by the researcher using a questionnaire. The interview will last approximately 30 minutes. If you are called for your appointment in the middle of the interview, we will put the interview on hold to allow you to see your specialist. We request that you return after your consultation to complete the questionnaire.

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If you would like to know more at any stage, please feel free to contact Ms Michelle Koo on 02-9351 3647. This information sheet is for you to keep.

Thank you for your time and participation.

This study has been approved by the St Vincent's Hospital Human Research Ethics Committee and The University of Sydney Human Ethics Committee.

If you have any concerns or complaints about the conduct of the research study, you may contact The Executive Officer, St Vincent's Hospital Research Ethics Committee (phone 02-8382 2075, fax 02-8382 3667, email recclestone@stvincents.com.au) or the Manager of Ethics and Biosafety Administration, University of Sydney (phone 02-9351 4811).

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The University of Sydney,
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The St George Hospital &
Community Health Service,
Gray Street, Kogarah,
NSW 2217, AUSTRALIA.

PARTICIPANT CONSENT FORM- PHASE 1

The Use of Written Medicine Information by Consumers

I, ...(please print your name)

have read and understood the "Participant Information Sheet" on the above research study and have discussed it with one of the researchers, Ms Michelle Koo. I am aware of the procedures involved in the study and understand what is expected of me.

I freely choose to participate in this study and understand that I can withdraw from the study at any time without penalty or prejudice. I also understand that the research study is strictly confidential and that only group data will be published and used in future research. No personal details will be revealed at any time during or after the study.

Signature: .....

Name (please print): .....

Date: .....

Signature of witness: .....

Name of witness (please print): .....

Date: .....

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PARTICIPANT CONSENT FORM- PHASE 1

The Use of Printed Medicine Information by Consumers

I, _____[name]

of _____[address]

have been invited to participate in the above named research study and have discussed the study with one of the researchers, Ms Michelle Koo.

- I acknowledge that I have received and read the Participant Information Sheet and the purpose and nature of this research has been explained to me.
- I understand that my participation in this study is entirely voluntary and I may withdraw at any stage. If I withdraw, this decision will not affect in any way my future treatment or my relationship with my doctors and other members of my health care team.
- I also understand that information relating to my participation in the study is strictly confidential. I agree that research data gathered from the results of the study may be published, provided I cannot be identified.
- I understand that the research project will be carried out according to the principles of the National Health & Medical Research Council Statement on Ethical Conduct in Research Involving Humans.

(please turn over)

- I understand that if I have any questions relating to my participation in this research study I may contact Ms Michelle Koo on (02) 9351 3647 who will discuss any concerns I may have.
- I understand that if I have any questions about my rights as a research subject, or on other administrative matters, I may contact the Secretary of the Concord Hospital Human Research Ethics Committee on (02) 9767 6233.
- I also understand that if I wish to speak with an independent person within the Hospital with any problems or queries about the way in which the study is being conducted, I may contact the Patient Representative on (02) 9767 7488.

I hereby freely agree to participate in this research study.

Name (Print): _____

Signature: _____ **Date:** _____

Name of Witness (Print): _____

Signature of Witness: _____ **Date:** _____

This study has been approved by the Human Research Ethics Committee - CRGH Zone of the Central Sydney Area Health Service and The University of Sydney Human Ethics Committee.

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PARTICIPANT CONSENT FORM- PHASE 1

The Use of Printed Medicine Information by Consumers

I, _____[name]

of _____[address]

agree to participate as a subject in the study described in the Participant Information Sheet provided to me.

1 I acknowledge that I have read the Participant Information Sheet, which explains the aims of the study and the nature of the investigation, and the information has been explained to me to my satisfaction.

2 I understand that I can withdraw from the study at any time without prejudice to my relationship to The University of Sydney or the doctors and staff of St Vincent's Hospital.

- I also understand that information relating to my participation in the study is strictly confidential. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
- I understand that if I have any questions relating to my participation in this research, I may contact Ms Michelle Koo on 02-9351 3647, who will be happy to answer them.
- I understand that if I have any complaints or questions about my rights as a research subject, or on other administrative matters, I may contact the Executive Officer, St Vincent's Hospital Research Ethics Committee on 02-8382 2075.

Name (Print): _____

Signature: _____ **Date:** _____

Name of Witness (Print): _____

Signature of Witness:_____ **Date:** _____

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PHARMACIST INFORMATION SHEET

For the attention of the Pharmacist-in-Charge

The Use of Written Medicine Information by Consumers

Dear Colleague,

The above study is being conducted by Ms Michelle Koo as part of the degree of Doctor of Philosophy under the supervision of Dr Parisa Aslani and Dr Ines Krass at the Faculty of Pharmacy, The University of Sydney. Your pharmacy appeared in a random selection of Sydney community pharmacies, and your participation in this study will be greatly appreciated.

Our study focuses on written medicine information, in particular Consumer Medicine Information (CMI). The National Strategy for Quality Use of Medicines has identified CMI as a means of facilitating the uptake of objective information about all medicines by consumers. You may also be aware that as of this year, all prescriptions are required to have a CMI, and that pharmacies have been given financial assistance under the Third Community Pharmacy Agreement to ensure that they are well-equipped to provide CMI to consumers.

Despite all the efforts and resources put into CMI, few research studies have been conducted to determine the readership of CMI and the factors which influence the use of CMI by consumers. Hence, our research aims to investigate the awareness and use of CMI in the community and to investigate the factors influencing the use of CMI by consumers. The results of this study will reveal to the profession the needs of consumers and aid pharmacists in tailoring information to meet these needs.

If you agree to take part in the study, Ms Michelle Koo will be visiting your pharmacy to recruit consumers and administer the questionnaires on-site to eligible and consenting consumers. It is anticipated that the interviews will last approximately 30 minutes. ***We would like to engage your assistance in referring all consumers who meet the inclusion criteria listed below to Ms Koo.***

In order to participate, consumers must be:
1. Over the age of 18 years
2. Able to take part in this study without the help of a translator
3. Currently taking at least one prescription medication for hypertension

We would also appreciate it if you could inform the pharmacist(s) on duty about the study. Together with this letter, we have included several copies of Pharmacist Information Sheet for the pharmacist(s) on duty.

This study has been approved by the Human Ethics Committee of The University of Sydney. All aspects of the study, including results, will be strictly confidential and only the investigators named below will have access to information on participants. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report and only group data will be reported. Participation in this study is entirely voluntary, and you and your consumers can withdraw at any time without penalty or prejudice.

We look forward to a favourable reply from you. Ms Michelle Koo will be contacting you by telephone approximately one week after the initial mailing to confirm that you have received this information sheet and to ascertain your willingness to participate in the study. If you do agree to take part, we will obtain written consent from you when we commence recruiting consumers from your pharmacy.

This information sheet is for you to keep. If you would like further information at any stage, please feel free to contact Ms Michelle Koo on (02) 9351 4445.

Thank you very much for your time and assistance.

Yours sincerely,

MICHELLE KOO INES KRASS PARISA ASLANI

Any person with concerns or complaints about the conduct of a research study can contact the Manager of Ethics and Biosafety Administration, University of Sydney, on (02) 9351 4811.

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PHARMACIST INFORMATION SHEET

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Thank you very much for your time and assistance.

Yours sincerely,

MICHELLE KOO INES KRASS PARISA ASLANI

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PHARMACIST CONSENT FORM

The Use of Written Medicine Information by Consumers

I, ...(please print your name)

of .....(your address)

have read and understood the "Pharmacist Information Sheet" on the above research study and have discussed it with one of the researchers, Ms Michelle Koo. I am aware of the procedures involved in the study and understand what is expected of me.

I freely choose to participate in this study and understand that I can withdraw at any time without penalty or prejudice. I also understand that the research study is strictly confidential and that only group data will be published and used in future research. No personal details will be revealed at any time during or after the study.

Signature: .....

Name (please print): .....

Date: .....

Signature of witness: .....

Name of witness (please print): .....

Date: .....

Any person with concerns or complaints about the conduct of a research study can contact the Manager of Ethics and Biosafety Administration, University of Sydney, on (02) 9351 4811.

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PARTICIPANT INFORMATION SHEET- PHASE 1

The Use of Written Medicine Information by Consumers

Dear Participant,

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If we have your permission, we may also contact you for a separate follow-up telephone interview at a time which is convenient for you. The telephone interview will last approximately 30-45 minutes.

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If you would like to know more at any stage, please feel free to contact Ms Michelle Koo on (02) 9351 3647. This information sheet is for you to keep.

Thank you for your time and participation.

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PARTICIPANT CONSENT FORM- PHASE 1

The Use of Written Medicine Information by Consumers

I, ...(please print your name)

have read and understood the "Participant Information Sheet" on the above research study and have discussed it with one of the researchers, Ms Michelle Koo. I am aware of the procedures involved in the study and understand what is expected of me.

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Signature: .....

Name (please print): .....

Date: .....

Signature of witness: .....

Name of witness (please print): .....

Date: .....

Any person with concerns or complaints about the conduct of a research study can contact the Manager of Ethics and Biosafety Administration, University of Sydney, on (02) 9351 4811.

APPENDIX H

- WMI Study Phase 2 interview guide
- WMI Study Phase 2 interview procedure

Phase 2: Telephone Interview Guide

Please note that the questions below are *only* a guide.

1. COPING

(a) When you found out that you had *(insert diagnosis)*, how did you react to that?

- How did you cope?
- How do you think receiving information (written vs verbal) about your condition and your medicines would have affected how you reacted?
- Any preference as to when this information should be given?

(b)* With *(insert diagnosis)*, you have to put up with *(insert symptom)*. If you knew that the *(insert symptom)* would be short term, would that have changed your reaction to the diagnosis?

- How do you think that would influence your interest in reading the information about your medicines?

(c)* What about if it was a chronic condition without symptoms?

*NB Sections 1(b) and 1(c) to be adapted based on presenting condition

2. INTEREST IN INFORMATION

(a) In general, how interested would you say you are in getting any kind of information (eg verbal, written) about your medicines? Why?

(b) In what way would you prefer to get information about your prescription medicines?
(Prompt: Verbal? Written? Both?)

(c) If we look in more detail about written information, do you normally read written information about your prescription medicines?

- Can you recall the last time you did this? Can you recall what the medicine was?
- What was the source of this written information?
- Besides this source, what other sources of written information have you used in the past?
- How do they compare?

3. ACCESS TO INFORMATION/ ROLE OF HEALTH PROFESSIONAL

(a) How have you been receiving information about your medicines?
(Prompt: From health professional? By reading CMI? By searching the net?)

(b) Some people find it easy and others find it difficult to find written information about medicines.

- How about yourself?
- What do you think could be done to improve the situation?

(c) Following on from that, who do you think should provide the information on medicines?

(d) What do you think is the role of the health care professional when it comes to information about medicines?
(Prompt: What about the Dr? The Pharmacist?)

4. FORMAT AND PRESENTATION OF CMI

(a) There have also been a lot of comments about Consumer Medicine Information or CMI *(define CMI if necessary)*, which is the commonly available form of written information about medicines.

- What are your impressions about the current layout/user-friendliness of the two different kinds of CMIs, ie the one that you find in the box and the one which is printed from a computer?
- How do you think this affects your use of CMI?

5. LITERACY

(a) Besides the overall layout and design, some people have also commented that CMI is difficult to understand.

- What do you think?
- How do you think the situation could be improved?

6. HEALTH LOCUS OF CONTROL

(a) Who would you say is involved in making decisions that affect your health?

- Of the people that you have mentioned, who would you say has the most influence on your health care?
- How do you think this affects the way you use written information about your medicines?

(b) If I can once again touch on what we have mentioned earlier, how do you think the severity of your condition influences who makes decisions with regards to your health care?

- How would this affect your need of written information?

7. MISCELLANEOUS

(a) Finally, are there any comments that you would like to make in relation to written information that we may or may not have covered today?

Interview procedure

1. The interviewer greeted and thanked the participant for consenting to be interviewed.
2. The interviewer reminded the participant that the interview will be recorded and hence the requirement to use a speaker phone. However, the patient was assured that no one else was present in the room. The interviewer also informed the patient that their verbal consent to record the interview would once again be obtained when the recording commenced.
3. The interviewer informed the participant that he/she will be introduced as a coded person to maintain anonymity.
4. Both digital and tape recorders were started.
5. The interviewer introduced the participant on 'tape' and started off the interview by obtaining consent to record the interview.
6. The interviewer interviewed the participant using the interview guide.

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APPENDIX I

- WMI Study Phase 2 patient information sheet (St George Hospital)
- WMI Study Phase 2 patient information sheet (Concord Hospital)
- WMI Study Phase 2 patient information sheet (St Vincent's Hospital)
- WMI Study Phase 2 patient information sheet (community pharmacy)
- WMI Study Phase 2 consent form (St George Hospital)
- WMI Study Phase 2 consent form (Concord Hospital)
- WMI Study Phase 2 consent form (St Vincent's Hospital)
- WMI Study Phase 2 consent form (community pharmacy)

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The St George Hospital &
Community Health Service,
Gray Street, Kogarah,
NSW 2217, AUSTRALIA.

PARTICIPANT INFORMATION SHEET- PHASE 2

The Use of Written Medicine Information by Consumers

Dear Participant,

Thank you for taking part in our initial questionnaire and for giving us permission to contact you for this follow-up telephone interview.

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of .....(please print your address)

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I freely choose to participate in this study and understand that I can withdraw from the study at any time without penalty or prejudice. I also understand that the study is strictly confidential and that only group data will be published and used in future research. No personal details will be revealed at any time during or after the study.

Telephone: .....

Best time of day for contact: .....

(please turn over)

Signature: ..... **Date:** .....

Name (please print): .....

Signature of witness: .....**Date:** .....

Name (please print): .....

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- I understand that the research project of which this interview is part of, will be carried out according to the principles of the National Health & Medical Research Council Statement on Ethical Conduct in Research Involving Humans.

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APPENDIX J

- Ancillary results to Chapter 5 (WMI Study Phase 2)

Suggestions for CMI

1. Participants did not mind the use of medical terms in CMI but requested that these were explained in simple language that a lay person could understand.

   "... a better understanding of what a beta blocker is would be more appropriate that just saying it's a beta blocker." (C15007)

2. In addition to wanting explanations of medical terms, there was also a request for explanation on why things are to be done a certain way rather than just being given instructions.

   "I probably wonder why I'm taking it at that particular time and if I forget it, I can go to the leaflet and see why I'm taking it at that time and see if it's safe to take it at another time." (C19003)

3. Participants requested for a summary of all the important points at the start of CMI. This was considered useful for people who did not have time to read the whole CMI.

   "[Reading through all sections] takes time and people don't always have time between when they pick it up and when they got to take the first dose." (C33005)

4. A similar request to the one above was made by another participant who requested for the more important information to be placed at the start of CMI.

   "I think it just needs a bit more prioritisation? Important things up front, little bit more with the information towards the back..." (H02046)

5. Participants requested for the information to be presented in point form to make CMI more succinct.

   "Probably less words... I don't know if it's possible to explain things in point form. When I say point form, you might start off with a major heading... and it might say something like, "these are the possible side effects" and then you can list them." (H01002)

6. There was a request for CMI to be improved to make it more appealing to the reader.

   "They should make it more interesting to read somehow, I don't know how but yeah..." (H01009)

7. One participant requested for the inclusion of a statement to inform the patient where to go for further information.

   "At the bottom of the CMI they could write "for more information, see this website" and... then you could go on the internet and have a look." (H03028)

8. A participant requested for the benefits in CMI to be expressed more explicitly as it was felt that CMI currently emphasised the potential negative effects more than its potential benefits.

   "... it needs to express the benefits as well as the, the potential side effects... you sort of feel like you're taking a poison as opposed to a something that can have an efficacious effect... when you read these things, you can be depressed by the extent of... (laughs) of down side and you know you're being generally being given it for positive reasons... but there is nothing positive about... written about the drug that... in the information." (H03043)

Other factors influencing interest in WMI

1. Some interviewees viewed personality as a factor that influenced their own interest in WMI.

   "I'm that sort of person, I'm interested about things, so I'm interested in things that things that you know, happen to me or my family or friends. So I think it's me. I'm interested that way." (C34004)

2. In addition to personality, some participants attributed their interest in WMI to their occupational background or career.

   "I'm the sort of person who likes to get to the bottom of everything and I've got a research mind… I've been an academic in the past and… I'm obviously got that desire to know as much as possible." (H03043)

   "I guess I'm that sort of person. I worked in the medical field, I was a dental assistant…" (C34004)

3. Past experience seemed to play an important role in influencing participants' interest in medicine information. On the one hand, positive experience in using the information was thought to motivate future use of it. On the other hand, negative experience with medication or treatment was also considered an impetus to seek and use medicine information.

   "…But I think it really depends on whether you've had positive experiences one way or the other, you know, with trying to find info or being given information." (H01020)

   "So I wasn't reading about sickness or medication at all. Because I had the bad reaction, like I came out it like oedemas and lumps all over my body from medication… I had to be [interested]." (C20003)

   " Fairly interested [in information about medicines]… Yeah you see, I've had a bit of trouble… Because sometimes the medicines have worked for a while and then sort of… not worked for a bit." (H01031)

   "I've had yeah [bad experience in the past]… I mean, I know [doctors] know… but they don't know me. I know me better than they do... So, now I… read as much as I can." (H03028)

4. The timing of information was thought to be important in influencing interest in WMI.

   "Depending on the time of point. I mean, for my injury, like I mean usually I like to know what I am taking… but for the injury, I was more concerned about the rehabilitation that I didn't care what they gave me, that if it did the job, it's all that mattered to me." (H03007)