

A health literacy education-focused intervention to improve community pharmacy adoption of universal precautions

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Bachelor of Pharmacy (Honours)
Graduate Certificate in Pharmacy Practice

A thesis submitted for the degree of
Doctor of Philosophy
November 2014



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*This thesis is dedicated to my very dear friend
Melissa “Mozza” Van Doeselaar.*

Your smile and your soul will live on in the hearts of us all forever.

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Abbreviations

ABS	Australian Bureau of Statistics
AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
CALD	Culturally and linguistically diverse
CI	Confidence interval
CMI	Consumer Medicine Information
CPD	Continuing professional development
CPE	Continuing professional education
EOV	Educational outreach visit
ERG	Expert Reference Group
FECCA	Federation of Ethnic Communities' Councils of Australia
GP	General practitioner
HCPs	Health care professionals
HeLP	Health Literacy in Pharmacy
HIV	Human Immunodeficiency Virus
HREC	Human Research Ethics Committee
NA	Not applicable
NB	Nota bene
NSW	New South Wales

NHHRC	National Health and Hospital Reform Commission
NVivo	NVivo: version 9.0, QSR International
NVS	Newest Vital Sign
OR	Odds ratio
OSCE	Objective structured clinical examination
PBS	Pharmaceutical Benefits Scheme
PhARIA	Pharmacy Access/Remoteness Index of Australia
PSA	Pharmaceutical Society of Australia
RCT	Randomised controlled trial
REALM	Rapid Estimate of Adult Literacy in Medicine
RR	Relative risk/rate ratio
S2	Schedule 2 (Pharmacy Medicine)
S3	Schedule 3 (Pharmacist Only Medicine)
S4	Schedule 4 (Prescription Only Medicine)
S8	Schedule 8 (Controlled Drug)
SPSS	Statistical Package for the Social Sciences for Windows: IBM: version 19, New York, USA
TAFE	Technical and Further Education
TBP	Theory of Planned Behaviour
TOFHLA	Test of Functional Health Literacy in Adults
TTT	Train-the-trainer
UK	United Kingdom

US	United States
USB	Universal Serial Bus
VIC	Victoria
WA	Western Australia
WHO	World Health Organization

List of publications during candidacy

1. **Swinburne G**, Duncan GJ, Mc Namara KP, Emmerton LM, Hussainy SY. An international survey of health literacy education within schools of pharmacy. *Pharmacy Education*. 2014; 14(1):101-8.

List of presentations during candidacy

1. **Swinburne GJ**, Emmerton L, Hughes J, Darzins P, Stewart K, Chaar B, Kairuz T, Ostini R, Williams K, Hussainy SY, McNamara KP, Hoti K, Bush R, Boyle F, Jiwa M, Suen B, Duncan GJ. An international survey of health literacy education within schools of pharmacy. In: Kirkpatrick C, McLachlan A, Le Couteur D. *Proceedings of the Australasian Pharmaceutical Science Association Annual Conference*; 2012 December 2-5; Sydney: 10. (Oral presentation).
2. **Swinburne GJ**, Emmerton LM, Hughes J, Darzins P, Stewart K, Chaar B, Kairuz T, Ostini R, Williams K, Hussainy SY, McNamara KP, Hoti K, Bush R, Boyle F, Jiwa M, Suen B, Duncan GJ. An international survey of health literacy education within schools of pharmacy 8th Annual Postgraduate Research Symposium. Monash University, Melbourne, Australia, 2013. (Oral presentation).

3. **Swinburne GJ**, Hussainy SY, Duncan GJ, Mc Namara KP, Stewart K, Emmerton LM. An Evaluation of the Impact of a Health Literacy Educational Package for Community Pharmacists and Pharmacy Staff in Australia. In: Proceedings of the 13th Annual Health Literacy Conference, Institute for Healthcare Advancement; 2014 May 7-9; Los Angeles, United States, 2014. (Poster presentation).
4. **Swinburne GJ**, Hussainy SY, Duncan GJ, Mc Namara KP, Stewart K, Emmerton LM. An Evaluation of the Impact of a Health Literacy Educational Package for Community Pharmacists and Pharmacy Staff in Australia. In: Proceedings of the National Medicines Symposium, NPS MedicineWise; 2014 May 21-23; Brisbane: 5. (Poster presentation).
5. **Swinburne GJ**, Hussainy SY, Duncan GJ, Mc Namara KP, Stewart K, Emmerton LM. An Evaluation of the Impact of a Health Literacy Educational Package for Community Pharmacists and Pharmacy Staff in Australia. 9th Annual Postgraduate Research Symposium. Monash University, Melbourne, Australia, 2014. (Poster presentation).

Abstract

Background

Health literacy is quickly becoming an important social determinant of health. Limited health literacy has a major impact on consumers' ability to access, understand and use health information, as well as navigate complex healthcare systems. In the context of pharmacy, this can cause inappropriate medicine use and non-adherence, leading to medication misadventure and potential life-threatening consequences. It also has a costly impact on the health care system.

The impact of limited consumer health literacy in the pharmacy setting in Australia has yet to gain significance. Health literacy awareness in the Australian pharmacy setting is low, yet pharmacies are at the forefront of healthcare in the community and are thus well-positioned to manage the issue of limited consumer health literacy. This requires pharmacists and pharmacy staff members to be skilled communicators, providing information to consumers at an appropriate level of complexity.

Educational initiatives to increase the adoption of communication techniques by pharmacists and pharmacy staff members that focus on increasing consumer understanding of health information should be employed. A potential approach to achieving this is the use of communication techniques known as 'universal precautions'. The universal precautions framework includes techniques to increase consumer engagement, such as use of open-ended questions (e.g. 'What questions

do you have?'), the teach-back method and demonstrating device technique where appropriate.

Aims

The overall aim of this research was to promote the adoption of universal precautions in community pharmacies in Australia using a health literacy education-focused intervention.

Methods

The research project was divided into five phases, four of which were led by the PhD candidate:

- **Phase 1** was an online survey to explore the various methods used to teach health literacy in schools of pharmacy in English-speaking countries.

- **The HeLP phase** (*not led by the PhD candidate*) involved the design, development and implementation of a health literacy education-focused intervention for community pharmacists and pharmacy staff members in Australia. The purpose of this phase was to create an education-focused intervention designed to encourage the adoption of universal precautions by pharmacists and pharmacy staff members participating in the research project. This intervention was then evaluated in Phases 2, 3 and 4 of the project.

- **Phase 2** explored community pharmacists' and pharmacy staff members' motivations towards implementing health literacy training and how this may influence their intentions to do so. This phase utilised four types of mailed questionnaires designed for pharmacists and pharmacy staff members who were recruited in the HeLP phase of the research project. Factor analysis was undertaken to determine the underlying factors, followed by ordinal logistic regression to determine how these factors relate to intentions to implement the health literacy education-focused intervention and apply universal precautions with consumers

- **Phase 3** was an evaluation of the efficacy and effectiveness of the health literacy education-focused intervention on pharmacists' and pharmacy staff members' communication practice behaviours with consumers, particularly the use of universal precautions. Pre- and post-intervention data collection was conducted in this phase. Researcher-administered consumer questionnaires were conducted in-pharmacy before and after participating consumers interacted with a pharmacist or pharmacy staff member to determine the application of universal precautions. Simulated patients were also used pre- and post-intervention to objectively determine the uptake of universal precautions by pharmacists and pharmacy staff members. Pharmacists and pharmacy staff members were recruited in the HeLP phase of the research project. Consumers were recruited in-pharmacy by a research officer. Data analysis involved the use of Pearson's Chi squared analysis.

- **Phase 4** involved focus groups with participating pharmacists and pharmacy staff members to explore their opinions on the usability, perceived effectiveness and ease of implementation of the health literacy education-focused intervention. Data in this phase was collected and transcribed, then analysed using thematic analysis based upon the grounded-theory approach. Participants were pharmacists and pharmacy staff members recruited using mailed invitations from the pool of participants recruited in the HeLP phase of the research project.

Key findings

The **Phase 1** study incorporated results from 21 pharmacy schools in a total of six English-speaking countries. The study highlighted that the most favoured method by pharmacy academics to deliver health literacy education to pharmacy students in English speaking countries was through lectures and small-group learning sessions (38.1%; 8/21 for each). This study helped inform the delivery method of the health literacy education-focused intervention for community pharmacists and pharmacy staff members.

In the **HeLP phase**, an evidence-based health literacy education-focused intervention was designed and developed, focusing on the use of universal precautions with consumers. The purpose of the HeLP phase was to create an education-focused intervention to encourage participating pharmacists and pharmacy staff members to adopt the use of universal precautions with consumers to help enhance the provision of health and medicines information. The intervention

was underpinned by a train-the-trainer approach. The intervention was developed in two components: an initial train-the-trainer component, which aimed to train selected 'pharmacy trainers' from each pharmacy in the delivery of health literacy training, and an in-pharmacy delivery component, implemented by the pharmacy trainer in the pharmacy. A total of 77 community pharmacies from New South Wales, Victoria and Western Australia were recruited into the project. Pharmacies were block randomised into three groups: two experimental groups (receiving either face-to-face [Group 1, n=26] or electronic [Group 2, n=26] train-the-trainer training) and a control group (Group 3) that received no training. In Group 1, 20/26 pharmacies completed the intervention and in Group 2, 11/26 pharmacies completed the intervention. An additional 3/26 in Group 1 and 6/26 in Group 2 partially completed the intervention, while 3/26 and 9/26 pharmacies from Group 1 and Group 2, respectively, withdrew from the project. This study highlighted the barriers associated with implementing continuing education training into community pharmacies.

This education-focused intervention was then evaluated using a variety of quantitative and qualitative research methods in Phases 2, 3 and 4 of the research project. This was conducted to determine the openness of participants to integrate the intervention and adopt universal precautions with consumers (Phase 2), the efficacy and effectiveness of the intervention (Phase 3), and to gather qualitative feedback regarding various aspects of the intervention for potential future revisions.

Phase 2 revealed that pharmacists and pharmacy staff members are generally favourable towards undertaking health literacy training. Factor analysis was used to extract correlated factors, followed by ordinal logistic regression to determine the

association of these factors to intentions to undertake health literacy training (the dependent variable). Following analysis, it was found that particular extracted factors, for example, having positive attitudes and beliefs towards applying health literacy training to consumer counselling, were significantly associated with having an intention to implement health literacy training ($p<0.001$). Preparedness and sustainability for implementation, and relevance of universal precautions and their potential benefits, were also associated with intentions to undertake training ($p<0.001$).

Phase 3 demonstrated that the health literacy education-focused intervention had a significant impact on the use of the phrase ‘What questions do you have?’ by participating pharmacists and pharmacy staff members. Patient-recall data showed that the face-to-face group (Group 1) and the electronic group (Group 2) were significantly more likely to use the phrase compared to the control group (Group 3), post-intervention (RR: 4.86; CI: 2.27-10.52; $p<0.001$ and RR: 2.98; CI: 1.02-8.67; $p=0.032$, respectively). Simulated patient data showed an improvement in use of the same phrase within Group 1, pre- versus post-intervention (RR=8.17, CI: 1.06-62.78, $p=0.013$). Use of the teach-back method proved difficult to use with consumers, and was not widely implemented by pharmacists and pharmacy staff members. Phase 3 highlighted the difficulty in implementing more complex universal precautions such as the teach-back method compared to more simple techniques whose use was met with more success.

In **Phase 4**, pharmacists and pharmacy staff members believed that the health literacy education-focused intervention was relevant to practice. Some difficulties

were met in regard to the implementation of the intervention, in particular, arranging training sessions with staff. Concurring with the findings of Phase 3, participants believed use of the phrase ‘What questions do you have?’ was easy to implement, yet faced difficulty in the use of the teach-back method due to a lack of confidence and self-efficacy. Based on the results of this phase, future refinements to the intervention are recommended, such as including more video examples and activities demonstrating the teach-back method to build pharmacists’ and pharmacy staff members’ confidence in adopting this universal precaution.

Conclusion

This research project has identified that health literacy education is both prevalent in pharmacy schools in English-speaking countries, taught using a variety of methods, and that the gap in health literacy education for community pharmacists and pharmacy staff members in Australia can be partly addressed using a multi-modal health literacy education-focused intervention. The project has provided evidence to support the notion that communication behaviours, particularly the adoption of universal precautions by pharmacists and pharmacy staff members, can be modified using continuing education. Providing Australian pharmacists and pharmacy staff members with the knowledge, self-efficacy, confidence and support to address the health literacy issues faced by consumers can help improve the health outcomes of pharmacy consumers.

Declaration for thesis based or partially based on conjointly published or unpublished work

General Declaration

In accordance with Monash University Doctorate Regulation 17.2 Doctor of Philosophy and Research Master's regulations the following declarations are made:

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

This thesis includes **one** original paper published in peer reviewed journals and **no** unpublished publications. The core theme of the thesis is *to determine the efficacy and effectiveness of a health literacy education-focused intervention on community pharmacists' and pharmacy staff members' communication behaviours with consumers, specifically the use of universal precautions*. The ideas, development and writing up of all the papers in the thesis were the principal responsibility of myself, the candidate, working within Centre for Medicine Use and Safety under the supervision of Dr Safeera Hussainy, Mr Gregory Duncan, A/Prof Kay Stewart and Dr Kevin Mc Namara, and A/Prof Lynne Emmerton from the School of Pharmacy, Curtin University.

[The inclusion of co-authors reflects the fact that the work came from active collaboration between researchers and acknowledges input into team-based research.]

In the case of **Chapter 3.3** my contribution to the work involved the following:

Thesis chapter	Publication title	Publication status*	Nature and extent of candidate's contribution
3.3	An international survey of Health Literacy Education within schools of pharmacy.	Published	Reviewed literature, drafted survey tool, disseminated online survey, collected and analysed results, constructed conclusions

I have / have not (circle that which applies) renumbered sections of submitted or published papers in order to generate a consistent presentation within the thesis.

Signed:

Date:

Acknowledgements

The work presented in this thesis would not have been possible without the support of many people, of who will be mentioned below.

I would firstly like to thank my main supervisor, **Dr. Safeera Hussainy**. Safeera, you provided me with the strength and motivation to complete this thesis even when it would have been easier to just give up. Your knowledge and experience in pharmacy and research is second-to-none, and I couldn't have asked for a better person to mentor me through this journey. Your door was always open whenever I needed help or simply someone to chat to or vent my frustrations. I am very proud to call you my primary supervisor. I really cannot thank you enough for everything, not only for what is in the pages of this thesis, but also the life lessons you taught me over the past three years.

I would like to thank **Mr. Gregory Duncan** for the incredible opportunity to undertake this PhD as a part of his project. Since my first year as a pharmacy student at Monash University in 2007, I have always looked up to you as a mentor and now most certainly, a friend. Your enthusiasm for public health cannot be matched and is evident in your passion for helping others. Thank you for everything.

To **Assoc. Prof. Kay Stewart** – there are no words to describe you. I have never met someone so happy, delightful, intelligent and caring, and I truly believe you are one-of-a-kind. If I could have half as much knowledge as you in research and pharmacy practice then I'd be very content!

Thank you to **Dr. Kevin Mc Namara** who always provided laughs, but also the experience with everything research related. Your help throughout my journey is much appreciated, specifically your attention to detail! I still find it difficult to work out if you're being serious or sarcastic...or both. Thank you for being a great mentor and friend!

Secondly, I would like to thank the fellow members of the Health Literacy in Pharmacy team. **Assoc. Prof. Lynne Emmerton, Dr. Betty Chaar, Dr. Therese Kairuz, Dr. Remo Ostini, Assoc. Prof. Kylie Williams, Dr. Kreshnik Hoti, Prof. Jeff Hughes, Prof. Peteris Darzins** and **Dr. Sam Elhebir**. What a great team to have the privilege of working with!

Thank you to my PhD panel members, **Prof. Carl Kirkpatrick, Dr. David Kong** and **Dr. Ian Larson** for your help and support throughout my journey as a PhD student.

To all the staff at the **Centre for Medicine Use and Safety, Monash University** – I greatly appreciate your help and support, and thank you for the great, supportive environment you've created to nurture both undergraduate and postgraduate students alike.

Thank you to all the **pharmacists, intern pharmacists, and pharmacy assistants** who took part in this study. Without their help this project would not have been possible.

Thank you to **Catherine Smith** for assistance with statistics and helping manage the large amounts of data for this study.

To everyone in NAPE – **Michelle, Liz, Angela, Laura and Kirstie** – thank you for your support, assistance, kind words and coffee breaks.

I would also like to thank the **Department of Health of the Commonwealth of Australia** and the **Pharmacy Guild of Australia** for providing the financial grant for this project, as well as **Monash University** for providing travel grants as well as a great environment to complete my PhD within.

Clare – without you as my desk neighbour I'd have gone crazy much sooner! I always had a great laugh and long (sometimes) intelligent conversations with you. Whether it was sharing gym exercises, Poptarts, or Pepsi Max, the last 3 years sitting next to you have been great, and I'm so happy to now have you as a close friend.

Paulie – your energy is infectious and thus you were always so great to have around. Your advice and support throughout my PhD journey was invaluable. Conferences were always so much better with you as my partner in crime! Here's to many more fun adventures!

Sou, Angelina, Tan, Katrina, Ed, Hamza, Aameena, Elida, Agnes, Cikie, Julia, Jo, Barbara, Wi, Susan, Jenifer, Dennis and Celine. Thank you for all the coffees, dinners and chats – you made the PhD journey a lot of fun!

I extend a great appreciation and thanks to **Kim Bellamy** from the University of Queensland for being a great friend and confidante throughout this rollercoaster of a journey. Good luck for your PhD! Health literacy all the way!

A huge thank you to everyone at the **Yarra Yarra Rowing Club**. Thank you for fostering such a supportive environment for not only rowing, but building lasting friendships.

To my favourite pharmacists – **Dan, Sarah, Helen D, Caz** and **Janelle**. You taught me that being a pharmacist can be not only interesting, but a lot of fun too. Thank you to **Angelo, Hannah, Tania, Marisa**, and everyone at **Tambassis Pharmacy** for your support for me as a pharmacist during my PhD.

To all my past teachers, especially **Karen Burgess, Veronica Hudson, Katie Johnston, Dr. Angela Fitzgerald, Jeanette McNamara** and **Claire Couling** from Maffra Secondary College. Thank you for pushing me to achieve my best during my schooling, and encouraging me to excel not only academically but personally as well.

Without the help of my friends throughout the past three years and beyond, this thesis would not have been possible. Thank you to my oldest and dearest friend **Marnie**. Whether it be road trips, Taco Nights, the failed Pizza Night, or Easter with your family, you make every moment glorious, so thank you. Who would have thought that back in Grade 5 at Boisdale Consolidated that in 15 years I'd be writing about you in my thesis? We wouldn't have even known what that was!

To **Jenna** and **Laura** – thank you both for your support, words of advice and simply being a sounding board for my ideas and concerns. You made living at Cook Street enjoyable over the past 3 years of this journey and hope there are many more fun times to come.

To **Heszy** – thank you for your endless philosophical insights into my life. I won't take them all onboard but thank you for your efforts anyway. Thank you for being a great friend over the past 14 years, and so glad to have you home. Good luck on your journey as a PhD student!

Huge thanks to **Maire, Tori, Fran, Cat, Jess, Michal, Steven, Sammy, Marina, Tania, Kane, Davern, Mick P, Antonio, Luce, Joanna, Izzy, Kait (and GzPz), James 2.5, Pip, Michael DV, Glenn, Josh, Sam, Mel, Jas, Daniel, Jeremy, Eloise, Sebastian, Drew, Tracey, Cam, Tina, Dani, Tris, Tiff** and **Alex** for always being there through the good and the bad; your motivation and support is priceless.

A very special thank you goes to two of my very good friends, **Matt** and **Pete** who never cease to amaze me with their kindness and ability to make light of any situation. Without these two people I wouldn't be the person I am today.

Matt – you are the nicest, most loving person I have had to pleasure of calling a friend. The tears, the smiles and the moments we've shared will be treasured for a life-time. I am so glad to have met you, and I know our friendship will only grow stronger. Thank you for your insight into health literacy – “Glen, your PhD can be summed up into seven words – twice a day means morning and night.” I do hope

that this thesis has proven to you that health literacy is a little more involved than this, but thank you none-the-less.

Pete – your words of advice and support for me are immeasurable. Our friendship is unique and I love that it is. Be it our competitions where Matt always seems to be the victim or our love of Grill'd and Pepsi Max, so much brings us together that you will always be one of my closest, dearest friends. Thank you for everything.

I would like to thank my incredible family. Thank you to my amazing parents, **Dianne** and **Barry** who always nurtured me academically, and gave me every opportunity to pursue my dreams – without your help, support, and most importantly, your love, this thesis would never have been possible.

To my sisters, **Mallory** and **Emily**. We've spent over 20 years together and each one of those I treasure. We've been through it all – the ups and the downs – and I couldn't have asked for anything more than to have you both by my side.

To my half brother and sister, **Dave** and **Suz**. Thanks for all the laughs and for all your support. Looking forward to all the fun times ahead!

To **Ben**, **Gareth** and **Josh**. Thank you for the support and love, and the great times in Queensland!

And finally to my loving **Grandma Mavis**, who passed away in December 2012 – thank you for all your life lessons, your unconditional love, and your infectious, charismatic nature. You taught me so much. Love you always.

In my endless efforts to remain untraditional, I finish these acknowledgments with a meaningful lyric:

I'm not asleep; I'm up for the fight into the magic

And I don't want the concrete

I am alive, comes with the tragic

So if it's just tonight, the animal inside, let it live then die.

- 'Animal', Kesha Sebert.

Once again, thank you to everyone mentioned above, and anyone else I've accidentally forgotten!

Many many thanks,

Glen.

1 LITERATURE REVIEW

1.1 INTRODUCTION TO HEALTH LITERACY

1.1.1 Literacy

The World Health Organization (WHO) defines literacy as “the ability to read, write, listen, comprehend, and speak a language”,¹ but due to constant changes in the way in which we interact, they further specify the definition as the “ability to read and write at a level that is deemed to allow communication, or the understanding and sharing of abstract ideas in society”.¹ Further to this, three levels of literacy classes have been suggested to exist: illiterate, functionally illiterate and literate.² Those who are considered illiterate cannot read and write in their native language, while functionally illiterate people can, but to varying degrees of speed, style and grammatical correctness. Functionally illiterate people are still considered unable to follow written information, and therefore cannot function in society when relying solely on the use of written information to understand an idea or follow instructions.²

In the Adult Literacy and Life Skills Survey conducted by the Australian Bureau of Statistics (ABS) in 2006, it was shown that 46% of the Australian population aged between 15 and 74 scored at level 1 or 2 on a scale of 1 (lowest literacy ability) to 5 (highest literacy ability), where a level of 3 is considered the “minimum required for individuals to meet the complex demands of everyday life and work in the emerging knowledge-based economy”.³ This suggests that the level of literacy in a large

segment of the Australian population is not at a level adequate to allow complete participation in society.

1.1.2 Health literacy

Health literacy is defined as a subset of literacy, and the WHO makes a point that many literacies exist, and that one must have a functional ability to utilise these literacies to communicate in the 21st century.¹ It is inappropriate to assume that if a person is considered literate, that they would also have functional health literacy.⁴ A low level of health literacy is specific to the context of healthcare and health information. For example, one may not have adequate understanding of medical vocabulary to understand medical information. This is why the concept of health literacy needed to be defined and understood.

Many definitions of health literacy exist, yet most attempt to explain essentially the same idea. The WHO defines health literacy as: “the degree to which people are able to access, understand, appraise and communicate information to engage with the demands of different health contexts in order to promote and maintain good health across the life-course.”¹ Alternatively framed, it is the ability to access, read, understand, comprehend and put into practice health information, delivered in a variety of media, be they written or verbal, which allows an individual to make decisions and perform actions regarding their health. As a result, this should lead to positive health outcomes, and therefore an improved quality of life.

The definition of health literacy has evolved over time from a purely technical meaning to a definition that encompasses empowerment in a complex healthcare system. The term 'health literacy' first appeared in 1974 in a paper published by Simonds titled 'Health Education as Social Policy'.⁵⁻⁷ He used the term 'health literacy' to describe the minimum level of understanding of health considered adequate through health education in schools, yet this made his definition rather limited in its application. In 1999, the American Medical Association (AMA) released a report titled 'Health literacy - Report of the Council of Scientific Affairs', which quoted their own definition of health literacy: "... ability to read and comprehend prescription bottles, appointment slips, and the other essential health related materials required to successfully function as a patient".⁸ This definition, whilst broader in scope than Simonds' 1974 definition, still failed to recognise the need for the consumer to utilise health information and health promotion materials to adopt a proactive approach to their own healthcare.

As research in health literacy became more prevalent, suggestions that health literacy be extended to consumers adopting an awareness of public health issues and how health decisions can affect it, arose, such as the idea of health literacy as a tool for empowerment of decision-making regarding one's health.^{1, 9} In particular, one study suggested that health literacy be expanded to an ability to understand public health communications, such as in biochemical disasters or bioterrorism threats.¹⁰ This action was taken following the threat of anthrax being used as a biological weapon in the United States. In response, the Center for Disease Control disseminated postcards to every address in the United States, providing information on anthrax. Unfortunately, the information provided was of a high technical level with

statements such as “Human anthrax has three clinical forms: cutaneous, inhalation and gastrointestinal”. This sentence used very few easy-to-read words, e.g. has, three, forms.

A more expanded definition of health literacy theorised that three levels of health literacy exist - functional, interactive and critical:

- **Functional health literacy** is the ability to function at a basic, yet adequate level to read and write in a healthcare context for situations that one faces in day-to-day life.^{1, 11}
- **Interactive health literacy** describes one’s ability to participate in everyday life with more control, and apply new information to evolving situations.^{1, 11}
- **Critical health literacy** is the use of a higher level of cognitive and social skills to critically derive data from health information to take a more active role in one’s health. It is the ability to take control over one’s own health.^{1, 11}

These degrees or grades of health literacy are aimed at identifying what the consumer’s level of knowledge enables them to do, rather than measuring certain achievements in reading or writing.^{1, 11} As an individual moves to a higher level of health literacy, their ability to function independently in managing their own health and becoming empowered to make critical decisions increases.¹¹

One study labelled health literacy as a ‘heterogeneous phenomenon’, meaning that it draws influence from a variety of contexts, including medical, social and cultural, and that as a result of the complex nature of health literacy, one’s ability to understand health information may change day-to-day depending on the conditions of the particular context.¹²

Finally, the particular definition of ‘health literacy’ used in various studies and reports, especially what is considered ‘limited health literacy’, has an impact on research findings, particularly generalisability. In the Adult Literacy and Life Skills (ALLS) study, it was shown that 59% of Australian adults between 15 and 74 scored at levels 1 and 2 in the health literacy section, which can be interpreted as an inadequate health literacy level.³ In contrast, in the United States (US), the National Assessment of Adult Literacy (NAAL) in 2003 found that 36% of adults aged over 16 years old had inadequate health literacy levels.¹³ The varying rates of limited health literacy detected in each study may be as a result of a difference in methods used to collect and interpret the data. Data from the ALLS study was collected by presenting participants with 191 survey items covering five domains: health promotion (60 items), health protection (65 items), disease prevention (18 items), health-care and disease management (16 items), and navigation (32 items).¹⁴ This was conducted in an interview-style format with a researcher. On the other hand, the NAAL study was conducted using a survey consisting of 28 health-related items, covering three domains: clinical, preventive and navigation.¹⁵ The survey, as with the ALLS study, was delivered in-person by a researcher. Differences in the number of questions asked and the difficulty level of each question may be responsible for variances between the results.

Standards for literacy in different countries may also contribute to variations in values reported, as well as educational standards and curriculum content taught in schools. Although, it is clear from data reported, that large proportions of given populations have a limited health literacy level, and that this must be addressed.

1.1.3 Effect of limited health literacy levels on the individual

As a result of inadequate health literacy skills, consumers have complex issues surrounding communication, including difficulty accessing, understanding and using health information.⁸ There are many consequences as a result of having inadequate health literacy that can affect knowledge and awareness of consumers' own health status, navigation of the healthcare system and knowledge regarding health and illness.⁸

The current complexity of healthcare requires consumers to be able to understand a number of processes. These include the requirement to understand prescription medicines information, the ability to recognise when to seek acute care, as well as preventative medicine. These expectations all require a high level of health literacy, and inadequacies may result in adverse health outcomes and poorer health outcomes.^{8, 16, 17} In one study, it was shown that 92% of patients with hypertension who were considered to have an adequate health literacy level were aware that a blood pressure reading of 160/100 mmHg was high. In comparison, only 55% of patients with a low level of health literacy were aware of this same fact. Similarly, 94% of patients with diabetes and an adequate health literacy were able to recall the symptoms of hypoglycaemia, compared with 50% of patients who were classed as

having inadequate health literacy.¹⁸ However, this study had a number of limitations. Firstly, the small sample size may have impacted on the ability to detect a significant relationship between participants' health literacy levels and blood pressure and HbA_{1c}. A larger sample size may have overcome this. Secondly, the study assumes that participants with adequate health literacy are more knowledgeable, yet they may simply be more able to perform better at tests and surveys. The generalisability of this study is therefore limited, but does provide insight into the relationship between limited health literacy and poor knowledge of one's health status.

A study conducted in an American hospital, measuring the correlation between health literacy levels and risk of hospital admission, showed that patients with inadequate health literacy were twice as likely to be admitted to hospital as those who had adequate health literacy skills (31.5% vs 14.9%, $p < 0.001$).¹⁹ After adjusting for age, gender, race, self-reported health, socioeconomic status, and health insurance, patients with inadequate health literacy were almost 70% more likely to be admitted to hospital than those with adequate health literacy (OR=1.69; 95% CI: 1.13-2.53; $p = 0.01$). However, the admission rate for African American participants was 89%, much higher than the true proportion in the American population, and therefore generalisability to the Australian setting is limited, but does suggest a higher risk in more disadvantaged groups.

Consumers with limited health literacy are also more likely to favour use of the emergency department than regular doctor visits. An American study of structured interviews with 492 emergency department patients examined the relationship between health literacy, access to primary care and emergency department use.²⁰

The study showed that those with limited health literacy reported fewer doctor visits (OR=0.6; 95% CI: 0.4-1.0) and more frequent use of the emergency department (OR=1.6; 95% CI: 1.0-2.7) than those with adequate health literacy. Reducing barriers towards accessing primary care and improving attitudes towards use of regular doctors may reduce this potentially costly issue. The generalisability of this finding to the Australian setting may also be limited due to differences in access and delivery of health care services between the two countries. It does although provide support towards the link between limited health literacy and the potentially costly, inappropriate use of emergency services.

In the Australian setting, Diug *et al.* studied the psychosocial factors that influence warfarin stability in consumers taking the medication regularly in 486 participants.²¹ The authors concluded that limited health literacy displayed a strong relationship with increased bleeding risk, nearly five times higher than those with adequate health literacy (OR=4.8; 95% CI: 2.9-7.8).

It can therefore be acknowledged that limited health literacy can have significant effects on the individual, including poorer health outcomes, increased adverse events, inappropriate use of the healthcare system, as well as reduced ability to navigate the healthcare system effectively.^{8, 16, 17}

1.1.4 Effect of limited health literacy levels on the population and healthcare system

Limited health literacy in the population has ramifications for the community in relation to both an increase in the rates of chronic disease, and increased costs to the healthcare system.^{1, 12} An escalation of chronic disease in society will have the knock-on effect of increasing costs associated with providing healthcare to patients for conditions that may have been preventable if adequate self-management were available.^{1, 22} McGowan defines self-management as “tasks that an individual must undertake to live well with one or more chronic conditions. These tasks include gaining confidence to deal with medical management...”.²² A broader definition by Health Canada may better capture the true meaning of self-management in the current healthcare setting.²³ It omits the word ‘chronic’, and aims to include all health conditions in self-management, assuming both acute and chronic, as well as health promotion and disease prevention. They defined self-management as “...the range of activities individuals undertake to enhance health, prevent disease, evaluate symptoms and restore health.” Self-management and understanding of one’s health are important in reducing the unnecessary use of the healthcare system. To enable effective self-management of chronic disease, adequate health literacy skills are required to comprehend and assess health information.^{1, 24}

The concept of self-management must then feed into the idea of empowerment of the individual, as it aims to promote self-sufficiency and awareness of one’s health, in both a preventative and management context. Thus for this to occur, one must possess adequate health literacy.

A costs study on health literacy using US national data conducted in 2007 suggested that the cost for the US economy relating to limited health literacy is between US\$106 and US\$238 billion each year.²⁵ The report estimates that if one considers “current actions (or lack of action), the real present day cost of limited health literacy is closer in range to US\$1.6 trillion to US\$3.6 trillion”.²⁵ No Australian costs study exists relating to the impact of limited health literacy on the Australian economy. Using an American model to draw conclusions on the Australian system may have limitations due to the differences in how healthcare is provided and funded by the individual and the government, one being the mostly private healthcare system of the US compared to the mostly public, government funded system in Australia. A private system may mean that consumers who are less able to afford healthcare, also have higher levels of limited health literacy in lower socioeconomic groups,²⁶ may go longer without care. They may therefore present to a medical professional at a critical, more serious point, which in turn may result in higher costs to the healthcare system.

A systematic review of literature associated with costs of limited health literacy and cost-effectiveness of interventions found that limited health literacy adds an additional 3-5% to the total expenditure on healthcare per year.²⁷ On a per year per patient level, it costs an extra US\$143 to US\$7,798 to treat a patient with limited health literacy compared to a patient with adequate health literacy levels.²⁷

Limited health literacy skills also cause patients to harbour feelings of shame and low self-esteem, which can lead to psychological consequences, particularly depression,²⁸ and a possible further detachment from the healthcare system.²⁹ This

may place further burden on the population through increased costs associated with mental healthcare.

1.1.5 Measuring health literacy

Since the advent of health literacy as a problem, a large focus has been placed on attempting to quantify and measure consumer health literacy. The reasoning for this was to identify those with limited health literacy, and subsequently tailor healthcare delivery specifically for these people to improve their access and understanding to medicines and health information.³⁰

Tests to measure health literacy ability generally require consumers to undertake tasks in word pronunciation and recognition, or assessing their understanding of the meaning of particular medical or health-related terms.³¹ Following assessment, consumers are graded on their ability and categorised into varying levels of health literacy ability. These tests are not comprehensive measures of consumer health literacy ability; instead they provide an assessment of selected domains that are believed to be markers of overall capability.³¹

A range of tests have been developed, including the Test of Functional Health Literacy in Adults (TOFHLA),³² the Rapid Estimate of Adult Literacy in Medicine (REALM),³³ and the Newest Vital Sign (NVS).³⁴ A variety of shorter versions of some tests have been developed, including the S-TOFHLA, a shortened version of the TOFHLA.³⁰

The TOFHLA consists of a 50-item reading comprehension and 17-item numerical ability test. It can take up to 22 minutes to administer.³² A shortened version was developed in 1999, the S-TOFHLA, with a reduction in the number of numerical items from 17 to 4, and from three prose passages to two.³⁰ This reduced the amount of time required to complete the test to around 12 minutes.

The REALM, developed in the 1990s, requires much less time than the TOFHLA to administer, on average, three to five minutes.³³ The test assesses the consumer's ability to pronounce a list of 66 medical and clinical terms of increasing difficulty. The person administering the test asks the consumer to say out loud each word, with the scores based on the number of words pronounced correctly. A major limitation to the REALM is the lack of determination whether the consumer actually understands the meaning of the word.

The TOFHLA and REALM, although measuring different health literacy abilities, are highly correlated to each other.³²

The NVS was developed in 2005 to create a test that is quick and easy to deliver.³⁴ It takes on average three minutes to administer. Consumers are required to answer six questions from an ice-cream nutrition label they are provided to inspect. If the consumer can answer four or more questions correctly, they are unlikely to have limited health literacy ability.

The usefulness of these tests in clinical practice is questionable, given the time it takes to deliver the test, the actual usefulness of the results, and the malleability of

health literacy itself. Health literacy abilities may change on a regular basis depending on the medical condition being treated, the health care provider, and the system providing the care,³⁵ and therefore classifying consumers into various health literacy ability levels may prove to be a futile and meaningless task.

Despite this, researchers have continued to attempt to develop quick, easy and non-intrusive tools to measure a consumer's health literacy. An American study by Sharp *et al.* investigated the relationship between time taken to sign a medical document and the consumer's health literacy level.³⁶ Ninety-eight consumers took part in the study, which first involved each undertaking a REALM health literacy test, followed by measuring the time it took for them to sign their names on a consent form. The relationship between the results of the REALM and the time to sign showed that individuals with signatures completed in six seconds or less were highly likely to have adequate health literacy ($p=0.005$), while those who took longer to sign were increasingly likely to have limited health literacy. The study was limited by its exclusion of consumers who could not understand English, even though it is well documented that CALD consumers have a higher prevalence of limited health literacy (Chapter 1, Section 1.2.2).^{37, 38} Although this study was conducted in an American setting in a physician's clinic, the results may still be relevant to the Australian community pharmacy setting where consumers are frequently required to sign prescriptions following medicine supply. Unfortunately, using this method to detect health literacy issues in situations where consumers do not sign, for example, in over-the-counter purchases, is not possible.

1.2 GROUPS AT HIGHER RISK OF LIMITED HEALTH LITERACY LEVELS

1.2.1 Older adults

A limited level of health literacy in older adults has been shown to be independently associated with poorer physical and mental health status.^{16, 39} This may be possibly attributed to a decline in executive function and episodic memory.⁴⁰ The Adult Literacy and Life Skills survey, conducted in Australia, demonstrated a relationship between increasing age and a decrease in health literacy levels.²⁶ Among adults aged 65 to 74 years, only 17% achieved level 3 or above, translating to adequate health literacy. It was suggested that this could be a result of reduced mental processing skills, lower levels of education received by older adults, and the length of time since receiving formal education.

A five-year prospective study conducted in 2005, aimed to associate limited literacy with mortality in older adults, and to determine whether lower literacy levels resulted in increased rates of death.⁴¹ It measured the literacy of 2,512 men and women, who were a part of The Health, Aging and Body Composition Study, using the REALM. After adjusting for demographics, socioeconomic status, co-morbid conditions, self-rated health status, health-related behaviours, health care access measures and psychosocial status, it was shown that those with limited literacy were nearly twice as likely to die over the same time period as those who had adequate functional literacy (HR=1.75; 95% CI:1.27-2.41). A limitation of this study is its exclusion of patients with functional difficulties, including the inability to walk one-quarter of a mile

or climb stairs, as well as dementia. The authors stated that they used the same sampling procedures as Harris *et al.*,⁴² which excluded these patients as the aim was to measure the effect of body composition on early disabilities. The significance of such exclusion criteria in this study is questionable and therefore may affect the ability for the results to represent the population as a whole. Cognitive difficulties are likely to further reduce functional health literacy in consumers, and therefore the results obtained from the Sudore *et al.* study may underestimate the true prevalence of limited health literacy in the older adult population.

A study by Bostock and Steptoe that investigated the relationship between health literacy and mortality in a sample of 7,857 British elderly people concluded that those with limited health literacy were 1.4 times more likely to die after a mean follow-up time of 63.2 months (OR: 1.4; 95% CI: 1.15-1.72) compared to those with a high level of literacy.⁴³ Limited health literacy was considered as making two or more errors on a health literacy test, which involved reading a medicine box and answering questions such as regimen duration. The study is limited by the effect of response bias. Those with limited health literacy are less likely to participate in health-related studies as a result of shame associated with having limited health literacy. Therefore, participants may have a higher health literacy level than the general population. This is a weakness of many studies which rely on participants responding to questionnaires.

1.2.2 Culturally and linguistically diverse (CALD) groups

The quality of healthcare accessible for patients from a non-English speaking background may be compromised as a result of inadequate English ability.^{37, 44, 45} In 2005, a telephone survey undertaken in 11 languages was conducted with 1,200 Californian residents with the objective of determining the effect of limited English-language ability on the comprehension of medical information delivered by both a medical practitioner that spoke the participants' language, and one that spoke English.⁴⁵ It was found that 49% of the respondents were classed as having limited English proficiency, and that these patients were at greater risk of adverse drug reactions, difficulties in understanding labels and greater frequency of reporting problems with understanding a medical situation. Studies show that patients who have an inadequate English speaking ability are less likely to access healthcare, and therefore are more prone to poorer health outcomes.^{37, 38}

In the Australian setting, it has been shown that Indigenous Australians have a high prevalence of limited health literacy levels, which may further add to social disadvantage in this population.⁴⁶ Dedicated research on health literacy issues in other CALD populations within Australia is lacking, yet limited health literacy within these populations may contribute significantly to the high prevalence of limited health literacy in Australia.

1.2.3 Children and adolescents

The effect of health literacy on children could be assumed to be related to the health literacy of the caregiver.^{47, 48} A systematic review of health outcomes in children related to the health literacy of their caregivers showed that a low parental literacy was related to poorer health outcomes for children.⁴⁸ In relation to health behaviours, the review suggested that while limited health literacy did have an effect on health behaviours such as smoking, violence and lack of breastfeeding, it was not the direct cause of such behaviours, which are likely to be influenced by other societal factors.

A study published in *Pediatrics* showed that there was no difference in health care use or cost for children whose caregivers were classed as having either adequate or limited health literacy.⁴⁹ This study was undertaken in an inner city urban hospital in the US, whose catchment is mostly an ethnic minority; therefore, cultural factors may also influence access to health care and potentially affect the results obtained. The study did find that there is a significant relationship between inadequate English proficiency and increased access to health care with an odds ratio of 2.17 (95% CI: 1.06-4.43).

Little is known about the health literacy levels of adolescents, as most studies focus on adults and the elderly. A study was conducted assessing the ability of adolescents to access health information on the internet, and involved 157 students from the US and UK aged between 11 and 19.⁵⁰ It showed that many students had difficulties in accessing health information on the internet. This stemmed from an inability to spell medical vocabulary and issues with being able to correctly describe

symptoms. It suggested that integrating health literacy into the health curriculum in adolescent education may aid in improving the future health of the community.

1.3 HEALTH PROFESSIONALS' AWARENESS AND ACTION ON HEALTH LITERACY

1.3.1. Awareness as an issue and subsequent action for improvement

Being a relatively new concept, the teaching of health literacy was minimal to non-existent in the past, and therefore generations of healthcare professionals exists with limited knowledge of health literacy.⁵¹ It is common for healthcare professionals to not consider that consumers may be unable to understand written material or include a literacy assessment in consumer visits.⁵¹ It has been suggested that healthcare professionals often are not prepared to help their consumers in overcoming the shame and embarrassment associated with limited health literacy.⁵² This therefore prevents adequate action being taken to improve the consumer's comprehension of the information they are presented.

Efforts to increase the understanding of health literacy amongst healthcare professionals have focused primarily on physicians, with education of other healthcare professionals having been neglected.⁵³ Many interventions aimed at improving the understanding of consumers with limited health literacy have focused on simplifying written material with an aim to enhance its readability.⁵² As health literacy is not purely associated with the ability to read, but also the ability to understand information, these sorts of interventions are limited by the consumer's

comprehension of the written material.^{52, 54} A number of studies have been undertaken to investigate current practices of healthcare professionals and possible new techniques for information provision, including the use of visual cues and pictographs.^{52, 55-57}

It has been suggested that potential barriers to the adoption of more effective communication techniques exist and therefore hinder their use in practice. These include, but are not limited to, the skill of the health professional, their knowledge of effective techniques, skills, lack of time and no incentive through reimbursement.⁵² The lack of research on the effectiveness of communication techniques for dealing with limited health literacy on health outcomes needs to be addressed, and from this, practitioner belief in their efficacy may aid uptake.⁵²

A variety of complex interventions, mainly comprising of consumer-focused education, have been trialled in an attempt to improve the health of those with limited health literacy. A systematic review of 15 such interventions found that 13 produced a statistically significant result in favour of intervention, and that initiatives similar to those reviewed may be effective if they are introduced more widely in the healthcare setting.⁵⁸ However, the review was unable to determine which type of initiative is more advantageous than another as they were diverse in nature.

The trials included in the systematic review, while showing support for the use of complex interventions in improving health outcomes in consumers with limited health literacy, had shortcomings. Four of the included studies did not perform randomisation of participants, eight failed to conceal the treatment allocation, and

blinding of the outcome assessor only occurred in three of the studies.⁵⁸ A modified Delphi List criteria was used to assess the studies, and of the nine criteria, five trials met six or more, and five met three or less. Therefore, the results of this review can be used to support the suggestion that complex interventions may be effective, but stronger evidence would be required to further support this claim, especially as cost can be a major factor. As with many systematic reviews, selection bias may limit the strength of the review. This review only included published journal articles, and excluded grey literature and other, unpublished data, reducing the scope of the study, and thus may limit the generalisability of the results to practice.

In relation to research on health literacy, an upsurge of studies in the last decade has provided greater insight in to health literacy and its effect on the individual and society. The Scopus database has shown an increase of articles with 'health literacy' in their titles from 13 in 1997 to 171 in 2009.¹² However, these are only articles that use 'health literacy' in their title without consideration of those that may use other related terms such as 'communication' or other synonyms. Therefore the number of articles on health literacy would most likely be higher than this figure.

1.3.2 Action by national organisations and governments

To improve health literacy, the responsibility must be placed on both consumers and society, and action to overcome limited health literacy must be directed towards the individual, the population, healthcare professionals and policy makers.¹²

The American Medical Association (AMA) became the first national medical organisation in the US to implement policies that consider the relationship between limited health literacy levels and poor health outcomes.⁵⁹ They developed a number of initiatives to target healthcare professionals in recognition of the role that health literacy plays in practice outcomes. These included tools and educational materials for professionals to help overcome barriers to limited health literacy.⁵⁹ Unfortunately, materials created for the American setting may not be applicable to practice in Australia, and would require amendments if they were to be used in this setting. The creation of Australian-specific materials to educate health professionals about health literacy would be the most appropriate action.

Other organisations have also adopted programs aiming to recognise and improve consumer health literacy in an attempt to improve public health.^{60, 61}

In 2009, the National Health and Hospitals Reform Commission (NHHRC), on behalf of the Australian Government Department of Health, submitted a final report titled 'A healthier future for all Australians', which identified the improvement of health literacy as important to enhancing consumer engagement with the healthcare system.⁶² The NHHRC recommended that health literacy be integrated into the National Curriculum in primary and secondary schooling, and that it be included in national skills assessment. Another recommendation was the development of a national campaign on mental illness to improve awareness, increase mental health literacy and reduce stigma associated with mental illness.

The US Department of Health and Human Services released a plan in 2010 to combat limited health literacy titled 'National Action Plan to Improve Health

Literacy'.⁶³ The aim of the scheme is to promote research and study into health literacy, and the creation of interventions that may aid in improving the health literacy level of the population. The action plan states their vision as “a restructuring of the ways we create and disseminate all types of health information... The plan also calls us to ensure that all children graduate with health literacy skills that will help them live healthier throughout their lifespan”.⁶³

1.4 HEALTH LITERACY IN THE PHARMACY SETTING

1.4.1. Services offered by a community pharmacist

The traditional role of the pharmacist was once considered that of a dispenser of medicines, with the function of supplying medicines to the population. The role of a pharmacist has evolved to a patient-focused healthcare professional integrated into the health care team, providing ‘enhanced pharmacy services’, such as diabetes screening, weight management, wound care and harm reduction programs. Unfortunately, this is often an aspiration rather than a reality in practice.

In 1998, six types of community pharmacy services were highlighted as new roles of the pharmacist, these being⁶⁴:

- Provision of medicines information;
- Provision of non-prescription medicines (Pharmacy Medicines and Pharmacist Only Medicines);
- Clinical interventions;

- Medication management services;
- Preventative care services for patients with chronic conditions; and
- Participating in therapeutic decisions.

The document concluded that there were three areas that the pharmacy profession lends itself to: the care of patients seen by a medical physician; the care of patients who present for issues that are treated in the primary care setting; and public health as a broad concept.

A systematic review of literature from 1990 to 2002 on services provided by pharmacists in 2002 further expanded on the pharmacist's role.⁶⁵ It stated that evidence for utilising the pharmacist to help educate both consumers and prescribers was strong. The review found that pharmacist-run educational sessions for consumers improved medication adherence in older adults and better symptom control in conditions such as heart failure, resulting in reduced risk of hospitalisation and improved quality of life. The implementation of educational outreach visits to prescribers on drug classes that commonly attract prescriber errors showed improved quality use of these particular medicines. Overall, the review demonstrated that a large amount of high quality evidence is present to support the ongoing development and implementation of pharmacy professional services, including educational initiatives.

1.4.2 Why pharmacists have an important role in understanding health literacy

Being one of the most accessible healthcare professionals in the healthcare team, the pharmacist must possess adequate communication skills to ensure accurate and comprehensible health and medicines information can be provided to the consumer and community. The WHO documents the qualities a pharmacist must exhibit to practice as a professional and competent member of the profession.⁶⁶ The document highlights eight attributes, titled 'The Eight Star Pharmacist':

- Care-giver
- Decision-maker
- Communicator
- Leader
- Manager
- Life-long learner
- Teacher
- Researcher

The importance of possessing these qualities is paramount to working effectively with other healthcare professionals and with the public.

The understanding of health literacy, its effect on the health outcomes of consumers and how it can be managed is heavily embedded in the role of the 'communicator'. The effective exchange of information between the consumer and the pharmacist requires the use of a variety of communication techniques to overcome health

literacy barriers, and it has been suggested that more training is necessary to make health professionals, including pharmacists, more health literacy sensitive.⁵¹ If a pharmacist were unable to recognise that a consumer had limited understanding, or the consumer was unable to explain their symptoms or illness accurately, negative consequences may result; for example, the consumer may receive inappropriate care or may misunderstand instructions. A reason that inadequacies in health literacy go undetected by healthcare professionals is that the issue of limited health literacy is widespread and is not immediately apparent or obvious with many consumers.² Limited health literacy can be viewed as a 'quiet disability' due to the shame associated with admitting the inability to read or write, and is therefore the reason why pharmacists need the ability to conceptualise health literacy as an issue in everyday practice.

In Australia, the Pharmaceutical Society of Australia (PSA) publishes a Code of Ethics that outlines the principles that a pharmacist must abide by to practice as an ethical and responsible health practitioner.⁶⁷ Principle 1 covers the consumer as the pharmacist's first priority, and states that their care and wellbeing must be dealt with in a professional and compassionate manner. It then defines the pharmacist's obligations under this principle to provide further guidance as to how they are implemented in the practice setting. Two of these obligations can be directly related to the issue of health literacy, these being:

- "1.3 Recognise consumers who are particularly vulnerable and tailor the provision of care accordingly"; and

- “1.4 Act to prevent harm to the consumer”.

It can therefore be assumed that to abide by these principles, pharmacists have an obligation to recognise consumers with inadequate understanding and tailor their interactions with them to optimise the exchange of information and ensure adequate understanding, with the aim of preventing harm and improving health outcomes.

It has been shown that pharmacists often overestimate the ability of consumers to read and comprehend information on medicines bottles, health information and forms associated with receiving care.^{2, 68} For the consumer to understand this information at a level deemed appropriate, they must have adequate reading, computational and self-management skills to navigate the health system.² A study investigating how patients cope with interacting with the healthcare system showed that patients employed a number of techniques in an attempt to overcome issues with their illiteracy.⁶⁸ One method was to continually ask questions until they understood the information, yet once they received a negative response from a healthcare professional regarding their inability to read or write, they were unlikely to mention their literacy issues in the future. This then further deepens the problems associated with recognising consumers with limited literacy levels. Other strategies involved using a surrogate who can read and write to attend appointments with them, or a reliance on oral instructions or demonstration of procedures.⁶⁸ It must be noted that studies like these can be flawed due to the sensitive nature of limited literacy and the associated shame and stigma, and therefore participants may be reluctant to admit limited literacy when directly asked.

This is where it is important for pharmacists to be able to recognise when someone does not understand a concept, as it may uncover hidden inadequacies in literacy abilities. A 2013 Australian study by Kairuz *et al.* utilised semi-structured interviews with pharmacists and pharmacy assistants to investigate factors impacting on consumer health literacy, from the perspective of pharmacy staff members.⁶⁹ The study showed that three overarching factors influenced consumer health literacy: complexity of the health system; clarity of information; and dialogue among consumers and healthcare professionals. The study went on to suggest that enhanced engagement between pharmacy staff members and consumers would limit potential confusion with medicines and health information may help reduce medication misadventure and improve consumer health outcomes. This study is limited by a very small sample size (11 pharmacists and 9 pharmacy assistants) and a relatively small geographical area (south-east Queensland), and therefore reduces the strength of the results and their ability to be generalised to larger populations.

There is a current lack of research into health literacy interventions directed at pharmacists both in Australia, and internationally, and therefore provides further reason to undertake research into this particular area.

For this to be possible, the pharmacist must understand health literacy as a concept, and subsequently as an issue that must be addressed to ensure positive health outcomes. Working in partnership with consumers and their caregivers in improving understanding and involving them in their own care as much as possible may help reduce the shame that limited health literacy can cause.⁶⁸

1.4.3 The primary and tertiary care setting

In Australia, one of the roles of the pharmacist is the provision of Pharmacy Medicines (S2)¹ and Pharmacist Only Medicines (S3)², which are commonly referred to as 'over-the-counter' medicines. The treatment of minor ailments by the pharmacist is called 'primary care'. In the supply of S2 and S3 medications, the pharmacist must ask a range of questions related to the consumer's condition, including symptoms, other medications being used, allergies and other medical conditions that may be relevant. For this information to be divulged, the consumer must have an adequate understanding of the questions being asked, but also an ability to recognise and describe their own symptoms in a way that is both accurate and comprehensible by the pharmacist.⁷⁰ As well as this, the consumer should be able to ask questions that they believe are important for their own understanding. Limited health literacy acts as a barrier to the effective exchange of this information. Shame related to this issue may also prevent the patient from asking questions in instances where they do not understand a concept.

Limited health literacy is also an important consideration in the provision of tertiary care to the consumer. Tertiary care involves the management of conditions that have been referred to more specialised medical practitioners for ongoing treatment and management. Limited health literacy may prevent a consumer from being able to recognise signs of disease progress, or changes in their condition or symptoms.⁷⁰

¹ Pharmacy Medicines: medicines that are only available for purchase from pharmacies. Consumers do not need to receive advice from a pharmacist before purchasing this medicine.

² Pharmacist Only medicines: medicines that are only available for purchase from pharmacies. Consumers must first be assessed by a pharmacist to determine whether these medicines are appropriate for the consumer.

The ability to effectively monitor one's own health may be paramount to ensuring that the best care is provided efficiently and effectively.

A commonly overlooked issue is the healthcare professional's own level of health literacy. For an effective exchange of information between the consumer and the pharmacist, the pharmacist must also have a solid understanding of healthcare. Little research has been done in relation to this matter, as pharmacists are generally, yet perhaps wrongfully, assumed to have a very high level of health literacy.

In addition to this, adjunct staff in the pharmacy, such as pharmacy assistants and dispensary technicians, are commonly involved in providing primary care under the supervision of a pharmacist. For this to be effective, the health literacy of the pharmacy staff members must also be adequate. Research and literature in this field is also lacking, and further investigation and subsequent action to improve staff health literacy may allow for more effective communication between the staff and consumer.

1.4.4 Medication related issues and medication misadventure

The issue of medication misadventure and non-adherence is prevalent in consumers who possess limited health literacy skills^{12, 71-73}, albeit with a possibly weak association as shown in a 2014 systematic review on the topic.⁷⁴ Medication misadventure is defined as 'any iatrogenic hazard or incident associated with drug therapy' and includes adverse drug events, which are instances where a drug has caused harm to the consumer.⁷⁵ A number of factors can contribute to medication

misadventure, including increasing age, which is usually accompanied by decreasing cognition, misinterpretation of medication labels and pharmacist advice, as well as inadequate time spent by a pharmacist in counselling consumers on medicines.^{52, 71,}

72, 76

A study by Lindquist *et al.* that investigated the incidence of medication non-adherence after discharge from hospital showed that patients with limited or marginal health literacy levels had an increased risk of unintentional non-adherence to discharge medications.⁷² Of those with limited health literacy, 47.7% had unintentional non-adherence 48 hours after discharge, compared with 31.8% in those with marginal health literacy, and 20.5% in the group who were considered to have adequate health literacy ($p < 0.002$).

It had previously been shown that health literacy played no part in medication adherence levels^{77, 78}, yet Lindquist *et al.* explained that previous studies had not separated intentional and unintentional non-adherence.⁷² The study by Lindquist *et al.* showed that patients who had adequate health literacy were more likely to intentionally non-adhere to medication (73.3%), compared to those with marginal and limited health literacy patients (11.1% and 15.6% respectively, $p = 0.001$).⁷² From this, it was suggested that limited health literacy does result in medication non-adherence, but more specifically, it results in unintentional non-adherence, but also that a higher level of understanding of medication information may translate into decision making regarding medication taking and health behaviours.

Limited health literacy also contributes to misunderstanding of prescription warning labels.^{71, 79} Patient warning labels or ancillary labels are stickers attached to medication containers that provide specific warnings to consumers about the medication, or give instructions in regard to how, or how not to, take medications. Davis *et al.* reported that those with limited literacy were three times more likely to misinterpret patient warning labels than those that had adequate literacy levels (OR=3.4; 95% CI: 2.3-4.9). Most patients were able to understand basic instructions such as ‘Take with food’, yet struggled to understand instructions that required more complex thought and comprehension such as ‘For external use only’ or ‘Do not take dairy products, antacids, or iron preparations within 1 hour of this medication’.

Common misinterpretations are shown in Table 1.1 below.

Table 1.1: Misinterpretations of patient warning labels used in medication labelling

Patient warning labels	Misinterpretations
Take with food	Don't take food
Do not chew or crush. Swallow whole	Chew pill and crush before swallowing Just for your stomach
You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication	Don't leave medicine in the sun Don't leave [medicine] in sunlight, but a cool place.
For external use only	Take only if you need it

The study by Davis *et al.* concluded that a review of current labels used in pharmacy practice should be undertaken to allow for a better understanding of what healthcare professionals would consider basic instructions.⁷¹

1.5 THE CURRENT STATE OF PHARMACIST EDUCATION OF HEALTH LITERACY

1.5.1 Tertiary education - curriculum design and how health literacy is taught

Being a relatively new concept, health literacy in pharmacy curricula is not well represented. With healthcare professional courses, such as pharmacy, being very content heavy and having many issues demanding space in undergraduate or post-graduate pharmacy curricula, it may become difficult to integrate new concepts, such as health literacy. The Institute of Medicine (US) has stated the importance of teaching students about health literacy, and has noted a number of initiatives by medical schools in the US in regard to teaching health literacy to students.⁸⁰

The Harvard School of Public Health offers graduate students an ongoing course on health literacy and its implications on society, while the University of Virginia School of Medicine introduces health literacy in an introduction lecture in first year, with the concept being integrated into other year levels.⁸⁰

Literature on health literacy education implementation in to pharmacy courses is minimal. A study conducted in America in 2013 investigated the impact of a health literacy assignment on pharmacy students' knowledge of health literacy.⁸¹ Both before and after the assignment, students completed a self-reflective exercise of their awareness and skills associated with health literacy. The study showed an improvement in their understanding of the challenges, significance, and methods of

health literacy level-appropriate communication. Students also demonstrated a greater awareness of the role of pharmacists in presenting medicines and health information clearly to patients. While adding support to the integration of health literacy education into pharmacy curricula, the study was unable to determine the long term sustainability of skills students gained through the health literacy assignment. Long term retention and use of health literacy level-appropriate communication is important if a sustained impact on consumer health is to be seen.

A review conducted by the PhD candidate of current pharmacy curricula in Australian universities shows that health literacy is taught in a number of ways, under a variety of different labels (Table 1.2). Table 1.2 outlines each university's acknowledgement of health literacy in the learning outcomes in their pharmacy course.

From the 18 schools of pharmacy in Australia, only one, Monash University, mentioned 'health literacy' in the learning objectives or course outline. It must be added that Table 1.2 does not show whether a university teaches health literacy in their course; it simply aims to list universities that mention health literacy in the university handbooks and subject outlines available to the public. The table contains extracts from university handbooks that were deemed closest to the definition of health literacy education. It must be noted that communication and interpersonal skills are taught across a number of subject in each curricula, not solely in those mentioned in the table.

The omission of health literacy in subject outlines may provide an opening for further investigation as to why it does not take a higher priority in unit outline descriptions.

The survey of academic pharmacists (Chapter 3, Section 3.3) provides a greater insight into how health literacy is taught and assessed both in Australia and in an international context.⁸²

Table 1.2: Use of the term ‘health literacy’ within the learning objectives of current pharmacy curricula in Australian universities

University	Program	Subject	Learning Objectives
University of Canberra ⁸³	MPharm	Healthcare Professional Practice 1	Doesn't use the term 'health literacy'. Describes the learning outcomes as: • “Understand the importance of and demonstrate, clear techniques in verbal and written communication as they apply to different areas of professional practice, involving patients, carers and healthcare professionals”. • “Identify and overcome barriers to effective communication including consideration of culture and ethnicity”.
Charles Darwin University ⁸⁴	BPharm	Fundamentals of Pharmacy Practice	Doesn't use the term 'health literacy'. Describes the learning outcomes as: • “This unit introduces the learner to the role of the pharmacist in...communication skills.”

University	Program	Subject	Learning Objectives
Charles Sturt University ⁸⁵	BPharm	Introduction to Pharmacy	Doesn't use the term 'health literacy'. Describes the learning outcomes as: • "Presents a theoretical framework on which to develop effective written and oral communication skills."
Curtin University of Technology ^{86, 87}	BPharm	Pharmaceutical Practice 321	Doesn't use the term 'health literacy' Describes the learning outcomes as: • "Patient counselling, communication skills, compliance and concordance..."
	MPharm	Pharmaceutical Practice 521	Doesn't use the term 'health literacy' Describes the learning outcomes as: • "Patient counselling, communication skills, compliance and concordance..."

University	Program	Subject	Learning Objectives
Griffith University ⁸⁸	BPharmSci /MPharm	Professional Pharmacy Practice I and II	Doesn't use the term 'health literacy'. Describes the learning outcomes as: • "...provides the student with the knowledge and understanding of verbal communication, history taking and interpersonal counselling skills, while highlighting the needs of the patient."

University	Program	Subject	Learning Objectives
James Cook University ⁸⁹⁻⁹¹	BPharm	Professional Pharmacy Practice I, II and III and Advanced Professional Pharmacy Practice	Doesn't use the term 'health literacy'. Describes the learning outcomes as: • "...increase the students' knowledge and understanding of verbal communication, history taking, interpersonal and counselling skills that consider the different cultural and socioeconomic needs of the patient." • "This subject will further develop the students understanding of aspects of professional pharmacy practice including communication, counselling skills... An emphasis will be placed on how this applies to cross cultural communication." • "An emphasis will be placed on good listening and communication skills."

University	Program	Subject	Learning Objectives
La Trobe University ⁹²	BPharm	Pharmacy Practice and Advanced Counselling	Doesn't use the term 'health literacy'. Describes the learning outcomes as: • "Topics to be covered include making decisions about how to respond, ways to respond, crisis intervention, telephone counselling, dealing with people from culturally and linguistically diverse (CALD) backgrounds, values and beliefs about people, customers in difficult situations, assertive skills, grief and loss, teamwork and counselling across the life span."
Monash University ⁹³	BPharm	Pharmacists as Communicators	Does mention 'health literacy'. Describes the learning outcomes as: • "effective communication with patients and prescribers; health literacy; the problems of medication non-adherence and means of overcoming them; the role of the pharmacist in patient education."

University	Program	Subject	Learning Objectives
University of New England ⁹⁴	BPharm	Communication for Health Workers	Doesn't use the term 'health literacy'. Describes the learning outcomes as: • "...introduces students to the development of effective communication in the health care context. It addresses communication with clients, colleagues, families and significant others and deals with conflict resolution, cross-cultural communication and professional responsibility and accountability. It assists students to identify barriers to communication and the causes of communication breakdown and offers ways for them to approach overcoming these problems in their professional environment."
University of Newcastle ⁹⁵	MPharm	Pharmacy Practice 2	Doesn't use the term 'health literacy'. Describes the learning outcomes as: • "Communication skill is an important competency for pharmacists and this course will examine ways of effective communication with consumers and other healthcare professionals."

University	Program	Subject	Learning Objectives
University of Queensland ^{96, 97}	BPharm	Quality Use of Medicines A1 and A2	Doesn't use the term 'health literacy'. Describes the learning outcomes as: • "Communicate information about medicines clearly, accurately and at a level appropriate to the context." • "To introduce the pharmacy student to patient counselling techniques."
Queensland University of Technology ⁹⁸	BPharm	Pharmacy Practice 1	Doesn't use the term 'health literacy'. Describes the learning outcomes as: • "Demonstrate effective communication and counselling methods used to convey the appropriate drug information to patients following the dispensing of medication or to patients seeking advice on their current medications and introduce the concepts of compliance, concordance and an understanding of health beliefs in patients."

University	Program	Subject	Learning Objectives
University of South Australia ^{99, 100}	BPharm	Pharmacy Practice 2 and Issues in Contemporary Pharmacy Practice	Doesn't use the term 'health literacy'. Describes the learning outcomes as: • "Cultural, social, behavioural and communication issues in pharmacy practice." • "Consumer issues such as self-medication and the 'informed consumer'...Patient diversity: multicultural issues that impact on health, and issues for indigenous populations, including indigenous Australians."
University of Sydney ^{101, 102}	BPharm MPharm	Social Pharmacy and Aboriginal and Rural Health	Doesn't use the term 'health literacy'. Describes the learning outcomes as: • "Topics include chronic illness, self-management, pain, and communications. The emphasis will be on the psychosocial processes that underpin patient health behaviours." • "...different modes of communication and service delivery will be investigated."

University	Program	Subject	Learning Objectives
University of Tasmania ¹⁰³	BPharm	Pharmacy in Health Care	Doesn't use the term 'health literacy'. Describes the learning outcomes as: • "Students will be introduced to basic psycho-social aspects of healthcare and communication..."
University of Western Australia ¹⁰⁴	MPharm	Introduction to Pharmacy Practice	Doesn't use the term 'health literacy'. Describes the learning outcomes as: • "...become familiar with the process of communicating health care information to the patient..."
RMIT University ¹⁰⁵	BPharm	Introduction to Pharmacy	Doesn't use the term 'health literacy'. Describes the learning outcomes as: • "You will examine, in the context of the Australian healthcare system, the theory and practice of personal and interpersonal skills, including written and oral communication skills..."

University	Program	Subject	Learning Objectives
University of Technology Sydney ^{106, 107}	MPharm	Professional Services: Introduction and Professional Services 1	Doesn't use the term 'health literacy'. Describes the learning outcomes as: • "Patient information covers consumer rights to be informed, and behavioural, communication and cultural diversity factors." • "The communication and behavioural aspects of patient–pharmacist interactions are also covered."

1.5.2 Continuing education on health literacy

Continuing education (CE) in pharmacy has been available since 1960, and attempts to help pharmacists improve their knowledge and skills in pharmacy practice, such as emerging and current diseases and approaches to therapy.¹⁰⁸

Due to the relative novelty of health literacy as a concept, many pharmacists who graduated before the concept was taught at university may lack an awareness of its existence. This highlights the importance of providing education on health literacy to ensure that all pharmacists are aware of it, how it affects consumer outcomes, how to identify consumers who may have limited health literacy levels, and interventions and techniques that can be employed to improve information exchange.

Schwartzberg *et al.* notes that “enhancing the interaction between health care professional and patient is a matter of continuing professional education.”⁵² The authors go on to suggest that healthcare professionals require specific education on the various techniques that can be employed to improve information exchange between themselves and the patient, as well as the implications that limited health literacy levels have on the healthcare system.

There appears to be a lack of CE resources on health literacy in Australia and internationally, with this possibly attributable to the concept being relatively new and unknown.

1.5.3 Communication techniques already known and utilised by pharmacists

Adaptable and effective communication skills are essential for pharmacists to interact with consumers who have varying levels of health literacy. Universities teach a range of skills that can be employed in practice settings to enhance the exchange of information between the consumer and the healthcare professional, yet the degree to which these are utilised may be less than desirable.

Communication skills can vary from basic skills, including using simple language, speaking slowly, using printed material to supplement spoken information and reading aloud, to more advanced methods. Advanced methods involve greater interaction on the consumer's behalf, and include the teach-back method where the consumer is asked to repeat back or demonstrate what has been taught to them to assess their understanding.^{35, 109, 110} Using the teach-back method could constitute asking the consumer: "To make sure I've explained things clearly, could you please tell me how you will use this medicine when you get home?"

Schwartzberg *et al.* conducted a survey of healthcare professionals attending health literacy information sessions on methods they use in their everyday practice. It was found that pharmacists are more likely to read instructions aloud compared to physicians and nurses (70.0% vs. 46.9% vs. 57.6%, $p < 0.003$), and were the least likely to employ methods that check for patient understanding (36.4% vs. 55.1% vs. 42.5%, $p < 0.020$).⁵² The use of these basic techniques, while beneficial in conveying information to consumers with the most basic level of understanding, is associated

with a number of limitations in trying to achieve consumer understanding. Reading aloud does not add meaning to the information, and is not likely to improve a consumer's comprehension of the information, while failure to use the teach-back method does not assess a consumer's understanding. While this study by Schwartzberg *et al.* does shed some light on the frequency of use of communication methods, the survey was completed by healthcare professionals attending a health literacy seminar, who therefore may already be more proactive in employing these methods in their practice. As a result, the actual frequency of use may be lower than what is suggested in this study.

1.5.4 Universal precautions in health literacy

It has been suggested that 'universal precautions' in health literacy be adopted for all consumers.^{31, 111, 112} The concept of universal precautions came to light in the early 1990s in an attempt to reduce the spread of Human Immunodeficiency Virus (HIV) by assuming that any patient could be infected and thus taking the same appropriate measures with all patients to reduce the risk of exposure to blood and other bodily fluids. A similar framework idea now exists for managing the effects of limited health literacy in the community; assume that all consumers have a limited level of health literacy until indicated otherwise. For healthcare professionals, this would mean that they would communicate information to all consumers, both verbal and written, at a level that would be appropriate for consumers with limited health literacy.^{111, 112} This approach also removes the need to screen consumers for limited health literacy.

Universal precautions for health literacy include the use of simple language, particularly lay language, and avoiding medical jargon that could be likely to confuse the consumer.¹¹² The American Healthcare Research and Quality group (AHRQ) created a Health Literacy Universal Precautions Toolkit, which includes a number of communication strategies that can be employed in practice to improve consumer understanding of medical information.¹¹² These include, but are not limited to:

- Prioritise information
- Limit content
- Provide written information in a simplified form
- Encourage questions from the consumer
- Establish understanding (e.g. use the teach-back method)
- Ask the consumer to demonstrate a particular process, if appropriate
- Use simple, plain language when counselling
- Speak clearly
- Repeat important points

An impediment to using these skills in everyday pharmacy practice could be the small window of opportunity to interact with a consumer, and therefore time may not permit for more advanced techniques to be utilised. Teaching pharmacists and pharmacy staff members effective skills for consumer interaction is paramount to ensuring the best health outcomes are achieved for consumers. Pharmacists should not be afraid to spend extra time consulting a consumer with a lower level of understanding as it reduces the likelihood of representations due to issues such as medication non-adherence.

1.6 BEHAVIOURAL CHANGES OF THE HEALTHCARE PROFESSIONAL IN ADOPTING NEW CLINICAL PRACTICES

1.6.1 Influences, motivations and approaches for implementing innovations and interventions

The translation of research and knowledge into practice is not a new challenge. For interventions that involve the addition of new, voluntary practices to be successful, the healthcare professional being targeted must be receptive to change and open to the adoption of new practice techniques. The outcomes of research aim to support new, voluntary practices in patient care and their subsequent implementation into everyday practice, but a gap exists between what is suggested and what is actually applied to practice by healthcare professionals. This gap in implementation of research could be concerning and disheartening for those who invest time and money into developing new practices, yet fail to see a return on investment through uptake into clinical practice.

The difference between ‘diffusion’, ‘dissemination’ and ‘implementation’ must firstly be defined to understand the process of changing clinical behaviours. Diffusion is defined as “the process by which innovation is communicated through certain channels over time among the members of a social system”, while dissemination is “diffusion that is directed and managed”.¹¹³⁻¹¹⁵ Diffusion therefore may be thought of as the natural, passive spread of information, while dissemination is a more planned and active process. Although on the contrary, a definition by Rogers of dissemination also mentions that it includes “both the planned and spontaneous spread of new

ideas”, therefore suggesting that dissemination can be both natural and planned.¹¹³ Although these definitions do differ slightly, they both attempt to encompass the act of spreading information and ideas into society.

Implementation goes a step further to involve the translation and application of innovations or guidelines into practice.¹¹⁶ It could be suggested that while diffusion and dissemination of clinical innovations and guidelines are important factors in changing clinicians’ behaviour, it is their effective implementation that is paramount to ensuring that they are embedded into everyday practice.¹¹⁶

Grol suggests that there are a variety of influences and processes that motivate a healthcare professional to adopt changes in their clinical practice, being either internal or external influences.^{117, 118}

Internal influencers come from within the healthcare professional’s own desire to implement change.^{117, 118} Three approaches for encouraging internal change are suggested to exist: educational, epidemiological and marketing. The educational approach is based on the healthcare professional’s own intrinsic motivation to achieve competence in practice and remain up to date with emerging literature. Utilising approaches based on everyday problems faced in practice and using problem-based and interactive group learning are thought to be effective forms of this approach.

The epidemiological approach is based on assuming that healthcare professionals make decisions based on the evidence available, weighing up the benefits and risks

before implementing change into their clinical practice. This approach can involve providing evidence in a user friendly form, particularly with the use of summaries and guidelines, to deliver succinct and critiqued information.

Lastly, the marketing approach involves the promotion of a proposal for change by disseminating the information in an attractive fashion that can aid the target user to achieve their personal goals. The utilisation of media in advertising such proposals is an example of the marketing approach.

On the other hand, external influences can also be necessary for the uptake and implementation of change in clinical practice, and thus a variety of approaches can be developed to target this.^{117, 118} External influences are influences that come from a source other than the individual. Four approaches have been identified as ways of encouraging implementation of change, these being: external influence; social interaction; managerial; and control and compulsion.

External influence approaches focus on the belief that the behaviour of the healthcare professional can be shaped by external motivators, such as feedback, sanctions and rewards.^{117, 118} Social interaction approaches are based on the belief that healthcare professionals will look to role models or exemplary figures in their field, and emulate their behaviour in clinical practice. These approaches can involve organising 'outreach visits' by respected experts who already undertake these new practices, as well as utilising peer review and assessment.

The managerial approach involves changing and improving organisational frameworks and systems, rather than focusing purely on the healthcare professionals as individuals. Promoting a system where implementing change is easily facilitated can help ensure smoother and more effective adoption of new proposals for change. Lastly, control and compulsion involves the influence that external powers exert over healthcare professionals' behaviour. It can involve the avoidance of negative consequences, such as lost income and loss of extra benefits. Examples of this form of influence approach include laws and legislation, accreditation and professional registration.

A systematic review by Greenhalgh *et al.* on innovation diffusion in service organisations also discussed influences for innovation adoption, and described 'homophily' and 'boundary spanners' as additional influences to the adoption of innovations.¹¹⁵ Homophily describes a characteristic of individuals who are more likely to implement and utilise an innovation if those who are currently using it are characteristically similar to them, for example in relation to education, culture and socioeconomic status. Boundary spanners are individuals who work within an organisation but have links to the outside world, and are able to link the organisation to external networks in relation to the innovation being implemented, and thus improve the likelihood of implementation of the innovation.

Understanding the factors that may influence implementation is important, yet without being able to identify particular factors which are vital for the implementation of clinical interventions in individual situations or settings, the applicability of the theory is limited in practice. It does, however, provide a basis to work upon when

creating interventions, in particular, possible enablers and barriers that may be targeted.

1.6.2 Attributes of an innovation

In the practice setting, innovations are implemented and adopted at varying rates, and have therefore been suggested to comprise of a number of key attributes. In a review by Greenhalgh *et al.*, a set of characteristics of an innovation were outlined, which are as follows¹¹⁵:

- **Relative advantage:** being able to show well defined advantages in efficacy or cost improves the likelihood of implementation into practice.
- **Compatibility:** if the innovation complements the needs and values of the targeted individual or organisation, there is an improved rate of adoption.
- **Complexity:** simple innovations are more likely to be implemented.
- **Trialability:** success of adoption increases if the user is able to trial the innovation in a limited capacity before implementation.
- **Observability:** if visible benefits can be seen, ease of implementation improves.
- **Reinvention:** the ability to adapt innovations to better suit the needs of the user will aid in adoption into practice.
- **Fuzzy boundaries:** the concept that the more malleable and adaptive the organisational systems are, the easier full implementation of an innovation can occur.
- **Risk:** innovations considered risky for the individual are harder to implement.

- **Task issues:** innovations that are perceived to increase the individual's normal task performance will be adopted more readily.
- **Knowledge required to use it:** likelihood of adoption is improved if the knowledge necessary to utilise the innovation can be easily coded and used in varying contexts.
- **Augmentation/support:** innovations that come with support are more likely to be adopted.

The review suggests that while the attributes of the innovation are important, they are not the defining factors that influence the rate of implementation and adoption into practice. Rather, it is the “interaction among the innovation, the intended adopter(s), and a particular context” that determines the rate of adoption.¹¹⁵ It could therefore be suggested that while it is important to consider the attributes of an innovation during its design, the contextual differences in varying settings and the attributes and skills of each individual will play a large role in the rate of adoption of an innovation. This is where the barriers to implementation may play a marked role in implementation and sustainability in practice.

The Greenhalgh *et al.* systematic review included innovations from many fields of practice, including rural and medical sociology, communication studies and marketing, and therefore conclusions made may not be completely applicable to the implementation of innovations into the health care system. The review was unable to include information on the sustainability of implemented innovations in practice, as there was very little literature on this topic, and may therefore benefit from further

research into this area to gain a better understanding of factors that influence sustainability in practice.

As mentioned previously (Chapter 1, Section 1.3.1), systematic reviews may be limited by their inclusion criteria. Publication bias may inadvertently exclude important insights into a particular topic, thereby reducing the potential impact of the review. Overcoming this is difficult, as ensuring that the best-quality research is included in a review is an important aspect of the process.

1.6.3 Barriers in the implementation of change in clinical practice

A number of barriers exist that impede the adoption of new practice techniques and innovations, including time, lack of reimbursement and lack of skill.¹¹⁹ Some practitioners may lack the ability to critically evaluate medical literature, and therefore may be unable to adopt suggested techniques, or may attempt to utilise techniques that are suggested by low quality studies.

A review of the literature surrounding adoption of clinical guidelines and barriers that impede implementation suggested that the following seven barriers exist on the individual level¹²⁰:

- **Lack of awareness** - healthcare professionals are not aware that the guidelines exist.
- **Lack of familiarity** - healthcare professionals are not familiar with particular guidelines, and therefore may present issues with implementation.

- **Lack of agreement** - healthcare professionals may disagree with the guidelines or recommendations due to a number of issues including lack of evidence, lack of relevance to the patient population, cost, patient discomfort or lack of credibility of the author(s).
- **Lack of self-efficacy** - a belief that the healthcare professional cannot implement the guidelines due to a lack of training or skill.
- **Lack of outcome expectancy** - healthcare professionals may believe that the implementation of the particular guideline will not have an effect on the patient population that is being targeted.
- **Inertia of previous practice** - healthcare professionals may not adopt a new guideline due to influence by their previous practice techniques or lack of motivation to change previous practice.
- **External barriers** - external barriers such as lack of convenience, lack of reimbursement, and confusion may inhibit guideline implementation.

Overcoming these barriers to enable effective implementation, uptake and maintenance of guidelines and new practice methods requires a variety of delivery modes that show increased involvement and participation in learning.

Along with the above barriers to implementation, the influence of subjective norms and the belief that a problem exists to change also impacts on the likelihood for an individual to change their behaviours.¹²¹⁻¹²³

A Cochrane systematic review explored tailored interventions that aimed to overcome barriers identified as limiting the implementation of new practice guidelines

and methods.¹²⁴ Twenty-six randomised controlled trials were included in the systematic review. The review concluded that interventions that are tailored to overcome identified barriers are better than not attempting to identify possible barriers or simply disseminating the information without a focus on effective implementation.

The review also found that there is currently no “single, standard method for tailoring strategies to identified barriers”, and that by referring to currently available evidence, it is not possible to decide the most effective approach.¹²⁴ It would therefore be wise to identify barriers to implementation in the specific target population before dissemination of material, and to tailor the information, taking into account these identified barriers. Barriers may be identified a number of ways, including surveys, focus groups, observation or by interviews with healthcare professionals.

As mentioned, publication bias may limit to potential impact of systematic reviews. Furthermore, the inclusion of studies utilising RCT study designs only also reduces the scope of the review, yet may be outweighed by the strength RCT studies provide over other study designs.

1.7 INFORMATION DELIVERY FOR TEACHING HEALTHCARE PROFESSIONALS

1.7.1 The effective and economical dissemination of information to healthcare professionals

Effective information dissemination strategies are fundamental to promote understanding and adoption of new approaches to practice. An overview of systematic reviews related to interventions for changing practice behaviour found that passive approaches, such as mailing out educational material, were the least effective form of information provision.¹²⁵ The overview of systematic reviews did suggest though that these forms of information dissemination may be effective for raising awareness of a concept. Active dissemination of information, such as classes and workshops, is more effective yet the costs of implementation may be a barrier to the use of these delivery methods.^{125, 126}

A Cochrane systematic review on the effects of education outreach visits (EOVs), also called academic detailing¹²⁶, on professional practice, found that while they can be effective in bettering practice, the effect is variable.¹²⁵ The review defined EOVs as “use of a trained person from outside the practice setting who meets with healthcare professionals in their practice settings to provide information with the intent of changing their performance”. For non-prescribing behaviours of health professionals, the median adjusted relative difference in behaviour change and the implementation of new knowledge was 6%, with an interquartile range of 3.6% to 16%.¹²⁵ While this shows some improvement in practitioner behaviour following an

EOV, the costs associated with delivering EOVs are high, and should be targeted effectively to produce cost savings associated with practitioner behaviour.

Two studies included in the Cochrane systematic review involved an economic analysis of the EOV. Fretheim *et al.* studied the effect of increasing the use of thiazides in patients initiating hypertensive therapy, and reported that the net annual cost per practice was US\$763, while the net annual saving was US\$540.¹²⁷ The authors reported that while there was a net annual cost in the first year, they predicted modest savings over a two year period. They believed one reason was that practitioners would continue to consider prescribing thiazides in the years following the intervention, and thus the cost of the intervention in subsequent years would be nil for these practitioners. The use of this study to model cost effectiveness for an intervention that does not involve prescribing behaviour is limited, yet demonstrates that not all interventions involving EOVs will produce cost savings. The review concluded that the cost effectiveness of EOVs will depend on a number of variables, including the targeted behaviours, the comparisons that are made and the context in which the interventions are provided. The study is limited by the assumptions made by the authors. The study period was 1 year, yet the cost-savings model created is used to predict savings at 2 years. The economic climate is at times unpredictable, and can fluctuate year-to-year, which in turn may affect the predicted result created by the model.

A review by Bloom of a number of systematic reviews on the effects of CE on physician care for patients showed that the most effective forms of information delivery for practitioners were interactive sessions.¹²⁸ Most studies showed a

moderate to high effect on care processes, whereas those involving didactic information delivery methods showed low to no effect on clinical behaviour. The review showed that the most common way of providing continuing professional education (CPE), being didactic, is ineffective in changing both clinical behaviours and improving patient health outcomes. It can therefore be suggested that for the effective implementation of CE that encourages clinical behavioural changes, an interactive component should be considered. This type of intervention should be delivered alongside a set of supports that aim to overcome common barriers to effective implementation.

1.7.2 Train-the-trainer methods

Train-the-trainer (TTT) involves instructing and educating an individual who is then equipped to teach others the same concept at their home agency using tools and resources provided by the training organisation.^{129, 130} It is also known as pyramidal training, triadic training and helper model training. TTT has a number of benefits. Firstly, it enables education and training to be sustained in the desired setting. After initial trainer training that utilises the resources of the development organisation, the trainers will continue to deliver the education within the community to the target audience. Secondly, information is disseminated between people within the target audience, and thus no one person acts as the single expert of the particular information, aiding in increasing its sustainability.¹³⁰

An added benefit of using the TTT method to deliver information is the investment, utilisation and promotion of social capital. Social capital is the resource of human

relationships, and it has been shown that it plays an important role in community-based education.¹³¹ Orfaly *et al.* state that education should not focus purely on information delivery, but also its context in building relationships within the community.¹³⁰ Due to the interactive process of the TTT method, it would employ social capital, and therefore help forge relationships both within the community, but also between the community and the organisation delivering the training.

1.7.3 Online and flexible delivery

With the advent of the internet, a new range of delivery media are available to provide education, including online lectures, videos, discussions, virtual field trips, and online course projects.^{132, 133} Many terms exist to describe online learning, including e-learning, distributed learning, virtual learning, web-based training and distance learning.¹³⁴

Online delivery of information can be adapted to cater for various learning types to improve the uptake of information, including the use of videos, games and simulations, and online chat and discussion with other participants¹³². Videos and images can be incorporated to cater for those who learn visually, while a largely text-based resource can be developed for those who prefer to learn through facts. For those who favour human interaction when learning, synchronous and asynchronous communication can be integrated into the online material.^{135, 136} Synchronous communication involves real time communication between participants, an example being the use of chat rooms.¹³⁶ Asynchronous communication involves the use of a

forums or noticeboards where electronic messages can be posted and responded to, but not necessarily instantaneously.

A review by Sanders *et al.* found that general practitioners liked online learning as it provided a platform to share experiences with other professionals, but with the benefit of working at one's own pace.¹³⁷ The review also suggested that identifying barriers to the effectiveness of online learning was important, particularly differences in the computer literacy of the intended users.

A number of advantages of online delivery of information exist over traditional, didactic methods, including improved accessibility to content, particularly for those in rural and remote areas, easier distribution to consumers, predictable costs, as well as the ability to easily update information in online learning environments.¹³⁴

Online learning does have a number of weaknesses, including delays in receiving feedback and responses from instructors^{138, 139}, a lack of sense of community, possible isolation from others^{139, 140} and technical problems.¹⁴¹

This section intended to describe the various educational delivery methods available for use in CE. It showed that while CE requires an initial outlay of funding to develop and implement, it can provide cost-saving measures in the long-term when appropriately targeted, particularly in regard to the implementation of new clinical guidelines. When developing CE initiatives, a number of delivery methods are available, and the use of these depends heavily on the target audience, funds available, and the content to be delivered, among other considerations. Pharmacists

may rely more heavily on online education, particularly if they are employed full-time, whereas pharmacy students may be more open to both online delivery and face-to-face instruction. The development of a pilot health literacy education-focused intervention for pharmacists and pharmacy staff, including students, in Australia may utilise a number of these methods in an attempt to determine the most effective delivery method for wider implementation of a larger program in the future. As studies regarding the implementation of health literacy interventions targeted towards pharmacists are lacking, further research is required to determine both the best methods of delivery, as well as research to ensure interventions are cost-effective in practice.

1.8 SUMMARY, AIMS AND OUTLINE OF RESEARCH

1.8.1 Summary

Health literacy is an emerging concept that must be adequately addressed to reduce the burden of poor health outcomes on the healthcare system. It is more than simply being able to read medical information – it encompasses understanding and comprehension of health literature and information, and how it can be employed both reactively and to prevent disease from occurring. The end goal is to promote empowerment of the consumer to be able to independently make positive decisions relating to their health through utilising health information, be it written or spoken, from a range of sources.

To do this, the promotion of health literacy education for healthcare professionals, specifically pharmacists and pharmacy staff members, needs to be encouraged. Many initiatives focus on simplifying material, yet without adequate understanding, the consumer may be unable to put into practice the information they are attempting to comprehend. Focusing on educating the pharmacist and pharmacy staff members on the concept of health literacy will hopefully provide another means of overcoming the effects of limited health literacy on both consumer health and the healthcare system. This can be achieved in a number of ways. Current practising pharmacists can be targeted through CE programs, while current pharmacy students can be educated on health literacy in pharmacy curricula. Various methods of education delivery can be utilised, including TTT techniques as well as online and flexible delivery to disseminate information to pharmacists and pharmacy staff members. Currently, this type of initiative does not exist. The research presented in this thesis aimed to bridge the current gap in health literacy education for pharmacists and pharmacy staff members.

1.8.2 Aims

In 2011, the Pharmacy Guild of Australia advertised a Request for Tender for a project to be undertaken in Australian community pharmacies to improve the state of health literacy among pharmacy consumers. A proposal was submitted by researchers from Monash University, Curtin University, the University of Queensland, the University of Sydney, University of Technology Sydney and the Pharmaceutical Society of Australia (Victorian branch) to undertake this project, led by Mr. Gregory Duncan (G.D.). Approval was granted, and the project commenced in

October 2011, with the working title 'The Health Literacy in Pharmacy (HeLP) project'. The HeLP project involved the design, development and implementation of a health literacy education-focused intervention into 77 community pharmacies around Australia. The project utilised a cluster randomised controlled trial approach to measure the efficacy and effectiveness of the intervention on changing the communication practices of pharmacists and pharmacy staff members, particularly the use of universal precautions.

The research described in this thesis was embedded within the HeLP project, and disclaimers are included in sections that describe work not conducted or led by the PhD candidate, yet were included in the thesis for context's sake.

Table 1.3 describes the tasks completed by the PhD candidate and those conducted by investigators according to each phase of the HeLP project.

Table 1.3 Tasks completed by the PhD candidate and other investigators in the HeLP project

HeLP project phases	Tasks completed by the PhD candidate	Tasks completed by other Investigators and Project Officers
Literature review	• The candidate completed his own literature review that was independent of the HeLP project. This literature review is presented in Chapter 1.	• A separate literature review was completed by HeLP project investigators for inclusion in the project final report. This literature review has not been included in this thesis.
Phase 1 – An international survey of health literacy education within schools of pharmacy	• Helped create survey items. • Uploaded survey to an online platform. • Collected potential participants' contact details. • Drafted ethics submission. • Delivered e-mail invitations to potential participants.	• Decided on study methodology. • Helped create survey items.

HeLP project phases	Tasks completed by the PhD candidate	Tasks completed by other Investigators and Project Officers
	• Collected and analysed data using appropriate statistical methods. • Constructed conclusions from data analysis. • Drafted this phase as a journal article for <i>Pharmacy Education</i> in September 2014.	
HeLP phase - Design, development and implementation of a health literacy education-focused intervention for community pharmacists and pharmacy staff members in Australia	• Performed a piloting session of the intervention with postgraduate students at Monash University. • Drafted Monash University ethics submission. • Drafted all consent forms and explanatory statements.	• Assembled an Expert Reference Group to consult on the content to be included in the intervention. • Designed the structure of the intervention, including the visual layout of the slides. • Created the content for inclusion and populated the slides with selected content.

HeLP project phases	Tasks completed by the PhD candidate	Tasks completed by other Investigators and Project Officers
	• Created a database of all potential Victorian community pharmacies for recruitment into the project. • Recruited community pharmacies for the Victorian arm of the project. • Supplied all recruited pharmacies with the relevant consent forms and explanatory statements. • Arranged dates, times and venues for initial training to begin in Victoria. • Monitored the implementation of the education-focused intervention in each community pharmacy in Victoria.	• Led the creation of videos to be included in the education-focused intervention. • Research Officers in New South Wales and Western Australia led the recruitment of pharmacies in these states and performed identical tasks to those performed by the PhD. candidate in Victoria excluding randomisation. • Randomised all recruited pharmacies in Australia.

HeLP project phases	Tasks completed by the PhD candidate	Tasks completed by other Investigators and Project Officers
Phase 2 - Motivational factors influencing the intentions of pharmacists and pharmacy staff members to undertake health literacy training	• Selected the study method and relevant theories underpinning the project. • Drafted Monash University ethics submission. • Drafted all consent forms and explanatory statements. • Drafted all surveys, including survey items and formatting. • Mailed out survey packs containing all relevant documents and surveys to each participating pharmacy in Victoria.	• Mailed out survey packs containing all relevant documents and surveys to each participating pharmacy in New South Wales and Western Australia. • Regularly reminded participating pharmacies in New South Wales and Western Australia to complete and return surveys.

HeLP project phases	Tasks completed by the PhD candidate	Tasks completed by other Investigators and Project Officers
	• Regularly reminded participating pharmacies in Victoria to complete and return surveys. • Created all databases for data entry and analysis. • Entered data for all surveys completed in Victoria. • Analysed data collected from Victoria, New South Wales and Western Australia. • Constructed conclusions using results obtained from data analysis.	

HeLP project phases	Tasks completed by the PhD candidate	Tasks completed by other Investigators and Project Officers
Phase 3 – Evaluation of the efficacy and effectiveness of the health literacy education-focused intervention	• Helped select and design the evaluation methods. • Developed all data collection items, including consumer data collection forms and simulated patient data collection forms. • Recruited and trained all simulated patients used in the Victorian arm of the project. • Recruited consumers from participating community pharmacies in Victoria and	• Selected and designed the evaluation methods. • Recruited and trained all simulated patients used in the New South Wales and Western Australian arm of the project. • Recruited consumers from participating community pharmacies in New South Wales and Western Australia and collected consumer data, both pre- and post-intervention. • Entered data for all data collection forms completed in New South Wales and Western Australia.

HeLP project phases	Tasks completed by the PhD candidate	Tasks completed by other Investigators and Project Officers
	collected consumer data, both pre- and post-intervention. • Created all databases for data entry and analysis. • Entered data for all data collection forms completed in Victoria. • Analysed data collected from Victoria, New South Wales and Western Australia. • Constructed conclusions using results obtained from data analysis.	
Phase 4 – Pharmacist and pharmacy staff member	• Helped select and design the study method.	• Recruited all participants in the Western Australian arm of the project (no focus

HeLP project phases	Tasks completed by the PhD candidate	Tasks completed by other Investigators and Project Officers
perceptions of the health literacy education-focused intervention	• Drafted Monash University ethics submission. • Drafted all consent forms and explanatory statements. • Drafted the question guide, consisting of ten questions and prompts for the facilitator. • Recruited all participants in the Victorian arm of the study. • Took on the role of the note-taker in all focus groups conducted in Victoria.	groups were conducted in New South Wales). • Gregory Duncan (G.D.) acted as the facilitator in all focus groups conducted in Victoria. Lynne Emmerton (L.E.) acted as the facilitator in all focus groups in Western Australia. Elsamuel Elhebir (E.E.) acted as the note-taker in all focus groups conducted in Western Australia.

HeLP project phases	Tasks completed by the PhD candidate	Tasks completed by other Investigators and Project Officers
	- Analysed focus group data from all states, including coding and thematic analysis. - Constructed conclusions using results obtained from data analysis.	

The **overall aim** of the PhD project and the HeLP project was to determine the efficacy and effectiveness of a multi-modal health literacy education-focused intervention in changing communication practice and behaviours of Australian community pharmacists and pharmacy staff members to help overcome communication barriers with all consumers, particularly the use of universal precautions.

The **specific research objectives** were:

1. To investigate how health literacy education is currently delivered in pharmacy curricula from English speaking countries (**Phase 1**);
2. To identify motivational factors of pharmacists and pharmacy staff members that may influence intentions to implement and undertake health literacy education in the pharmacy (**Phase 2**);
3. To evaluate the efficacy and effectiveness of the health literacy education-focused intervention on pharmacists' and pharmacy staff members' communication practice and behaviours in relation to health literacy, specifically the use of universal precautions (**Phase 3**); and,
4. To attain participant feedback in relation to the usability, ease of implementation and perceived effectiveness of the intervention (**Phase 4**).

The **hypotheses** that were tested in this research project are:

1. Health literacy education is not widespread in pharmacy curricula from English speaking countries, but where it is taught, a variety of delivery methods are used (**Phase 1**).
2. The attitudes and motivational reasons behind potentially implementing health literacy education in the pharmacy will be favourable (**Phase 2**).
3. The health literacy education-focused intervention will improve Australian community pharmacists' and pharmacy staff members' communication practice in relation to using universal precautions for all consumers regardless of their perceived health literacy abilities (**Phase 3**).
4. Feedback in regard to the health literacy education-focused intervention will be favourable, and allow for possible refinements in the future before wider implementation (**Phase 4**).

1.8.3 Project outline

This thesis is structured as follows:

Chapter 2: The research methodology underpinning the project.

Chapter 3: An explanation of the design, development and implementation of the health literacy education-focused intervention for community pharmacists and pharmacy staff members in Australia (**HeLP phase**), including an international survey of pharmacy academics (**Phase 1**).

Chapter 4: Investigation of the motivational factors that may influence the intentions of pharmacists and pharmacy staff members to undertake health literacy training (**Phase 2**).

Chapter 5: Evaluation of the efficacy and effectiveness of the health literacy education-focused intervention in regard to changing communication practice and behaviours of community pharmacists and pharmacy staff members, particularly the use of universal precautions (**Phase 3**).

Chapter 6: Exploration of participants' perceptions and opinions of the intervention following implementation (**Phase 4**).

Chapter 7: A summary of the study and its findings and suggestions for further research in this area.

The progression of the PhD project phases are outlined below in Figure 1.

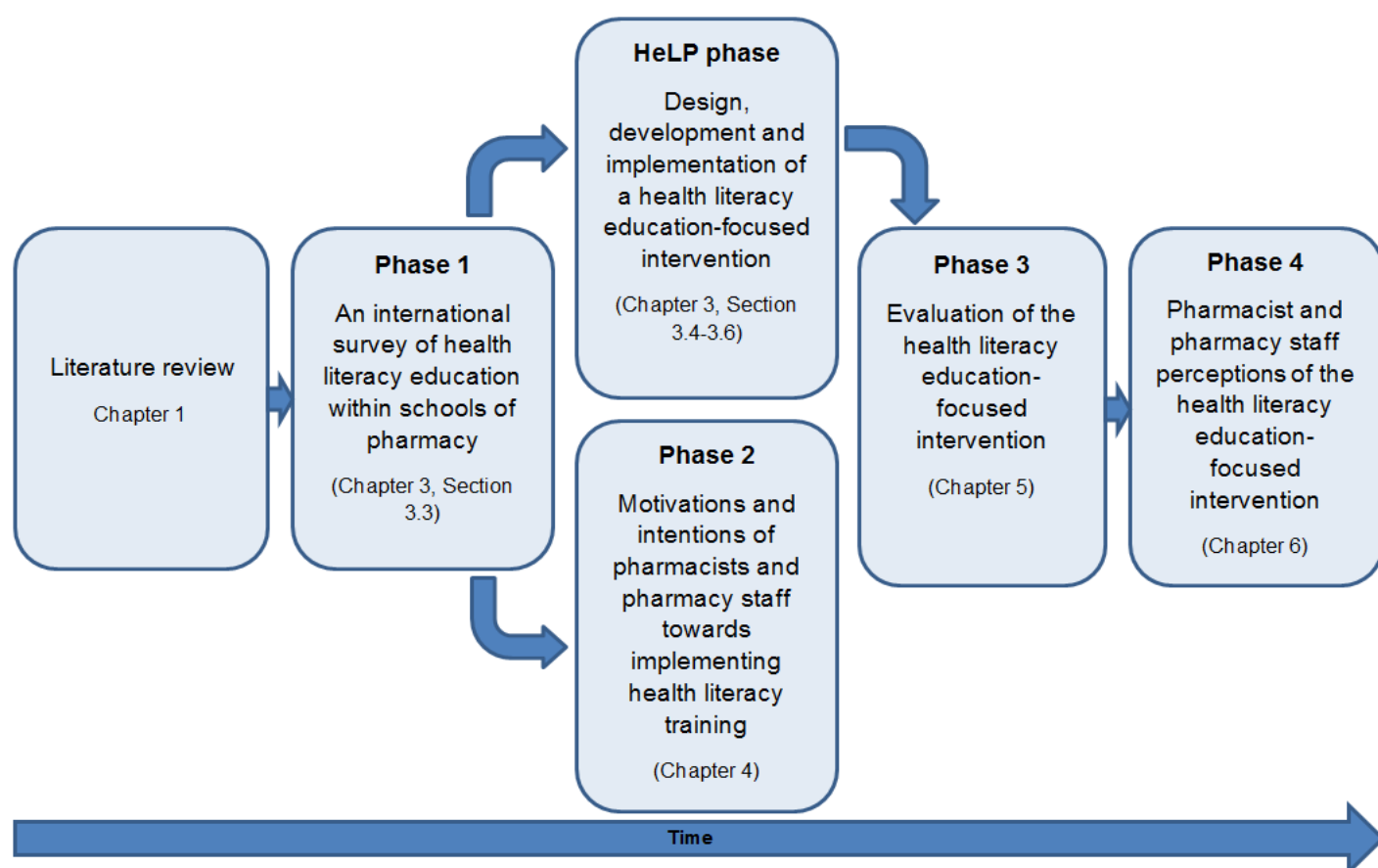


Figure 1: Phases of the PhD project and corresponding thesis chapters.

The PhD project comprised four phases. **Phase 1** involved an internationally disseminated, online survey of academic pharmacists regarding the current state of health literacy education in their universities or educational organisations. Subsequently, the health literacy education-focused intervention was designed, developed and implemented into community pharmacies in the HeLP phase of the project.

In **Phase 2**, a cross-sectional, mailed survey was conducted to assess the motivations and intentions of all pharmacists and pharmacy staff member participants in regard to undertaking health literacy training. This phase was conducted parallel to the design and development stage of the **HeLP phase**, but before the implementation component. The intervention was implemented via a cluster randomised controlled trial (RCT) of community pharmacies. Pharmacies were recruited from Victoria, New South Wales and Western Australia, and were allocated to either of the intervention groups, or a control group. Intervention groups received either face-to-face training (Group 1) or electronic training (Group 2). The control group (Group 3) did not receive the education-focused intervention.

The intervention was evaluated in **Phase 3**, which was divided into two components. A researcher-administered consumer survey both pre- and post-intervention was conducted, followed by simulated patient visits to each pharmacy, again, both pre- and post-intervention. In **Phase 4**, focus groups were used to receive feedback on the education-focused intervention in relation to its usability, perceived effectiveness and sustainability in pharmacy practice. All phases of the study were approved by the Monash University, Curtin University and University of Sydney Human Ethics Research Committees (Appendices 1, 3, 5 and 8).

The next chapter will discuss the various research methodologies that were used in all phases of the research project.

2 RESEARCH METHODOLOGY

2.1 SUMMARY

This chapter aims to describe the various quantitative and qualitative methodologies that were utilised to conduct the research project.

2.2 QUANTITATIVE METHODOLOGY

2.2.1 Questionnaires and surveys

The use of questionnaires and surveys is common in research, and allows for the collection of both quantitative and qualitative data from the sample population.¹⁴²

Questionnaires and surveys are not interchangeable terms. 'Questionnaire' refers to a data collection tool comprising of a set of questions with a choice of answers, designed for the purposes of a survey or statistical study.¹⁴³ In contrast, 'survey' refers to the method of examining or describing someone or something.¹⁴³

Questionnaires are useful for collecting information in a structured format without the need for a researcher to be present, and generally allow for the straightforward analysis of data.¹⁴⁴

The types of questions that can be asked in a questionnaire will depend on both the type of data that is to be collected, being either quantitative or qualitative, and the size of the sample that is to be surveyed.¹⁴² To collect quantitative data, the use of

highly structured, closed questions that may use dichotomous options, such as 'yes' and 'no', are most useful, specifically when measurement is what is desired.¹⁴² On the other hand, to collect descriptive qualitative data, word-based, open-ended questions are more applicable, particularly when personal data is being sought. With regard to the sample size, it is a general consensus that the larger the sample size being surveyed, the more closed the questions should be. This is preferred as coding and analysis of the questionnaire data will be slow and labour intensive if open-ended questioning dominates.¹⁴²

There are a vast number of question formats that can be used, including dichotomous or multiple choice questions, rating scales, rank ordering, and open-ended questions, to name a few.¹⁴² The question formats that are used in questionnaires will largely depend on the type of information that is being gathered.

Questionnaires and surveys can be disseminated and delivered to the sample participants in a number of ways, which are discussed below.

2.2.1.1 Online questionnaires

Online questionnaires are delivered electronically via the internet and are increasing in popularity due to the vast array of technology available for accessing the internet.¹⁴⁵⁻¹⁴⁸ They are cheap to distribute, usually arrive instantaneously, and similarly can be returned just as quickly, thus allowing for a faster rate of response. Other specific benefits include the ability to target unique populations that exist primarily online and may prove difficult to reach by other means, for example, groups who may be stigmatised offline, and therefore feel more comfortable discussing

sensitive issues in a more anonymous fashion (e.g. individuals with HIV or eating disorders).¹⁴⁵

Disadvantages do exist, and focus heavily on access to technology to complete the survey as well as the participant's computer literacy. Firstly, a selection bias may exist as institutions with easy access to computers and the internet are more likely to respond to the survey, whereas in places where computers are not readily available, or where the internet is not accessible, there is less likelihood of a response. Secondly, selection bias also exists in relation to the computer literacy of the participant.¹⁴⁸ Online questionnaires favour those who are able to use computers effectively, and thus are able to complete and return the survey.

The survey in Phase 1 (Chapter 3, Section 3.3) of the research project was delivered online. As the survey was intended for an international sample, it allowed for easier delivery and return, and also reduced the need to actively seek the contact details of academic pharmacists. Also, as pharmacy academics and researchers usually spend a significant amount of time working at a computer, it was deemed more convenient for participants to complete a computer-based survey than to fill out a paper-based survey. Paper-based, mailed questionnaires were not used for Phase 1 due to the cost and difficulty of delivery and return being the main issues. Similarly, for telephone-based and personally-administered questionnaires, the cost of contacting each participant would have been too great to undertake and the time spent trying to identify relevant participants, gather their contact details and arrange a mutually convenient time to deliver the questionnaire would have been very costly and time consuming.

2.2.1.2 Mailed questionnaires

Mailed questionnaires involve sending hard copies of the questionnaires via the postal service to be physically delivered to the participants, completed and sent back to the researcher, usually by return post.^{146, 148-150} While it is generally an inexpensive process, questionnaires may be completed incorrectly or only partially completed. Mailed questionnaires are also disadvantaged by the longer length of time for their return to the researcher. This is disadvantageous if a survey is to be conducted in a short period of time.^{151f}

A mailed survey was not chosen as the method of delivery for the Phase 1 (Chapter 3, Section 3.3) questionnaires in the research project due to the cost of posting internationally, the complexity for participants regarding the return of questionnaires via international post and issues surrounding the length of time taken to receive mail from certain parts of the world. Phase 2 (Chapter 4) involved the use of paper-based, mailed questionnaires, as all participants were located within Australia, keeping postage costs low. Also, the completion of paper-based questionnaires in the pharmacy workplace may be easier, as sufficient numbers of computers may not be available to enable the completion of numerous computer-based questionnaires in the pharmacy.

2.2.1.3 Personally-delivered questionnaires

This form of survey delivery involves the researcher interviewing the participant in person.^{148, 152-154} It allows for a greater amount of information to be delivered via asking open-ended questions, and can help overcome ambiguities relating to question meaning or wording that may be faced in paper-based questionnaires as

clarification can be sought.¹⁴⁸ Potential for bias exists in a number of ways. Firstly, the recording of responses can be subject to bias as the researcher may choose to interpret responses in a way that supports the desired outcome.^{148, 154} Secondly, the same question may illicit varying responses depending on the questioning technique, and thus a consistent method must be used to reduce this effect.¹⁴⁸

This method was not selected to deliver the Phase 1 (Chapter 3, Section 3.3) and Phase 2 (Chapter 4) questionnaires purely due to the costs associated with personally interviewing all Australian participants (Phases 1 and 2), as well as academic pharmacists from around the world (Phase 1). Phase 3 (Chapter 5) comprised personally-delivered questionnaires with pharmacy consumers in the pharmacy following consultation with a pharmacist or pharmacy staff member, delivered by a research officer using a piloted data collection tool. They were used in this phase to ensure that the data collected from consumers was accurate, objective and recorded correctly. Allowing consumers to complete their own questionnaires in the pharmacy may have resulted in the misinterpretation of questions or incorrect recording of answers.

2.2.1.4 Telephone-based questionnaires

The use of telephone questionnaires in the research project would have been costly and time consuming. Due to the large number of participants in Phase 1 (Chapter 3, Section 3.3) and 2 (Chapter 4), and the difficulty in obtaining contact details for each, this method would have been very time consuming and costly. The cost associated with delivering the survey would also have been very high, due the need to make numerous, lengthy telephone calls.

Research has provided additional insight into consumer acceptance of telephone surveys as a survey research method. Compared to face-to-face interviews, participants taking telephone surveys may tend to be less engaged and cooperative, and exhibit a higher level of dissatisfaction with the length of time the interview is conducted.¹⁵⁵

2.2.2 Randomised controlled trials (RCTs)

Randomised controlled trials are an experimental study design that aims to compare two groups of similar participants; one that is exposed to an intervention, and one that is not and acts as a control. The effect of the intervention on a set of defined outcome measures is then measured in both groups.¹⁵⁶ The RCT is considered the gold standard of study design due to a number of attributes. Firstly, participants undergo randomisation, ensuring that a participant is just as likely to be allocated to the intervention group as they would to the control group.¹⁵⁷ This is essential as it increases the likelihood that each group is similar with respect to prognostic factors, thus reducing the chance of over-estimating or under-estimating the effect of the intervention on target outcomes in the experimental group.¹⁵⁷ Secondly, RCTs generally have large sample sizes, which establishes the power of effect of the specific intervention being tested, thus producing results that have a higher validity than studies conducted with smaller sample sizes.¹⁵⁶

Limitations exist when evaluating health care services using RCTs and when incorrectly performed, can influence the validity of the results. It is often the case that RCTs involving the evaluation of health care services are conducted in a well-

controlled, academic environment where the researcher is able to control variables and factors in relation to the trial.¹⁵⁸ This then creates internal validity, that is, the results are specific to a certain, unique environment in which the study was conducted, and may be difficult to generalise to healthcare settings in practice, such as community pharmacies. Therefore, the external validity, or the validity of the results in the practice setting, may be reduced.

For the research project, a cluster RCT was chosen as the most suitable method in the HeLP phase (Chapter 3, Section 3.6) to implement the health literacy education-focused intervention into participating pharmacies. Measurement of the efficacy and effectiveness of applying universal precautions with consumers in community pharmacies in Australia following the implementation of the intervention was conducted in Phase 3 (Chapter 5). This involved the comparison of performance in the use of universal precautions with consumers between the two intervention groups, face-to-face (Group 1) and electronic delivery (Group 2), and the control group (Group 3), who received no training. A cluster RCT differs from a standard RCT in that groups of individuals are randomised, rather than individuals.¹⁵⁹ In this project, individual pharmacies were the clusters. A cluster RCT was chosen over a standard RCT. This was due to the inability of standard RCTs to direct the educational intervention towards selected individuals in the pharmacy, as well as the inability to properly control for contamination within the pharmacy between individuals.

2.2.3 Simulated patients

Simulated patients, also known as mystery shoppers, are used in pharmacy to assess and evaluate current practice, or to measure outcomes when involved in effectiveness research.^{160, 161} A simulated patient is defined as “an individual who is trained to visit a pharmacy to enact a scenario testing specific behaviour of the pharmacist or pharmacy staff”.¹⁶⁰

The process of using simulated patients in research involves a number of steps, including training of the actor, designing a standardised tool to collect the data, and possible piloting to assess the actor’s performance.¹⁶⁰ Formal training of the actors and using standardised scenarios helps to increase the consistency of the visits between actors. It is recommended that standardised data collection tools be used to increase the validity of the self-reported data. If possible, audiotaping of the case vignette delivery may further increase validity and data integrity.^{160, 162}

To improve the quality of the simulated patient visits, it has been recommended that actors be supplied with current and accurate lists of pharmacies to visit, and addresses or maps to help locate the premises.¹⁶³ It has been reported in some studies involving simulated patients in pharmacy practice that actors entered the wrong pharmacy.¹⁶⁰ It is also important to maintain face validity, or believability, to ensure that simulated patients are not detected by the pharmacy staff members.^{160,}
¹⁶¹ This could be improved by training and piloting before beginning.

The simulated patient method was chosen for Phase 3 (Chapter 5) of the research project due to its acceptance as a valid tool to measure and evaluate behavioural changes and counselling practices in pharmacy practice.¹⁶⁰ A standardised tool to collect self-reported data on the use of universal precautions by pharmacists and pharmacy staff members with the simulated patients was developed, and actors underwent training to ensure consistency between visits.

2.2.4 Pretest-posttest design

Pretest-posttest design is useful in describing the impact of introducing an independent variable on a sample.¹⁶⁴ It involves measuring the change of a sample following the exposure to an independent variable by first testing the group before exposure, pretest, then measuring the subjects after the introduction of the intervention, posttest.¹⁶⁴ The limitation of using pretest-posttest design to prove causation is the absence of randomisation as well as limited control over the subjects.¹⁶⁴

Pretest-posttest design was not used in this project due to the desire to randomise pharmacies, and thus an RCT was preferred and subsequently chosen.

2.3 QUALITATIVE METHODOLOGY

Qualitative research is distinct from quantitative research in that it aims to describe and understand, as opposed to testing and evaluating, data.¹⁵⁷ It encompasses the investigation and understanding of social aspects of research, rather than its

quantifiable facets.¹⁵⁷ The research project utilised qualitative methods in the form of focus groups to collect descriptive data on pharmacists' and pharmacy staff members' opinions of the usability, perceived effectiveness and sustainability of the health literacy education-focused intervention (Phase 4, Chapter 6).

2.3.1 Focus groups

Focus groups are an effective way to gain information from research participants by stimulating discussion between subjects and promoting group communication and interaction.¹⁶⁵ They allow the researcher to gain information from more than one participant at a time, which can translate to time saved. Instead of individually interviewing participants where a question is asked and the response is documented, focus groups allow discussion of a question, the generation of comments regarding different experiences and opinions and the sharing of anecdotes, especially when open ended questions are asked.^{165, 166} Focus groups also allow the researcher to uncover the process in which people think, and why they think in a particular way, rather than simply discovering what it is the participant is thinking.¹⁶⁵

Groups can be created to be representative of the population being studied, can include representatives from a range of groups within the population, or may be 'naturally-occurring', such as a group of people who work together.¹⁶⁵ In some cases, homogeneity is desired to bring people together with similar experiences and knowledge, yet in other cases, a diverse group can be beneficial in the exploration of ideas and differing perspectives.^{165, 167} If the group is purposively chosen to include participants from a range of diverse backgrounds, the data generated may not be

representative of the population.¹⁶⁷ Participants will generally share one or more similar characteristics, including demographic, situational, behavioural, or ideological.¹⁶⁷

Focus group sessions begin with a statement by the facilitator to explain the purpose and aims of the session, and an explanation of the rules of the session. Participants are then encouraged to introduce themselves.¹⁶⁷ Analysis of focus group data should include the creation of themes to bring together discussions and opinions related to particular topics.¹⁶⁵ The use of quantitative methods, such as percentages to explain data, should be avoided. It is important to pay attention to minority opinions, as well as noting opinions of individuals that differed from the general group consensus.

Focus groups were used in Phase 4 (Chapter 6) of this project to obtain feedback from participants on the usability, perceived effectiveness and sustainability of the health literacy education-focused intervention. Focus groups were used due to their ability to collect a wide range of opinions from participants through the utilisation of open-ended questions in a semi-structured format.

2.4 EFFICACY AND EFFECTIVENESS

Determining the efficacy and effectiveness of an intervention is vital to concluding whether it will be beneficial or not. In health, efficacy relates to the ability of an intervention to produce a desired response under controlled conditions, whereas effectiveness is the degree to which an intervention can produce a desired response

under realistic clinical conditions.¹⁶⁸⁻¹⁷⁰ Essentially, efficacy is determining whether something *can* work, while effectiveness determines whether something *does* work.

The research project described in this thesis can be classed as a hybrid study – it contains elements of both an efficacy study and an effectiveness study. While many aspects of the project were controlled, for example, time frames and intervention exposures, it was impossible to control for all possible confounders in the pharmacy setting. As the project was conducted in community pharmacies, a ‘real-life’ element is apparent, and thus prevents it from being purely an efficacy study.

Throughout this thesis, the project was therefore referred to as an ‘efficacy and effectiveness project’ to acknowledge its hybrid nature.

2.5 SAMPLING

Sampling involves the selection of participants to be included in a sample from the population to be studied.¹⁷¹ Consideration of the size of the sample is crucial as it influences the methods used to collect the data, recruitment procedures, costs and the external validity of the results obtained.¹⁶⁴ The statistical power, which is the “probability that a test will detect a significant difference if one exists”,¹⁶⁴ influences the size of the sample. Generally, 80% or 0.8 statistical power level is the minimum acceptable level.¹⁶⁴ A power analysis can be used to determine the size of the sample when the significance level, the effect size and the statistical power are known.¹⁶⁴

There are two forms of sampling, being probability sampling, and non-probability sampling. Probability sampling involves the creation of a sample that is representative of the population being studied and is generally used in quantitative studies where a large sample size is required.¹⁵⁷ Non-probability methods of sampling involve non-random selection of participants from a sample, generally when it is not possible to obtain a representative sample from the population, it is unethical or undesirable for the particular research or when qualitative observations of particular groups of the population are sought after.^{157, 164} The sample size used in qualitative studies is generally smaller, and can also be referred to as purposive sampling.¹⁵⁷ Both of these forms of sampling were used in this research.

2.6 VALIDITY

Validity refers to the ability of a particular instrument to accurately measure what it is intended to. The validity of a data collection instrument, such as a survey tool, can be increased by undertaking a validation process. This involves testing the instrument in a pilot situation using participants from the intended population to confirm that the data retrieved accurately reflects the qualities and variables that are being studied.

A number of types of validity exist, including face validity, criterion validity, construct validity and content validity.¹⁷² Face validity is generally the first type of validity that is analysed when evaluating data collection instruments. It involves judging the tool on face value, and asking questions about whether the questions are expected to return the information that is desired.^{173, 174} If a question is not valid at face value, then it is

unlikely to successfully produce the desired responses. Criterion validity refers to the ability of the questions to produce results that draw a parallel with current measures of the same variable.¹⁷⁵ Construct validity is the extent to which a question relates to what is understood by a theoretical construct or concept, while content validity is related to whether the survey or data collection tool contains enough questions to obtain all the information about a topic or issue that is required.^{172, 176, 177}

In this project, all survey tools used in Phases 1 (Chapter 3, Section 3.3), 2 (Chapter 4) and 3 (Chapter 5) underwent assessment to ensure both face validity and content validity, as did the focus group/interview questioning guide used in Phase 4 (Chapter 6).

2.7 RELIABILITY

Reliability is an important aspect in quantitative research, and relates to the extent to which the findings are reproducible or internally consistent.^{172, 178, 179} Reliability does not ensure validity of survey responses, but without reliability, validity is not possible. Reliability can be compromised in a number of ways, including ambiguity of question wording, inconsistent interpretation of questions by respondents, variation in the style of questioning by different interviewers, or inability of respondents to provide accurate information, leading to guesses or poor estimates. Piloting and peer evaluation helps overcome issues surrounding reliability, which was undertaken during creation and refinement of all survey tools used in Phase 1 (Chapter 3, Section 3.3), 2 (Chapter 4) and 3 (Chapter 5) of this project, as well as the focus group/interview questioning guide used in Phase 4 (Chapter 6).

In relation to the reliability of qualitative methods, it is not as relevant when compared to quantitative research methods, as the data is context-specific. To ensure reliability when collecting qualitative data, it is important that interviewers adopt consistent techniques when administering surveys, as variation between interviewing methods can affect the reliability. If questions are highly structured and procedures have been standardised and directions are clear, variation should be minimal.¹⁷² It is important to note that when expecting practising pharmacists or other healthcare professionals to gather the data themselves, the process must be acceptable, workable and followed in each setting.¹⁷²

2.8 GENERALISABILITY

Concerning the generalisability of research findings, the data obtained from a particular sample can only be generalised to the population from which that sample was created.^{171, 179}

Generalisability is influenced by a number of factors, including the sampling procedures, sample sizes and response rates.¹⁷² For results to be generalised to the population, probability sampling procedures must have been utilised, sample sizes must be large enough to show statistical power, and response rates must have been adequate.^{172, 180} If all of these factors have been successfully accounted for, and the tool used in the research has retrieved valid data, then the data can be generalised to the population once appropriate probability statistics have been used to interpret the results.¹⁷²

2.9 ANALYSIS

The analysis of quantitative data is most commonly conducted using frequency data and summary statistics (e.g. means, medians, standard deviations). Both parametric and non-parametric tests can be utilised to explore relationships between variables and undertake comparisons between population subgroups.¹⁷² The research project applied non-parametric procedures in analysing quantitative data obtained from the Phase 3 questionnaires and simulated patients (Chapter 5, Section 5.2.1.4 and Section 5.2.2.6).

Being a cross-sectional study, frequency data was chosen as the most appropriate way to analyse the results from the international online survey in Phase 1 (Chapter 3, Section 3.3). Factor analysis was chosen for the analysis of the pre-intervention questionnaires in Phase 2 (Chapter 4) due to its ability to condense a large number of correlated variables into a smaller number of common factors for easier interpretation. Ordinal logistic regression was used in this analysis as it allows for the relationship between a number of independent continuous variables and a dependent variable with more than two outcomes to be explored.¹⁸¹⁻¹⁸³ The model was used to test the relationship between the independent variables (factors composed of attitudes, perceived behavioural control and subjective norms) with the dependent variable (intentions to undertake health literacy training). The non-parametric Pearson's Chi squared test was chosen for Phase 3 (Chapter 5) because it was the most appropriate statistical test for analysing the association between two nominal variables generated in the personally-delivered questionnaires and in the simulated patients study.

A p-value of less than or equal to 0.05 was used in all of the above tests to confer statistical significance. A p-value provides a measure of the degree to which the observed association between variables in a data set could be expected to occur by chance.¹⁷² The smaller the p-value limit chosen, the higher likelihood that genuine differences may be ignored when sample sizes are small, and thus, smaller p-values such as <0.001 were not chosen.

Statistical Package for the Social Sciences (SPSS IBM: version 19, New York, USA) and Microsoft Excel (Microsoft: Excel 2010, Redmond, USA) were used to manage all quantitative data.

In contrast, the analysis of qualitative data is conducted using systematic, reproducible methods, most commonly content or thematic analysis.¹⁸⁴ Thematic analysis was utilised in Phase 4 (Chapter 6) of the project, and was primarily conducted by the PhD candidate, with the aid an independent researcher. It involved the development of a coding system to isolate various themes and dimensions in the data, which were then compared, discussed and grouped into categories.¹⁷²

Dialogue from the data was recognised as ‘text units’ and placed into one of these categories. Thematic analysis can be conducted manually or via a software package, such as NVivo (NVivo: version 9.0, QSR International), which was used in this phase (Chapter 6, Section 6.2.2.4).

Analysis of qualitative data is generally ceased when theoretical saturation is reached, meaning, that further observations produce no new information to dispute

current findings.¹⁸⁵ The Phase 4 study (Chapter 6) was limited by the number of consenting participants, and thus presented difficulties in reaching data saturation.

2.10 CONCLUSION

This chapter presented the quantitative and qualitative methodology that was used to design and develop a health literacy education-focused intervention for community pharmacists and pharmacy staff members in Australia, and subsequently measure its efficacy and effectiveness in changing communication behaviours, particularly the use of universal precautions with consumers. A more detailed description of the methods utilised is discussed in the following chapters.

3 HeLP PHASE: DESIGN, DEVELOPMENT AND IMPLEMENTATION OF THE HEALTH LITERACY EDUCATION-FOCUSED INTERVENTION

3.1 SUMMARY

The following chapter describes the design and development of the health literacy education-focused intervention using the information gathered from the review of the literature (Chapter 1) and from an online survey of pharmacy academics (Phase 1, Chapter 3, Section 3.3). This information informed both the content of the intervention and the educational theory and formats utilised during the HeLP phase (Chapter 3, Section 3.4). Also described in this chapter is the process of implementation of the intervention into community pharmacies in Victoria, New South Wales and Western Australia.

The work described in this chapter was not wholly conducted by the PhD candidate and has been included for the sake of providing context to the remainder of the thesis. Work that was *not* conducted by the PhD candidate will be signposted. Any work not signposted is assumed to have been completed by the PhD candidate.

The online survey of pharmacy academics (Chapter 3, Section 3.3) has been published in *Pharmacy Education*. Monash University Human Research Ethics

Committee approval, the survey advertisement, explanatory statement and the survey tool developed for Phase 1 are shown in Appendices 1 and 2.

3.2 DECLARATION FOR THESIS CHAPTER 3, SECTION 3.3.

Declaration by candidate

In the case of Chapter 3, Section 3.3, the nature and extent of my contribution to the work was the following:

Nature of contribution	Extent of contribution (%)
Reviewed literature, drafted survey tool, disseminated online survey, collected and analysed results, constructed conclusions.	60%

The following co-authors contributed to the work. If co-authors are students at Monash University, the extent of their contribution in percentage terms must be stated:

Name	Nature of contribution
Dr Safeera Hussainy	Reviewed manuscript
Mr Gregory Duncan	Reviewed manuscript
A/Prof Kay Stewart	Reviewed manuscript
Dr Kevin Mc Namara	Reviewed manuscript
A/Prof Lynne Emmerton	Reviewed manuscript

The undersigned hereby certify that the above declaration correctly reflects the nature and extent of the candidate's and co-authors' contributions to this work*.

**Candidate's
Signature**

	Date
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**Main
Supervisor's
Signature**

	Date
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*Note: Where the responsible author is not the candidate's main supervisor, the main supervisor should consult with the responsible author to agree on the respective contributions of the authors.

3.3 PHASE 1: AN ONLINE SURVEY OF PHARMACY ACADEMICS – PUBLISHED MANUSCRIPT

Pharmacy Education, 2014; 14 (1) 101 - 108



An international survey of Health Literacy Education within schools of pharmacy

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Abstract

Background: Health literacy (HL) influences patients' health status, use of the healthcare system and medication-related behaviours. However, the concept is relatively new to pharmacy and its incorporation in academic curricula has not been examined.

Aims: To explore HL training in pharmacy schools internationally, and academics' opinions in regards to how it should be taught and assessed.

Methods: An anonymous, online survey was administered to academics who teach within pharmacy degree courses from countries where English is the main language.

Results: Responses were received from 21 pharmacy schools in seven countries; 20 stated that HL was taught within their pharmacy degree, in four as a stand-alone topic. Small-group tutorials were thought to be the most beneficial form of teaching health literacy, best assessed using oral and objective structured clinical examinations.

Conclusion: The majority of pharmacy schools taught health literacy and had similar opinions regarding best practice teaching and assessment.

Keywords: *Communication, curriculum, education, health literacy, pharmacy, students.*

Introduction

Health literacy is the degree to which people are able to access, understand, appraise and communicate information to engage with the demands of different health contexts in order to promote and maintain good health across the life-course (Kwan *et al.*, 2006). The health literacy abilities of patients influence their knowledge and awareness of their own disease and health status, navigation and use of the healthcare system, and knowledge and awareness of health and illness (Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs 1999). Studies have shown that large proportions of the general public and specific patient populations have what is considered a low level of health literacy, and thus may face difficulties accessing, understanding and appropriately utilising health information. The National Assessment of Adult Literacy conducted in the United States in 2003 concluded that 36% of adults aged over 16 years had low health literacy levels. In Australia, the Bureau of Statistics reported that 59% of adults aged between 15 and 75 years were considered to have low health literacy (Kutner *et al.*, 2006; Australian Bureau of Statistics 2008).

In the pharmacy setting, low health literacy may affect a number of medicines-related behaviours that increase the likelihood of medication misadventure. These might include incorrect interpretation of medicine labels (for example, directions for use and cautionary ancillary labels), and unintentional medicine non-adherence (Lindquist *et al.*, 2006; Davis *et al.*, 2006; Mårtensson & Hensing 2011).

Pharmacist and pharmacy intern/student/assistant awareness of health literacy as a barrier to effective patient care in the pharmacy setting coupled with an ability to implement strategies to overcome these issues, are important and necessary components of pharmacy curricula.

The inclusion of health literacy into pharmacy curricula is, in some countries, dictated by the accreditation standards for pharmacy degrees set out by the relevant regulatory authority. In Australia, the current accreditation standards of the Australian Pharmacy Council do not overtly state health literacy training as a requirement in Australian pharmacy curricula. Instead they make overarching, general statements regarding interpersonal skills and the pharmacist's contribution to

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ISSN 1447-2701 online © 2014 FIP

the promotion of good health and disease prevention (Australian Pharmacy Council 2009). In the United States of America, the Accreditation Council for Pharmacy Education includes health literacy as a requirement for the accreditation of all PharmD degrees, stating: "The college or school must ensure that the curriculum addresses...health literacy..." (Accreditation Council for Pharmacy Education 2011). Curricular standards regarding health literacy differ between countries and jurisdictions, and therefore inferences regarding the prevalence of health literacy education in pharmacy curricula cannot be made solely from this information. Also, as no previous studies exist regarding health literacy instruction in pharmacy curricula, inferences cannot be drawn from this source either.

In this study, we explored current methods of teaching health literacy, competency evaluation, and resources used for instruction within pharmacy curricula in universities from English-speaking countries. This was conducted to provide insight into methods for future implementation of health literacy education into current pharmacy curricula, and provide possible guidance for the development of future pharmacy curricula.

Method

Respondents

Pharmacy academics were selected as the population of interest for this study, with two methods of recruitment being used to invite respondents to complete an online questionnaire. The first method involved advertising the survey through the Academic Section of the International Pharmaceutical Federation newsletter. After a low response rate, a second method of recruitment was used. This involved hand-searching publicly available staff directories on university websites in Australia, Canada, Ireland, New Zealand, South Africa, the United Kingdom, and the United States to identify relevant pharmacy academics. We contacted them directly via email with an invitation to be involved in the study. Invited participants were forwarded a reminder email to take part in the survey approximately two weeks following the initial invitation.

Inclusion criteria

- a) Currently teaching within or overseeing an accredited pharmacy degree; and
- b) English being the language of instruction.

Study design

The questionnaire was specifically designed to assess the current state of health literacy within pharmacy curricula. The literature was consulted to determine topics for inclusion in the questionnaire, which were discussed by the research group. The questionnaire was reviewed by the research team for face and content validity.

The final questionnaire collected information regarding:

1. Demographics (country of institution, type of pharmacy degree program, position held at the institution);
2. Whether health literacy is taught within the pharmacy curriculum;
3. The method of delivery and forms of assessment of health literacy education employed;
4. Opinions as to the importance of health literacy education in pharmacy curricula;
5. Opinions as to how health literacy should be taught and assessed; and
6. Materials and textbooks used to teach health literacy.

The questionnaire comprised 25 questions, of which four allowed the respondent to enter free text.

Respondents had the option of submitting their contact details if they wished to discuss their responses further or to request further information.

The survey was delivered via Survey Monkey® (SurveyMonkey, 2013), an online survey platform. Descriptive analysis was performed using SPSS 19.0 (SPSS Statistics Inc. 2010).

The study was approved by the Monash University Human Research Ethics Committee.

Results

Twenty-three pharmacy academics completed the online survey. Two responses were registered as originating from universities from which a response had already been received, and hence were excluded, resulting in a total of 21 valid responses. Country of origin of respondents is listed in Table I.

Table I: Countries of Employment of Respondents

Country	n
Australia	7
United Kingdom	6
United States of America	4
New Zealand	2
Canada	1
South Africa	1

The types of degree into which respondents taught or which they oversaw are shown in Table II.

Of the 21 respondents, 20 (95.2%) reported health literacy being a component of their institution's pharmacy curriculum.

Lectures and small group learning (*e.g.* tutorials and workshops) were the most common primary forms of delivery of health literacy education, as listed in Table III. One respondent listed the main delivery method as a "combination of lectures, workshops and a health promotion campaign devised and conducted by the students".

Table II: Degree Programs In Which Respondents Teach or Oversee

Degree	n
Bachelor of Pharmacy (BPharm)	12
Master of Pharmacy (MPharm)	10
Doctor of Pharmacy (PharmD)	5
Master of Science (Pharmacy)	1
Total frequency is larger than 20 as respondents were able to select more than one option where more than one pharmacy degree was delivered in their institution of employment.	

Table III: Primary Delivery Methods of Health Literacy Education

Method of delivery	n
Lectures	8
Small-group learning (e.g. tutorials, workshops)	8
Experiential learning (e.g. clinical practice, practice-based learning)	2
Self-directed learning, including online materials	2
Other	1

The primary delivery methods of health literacy education differed by country. Lectures and small group learning were equally the primary method of delivery in Australia (n=3, 14.3%), while lectures were the primary method in the United States (n=2, 9.5%). In the United Kingdom, lectures were the primary method of delivery for only one institution, with small group learning, self-directed learning, and experiential learning dominating. Both respondents from New Zealand selected small group learning as the primary method of delivery (n=2, 9.1%).

While health literacy was sometimes taught explicitly (n=4, 18.2%), it was more often integrated into various components of pharmacy practice education, such as communication and counselling (n=14, 63.6%).

Assessment of students' health literacy competency was most often done by written examination (n=12, 57.1%), followed by performance-based assessments, e.g. practical exams and objective structured clinical examinations (OSCEs) (n=10, 47.6%). Less common assessment methods included presentations and assignments. Respondents were able to select more than one option when answering this question.

The most commonly reported drivers influencing the incorporation of health literacy into pharmacy curricula were professional practice standards or competency standards, and health literacy being considered part of the scope of practice for pharmacists in that particular country (Table IV).

Of the four respondents from the United States, only two selected 'National/State curriculum standards' as a driver for the incorporation of health literacy into pharmacy curricula, even though it is outlined as a curriculum requirement by the Accreditation Council for Pharmacy

Education. In contrast to this, five of the seven respondents from Australia selected the same option, yet at the time of the survey, health literacy education was not a requirement by the Australian Pharmacy Council. The South African respondent selected 'The country has a high number of people with low literacy' as the only driver for its inclusion into the pharmacy curriculum.

Table IV: Drivers for the Incorporation of Health Literacy into Pharmacy Curricula

Drivers	n
Professional practice standards or competency standards	16
Part of the scope of practice for pharmacists in this country	16
Motivation of individual staff members	9
National/State curriculum standards (dictated by an accreditation body or official organisation)	5
The country has a high number of people with low literacy	1
Total frequency is larger than 20 as respondents were able to select more than one option	

When respondents were asked about the content included in the health literacy component of the pharmacy curriculum, the most common content taught were methods to target communication to consumers of varying health literacy needs (n=17, 81%), followed by health literacy concepts (n=15, 71.4%) and awareness of health literacy by health professionals (n=13, 61.9%). Definitions of health literacy were included in 12 of the 21 curricula. Four respondents supplied alternative terms for health literacy that are used within their curricula, these being: 'drug and information literacy', 'evidence based medicine and communication to patients', 'health education', and 'information retrieval'.

The most common time for health literacy to be taught was Year 3 or Year 4 of the pharmacy degree, with responses of 15 (71.4%) and 16 (76.2%), respectively.

A pharmacist academic was usually the primary leader or coordinator of the health literacy component of the pharmacy curriculum in question (n=19, 90.5%).

Respondents were then given the opportunity to provide their opinions regarding the benefit of including health literacy education into pharmacy curricula. A number of responses were provided, including:

"Effectively communicating with patients (and other health care professionals) about their medicine is essential if they are to be used correctly and safely."

"It is fundamental to [know] how information for consumers is appropriately tailored by a pharmacist."

"Vital to the existing and developing roles of pharmacists."

"So that pharmacists can become more culturally competent, improve their communication skills and contribute to improving health outcomes for those with low health literacy."

Opinions were also collected regarding the methods of teaching and assessment respondents believe are best to teach health literacy in their institution. Small group learning ($n=7$, 33.3%) and self-directed learning ($n=6$, 28.6%) were the most common responses, whereas lectures were selected by three respondents. In regards to assessment, the highest responses were for oral examinations ($n=5$, 23.8%), OSCEs ($n=5$, 23.8%), and experiential placement assessment by a preceptor or supervisor ($n=5$, 23.8%). Only one respondent selected written examinations as their desired method of assessment.

Finally, respondents were provided the opportunity to list materials and resources used in their pharmacy curricula to teach health literacy. Seven respondents reported using textbooks or other resources, including: "Health Promotion for Pharmacists" (Blenkinsopp *et al.*, 1999), "Health Psychology: Topics in Applied Psychology" (Abraham, Connor *et al.* 2008), "Sociology and Healthcare" (Sheaff 2005), and "Foundation in Pharmacy Practice" (Whalley *et al.*, 2008). One institution reported using YouTube videos on motivational interviewing in their curricula.

Discussion

Health literacy has been incorporated into pharmacy curricula in a number of English-speaking countries using a variety of teaching and assessment methods.

Regarding course content, it was expected that definitions of health literacy would be a fundamental concept in health literacy education; however, only 12 respondents reported that this was the case. Similarly, it might be expected that the influence of health literacy on culturally and linguistically-diverse consumers, a population group in which low health literacy is known to have a significant impact, would also be considered, but only 12 respondents reported this (Weinick & Krauss 2000; Fiscella *et al.*, 2002; Wilson *et al.*, 2005; Hawkins 2010). It raises the question as to whether or not training is addressing the full scope of health literacy, or whether it is being blended with general communication issues. On the other hand, techniques for communicating with consumers with low health literacy abilities and assessment of the health literacy suitability of educational materials for consumers were taught in the majority of pharmacy curricula, confirming these as important concepts in health literacy education.

The majority of respondents reported that health literacy was most commonly taught in the later years of the degree, specifically, Year 3 or Year 4 of the pharmacy degree (15 [71.4%] and 16 [76.2%], respectively). Due to the importance of health literacy in pharmacy practice, and the significant impact low health literacy can have on consumer health care, its introduction into pharmacy

curricula in earlier years could be warranted. Introducing the topic to students at an earlier level, and building their knowledge over a number of years, may allow for the concept to be better understood, and readily applied at later year levels, and when practising as a pharmacist. Although due to the complexity of health literacy, a certain level of experience and maturity may be required of the student for them to appreciate the concept completely.

Knowledge of the current methods of delivery of health literacy education within pharmacy curricula may help guide future delivery of health literacy education. Ten respondents (47.6%) reported that small-group learning formed a part of health literacy education within their pharmacy curricula, the highest reported method of delivery, although it was not possible to determine the exact methods used in these small group learning sessions. Respondents also believed that small group learning was the best method of teaching health literacy. There is evidence to show that the small-group approach has positive outcomes on learning, including the promotion of deep learning, as opposed to surface learning, leading to a more long-term change in the learner's memories and abilities (Jones, 2007), development of skills in self-reflection and self-discipline, and the fostering of self-motivation as a result of active involvement in learning (Norman & Schmidt 1992; Schwartz, 1997).

The majority of respondents reported that health literacy was included in their pharmacy curriculum because it was considered to be part of the scope of practice of a pharmacist. This underscores the importance of competency frameworks. Regarding the drivers for including health literacy in pharmacy curricula, only a small number of respondents reported that health literacy was included in the curriculum due to national or state curriculum standards dictated by an accreditation body, with only the United States including health literacy in pharmacy degree accreditation standards. As mentioned in the results, it was interesting to note the influence that perceived accreditation requirements have on the inclusion of health literacy in pharmacy curricula, even if the requirement does not exist. Given that health literacy has a significant impact on consumer health care, a case may reasonably be made to incorporate health literacy as a requirement in pharmacy curricula accreditation standards.

Regarding assessment, the majority of respondents reported that health literacy knowledge was assessed in the form of a written examination, yet when respondents were asked to provide their opinions regarding the best way to measure the health literacy knowledge of students, the majority selected oral examination and OSCEs as their most preferred method, whereas only one respondent preferred written examinations as the method of assessment. This reflects the practical nature of health literacy education. Being a skill in communication, and consumer interaction and understanding, it could be most practical to measure students' abilities in this field through practical, oral examination, rather than in written format.

While the survey identified that health literacy training is delivered and assessed by a variety of methods, the effectiveness of these teaching methods and assessments was not explored. Such information would be useful in assessing teaching strategies for adult learners to guide curriculum development. Having now identified a number of universities that deliver health literacy education in variety of ways, a more intensive evaluation of the methods of assessment employed seems appropriate. This would inform development of strategies for wider implementation of health literacy education.

The low response rate (around 5%) limits the generalisation of the results. This was anticipated given that schools without such a focus were unlikely to respond. Whilst it would have been useful to determine the prevalence of health literacy education in pharmacy curricula internationally, the low response rate precluded such a conclusion being made. Given that the prevalence of health literacy education in pharmacy curricula reported in the survey was close to 100%, it is likely that self-selection bias occurred when respondents chose to complete the survey. Although the invitation explicitly explained that the survey was relevant both for schools that teach health literacy and those that do not, potential respondents from schools not teaching health literacy may have opted not to respond, believing that they had nothing of interest to report. The questionnaire could have included a section that allowed Schools who do not currently teach health literacy to explain why not, and possible routes they may envisage taking if they were to integrate health literacy in their curriculum.

Broader inclusion criteria may have also provided for greater generalisation of results, such as the inclusion of countries where English is not the main language of instruction; however, resource and time constraints precluded this.

Future research should attempt to determine the methods of health literacy education in more depth, particularly the variety of content employed in its delivery in pharmacy schools internationally. It would also be useful to determine the effectiveness and appropriateness of methods used in its delivery.

Conclusion

Health literacy training is currently included in pharmacy curricula in a number of English-speaking countries. Delivery, assessment and drivers for inclusion into the curriculum are common among responding institutions. Opinions on the methods of delivery and assessment of health literacy education differed from what is currently being used in practice.

Acknowledgements

The Healthy Literacy in Pharmacy program is funded by the Australian Government Department of Health and Ageing as part of the Fifth Community Pharmacy Agreement.

We acknowledge the valued input of Dr Therese Kairuz, Dr Betty Chaar, A/Prof Kylie Williams, Dr Remo Ostini, Prof Moyez Jiwa, Prof Peteris Darzins, Dr Kreshnik Hoti and Prof Jeff Hughes.

Conflict of interest

We certify that there is no conflict of interest with any financial organisation regarding the material discussed in the manuscript.

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Appendix 1

International survey of health literacy education provided within pharmacy curricula.

- 1) In which country do you work? (Required)
- 2) With which university or academic organisation do you hold this position? (Optional)
- 3) If applicable, what type of pharmacy degree do you teach within? BPharm (Bachelor of Pharmacy)/MPharm (Master of Pharmacy)/PharmD (Doctor of Pharmacy)/Other. (Required)
- 4) What is your position or role within the university or academic organisation? (Optional)
- 5) This survey explores the teaching of Health Literacy in Pharmacy Schools. As this term may not be used in all settings, a useful definition is: *Health literacy is the ability of people to obtain, understand and use health information to promote and maintain health*. Are other terms used to describe the concept of Health Literacy in your country? Please list:
 - a) _____
 - i) _____
 - ii) _____
 - iii) _____

6) Is the concept of Health Literacy explicitly taught by your university or academic organisation? Yes/No

(if you answered 'Yes', please complete Questions 7-20)

No (if you answered 'No', please go to Question 21)

7) In what context is Health Literacy taught

- i) Explicitly as stand-alone topic
- ii) Explicitly, integrated into various components (e.g. communication, counselling)
- iii) Not explicitly; implied in other course content
- iv) Other: _____

8) At what stage in the pharmacist career does your university or academic organisation deliver Health Literacy training? (Select all that apply; select Not Applicable [NA] if your organisation is not involved in training at that level)

- i) Year 1 undergraduate ☐ NA ☐
- ii) Year 2 undergraduate ☐ NA ☐
- iii) Year 3 undergraduate ☐ NA ☐
- iv) Year 4 undergraduate ☐ NA ☐
- v) Year 5 undergraduate ☐ NA ☐
- vi) Year 6 undergraduate ☐ NA ☐
- vii) Optional undergraduate elective ☐ NA ☐
- viii) Professional internship year ☐ NA ☐
- ix) Continuing education for all pharmacists ☐ NA ☐
- x) Postgraduate qualification ☐ NA ☐
- xi) For specialised pharmacist roles ☐ NA ☐
- xii) Pharmacy technician/pharmacy assistant training ☐ NA ☐

9) What is the main method of teaching Health Literacy in your university or academic organisation? (Select one option)

- i) Lectures
- ii) Small-group learning, e.g. tutorials, workshops
- iii) Self-directed learning (including online materials)
- iv) Experiential learning (i.e. clinical practice; practice-based learning)
- v) Other: _____

10) What are the other additional methods of teaching are used to complement the main method? (Select all options that apply)

- i) Lectures
- ii) Small-group learning, e.g. tutorials, workshops
- iii) Self-directed learning (including online materials)
- iv) Experiential learning, i.e. clinical practice, practice-based learning
- v) Other: _____

11) In your university or academic organisation, is Health Literacy taught

- i) To Pharmacy students/pharmacists separate to other professions?
- ii) In an interprofessional learning environment (more than one profession taught together)?

12) What is/are the background(s) of the person(s) leading or coordinating Health Literacy teaching in your university or academic organisation? (Select all options that apply)

- i) Pharmacist academic
- ii) Pharmacist teacher/practitioner
- iii) Sociologist
- iv) Psychologist
- v) Other social scientist
- vi) Medical academic
- vii) Medical practitioner
- viii) Other: _____

13) What were the key drivers/reasons for inclusion of Health Literacy in the curriculum in your university or academic organisation? (Select all that apply)

- i) National/State curriculum standards dictated by an accreditation body or official organisation
- ii) Professional practice or competency standards
- iii) Part of the scope of practice for pharmacists in this country
- iv) Motivation of individual staff members
- v) Direction from administration/management
- vi) Other: _____

14) Which of the following elements are included in the Health Literacy curriculum in your university or academic organisation? (Select all that apply)

- i) Definitions of Health Literacy [e.g.... Institute of Medicine; World Health Organisation definitions]
- ii) Health Literacy concepts
- iii) Awareness of Health Literacy by health professionals
- iv) Raising awareness of Health Literacy in consumers
- v) How to assess Health Literacy capacity of consumers
- vi) How to target communication to consumers' Health Literacy needs
- vii) Assessment of Health Literacy suitability of educational materials (e.g. consumer information leaflets and other resources)
- viii) Assessment of Health Literacy of students
- ix) Health Literacy and culturally and linguistically-diverse consumers
- x) Health Literacy in special settings (schools, nursing homes, etc.)
- xi) Health Literacy issues for pharmacy staff (including technicians and assistants)
- xii) Other: _____

15) How does your university or academic organisation assess learning outcomes following delivery of Health Literacy education or training? (select all that apply)

- i) Written examination
- ii) Oral examination (viva voce)
- iii) Individual written assignment tasks
- iv) Group written assignment tasks
- v) Presentations
- vi) Task-oriented assessments (OSCE, practical exams)
- vii) Experiential placement assessment by preceptor/supervisor
- viii) Not assessed
- ix) Other: _____

16) Do you use any textbooks or other resources to assist learners to understand the concept of Health Literacy? Yes/No

17) If you answered yes, please list the textbooks or resources.

18) Do you use any textbooks or other resources to illustrate methods or strategies that can be employed to teach the concept of Health Literacy? Yes/No

19) If you answered yes, please list textbooks or resources.

20) This project also seeks to review Health Literacy educational material and resources to assess common effective educational strategies in Health Literacy, for the purposes of developing an educational package for community pharmacists and pharmacy assistants in Australia.

With consent, we would be very grateful to have access to your curriculum or educational resources (de-identified if you wish) to be included in our review. A summary of the nature, extent and impact of various resources reviewed will be published in the pharmacy education literature. No materials created or developed by any institution or individual will be used in any way other than the summary review, without explicit permission of the appropriate person.

If you consent to be contacted regarding your curriculum, materials and resources, please provide the following contact information.

- a) Title and Name
- b) Position
- c) Organisation and address
- d) Email address
- e) Brief summary of potential resources

If you answered 'Yes' to Question 6, you have now completed the questionnaire. Thank you for your participation.

21) Do you believe that dedicated Health Literacy training or education should be delivered by your university or academic organisation? Yes/No

22) Please provide reasons for your answer to Question 21

If you answered 'No' to question 21, you have now completed the questionnaire. Thank you for your participation.

If you answered 'Yes' to Question 21, please answer questions 23-26.

23) In pharmacy practice education, at what stage do you believe Health Literacy should be delivered? (Select all that apply, select NA if not relevant to your university or academic organisation)

- i) Year 1 undergraduate ☐ NA ☐
- ii) Year 2 undergraduate ☐ NA ☐
- iii) Year 3 undergraduate ☐ NA ☐
- iv) Year 4 undergraduate ☐ NA ☐
- v) Year 5 undergraduate ☐ NA ☐
- vi) Year 6 undergraduate ☐ NA ☐
- vii) Optional undergraduate elective ☐ NA ☐
- viii) Professional internship year ☐ NA ☐
- ix) Continuing education for all pharmacists ☐ NA ☐
- x) Postgraduate qualification ☐ NA ☐
- xi) For specialised pharmacist roles ☐ NA ☐
- xii) Pharmacy technician/pharmacy assistant training ☐ NA ☐

24) If you were to introduce Health Literacy education/training, what would be your preferred method(s)? (Select all that apply)

- i) Lectures
- ii) Small-group learning, e.g. tutorials, workshops
- iii) Self-directed learning (including online materials)
- iv) Experiential learning, i.e. clinical practice, practice-based learning
- v) Other: _____

25) What elements of Health Literacy would you include in the curriculum? (Select all that apply)

- i) Definitions of Health Literacy [e.g.... Institute of Medicine; World Health Organisation definitions]
- ii) Health Literacy concepts
- iii) Awareness of Health Literacy by health professionals
- iv) Raising awareness of Health Literacy in consumers
- v) How to assess Health Literacy capacity of consumers
- vi) How to target communication to consumers' Health Literacy needs

vii) Assessment of Health Literacy suitability of educational materials (e.g. consumer information leaflets and other resources) viii) Assessment of Health Literacy of students ix) Health Literacy and culturally and linguistically-diverse consumers x) Health Literacy in special settings (schools, nursing homes, etc.) xi) Health Literacy issues for pharmacy staff (including technicians and assistants) xii) Other: _____ 26) How would you suggest Health Literacy be assessed within the curriculum? (Select all that apply) i) Written examination ii) Oral examination (viva voce) iii) Individual written assignment tasks iv) Group written assignment tasks v) Presentations vi) Task-oriented assessments (OSCE, practical exams) vii) Experiential placement assessment by preceptor/supervisor viii) Other: _____ Thank you for your participation

3.4 HeLP PHASE: DESIGN OF THE HEALTH LITERACY EDUCATION-FOCUSED INTERVENTION

NB. The following description of the design of the health literacy educational education-focused intervention was not led by the PhD candidate but is provided for context.

3.4.1 Educational theory

The content of the education-focused intervention was structured based on Miller's Pyramid, also known as Miller's Prism of Clinical Competence.¹⁸⁶

This theory was chosen because the process of developing skills in health literacy must first begin with a basic knowledge of the concept, building up to a level where the learner feels competent to teach others about health literacy. This formed a key component in the delivery of the intervention to pharmacists and pharmacy staff members.

Other educational theories were considered in the development of the education-focused intervention, including the cognitive domain within Bloom's taxonomy. The cognitive domain contains a step-up approach similar to Miller's Pyramid, where progression to the next level involves being able to demonstrate an expertise or accomplishment of objectives in that particular stage.^{187, 188} The stages within the cognitive domain are: remember, understand, apply, analyse, evaluate and finally,

create. Progression through these domains is related to the increased understanding and adoption of skills that allow the learner to finally be able to utilise skills gained throughout the learning process. Miller's Pyramid was chosen over Bloom's Taxonomy due to the simpler nature of the educational theory in developing the intervention.

Miller's Pyramid is composed of four stages, beginning at a novice level, working towards becoming an expert in the field.¹⁸⁹

The first and second stages are cognition based, forming a knowledge base for the learner to build more practical skills upon. The first stage is 'Knows', and is mainly a fact gathering stage aimed at learning about a concept and how it impacts practice. The second stage is 'Knows how', and builds on the knowledge gained in the first stage to help the learner develop the skills to interpret and apply this knowledge to real life cases.

The third and fourth stages are behavioural based, allowing the learner to demonstrate skills and influence practice in the workplace. The third stage is 'Shows', teaching the learner to be able to demonstrate the skills and knowledge. This was applied to the intervention through the inclusion of role-plays and simulations. The final stage known as 'Does' focuses on the learner being able to integrate the knowledge and skills learned into practice and actively utilise these skills in practice.

3.5 HeLP PHASE: DEVELOPMENT OF THE HEALTH LITERACY EDUCATION-FOCUSED INTERVENTION

NB. The following description of the development of the health literacy education-focused intervention was not led by the PhD candidate but is provided for context.

To develop the health literacy education-focused intervention, a number of developers were sought, including a module writer, reviewers and a graphic designer. The module writer was an expert in health literacy and pharmacy practice. An Expert Reference Group (ERG) was also established to review module content prior to finalisation to ensure relevance and accuracy, which was conducted prior to implementation. The survey conducted in Phase 1 (Chapter 3, Section 3.3) also provided insight into potential delivery methods, particularly the use of small-group learning.

3.5.1 Education-focused intervention content

The intervention was based on the idea of employing the use of universal precautions, as described in Chapter 1, Section 1.5.4. This involves engaging with a consumer based on the assumption that they have limited health literacy until indicated otherwise. This could be through increased engagement or involvement in discussions with the pharmacist or pharmacy staff member, for example, asking questions.

Figure 2 below is an outline of the modules developed for the education-focused intervention.

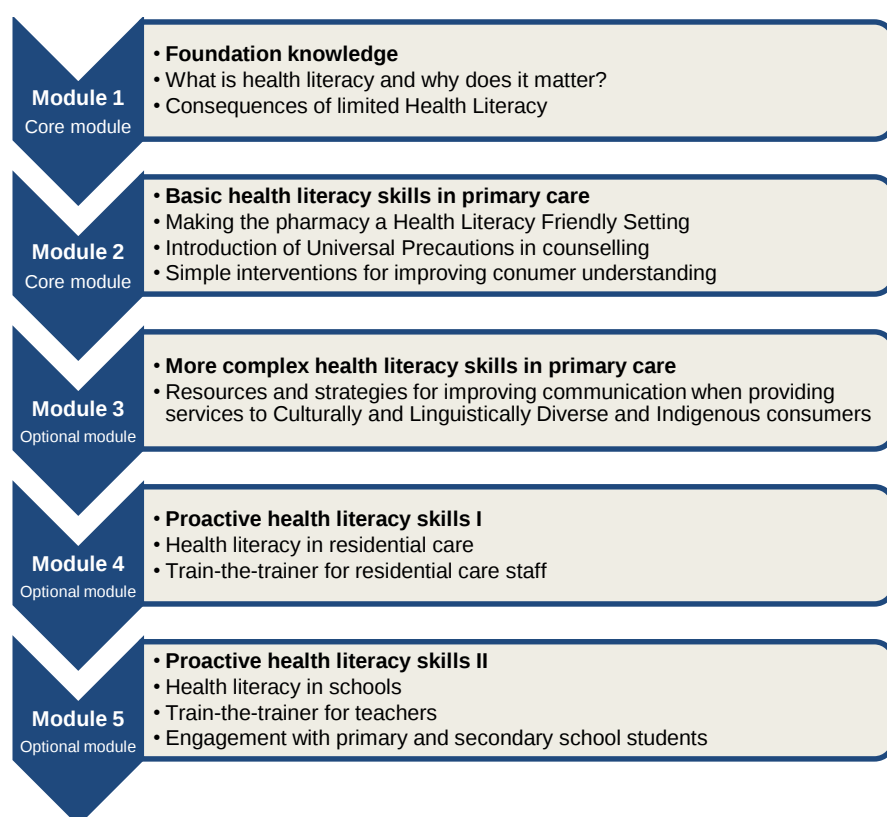


Figure 2: Outline of the education-focused intervention

Multimedia development

A review of the available multimedia resources currently available did not produce any materials suitable for use in the intervention. It was therefore deemed necessary to develop a variety of videos in-house for inclusion in the intervention. A series of short video vignettes and still images were produced, enabling the demonstration of health literacy issues consumers may face in an Australian context.

The videos provided a more meaningful demonstration of indicators for limited health literacy that consumers may exhibit, as well as strategies and techniques that can be

used by pharmacists and pharmacy staff members to enhance the provision of health and medicines information.

3.5.2 Module review

The PhD candidate, Lead Investigator (G.D.) and members of the ERG reviewed various drafts of the modules to ensure accuracy before final delivery to pharmacies.

3.5.3 Train-the-trainer

The train-the-trainer component (see Chapter 1, Section 1.7.2) of the education-focused intervention contained an extensive set of materials and resources to complement learning. A short presentation to introduce the nature of the intervention, its structure and what is involved, and an explanation of how to deliver the training in-pharmacy was also provided. To further enhance learning, a Trainer Guide was developed to guide the trainer through the learning process on a slide-by-slide basis. Each trainer was provided with the following materials to deliver the training within their pharmacy:

- PowerPoint presentations to give to the staff receiving the training;
- A Trainer Guide;
- Participant notes for staff to focus on key issues taught;
- Short quizzes to evaluate learning and for claiming continuing professional development (CPD) points; and

- Extra readings and links to other resources.

Face-to-face train-the-trainer delivery

The initial training of pharmacy trainers was designed to be delivered in a single session of four to five hours in duration. One to two facilitators in each state delivered the training session at a centre convenient to pharmacy trainer participants.

Electronic train-the-trainer delivery

This delivery element was developed as a series of videos for the introduction of the education-focused intervention and then one for each module. Voice-overs were used to complement the video, which took the trainer through each module presentation, providing an explanation of how to teach the content contained within. The total duration for this component was four to five hours, and could be taken as a single session or a series of smaller sessions.

3.5.4 In-pharmacy delivery

Following completion of the train-the-trainer component of the intervention, trainers were then instructed to deliver the training to pharmacists and pharmacy staff members in the pharmacy. Trainers were encouraged to deliver training in short, 30 minute sessions. The total time allocated to deliver the first two compulsory modules was three hours, with the remaining three modules taking an extra two hours.

3.5.5 Universal serial bus (USB) flash drive production

The health literacy education-focused intervention contents were stored onto USB flash drives and provided to trainers along with a printed copy of the Trainer Guide.

3.6 HeLP PHASE: IMPLEMENTATION OF THE HEALTH LITERACY EDUCATION-FOCUSED INTERVENTION

A cluster RCT was used to evaluate the efficacy of the health literacy education-focused intervention in community pharmacies in New South Wales, Victoria and Western Australia. Block randomisation into groups of three was used to randomise recruited pharmacies into one of three groups: a face-to-face group (intervention, Group 1), an electronic group (intervention, Group 2), and a control group (Group 3), who did not receive any health literacy training. The coding list was created by Sealed Envelope (Sealed Envelope. London, UK).¹⁹⁰

The unit of randomisation was the pharmacy. Metropolitan and rural pharmacies were randomised separately, as was each state. The following provides a description of the three study groups.

- **Group 1** pharmacies were recruited from metropolitan and regional areas of Victoria, New South Wales and Western Australia, and were provided with *face-to-face training* using the developed health literacy education-focused intervention.

- **Group 2** pharmacies were also recruited from metropolitan and regional areas of Victoria, New South Wales and Western Australia, and were provided with *electronic training* using the developed health literacy education-focused intervention.
- **Group 3** were also recruited from metropolitan and regional areas of Victoria, New South Wales and Western Australia, and were *not provided with the health literacy education-focused intervention*.

For both Groups 1 and 2, the train-the-trainer approach was adopted, as a means to disseminate knowledge and skills efficiently to pharmacy staff members. This involved one or two key staff members from each pharmacy receiving training and guidelines to conduct in-pharmacy training for their remaining staff. This process draws on the pedagogical principles described earlier in Miller's Pyramid as a model for stepwise learning, with the knowledge and skills further consolidated in training others (see Chapter 3, Section 3.4.1).

Ethics approval for this phase was granted by the Human Research Ethics Committees of Monash University, Curtin University and the University of Sydney (Appendix 3).

3.6.1 Recruitment of pharmacies

The recruitment process involved contacting 196 pharmacies from a number of metropolitan and regional areas within Australia. Pharmacies in Sydney, Melbourne, Perth, western New South Wales, western Victoria and south-western Western Australia were sent a letter of invitation via post or email, or were contacted via telephone and visited in the pharmacy, inviting them to participate in the project. An e-bulletin was also distributed through the NSW Branch of the Pharmaceutical Society of Australia, advertising the project. Pharmacies that registered their interest in participating were forwarded a letter of invitation, permission letters, explanatory statements and consent forms (Appendix 4) to complete prior to enrolment.

The sample represented a mix of both metropolitan and rural pharmacies, the latter of which was required to be PhARIA³ 3 or above, as instructed by the Pharmacy Guild of Australia. Pharmacies were of a range of types and sizes, including banner groups and independent ownership.

³ Pharmacy Access/Remoteness Index of Australia: composite index which incorporates measurements of general remoteness with a professional isolation component represented by the five closest pharmacies. The higher the value on a scale from 1 to 6, the more remote the area is considered.

3.6.2 Commencing, completing and working through the education-focused intervention

Pharmacists in the face-to-face group (Group 1) were notified of training venues and dates for the train-the-trainer portion of the intervention. The pharmacists were contacted one week later to confirm receipt of the information and to confirm attendance at training sessions for those allocated to Group 1. Managers were invited to send (or bring) a second key staff member to the training.

Face-to-face group pharmacies (Group 1) were provided with the education-focused intervention and initial train-the-trainer component in a workshop delivered by project team members at various locations deemed convenient for participants and instructors. A second key staff member from each pharmacy was welcome to attend, with a view to a second person available to train other staff, and to foster enthusiasm for the learning experience. Electronic group pharmacies (Group 2) were supplied the intervention in-person or via mail in the form of a USB drive and Trainer Guide. Control group pharmacies (Group 3) did not receive the intervention during the course of the project.

Pharmacies were instructed to train their remaining staff in the core modules (Module 1 and Module 2) by 30th November 2013, and if time permitted, to also complete Modules 3, 4 and 5 (see Figure 2).

Halfway through the intervention, further contact was made, reminding trainers that they had reached the halfway mark. Suggestions were provided to trainers who were

behind schedule, for example, blocking out chunks of time to complete and deliver the training sessions.

Pharmacists were offered up to 25 CPD points for completion and delivery of all five modules of the education-focused intervention, and 10 points if they completed only core Modules 1 and 2.

3.7 RESULTS

3.7.1 Recruitment of pharmacies

Of the 196 pharmacies approached to participate in the education-focused intervention, 119 declined to participate for the following reasons:

- Lack of time to complete and deliver training
- Staffing issues
- Already committed to a training intervention or research study
- No interest in health literacy
- Lack of managerial support

Consequently, 77 pharmacies from metropolitan and regional Australia were recruited to the project.

Figure 3 is a CONSORT diagram depicting the randomisation and allocation of the 77 participating pharmacies into the study groups.

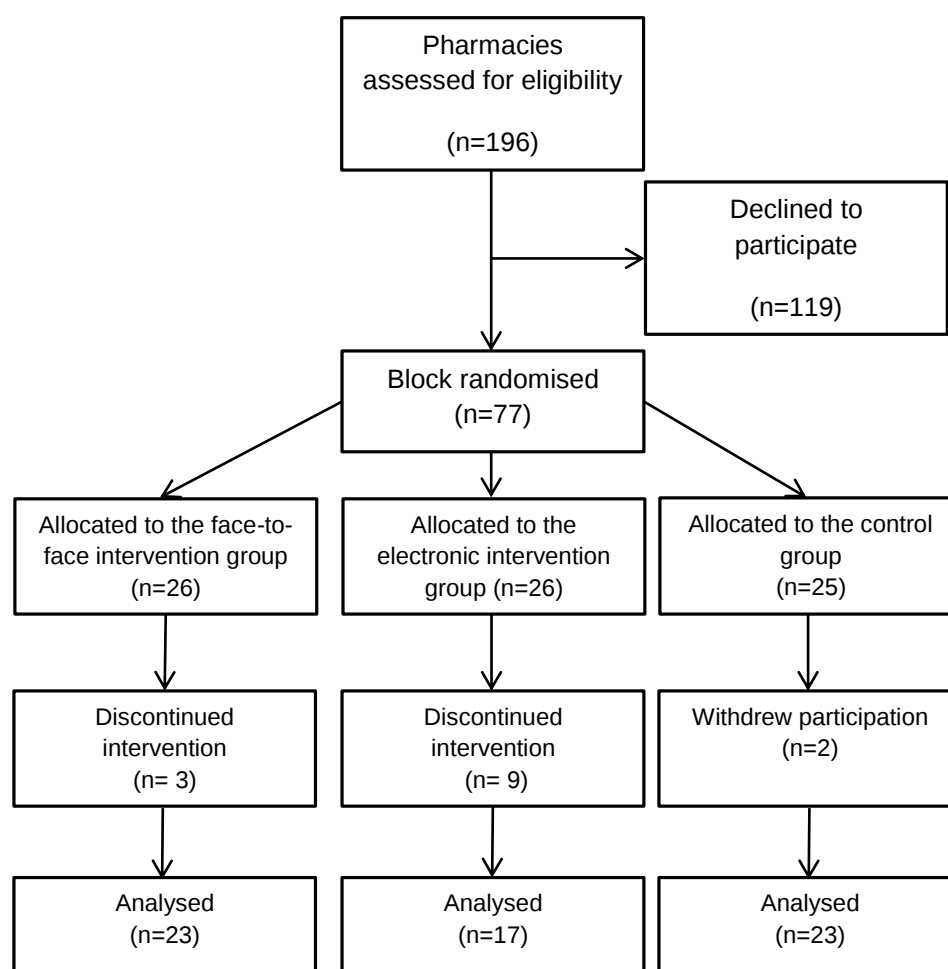


Figure 3: CONSORT diagram of the recruitment and allocation process of pharmacies

A total of 77 pharmacies from New South Wales, Victoria and Western Australia initially consented to being involved in the project. Table 3.5 provides a breakdown of the pharmacies by state and location.

Table 3.5 Location of recruited pharmacies at beginning of the project

	State			
	NSW	Victoria	WA	Total
Metropolitan	19	21	20	60
Rural*	4	4	9	17
<i>Total</i>	23	25	29	77

*Rural was defined as being in a location deemed PhARIA 3 or above in 2010.

Over the period of the project, a total of 14 pharmacies withdrew - three from NSW, two from Victoria, and nine from Western Australia - with final numbers shown in Table 3.6. Reasons for withdrawals, where given, predominantly related to workload and staffing changes.

Table 3.6 Location of recruited pharmacies at the conclusion of the project

	State			
	NSW	Victoria	WA	Total
Metropolitan	16	19	13	48
Rural*	4	4	7	15
<i>Total</i>	20	23	20	63

*Rural was defined as being in a location deemed PhARIA 3 or above in 2010.

The block randomisation into face-to-face delivery (Group 1), electronic delivery (Group 2), and the control group (Group 3) resulted in the distribution reported in Table 3.7.

Table 3.7 Allocation of pharmacies to face-to-face (Group 1), electronic (Group 2) and control (Group 3) groups.

	State			
	NSW	Victoria	WA	Total
Face-to-face (Group 1)	8	8	10	26
Electronic (Group 2)	8	9	9	26
Control (Group 3)	7	8	10	25
<i>Total</i>	23	25	29	77

3.7.2 Commencement and completion of the education-focused intervention

Table 3.8 shows the number of pharmacies who commenced, completed and partially completed the intervention from 15th July to 1st November 2013.

Table 3.8 Number of pharmacies who commenced (n=52), completed (n=31), partially completed (n=9) and withdrew from (n=12) the intervention

Group	Commenced	Completed	Partially completed	Withdrew
Face-to-face	26	20	3	3
Electronic	26	11	6	9

Reasons given for non-completion or partial completion of the intervention included:

- Staff constraints/resignations
- Annual leave
- Work commitments
- Frustration with the education-focused intervention format
- Difficulty organising in-pharmacy training sessions
- Lack of managerial support

3.8 DISCUSSION

The small number of rural pharmacies recruited for the implementation trial was a significant limitation of the project. The strict inclusion criteria set by the Pharmacy Guild of Australia, whereby all rural pharmacies must be situated in an area classified as PhARIA 3 or above, drastically reduced the number of eligible pharmacies. This was especially the case in Victoria where the majority of the state's population, and therefore pharmacies, are situated in areas classified as PhARIA 1

or 2. Broader inclusion criteria for this project in relation to rural pharmacies most certainly would have increased the number of rural pharmacies recruited.

Another limiting factor for the implementation trial was time. There was a significant time period between when pharmacies were recruited to the project and the beginning of the education-focused intervention implementation – approximately four months. During this time, 14 pharmacies withdrew from the project due to other commitments emerging, changes in management during that period, or other unreported reasons. This again reduced the number of pharmacies in the sample, possibly impacting on the statistical power of the project.

The recruitment and retention of pharmacies in studies is a known difficulty in pharmacy practice research.¹⁹¹ A number of studies cite the percentage of pharmacies willing to participate in research as ranging from 32 to 59%.^{192, 193} One particular study conducted in the UK determined that only 6% of responding pharmacists were actively participating in research.¹⁹⁴

A number of potential barriers exist that may discourage pharmacists to engage in pharmacy practice research, as discussed in Chapter 1, Section 1.6.3. These may include a lack of time, lack of financial remuneration, and a lack of perceived self-efficacy in their ability to be involved.

Time is a significant barrier to pharmacists participating in extra activities, including research, training and other practice initiatives.^{119, 191, 195-199} A focus group study by Marriott *et al.* was undertaken in Australia with community pharmacists to determine

the barriers to participating in CE programs.¹¹⁹ It was noted that time, along with relevance, lack of motivation, and accessibility were major barriers to undertaking CE. A similar result was found in a Canadian study by Zou *et al.*²⁰⁰ A survey was disseminated to 3,927 community pharmacists regarding their educational needs and practice patterns in geriatric care. It was found that the most significant perceived barrier to undertaking education and implementing practices was a lack of time. A similar study by Awad *et al.* was conducted in Kuwait with 223 community pharmacists in which a questionnaire was distributed to participants on self-reported practice in health promotion and education activities.²⁰¹ Particular attention was paid to the barriers that may discourage or limit their involvement in these activities. Lack of time was reported by 58% of pharmacists as a significant barrier to involvement. These studies clearly indicate that a lack of available time to dedicate to engaging in other practice initiatives is a major barrier.

Overcoming this barrier is difficult, as time is a commodity that cannot be purchased. Reducing the time taken to use and implement educational interventions may aid in improving the recruitment and retention of pharmacies in future studies. This may be enhanced by creating shorter education-focused interventions, which may help enhance the likelihood of implementation into practice.

Another barrier that may have impacted on the recruitment and retention of pharmacies in this project was the lack of financial remuneration for participation. The unfortunate tendency for managers to base pharmacist performance on workload and the number of scripts filled may also further impact on the willingness for pharmacists to engage in research.¹⁹² An exploratory survey study by Saini *et al.*

on Australian pharmacists' willingness to participate in research was conducted with 267 community pharmacists.¹⁹¹ Pharmacists who had not previously been involved in pharmacy practice research were more likely to identify a lack of reimbursement as a barrier to participating in research than those who had. A similar study was conducted in the UK with 651 community pharmacies in East London and Essex by Rosenbloom *et al.*²⁰² Most of the respondents (72%) stated that they would only participate in research if they were paid to do so. Having been conducted in Australia and the UK, these studies provide support to the notion that a lack of remuneration for participation in research is a major barrier for Australian community pharmacists. To reduce the impact of the lack of remuneration in this study, accreditation was sought and obtained from the Pharmacy Guild of Australia for the education-focused intervention, allowing pharmacists to claim CPD points for undertaking the intervention.

A lack of perceived self-efficacy or skills may also impact on the willingness of pharmacists to participate in pharmacy practice initiatives.^{196, 203-206} Overcoming this potential barrier may involve providing an adequate yet simple, unintimidating explanation of research studies to improve pharmacists' confidence in their ability to participate.

The delivery method was also a major contributor of the likelihood to complete the intervention. The face-to-face delivery method proved more successful in retaining pharmacies and achieving completion than the electronic delivery method. Mastery of technology is perceived as a challenge in the use of electronic or online educational training, as shown in a study conducted on final year pharmacy students

when completing a course on pain management.²⁰⁷ Electronic or distance delivery methods may present problems associated with the high degree of self-directedness required to undertake the training, the need to adapt to computer-mediated communication methods, time management, and technology issues.²⁰⁸ Uptake and completion of the education-focused intervention in the future may be best achieved using the face-to-face delivery method, yet this presents issues with accessibility for rural and remote pharmacies.

3.9 CONCLUSION

The findings from the literature review and the online survey of pharmacy academics (Chapter 3, Section 3.3) assisted in the design and development of the multi-modal health literacy education-focused intervention. The various barriers faced during the implementation of the education-focused intervention impacted on the recruitment and retention of pharmacies in the project, and on the rate of successful completion of the intervention. Implementing various strategies to reduce the impact of these barriers on the success of the intervention in community pharmacies is highly recommended, because as discussed in Chapter 1, Section 1.6.3, no *single* method to tailor strategies to overcome barriers has been developed.¹²⁴

The next chapter investigates the effects of motivations on the intentions of pharmacists and pharmacy staff members in undertaking health literacy training.

4 MOTIVATIONS AND INTENTIONS OF PHARMACISTS AND PHARMACY STAFF MEMBERS TOWARDS IMPLEMENTING HEALTH LITERACY TRAINING

4.1 SUMMARY

Described in this chapter are the methods that were used to evaluate the influence of pharmacists' and pharmacy staff members' motivations on their intentions to implement health literacy training in their pharmacy, and subsequently use universal precautions with all consumers (Phase 2). A survey was conducted concurrently, yet independently, with the HeLP phase of the project (see Figure 1), with surveys being completed by participants before the education-focused intervention was implemented into pharmacies.

Pharmacists and pharmacy staff members demonstrated that a variety of motivational factors influence their intentions to implement health literacy training and use universal precautions with consumers to varying degrees. The results of this study provide insight into potential barriers and enablers for successful implementation of health literacy education in pharmacy.

4.2 METHODS

As discussed in Chapter 2 (Section 2.2), a mailed questionnaire was chosen to evaluate the pharmacists' and pharmacy staff members' attitudes, intentions and motivations towards implementing health literacy training within their pharmacies. This phase was approved by the Human Research Ethics Committees of Monash University, Curtin University and the University of Sydney (Appendix 5).

4.2.1 Questionnaires

Two pre-intervention questionnaires were developed to evaluate pharmacists' and pharmacy staff members' motivations and intentions in regard to implementing health literacy training and using universal precautions. One questionnaire was developed for the lead training pharmacists and pharmacy staff members, and one for all other pharmacists and pharmacy staff members who planned to receive in-pharmacy training from the lead training pharmacist (Appendix 6). The pre-intervention questionnaires were completed by all groups of pharmacists and pharmacy staff members (face-to-face [Group 1], electronic [Group 2] and control [Group 3]).

4.2.1.1 Questionnaire design and piloting

The questionnaires were designed as mailed questionnaires for reasons discussed in Chapter 2, Section 2.2.1.2.

The questionnaires were designed based on the Theory of Planned Behaviour (TPB).¹²¹ The TPB was developed to model the various factors that dictate intentional human behaviours. The theory has been used extensively in the past to construct questionnaires to investigate the attitudes and beliefs that influence health-related behaviours. The TPB has been used to measure the impact of knowledge transfer and implementation of evidence-based practice initiatives with health care professionals, and has shown to be very effective at predicting health-related behaviours.^{209, 210} The theory has shown to be a good predictor of one's intentions and subsequent behaviour, accounting for 39-49% of the variance in intention, and 26-36% of the variance in behaviour.^{122, 209, 211-213}

The TPB explains behaviour as a result of an individual's intentions, which are determined and dictated by three key variables:

1. 'Attitudes' is composed of both the individual's belief about the consequences of a particular behaviour, as well as their positive or negative evaluation of the behaviour.^{121, 122, 211}
2. 'Subjective norms' is composed of both the individual's normative beliefs, that is, the degree to which the beliefs or opinions of others influence the likelihood to perform the behaviour, and the individual's own perception of the behaviour as influenced by others.

3. 'Perceived behavioural control' is both the individual's perceived ability to perform the behaviour, as well as their belief of the impact of particular factors that may make the behaviour easier or more difficult to perform.

The model is depicted in Figure 4.

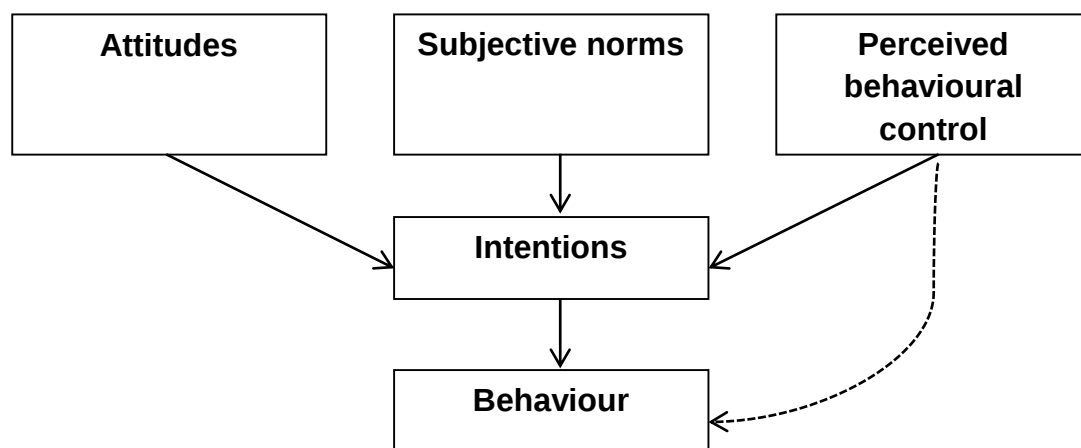


Figure 4: The Theory of Planned Behaviour

When compared to other models of behaviour change, for example the social cognitive theory (SCT), the TPB has distinct advantages.²¹⁴ Firstly, the SCT assumes that individuals already have a high level of intention to undertake a particular behaviour, whereas in the TPB, intentions are not measured or are assumed to be low. This makes the TPB suitable for preventative health interventions, as individuals may not have a particular intention to change, whereas the SCT is used to detect behavioural change of people who are already seeking help. The TPB also suggests which cognitions may be changed or influenced to alter an individual's intentions (attitudes, subjective norms and perceived behavioural control).

Before formulating questions for the pre-intervention questionnaires, it was important to first define the target behaviour that was desired. The TACT approach was used to define the target behaviour. The TACT approach involves defining the Target, Action, Context, and Time to determine the behaviour that is desired.²¹⁰ Using this approach, the behaviour was defined as ‘implementing an education-focused intervention in health literacy into a community pharmacy over a three month period’, where the target was the community pharmacy, the action was the use of universal precautions with consumers, the context was the condition (limited health literacy), and the time was three months.

Once the behaviour was defined, the method to measure behavioural intentions was then determined. The method most commonly used in the TBP model is the Generalised Intention method, due to its ease and the fact that it requires less time for respondents to answer questions.²¹⁰ Questions were formulated around three verbs: ‘expect’, ‘want’, ‘intend’, and their synonyms. Questions were based on one of the three key variables of the TPB (Figure 4), as well as intentions (the dependent variable). The aim was to measure each variable using a number of different questions and approaches. Each question was measured on a seven-item Likert scale, measuring from 1 (strongly disagree) to 7 (strong agree) – the higher the number, the more positive the response.

All of the questions were piloted for face and content validity by a group of four project investigators from the Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, and one pharmacy academic from the School of Pharmacy, Curtin University. Minor changes were made to the questionnaires in light of the

piloting phase. These changes were included in the questionnaires shown in Appendix 6.

4.2.1.2 Survey sample and recruitment

The survey sample was all community pharmacists and pharmacy staff members recruited for the project.

Pre-intervention, each pharmacy received a mailed package containing: twelve letters of invitation, one permission letter, twelve explanatory statements, twelve consent forms, at least two pre-intervention pharmacy trainer questionnaires, ten pre-intervention in-pharmacy participant questionnaires and reply paid envelopes (Appendix 6).

Two reminders were given to each pharmacy before the survey submission deadlines by telephone two weeks and four weeks following the supply of the questionnaires.

A total of 216 responses were received, 41 from pharmacy trainers, and 175 from in-pharmacy participants.

4.2.1.3 Survey analysis

Quantitative data was analysed using the Statistical Package for the Social Sciences (Statistical Package for the Social Sciences for Windows: IBM: version 19, New York, USA).

Exploratory factor analysis was conducted to condense the large number of survey items into a smaller number of common factors for easier interpretation (Chapter 2, Section 2.8). Results from negative statements were inversely recoded for straightforward analysis. Principal component analysis was the method of extraction, using Varimax with Kaiser normalisation rotation. The eigenvalue greater than 1 rule, inspection of the Scree plot, and the number of items loading well on the factor were used to determine the number of factors to preserve.²¹⁵

Cronbach's alpha was then calculated to determine the internal consistency of the items in each domain.²¹⁶ Internal consistency describes the ability for individual items to measure the same concept or construct.²¹⁷ A minimum Cronbach's alpha value of 0.70 is considered acceptable in most social sciences research, while some sources report lower values.²¹⁸ Cronbach's alpha was calculated separately for both pharmacy trainers and in-pharmacy participants' responses.

Following factor analysis, ordinal logistic regression was conducted to determine the influence of these factors on the dependent variable (intentions) (Chapter 2, Section 2.9). As the intentions data was skewed to the left, the median score for each survey item was used rather than the mean. The intentions variable was condensed into four categories: 1-4.9, 5.0-5.9, 6.0-6.9 and 7.0. This was to enable easier analysis. Following statistical consultation, it was decided that the pharmacy trainer data and in-pharmacy participant data were to be analysed separately using different methods due to a difference in sample sizes. Ordinal logistic regression could not be conducted on the pharmacy trainer data set due to the small sample size (n=41).

Instead, descriptive analysis was conducted to determine the median and interquartile range of each survey item within each factor. Non-parametric statistics were used as the data was not normally distributed.

4.3 RESULTS

4.3.1 Demographic characteristics

Table 4.1: Demographic characteristics of pharmacy trainers

Characteristic	Pharmacy trainers n=41 (%)	In-pharmacy participants n=175 (%)
Gender		
<i>Male</i>	15 (36.6)	30 (17.1)
<i>Female</i>	26 (63.4)	145 (82.9)
Age		
<i>18-25</i>	6 (14.6)	58 (33.1)
<i>26-35</i>	18 (43.9)	34 (19.4)
<i>36-45</i>	7 (17.1)	25 (14.3)
<i>46-60</i>	8 (19.5)	49 (28.0)
<i>60></i>	2 (4.9)	9 (5.1)
Role		
<i>Registered pharmacist</i>	32 (78.0)	39 (22.3)
<i>Pharmacy intern</i>	2 (4.9)	6 (3.4)
<i>Pharmacy assistant</i>	7 (17.1)	139 (79.4)
<i>Missing data</i>	0 (0)	1 (0.6)

4.3.2 Factor analysis

4.3.2.1 Pharmacy trainers

The Scree plot below identifies five factors extracted from the analysis (Figure 5). Factors below the dotted cut-off line were excluded.

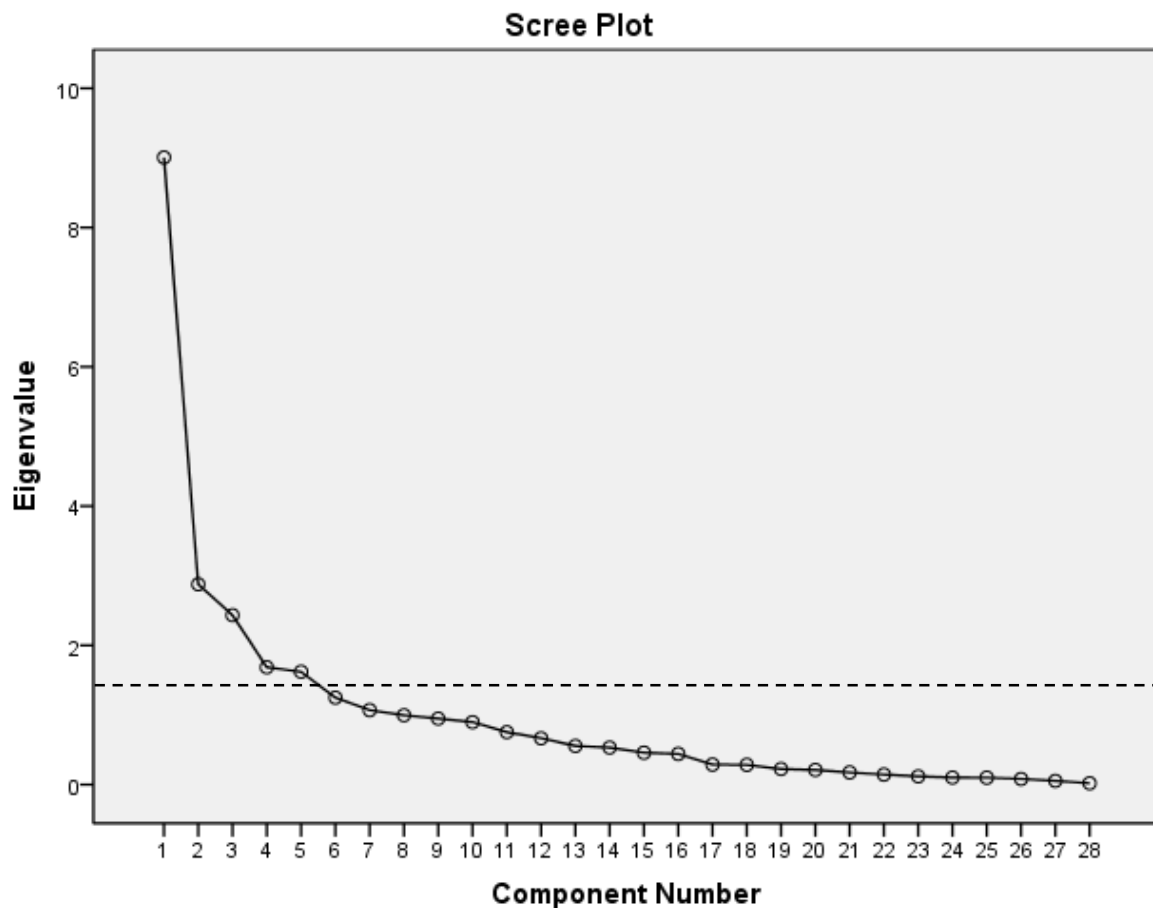


Figure 5: Scree plot of factors extracted from pharmacy trainers' survey responses

Following completion of the factor analysis, the survey items were condensed into five factors that are displayed in Table 4.2. Each factor was assigned a label according to the survey items assigned to that factor.

The Cronbach's alpha for each factor was above 0.70, apart from Factor 5. Factor 5 was included in the analysis, as this value is still considered acceptable.

Table 4.2: Factors extracted from pharmacy trainers' attitudes survey responses

Factor	Weighting Value	Cronbach's alpha
Factor 1 – Support to apply health literacy training to counselling		0.91
I believe that implementing a health literacy training program for pharmacy staff in my pharmacy is important.	0.737	
Most of the people working in my pharmacy will encourage my efforts to apply health literacy principles to my consumer counselling.	0.756	
Pharmacy management will be very keen to see health literacy principles applied consistently by all employees.	0.816	
The employees in my pharmacy will be very keen to see that health literacy principles are applied consistently to all consumer counselling.	0.714	
If I work towards achieving a high standard of service delivery in the pharmacy relating to health literacy, my managers and colleagues would be impressed.	0.597	
The ability for me to run the health literacy training session for the pharmacy staff is beyond my control.	0.542	
Implementing health literacy counselling in the pharmacy seems like a complicated process.	0.524	
I anticipate that my pharmacy would provide sufficient practical support for the implementation of a health literacy program.	0.87	
In the past, my pharmacy has provided reasonable support to implement professional programs.	0.825	
Factor 2 – Positive expectations surrounding and confidence in applying health literacy counselling		0.84
I feel I am adequately prepared to address my consumers' health literacy needs.	0.77	
I expect my pharmacy to achieve a high standard of service delivery in this pharmacy relating to health literacy.	0.603	
My consumers have strong expectations of me to counsel in a way that addresses their health literacy needs.	0.649	
The concepts described in health literacy training are logical and reasonable.	0.589	

Factor	Weighting Value	Cronbach's alpha
I am confident I have the skills to run a health literacy training program for my staff.	0.687	
I am confident that I could use effective communication techniques for all consumers when providing health information.	0.654	
Factor 3 – Positive evaluation of universal precautions and their potential benefits		0.71
Many of the consumers in my pharmacy have low levels of health literacy.	0.663	
Those consumers in my pharmacy with low levels of health literacy are likely to experience worse health outcomes than other consumers.	0.584	
A consumer should never be considered to have adequate health literacy without clear evidence.	0.575	
Suggestions provided for implementing health literacy training in the pharmacy are likely to be very helpful.	0.68	
It would be easy for me to apply the counselling principles outlined in a health literacy training program for all consumers when providing health information.	0.568	
Factor 4 – Positive belief that implementation of health literacy education would be successful		0.76
Whether I can run the health literacy training session for the pharmacy staff is entirely up to me.	0.786	
Whether or not I can achieve a high level of service delivery relating to health literacy in this pharmacy is not beyond my control.	0.569	
Whether or not a high level of service delivery relating to health literacy in this pharmacy can be achieved is entirely up to me.	0.855	
Factor 5 - Counselling rights and responsibilities		0.66
I do not have the right to assume that a consumer understands my advice, unless he/she indicates otherwise.	0.814	
It is not the consumer's responsibility to ask questions if he/she is uncertain about any advice provided in my pharmacy.	0.711	

4.3.2.2 In-pharmacy participants

The Scree plot below identifies seven factors extracted from the analysis (Figure 6).

Factors below the dotted cut-off line were excluded.

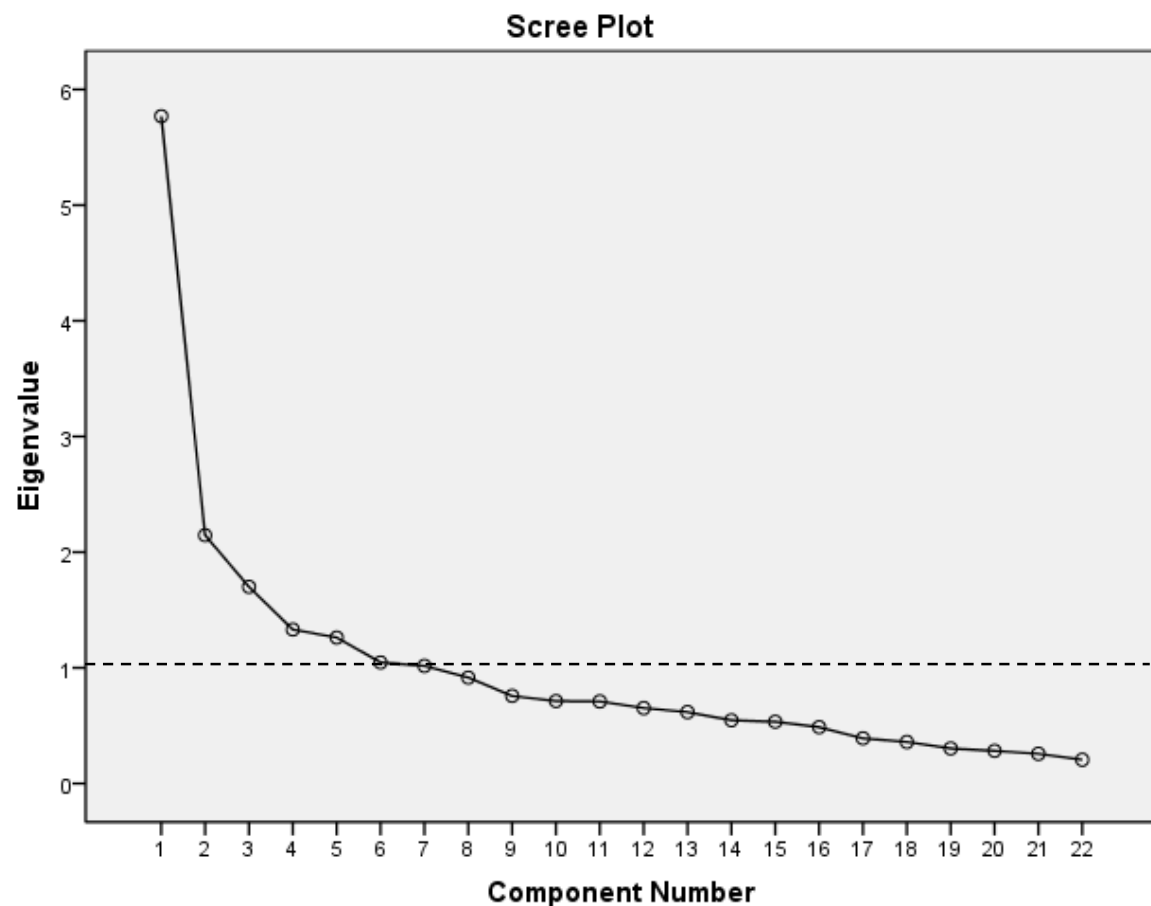


Figure 6: Scree plot of factors extracted from in-pharmacy participants' survey responses

Following completion of the factor analysis, the survey items were condensed into seven factors. Upon inspection of the survey, it was noticed that a question had been repeated (Question 6 and 7, Appendix 6), and both items were condensed into

Factor 6. As these were the only items in Factor 6, this factor was excluded from further analysis. The remaining six factors are displayed in Table 4.3. Each factor was assigned a label according to the survey items assigned to that factor. The Cronbach's alpha was above 0.70 for Factors 1 and 2, and below 0.70 for Factors 3, 4, 5 and 7.

Table 4.3: Factors extracted from in-pharmacy participant attitudes survey responses

Factor	Weighting Value	Cronbach's alpha
Factor 1 – Support to apply health literacy training to counselling		0.79
Following completion of the training, my managers will expect me to counsel consumers in a way that addresses their health literacy needs.	0.514	
Most of the people working in my pharmacy will encourage my efforts to apply health literacy principles to my consumer counselling.	0.713	
My consumers have strong expectations of me to counsel in a way that addresses their health literacy needs.	0.618	
Pharmacy management will be very keen to see health literacy principles applied consistently by all employees.	0.757	
The employees in my pharmacy will be very keen to see that health literacy principles are applied consistently to all consumer counselling.	0.673	
I am confident that I could use effective communication techniques for all consumers when providing health information.	0.517	
Factor 2 - Support for implementation of health literacy training		0.70
If I work towards achieving a high standard of service delivery in the pharmacy relating to health literacy, my managers and colleagues would be impressed.	0.746	
I anticipate that my pharmacy would provide sufficient practical support for the implementation of a health literacy program.	0.693	
In the past, my pharmacy has provided reasonable support to implement professional programs.	0.754	
Factor 3 - Preparedness for implementation and sustainability of health literacy training		0.68
I feel I am adequately prepared to address my patients' health literacy needs.	0.585	
I have a clear vision of how to implement health literacy counselling into all counselling in the pharmacy.	0.767	

Factor	Weighting Value	Cronbach's alpha
I have already successfully incorporated and sustained changes to the way I counsel patients in everyday practice.	0.827	
Factor 4 – Positive evaluation of universal precautions and their potential benefits		0.65
By providing appropriate counselling, pharmacy staff can help consumers to avoid many problems associated with low levels of health literacy.	0.583	
A consumer should never be considered to have adequate health literacy without clear evidence.	0.731	
It is essential to counsel all consumers in a manner that assumes they have limited health literacy, unless proven otherwise.	0.738	
Factor 5 - Positive belief that implementation of health literacy education would be successful		0.61
Whether or not I can achieve a high level of service delivery relating to health literacy in this pharmacy is within my control.	0.787	
Whether or not a high level of service delivery relating to health literacy in this pharmacy can be achieved is entirely up to me.	0.769	
Implementing health literacy counselling in the pharmacy does not seem like a complicated process.	0.578	
Factor 7 - Counselling rights and responsibilities		0.57
I do not have the right to assume that a consumer understands my advice, unless he/she indicates otherwise.	0.847	
It is not the patient's responsibility to ask questions if he/she is uncertain about any advice provided in my pharmacy.	0.722	

4.3.3 Non-parametric analysis and ordinal logistic regression

4.3.3.1 Pharmacy trainers

As mentioned in Section 4.2.1.3, logistic regression was not conducted on this data set due to the small sample size (n=41). Table 4.4 represents the medians and interquartile range (IQR) of each survey item within each factor.

Table 4.4: Medians and IQRs of factors extracted from pharmacy trainers' attitudes survey response

Factor	Median	IQR
Factor 1 – Support to apply health literacy training to counselling		
a) I believe that implementing a health literacy training program for pharmacy staff in my pharmacy is important.	6	2
b) Most of the people working in my pharmacy will encourage my efforts to apply health literacy principles to my consumer counselling.	6	2
c) Pharmacy management will be very keen to see health literacy principles applied consistently by all employees.	7	1.5
d) The employees in my pharmacy will be very keen to see that health literacy principles are applied consistently to all consumer counselling.	6	2
e) If I work towards achieving a high standard of service delivery in the pharmacy relating to health literacy, my managers and colleagues would be impressed.	6	1
f) The ability for me to run the health literacy training session for the pharmacy staff is beyond my control.	6	2
g) Implementing health literacy counselling in the pharmacy seems like a complicated process	4	1.75
h) I anticipate that my pharmacy would provide sufficient practical support for the implementation of a health literacy program	5.5	1
i) In the past, my pharmacy has provided reasonable support to implement professional programs.	6	2

Factor	Median	IQR
Factor 2 – Positive expectations surrounding and confidence in applying health literacy counselling		
a) I feel I am adequately prepared to address my consumers' health literacy needs.	6	1
b) I expect my pharmacy to achieve a high standard of service delivery in this pharmacy relating to health literacy.	7	1
c) My consumers have strong expectations of me to counsel in a way that addresses their health literacy needs.	6	2
d) The concepts described in health literacy training are logical and reasonable.	5	2
e) I am confident I have the skills to run a health literacy training program for my staff.	6	2
f) I am confident that I could use effective communication techniques for all consumers when providing health information.	6	1.5
Factor 3 – Positive evaluation of universal precautions and their potential benefits		
a) Many of the consumers in my pharmacy have low levels of health literacy.	5	2.5
b) Those consumers in my pharmacy with low levels of health literacy are likely to experience worse health outcomes than other consumers.	6	2
c) A consumer should never be considered to have adequate health literacy without clear evidence.	6	2
d) Suggestions provided for implementing health literacy training in the pharmacy are likely to be very helpful.	6	2
e) It would be easy for me to apply the counselling principles outlined in a health literacy training program for all consumers when providing health information.	6	1.5
Factor 4 - Positive belief that implementation of health literacy education would be successful		
a) Whether I can run the health literacy training session for the pharmacy staff is entirely up to me.	5	3

Factor	Median	IQR
b) Whether or not I can achieve a high level of service delivery relating to health literacy in this pharmacy is not beyond my control.	6	1.75
c) Whether or not a high level of service delivery relating to health literacy in this pharmacy can be achieved is entirely up to me.	5	3
Factor 5 - Counselling rights and responsibilities		
a) I do not have the right to assume that a consumer understands my advice, unless he/she indicates otherwise.	4.5	3
b) It is not the consumer's responsibility to ask questions if he/she is uncertain about any advice provided in my pharmacy.	5	2

The median for all survey items tended towards the upper end of the scale. Survey items 1c (*Pharmacy management will be very keen to see health literacy principles applied consistently by all employees*) and 2b (*I expect my pharmacy to achieve a high standard of service delivery in this pharmacy relating to health literacy*) both had a median score of 7, with the majority of survey items having a median value of 6. The lowest median value (median = 4.0) was for survey item 1g (*Implementing health literacy counselling in the pharmacy seems like a complicated process*).

4.3.3.2 In-pharmacy participants

When analysed with ordinal logistic regression, the model showed that having positive attitudes and beliefs towards support to apply health literacy training to consumer counselling (Factor 1) showed a positive statistically significant association with having intentions to implement health literacy training (Table 4.5).

Table 4.5: Association between factors and intention to undertake health literacy training of in-pharmacy participants (adjusted)

Factor	Adjusted OR	95% CI	p value
1. Support to apply health literacy training to counselling	3.07	1.97 – 4.79	<0.001
2. Support for implementation of health literacy training	2.73	1.94 – 3.84	<0.001
3. Preparedness for implementation and sustainability of health literacy training	2.44	1.67 – 3.58	<0.001
4. Positive evaluation of universal precautions and their potential benefits	2.42	1.61 – 3.63	<0.001
5. Positive belief that implementation of health literacy education would be successful	1.13	0.78 – 1.59	0.56
7. Counselling rights and responsibilities	0.95	0.69 – 1.37	0.79

There was also a statistically significant positive association between having support to apply and implement health literacy training (Factors 1 and 2, respectively) and having intentions to undertaking training. Preparedness and sustainability for implementation (Factor 3), and relevance of universal precautions and their potential benefits (Factor 4), were also associated with having intentions to undertake training.

There was no statistically significant association between the belief that implementation would be successful (Factor 5), as well as consumers' counselling

rights and responsibilities (Factor 7), with intention to participate in health literacy training.

4.4 DISCUSSION

This study identified four factors that influence intentions to undertake health literacy training. Similarities and differences exist between the beliefs of pharmacy trainers, which were mostly pharmacists (78.0%), and pharmacy staff members, which may be a result of varying levels of experience, training and professional responsibilities. Additionally, the majority of pharmacy trainers and in-pharmacy participants were female (63.4% and 82.9%, respectively), with most in-pharmacy participants comprised of pharmacy assistants (79.4%), perhaps reflecting the general demographic characteristics of the pharmacy profession, of which the majority are female.²¹⁹

Each factor is discussed below, with emphasis on their application to health literacy practice and training.

Support to apply health literacy training to counselling

Survey items that correlated onto this factor referred to the influence of others, and their opinions, on the likelihood of participants applying health literacy principles to consumer interactions. Pharmacy trainers scored these survey items highly, indicating a positive motivation towards applying health literacy training principles to counselling with consumers. In-pharmacy participants demonstrated the greatest association between this factor and intention to undertake health literacy training.

This factor was composed of mostly subjective norms and perceived behavioural control elements. Subjective norms have previously been shown to be considerable influencers of pharmacist counselling practices. The TPB model was used to determine the influence of each domain on pharmacists' intention to provide pediatric asthma counselling in the United States.²²⁰ A survey was provided to 389 eligible pharmacists, of which 98 responded. The study demonstrated that intention to provide counselling was significantly influenced by subjective norms (OR=1.88; 95%CI: 1.06-3.34).

Another study conducted in the United States investigated pharmacists' intention to provide Medicare subsidised medication therapy management services to eligible consumers.²²¹ A mailed survey was distributed to 500 pharmacists, with 203 usable surveys returned. All three domains of the TPB model had a significant influence on intentions, with subjective norms having the greatest influence.

Both of these studies support the findings of Phase 2 reported here, which demonstrated greatest influence of subjective norms on intentions to undertake health literacy training and implement these health literacy-focused communication techniques to patient counselling. These results differ from many other health-focused TPB studies, which showed attitudes and perceived behavioural control as having the greatest influence on intentions.²²² This result is, however, consistent with past research focusing purely on the pharmacy setting.^{220, 223} As with Phase 2, both these studies by Pradel *et al.* and Herbert *et al.* utilised mailed questionnaires to pharmacists, yet were conducted in the United States, making generalisability to the Australian setting limited. Sample bias may also exist with both these studies, and

the health literacy study. Non-respondents may inherently have lower intentions to undertake a particular behaviour, and therefore the results may overestimate the true level of intention. This again limits the generalisability of these studies, and may only estimate intentions of highly motivated pharmacists.

Positive expectations surrounding and confidence in applying health literacy counselling

This factor was only present in the pharmacy trainer component of Phase 2. Upon inspection, it constituted items related to participants' confidence and perceived behavioural control in implementing health literacy training, and applying health literacy principles to counselling. Following analysis, it could be seen that pharmacy trainers felt they had the confidence and skills (self-efficacy) to both implement health literacy training into their pharmacy, but also use these skills with consumers. Self-efficacy has been shown to be an important factor in one's belief that they can successfully perform a certain task.^{224, 225} A study by Martin *et al.*, conducted in United States, explored the effect of a tobacco cessation continuing professional training program on pharmacists' confidence, skills and practice-change behaviours.²²⁶ A total of 25 pharmacists were surveyed both before and after receiving the training program. Following training, pharmacists felt significantly more confident in providing smoking cessation advice to consumers (mean score of 35/60 pre training vs. 47/60 post training, $p < 0.001$). The pretest-posttest nature of this study varies considerably to the method used in Phase 2 (pre-intervention only), yet still provides support to the notion that self-efficacy of pharmacists is an important

consideration in the implementation of training interventions. While the study by Martin *et al.* did not explicitly refer to health literacy, its focus on the measurement of pharmacists' self-efficacy following the implementation of an education-focused intervention to enhance patient counselling makes it relevant for comparison to this study (Phase 2). Although, Martin *et al.* study is severely limited by its lack of a control group. Without one, it is difficult to determine the true impact of the training program on pharmacists' confidence in providing smoking cessation advice.

Another study investigating the likelihood of providing smoking cessation counselling to consumers was conducted in the United States by Hudmon *et al.*²²⁷ A survey was completed by 1,168 pharmacists in California, exploring various factors that may influence the provision of smoking cessation counselling. Pharmacists were more likely to deliver counselling if they felt they had the confidence and self-efficacy to do so (OR: 1.63; 95% CI: 1.30-2.05; $p < 0.001$). As with Martin *et al.*, the study by Hudmon *et al.* did not explicitly refer to health literacy, yet its focus on measuring the impact of pharmacists' confidence and self-efficacy to implement communication techniques to patient counselling following an education-focused intervention proved it a relevant comparison to this study (Phase 2).

Again, sample bias may play a role in overestimating the level of intentions of pharmacists in both these studies, and therefore may reduce the ability to generalise the results. Although both studies were conducted in the United States, and were focused on smoking cessation counselling, they support the notion that provision of training on particular counselling practices should focus on improving confidence in regard to their use with consumers.

Positive evaluation of universal precautions and their potential benefits

In-pharmacy participants demonstrated an association between the importance and possible benefits of using universal precautions and intentions to undertake training. Pharmacy trainers showed positive motivations towards using universal precautions with consumers, with median values ranging from 5 to 6 for survey items in this factor. These results show that pharmacists and pharmacy staff members may have a pre-existing belief that consumers should be counselled with the assumption that they may not understand complex terms, yet pharmacists and pharmacy staff members may not understand the link to the concept of health literacy. Research on universal precautions in pharmacy practice is limited and therefore prior evidence for this result is difficult to garner. Further research into the motivations and intentions of pharmacists and pharmacy staff members' in regard to their use of universal precautions by pharmacists and pharmacy staff members is essential. This will help ensure effective counselling practices are supported in practice and utilised with consumers.

Preparedness for implementation and sustainability of health literacy training and successful implementation of health literacy training

Pharmacy trainers demonstrated a belief that the implementation of health literacy training would not be hindered by their degree of control over the pharmacies' training program and schedule. Not surprisingly, the contrary was seen with in-pharmacy participants. Most pharmacy trainers in this project were managers, and

thus have a great amount of control over pharmacy training, whereas pharmacy staff members were mainly pharmacy assistants and interns.

The positive belief in the ability of pharmacy trainers to implement training may be a result of experience, training and role responsibilities. Perceived behavioural control, or self-efficacy, has been shown in previous health literacy research to be a modifiable factor in the implementation of health literacy training.²²⁸ This study conducted by Wilcoxon *et al.* in the United States with pharmacy students, used the TPB model to assess attitudinal and motivational factors influencing the successful implementation of health literacy training into the curriculum. Students were either assigned to an experimental group who received the health literacy training or a control group who did not receive training. At the completion of the study, students in the experimental group demonstrated a marked improvement in their mean perceived behavioural control scores to use health literacy training principles with consumers than the control group students (41.00 vs. 37.93, $p=0.033$).

Phase 2 of the research project is significantly different to the above mentioned American study in terms of participants and setting. Having been conducted with pharmacy students, possible influencers and motivational factors may differ from pharmacists. Pharmacists may be more influenced by managerial factors, workload and staffing, whereas students' motivations are perhaps more likely to be influenced by assessment and the motivations and attitudes of educators. It does, however, highlight the possible influence of pharmacists' perceived behavioural control on undertaking health literacy training and using these principles with consumers.

Counselling rights and responsibilities

The final factor for both pharmacist trainers and pharmacy staff members was consumer counselling rights and responsibilities. In-pharmacy participants demonstrated no association between consumer rights and responsibilities and intentions to undertake health literacy training. These results may be due to a lack of acknowledgement or understanding of a consumer's right to be counselled at a particular level of complexity.

The above factors may present opportunities to further enhance the delivery of health literacy training into pharmacies by drawing on various attitudes and beliefs of pharmacists and pharmacy staff members.

Subjective norms were shown to have the greatest influence on intentions to undertake training, and therefore ensuring that participants are encouraged by managers and other staff to undertake training may benefit from this strong association. Creating a supportive, encouraging learning environment has been shown to enhance training delivery.²²⁹⁻²³²

There is currently a dearth of research investigating pharmacists' and pharmacy staff members' intentions to counsel consumers, let alone use universal precautions and health literacy principles. This research gap therefore presents difficulties in comparing the Phase 2 study to other related studies. The relatively new area of health literacy in pharmacy practice may be a reason for this.

Limitations of this phase do exist, which may affect the generalisability of the results. Firstly, the Cronbach's alpha value fell below the usual 0.70 threshold for a number of factors. This may indicate that the items within each of these factors lack an acceptable degree of correlation. Relying on the Cronbach's alpha value alone may result in situations where a test is wrongly discarded.²¹⁷ A low value may not be the result of low correlation of items, but instead may be due to a low number of questions in each factor. In this study, the factors that produced Cronbach's alpha values below 0.70 were composed of only two to three items, making this a possibility.

Secondly, data from pharmacy trainers in Western Australia were not included in the analysis due to incorrect collection techniques. This resulted in a total of ten unusable returned surveys. This would not have altered the ability to conduct ordinal logistic regression on this data set, because even if these surveys were included, the sample size would have still been too small.

The inability to conduct logistic regression on the pharmacy trainer data set reduces the comparability of these results with the in-pharmacy participant results. This limitation was beyond the control of the PhD candidate given that two reminders were sent out to all participants prior to the survey submission deadlines.

Finally, this phase also only measured the pre-intervention, baseline level of participants' attitudes, perceived behavioural control, subjective norms and intentions. Measuring post-intervention levels may have provided greater insight into the effect of the health literacy education-focused intervention on these attributes.

This may then have allowed for more specific modification of the intervention to focus on particular strengths and weaknesses. If a post-intervention survey was conducted, it would have been useful to not only determine a change in intentions, but also a change in behaviour. This was not conducted due to time constraints imposed by the Pharmacy Guild of Australia for the project. Phase 2 of this PhD was not originally a planned component of the HeLP project, yet was conducted for interest's sake.

It cannot be assumed that a change in intentions may have a definite change in actual behaviour. A systematic review investigating the effect of health interventions on the change in intentions and behaviours following implementation was conducted using 30 intervention studies.²¹⁴ The review found that of the studies that mentioned intention and behavioural change, half reported a change in intentions following the intervention, and two-thirds reported a change in behaviours.

4.5 CONCLUSION

This phase provides insight into the influence that attitudes, perceived behavioural control and subjective norms have on the intentions of pharmacists and pharmacy staff members to undertake health literacy training. A wide variety of influencers exists, and impact on intentions to varying degrees, and therefore may either enable the implementation of health literacy training into the pharmacy setting, or create barriers.

Subjective norms was shown to have the greatest association with intentions, and therefore ensuring that participants feel supported and encouraged to learn may aid in successful implementation and uptake of the health literacy education-focused intervention in the future, as well as other, similar educational initiatives for pharmacists.

The next chapter describes the evaluation of the efficacy and effectiveness of the health literacy education-focused intervention for community pharmacies in Australia (Phase 3).

5 EVALUATION OF THE EDUCATION-FOCUSED INTERVENTION: EFFICACY AND EFFECTIVENESS OF UNIVERSAL PRECAUTIONS BY PHARMACISTS AND PHARMACY STAFF MEMBERS

5.1 SUMMARY

This chapter describes the evaluation of the efficacy and effectiveness of the health literacy education-focused intervention (Phase 3) in terms of adoption of universal precautions by pharmacists and pharmacy staff members. As discussed previously (see Chapter 3, Section 3.6), the education-focused intervention was delivered face-to-face (Group 1) or online (Group 2) to a pharmacist and/or a pharmacy assistant nominated as a 'lead trainer' from each of the participating pharmacies. This lead trainer then conducted a number of in-house training sessions with the remaining pharmacy staff members at their site. Pharmacists and pharmacy staff members in the control group (Group 3) did not undertake the health literacy training; pre- and post-intervention data were collected from this group for comparison with intervention groups' data.

5.2 METHODS

As previously discussed in Chapter 2 (see Sections 2.2.1.3 and 2.2.3), two methods to evaluate the efficacy and effectiveness of the education-focused intervention were selected:

1. Measurement of universal precaution use with *consumers* both before and after the education-focused intervention; and
2. Measurement of universal precaution use with *simulated patients* both before and after the education-focused intervention.

These methods were approved by the Monash University, Curtin University and the University of Sydney Human Research Ethics Committee (Appendix 3). The trial, of which this study was a component, was registered with the Australian New Zealand Clinical Trials Registry (ACTRN 12613000574741).

5.2.1 Measuring adoption of universal precautions with consumers

A survey tool was developed to identify the impact of the education-focused intervention on pharmacists' and pharmacy staff members' adoption of universal precautions with consumers. Consumers were invited by a research assistant to take part in the project in store after consulting with a pharmacist or pharmacy staff member. They were asked a series of questions relating to their demographic characteristics, personal health status, and the communication techniques used in

the consultation with the pharmacist or pharmacy staff member. This was conducted both before any health literacy training was undertaken by pharmacists and pharmacy staff members (pre-intervention), and following the completion of all training (post-intervention). The consumer survey was also conducted in all Group 3 pharmacies.

5.2.1.1 Questionnaire design and piloting

The questionnaires were designed to be delivered by a research assistant in an interview format with consumers, using an RCT study design (see Chapter 2, Section 2.2.2). The questions were developed to assess the application of the nine themes and skills that were determined to underpin universal precautions in health literacy (see Chapter 1, Section 1.5.4). The questionnaire was examined for face and content validity by a group of five project investigators from the Faculty of Pharmacy and Pharmaceutical Sciences, Monash University and the School of Pharmacy, Curtin University. Following this, it was piloted with a convenience sample of 10 pharmacy consumers in two community pharmacies in Victoria. Minor changes were subsequently made to some questions to enhance understanding and reduce ambiguity. These changes were included in the final questionnaire shown in Appendix 7.

5.2.1.2 Questionnaire delivery

The pre- and post-intervention questionnaires were administered to consumers in all trial pharmacies over a period of four weeks. Research assistants (G.S and S.S in Victoria, K.B in New South Wales, and E.E in Western Australia) contacted each

pharmacy to organise a three-hour period to conduct the survey with consumers during business hours at a time convenient for the pharmacy. The research assistant recruited eligible consumers in the pharmacy either before or after they consulted with a pharmacist or pharmacy assistant, depending on consumer or pharmacy preference. Consumers were eligible if they received advice on a Schedule 2 (Pharmacy Medicine), Schedule 3 (Pharmacist-Only Medicine) or a new prescription for a Schedule 4 (Prescription Medicine) medication as determined by the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) 2012.²³³ Consumers collecting medicines by proxy (e.g. a carer) were also eligible for inclusion. Consumers were excluded from participation if they were collecting a repeat supply of a prescription medicine (authorisation of the supply of a medicine that has already been dispensed using the same prescription), opioid substitution therapy, emergency contraception, receiving advice only, or were under 18 years of age.

Eligible consumers were briefed about the project and the survey. They were provided an explanatory statement and completed a consent form (Appendix 7) if they were interested in participating. The research assistant proceeded to ask the survey questions as written in the questionnaire, and documented the consumer's response on the questionnaire.

Researcher observations of use of the primary outcomes ('What questions do you have?' and the teach-back method) during consumer interactions were also undertaken in all pharmacies where consent was granted for this purpose by the consumer and the pharmacist/pharmacy staff member.

Sample size

The sample size was calculated based on the assumption that there would be a three-fold increase in the adoption of universal precautions by pharmacists and pharmacy assistants from 5% to 15% (in the absence of any published data, the assumption of 5% at baseline was based on the subjective impression that current use of universal precautions was low). With an alpha value of 0.05 and power of 0.8, it was determined that the required sample size per group was 160 consumers, and therefore a total of 480 consumers across the three groups. This was inflated by 10% to account for attrition, with the final sample size being 528 consumers (176 per group).

5.2.1.3 Primary and secondary outcomes

Table 5.1: Primary and secondary outcomes for the measurement of universal precaution use with consumers

Primary outcomes	Secondary outcomes
Use of the phrase 'What questions do you have?'	Consumer was asked if they had any questions (open or closed format)
Use of the teach-back method	Consumer was provided with printed/handwritten information
	Important points of information were repeated to the consumer
	Clinical terms/medical jargon was used during counselling

The first of these primary outcomes was based on the well-established recognition that open-ended questions are able to engage people more effectively and retrieve information more readily. The teach-back method was selected due to its usefulness in confirming understanding and because it was known to be under utilised by health professionals, particularly pharmacists.^{52, 234} Both outcomes can be applied to all interactions too; be it primary care, device demonstration, provision of medicines, or other scenarios.

5.2.1.4 Analysis

Coding the questionnaires

Questions with dichotomous outcomes (see Appendix 7) were marked as '0' for Yes, and '1' for No. Questions measured using a scale were marked according to their scale value, i.e. 1, 2, 3, 4, etc. The individual codes were entered into the Statistical Package for the Social Sciences database for statistical computations (SPSS for Windows: IBM: version 19, New York, USA).

Statistical analysis

Two statistical analyses were conducted:

1. Pearson's Chi-squared analysis to determine the differences between two proportions.

2. Rate ratios (relative risks) to investigate the likelihood of the intervention groups' (Group 1 and 2) using universal precautions following training compared to the control group (Group 3).

Analyses were conducted for each primary and secondary outcome both between groups post-intervention, and within groups pre- versus post-intervention.

The primary analysis was conducted using the *recall data only* (i.e. without researcher observations) as observations were not conducted in the majority of interactions, thus relying completely on patient recall. Conclusions are based on this primary analysis only.

A secondary analysis was conducted with researcher observations included for interest's sake. Where the observed data differed from the recall data, the observed data took precedence. It was anticipated that not all consumer interactions with a pharmacist or pharmacy staff member would be able to be observed due to lack of consumer and pharmacy consent; thus, it would not be valid to include observations in the primary analysis. Analysis including observations was conducted for methodological comparison i.e. to determine whether recall bias affected the data.

5.2.2 Measuring use of universal precautions with simulated patients

All trial pharmacies were visited by a simulated patient four times during the study period: twice prior to the health literacy education-focused intervention and twice

following the completion of the in-house training component by the lead trainers in the pharmacies in the intervention groups. This component of Phase 3 was conducted to objectively measure the adoption of health literacy techniques with simulated patients in everyday practice (i.e. effectiveness), without the potential influence of a researcher's presence. Pharmacy managers were not advised when simulated patients would be visiting their pharmacy.

5.2.2.1 Data collection tool design

Case vignettes were developed (Appendix 7) in conjunction with a data collection form to objectively evaluate the pharmacists' or pharmacy staff members' performance (Appendix 7).

The data collection tool for the evaluation of the pharmacists' or pharmacy staff members' performance was developed in tandem with the consumer survey (see Section 5.2.1). As both methods evaluated the adoption of universal precautions by pharmacists and pharmacy staff members, the tools carry many similarities. The nine skills identified as underpinning universal precautions in health literacy were used to formulate the objective assessments for the simulated patients (see Chapter 1, Section 1.5.4).

The tool was created in a fashion similar to that used in an Objective Structured Clinical Examination (OSCE), which is a common assessment method for measuring students' competence in communication and clinical skills.²³⁵ Students are presented with a short case by an impartial examiner, and are generally required to act as the medical professional. History taking, diagnosis, inter-professional communication

skills, and counselling are tasks commonly examined using this method. An analytical checklist is used to measure students' performance. A specific point value is assigned to each attribute or skill that the student must demonstrate to be considered competent. Each skill usually begins with an action verb, for example, 'heard', 'spoke', or 'utilised'. The data collection tool used in Phase 3 was designed as an analytical checklist with each item beginning with an action verb.

The data collection tool was evaluated for face and content validity by five project investigators from the Faculty of Pharmacy and Pharmaceutical Sciences, Monash University and the School of Pharmacy, Curtin University. Consequently, minor changes were made to some questions to enhance understanding and reduce ambiguity.

5.2.2.2 Development of case vignettes

Three case vignettes were developed for the project by the research team (Appendix 7). Ecological validity (the assumption that the method, materials and setting of a study mirror a real life scenario or situation²³⁶) was maintained by ensuring that scenarios were realistic and could be enacted with ease by the simulated patient. Each scenario was piloted with two project officers, who were also pharmacists.

Pre-intervention, the first scenario was a consumer presenting with what appeared to be heartburn, and the second was a consumer presenting with issues relating to the use of a salbutamol metered-dose inhaler (MDI) for the relief of asthma. Post-intervention, the MDI scenario was re-used, and another scenario was developed in place of the heartburn scenario – the presentation of a case of what appeared to be

seasonal rhinitis. The scenarios were developed based on the nine principles of health literacy universal precautions, for example, that scenarios facilitated the pharmacist or pharmacy staff member to apply technique demonstration (see Chapter 1, Section 1.5.4). Each principle was assessed either by a dichotomous question or using a scale.

5.2.2.3 Simulated patient recruitment and training

Two simulated patients were recruited in each of the three states. Older patients (e.g. over 60) were recruited, as health literacy issues are highly prevalent in older adults (see Chapter 1, Section 1.2.1). Following recruitment, the simulated patients attended a one-day training session in their home state, conducted by a project investigator and a project officer. The simulated patients were trained to act out the case vignette scenarios (see Chapter 5, Section 5.2.2.2) and to complete the data collection tool following their interaction with a pharmacist or pharmacy staff member.

5.2.2.4 Delivery of case vignettes

Each simulated patient visited every pharmacy in their state – once pre-intervention and once post-intervention, totaling four visits to each pharmacy (two pre-intervention and two post-intervention). The simulated patients were instructed to enter each pharmacy at separate times to avoid any chance of their true identity and purpose being revealed. They were instructed to wait to be approached by a pharmacist or pharmacy staff member for assistance, but in the case of a lengthy waiting period (over five minutes), they approached the nearest available staff

member. Before the visits began, the pharmacy managers were instructed not to inform any other pharmacy staff members, including other pharmacists, about the simulated patient visits. Pharmacy managers were only informed of the period of time the simulated patient may visit, e.g., sometime in the following month, and not exact times and dates.

Following delivery of the case vignette in the pharmacy, the simulated patient completed the data collection tool as soon as possible after leaving the premises in order to avoid recall bias.

5.2.2.5 Primary and secondary outcomes

The primary and secondary outcomes that were assessed in the consumer survey component of this phase were also assessed in this component of Phase 3, with the addition of one secondary outcome: the duration of counselling (see Chapter 5, Section 5.2.1.3).

5.2.2.6 Analysis

Coding the questionnaires

The individual codes were entered into SPSS for Windows (SPSS IBM: version 19, New York, USA). Questions with dichotomous outcomes were coded '0' for Yes, and '1' for No. Questions measured using a scale were marked according to their scale value, e.g. 1, 2, 3, 4, etc.

Statistical analysis

Identical analyses were performed to those conducted in the consumer survey component of Phase 3 (see Chapter 5, Section 5.2.1.3)

5.3 RESULTS

As described earlier (see Chapter 5, Section 5.2.1.4), the primary analysis used *recall data only*. The assumption that not all interactions would be able to be observed due to lack of consent proved to be correct: observations were conducted in only 27.5% (n=117) of interactions pre-intervention and 17.4% (n=59) post-intervention.

5.3.1 Measuring use of universal precautions with consumers

5.3.1.1 Consumer demographics

Table 5.2 shows the demographic characteristics, pre- and post-intervention, of the participants involved in the consumer survey component. As the consumers recruited pre-intervention were not the same consumers as those recruited post-intervention, two sets of demographic data are displayed.

The data show that more females participated in the pre- and post-intervention surveys than males; age categories were well represented in each group. The majority of participants across the three groups, both pre- and post-intervention, had completed some education beyond high school (e.g. university or technical school),

whereas the minority in all groups had not completed high school. The majority of participants stated that they had vision problems, and a small number reported having a hearing disability.

The majority of participants, both pre- and post-intervention, reported their reason for attending the pharmacy as the presentation of a new prescription, followed by primary care (purchasing S2 or S2 medications). Most consumers were attending the pharmacy for their own purposes rather than for someone else.

Results from Table 5.2 also show that the post-intervention electronic group is smaller than the number recruited in the pre-intervention group (79 versus 138, respectively).

Table 5.2: Demographic characteristics of consumers recruited pre- and post-intervention.

Variable	Pre-intervention			Post-intervention		
	Face-to- face (Group 1) N=153 n (%)	Electronic (Group 2) N=138 n (%)	Control (Group 3) N=149 n (%)	Face-to- face (Group 1) N=138 n (%)	Electronic (Group 2) N=79 n (%)	Control (Group 3) N=121 n (%)
Gender						
Male	48 (31.4)	54 (39.1)	59 (39.6)	49 (35.5)	37 (46.8)	37 (30.6)
Female	105 (68.6)	84 (60.9)	90 (60.4)	89 (64.5)	42 (53.2)	84 (69.4)
Age						
18-30	32 (20.9)	26 (18.8)	18 (12.1)	18 (13.0)	11 (13.9)	9 (7.4)
31-50	32 (20.9)	29 (21.0)	42 (28.2)	27 (19.6)	30 (38.0)	24 (19.8)
50-64	32 (20.9)	29 (21.0)	31 (20.8)	35 (25.4)	17 (21.5)	32 (26.4)
65-74	20 (13.1)	19 (13.8)	30 (20.1)	30 (21.7)	13 (16.5)	32 (26.4)
75+	37 (24.2)	35 (25.4)	28 (18.8)	28 (20.3)	8 (10.1)	24 (19.8)

Variable	Pre-intervention			Post-intervention		
Education						
Not completed high school	23 (15.0)	11 (8.0)	17 (11.4)	22 (15.9)	8 (10.1)	22 (18.2)
Completed high school	56 (36.6)	53 (38.4)	53 (35.6)	48 (34.8)	28 (35.4)	45 (37.2)
Higher level of education	74 (48.4)	73 (52.9)	79 (53.0)	68 (49.3)	42 (53.2)	54 (44.6)
Not reported	0	1 (0.7)	0	0	1 (1.3)	0
Visual impairment						
Yes	98 (64.1)	85 (61.6)	99 (66.4)	93 (67.4)	41 (51.9)	82 (67.8)
No	55 (35.9)	53 (38.4)	50 (33.6)	45 (32.6)	38 (48.1)	39 (32.2)
Hearing impairment						
Yes	14 (9.2)	9 (6.5)	12 (8.1)	9 (6.5)	8 (10.1)	7 (5.8)

Variable	Pre-intervention			Post-intervention		
No	139 (90.8)	129 (93.5)	137 (91.9)	129 (93.5)	71 (89.9)	114 (94.2)
Reason for visiting						
New prescription	87 (56.9)	74 (53.6)	84 (56.3)	88 (63.8)	53 (67.1)	79 (65.3)
Primary care	50 (32.7)	46 (33.3)	50 (33.6)	35 (25.4)	21 (26.6)	25 (20.7)
Combination of above	11 (7.2)	6 (4.3)	3 (2.0)	15 (10.9)	5 (15.2)	16 (13.2)
Not reported	5 (3.3)	12 (8.7)	12 (8.1)	0	0	1 (0.8)
Who is the visit regarding?						
Myself	131 (85.6)	113 (81.9)	125 (83.9)	114 (82.6)	66 (83.5)	99 (81.8)
Someone else	22 (14.4)	24 (18.1)	24 (16.1)	24 (17.4)	13 (16.5)	22 (18.2)
Not reported	0	1 (0.7)	0			

5.3.1.2 Primary outcomes

‘What questions do you have?’

Within-group comparison

Within each group, using *recall data only*, changes in the use of the phrase ‘What questions do you have?’ were not statistically significant pre- versus post-intervention. The face-to-face group (Group 1) demonstrated an absolute *increase* of 3.26%, from 25.00% to 28.26% (RR=1.13; 95%CI: 0.77-1.66; p=0.53) and the electronic group (Group 2) an absolute *increase* of 0.51%, from 15.94% to 16.45% (RR=1.11; 95%CI: 0.60-2.05; p=0.74). There was, however, a significant difference between the control group’s (Group 3) use of the phrase pre- and post-intervention, with an absolute *decrease* of 23.81%, from 29.60% to 5.79% (RR=0.195; 95%CI: 0.091-0.420; p<0.001).

Within each group, with *researcher observations included*, changes in the use of the phrase ‘What questions do you have?’ were also detected pre- versus post-intervention. Following training, the face-to-face group (Group 1) were twice as likely to use the phrase, with an absolute *increase* of 14.25%, from 11.11% to 25.36% (RR=2.28; 95%CI: 1.34-3.89; p=0.002), while the electronic group (Group 2) were three times more likely to use the phrase, with an absolute *increase* of 12.65%, from 5.07% to 17.72% (RR=3.49; 95%CI: 1.47-8.29; p=0.002). The control group (Group 3) had a significant absolute *decrease* of 7.72% from 11.85% to 4.13% (RR=0.349; 95%CI: 0.13-0.92; p=0.025).

Between group comparisons

Post-intervention using *recall data only*, the face-to-face group (Group 1) was nearly five times more likely to use the phrase 'What questions do you have?', with a rate of 28.26% (from 25.00% pre-intervention), than the control group (Group 3), at 5.79% (RR: 4.86; 95%CI: 2.27-10.52; $p<0.001$). The electronic group (Group 2) was around three times more likely to use the same phrase, at 16.45% (from 15.94% pre-intervention), than Group 3 (RR: 2.98; 95%CI: 1.02-8.67; $p=0.032$).

With *researcher observations included*, there was a significant difference in the adoption of the 'What questions do you have?' phrase, in both the face-to-face (Group 1) and electronic groups (Group 2) compared to the control group (Group 3). Group 1 was six times more likely to use the phrase, at 25.36% (from 11.11% pre-intervention), than Group 3, at 4.13% (RR: 6.14; 95%CI: 2.48-15.17; $p<0.001$). Group 2 was four times more likely to use the phrase, at 17.72% (from 5.07% pre-intervention), than Group 3 (RR: 4.29; 95%CI: 1.61-11.44; $p=0.001$).

There was no significant difference in the use of the phrase between Group 1 and 2 post-intervention using either recall data only (RR=1.56; 95%CI: 0.93-2.75; $p=0.082$) or with observations included (RR=1.58; 95%CI: 0.79-3.16; $p=0.195$).

Teach-back method

Within-group comparison

Within each group, using *recall data only*, changes in the use of the teach-back method were not significant pre- versus post-intervention: face-to-face group (Group 1) *decreased* by 4.74% from 8.50% to 3.76% (RR=0.43; 95%CI: 0.16-1.17; p=0.085) and the electronic group (Group 2) *decreased* by 6.17% from 8.70% to 2.53% (RR=0.29; 95%CI: 0.067-1.27; p=0.076). There was no significant difference in the pre- and post-intervention rates of the control group (Group 3) in regard to use of the teach-back method. There was an absolute *decrease* of 0.57% from 2.22% to 1.65% (RR=1.34; 95%CI: 0.23-7.91; p=0.74). Researcher observations did not differ from consumer responses regarding the use of the teach-back method, and were thus the same result.

Between group comparison

There was no significant difference in the adoption of teach-back among the three groups post-intervention. When compared to the control group (Group 3), the face-to-face group (Group 1) did not show any significant difference in use of the teach-back method, post-intervention (RR = 2.19; 95%CI: 0.43-11.09; p=0.329). The electronic group (Group 2) also showed no significant difference to Group 3, post-intervention (RR=1.53; 95%CI: 0.22-10.65; p=0.664). As mentioned above, researcher observations did not differ from consumer responses regarding the use of the teach-back method, and were thus the same result.

5.3.1.3 Secondary outcomes

Post-intervention, there were no statistically significant differences in the secondary outcomes between the face-to-face (Group 1) and control group (Group 3) or the electronic group (Group 2) and Group 3 (Table 5.3).

Table 5.3: Secondary outcomes pre-intervention and post-intervention in the face-to-face and electronic training group versus the control group.

	Pre-intervention			Post-intervention							
Secondary outcomes	Face-to-face N=153 n (%) [% CI]	Electronic N=138 n (%) [% CI]	Control N = 135 n (%) [% CI]	Face-to-face N=138 n (%) [% CI]	Control N = 121 n (%) [% CI]	P value	Rate ratio (CI)	Electronic N=79 n (%) [% CI]	Control N=121 n (%) [% CI]	P value	Rate ratio (CI)
Consumer was asked if they had a question											
Yes	142 (92.8) [87.6 - 95.9]	120 (87.0) [80.3 – 91.6]	123 (91.1) [85.1 – 94.8]	122 (88.4) [82.0 – 92.7]	109 (90.1) [83.5 – 94.2]	0.665	0.98 (0.90-1.07)	66 (83.5) [73.9 – 90.1]	109 (90.1) [83.5 – 94.2]	0.172	0.93 (0.83-1.04)
No	11	18	12	16	12			13	12		

	Pre-intervention			Post-intervention							
Printed/handwritten information was supplied											
Yes	33 (21.6) [15.8 – 28.7]	17 (12.3) [7.8 – 18.8]	32 (23.7) [17.3 – 31.5]	24 (17.4) [12.0 – 24.6]	25 (20.7) [14.4 – 28.7]	0.503	0.84 (0.51-1.39)	12 (15.2) [8.9 – 24.7]	25 (20.7) [14.4 – 28.7]	0.330	0.74 (0.39-1.38)
No	120	121	103	114	96			67	96		
Repeated any information											
Yes	88 (57.5) [49.6 – 65.1]	60 (43.5) [35.5 – 51.8]	73 (54.1) [45.7 – 62.3]	61 (44.2) [36.2 – 52.3]	40 (33.1) [25.3 – 41.9]	0.067	1.38 (0.98-1.83)	34 (43.0) [32.7 – 54.0]	40 (33.1) [25.3 – 41.9]	0.153	1.30 (0.91-1.86)
No	65	78	62	77	81			45	81		
Used clinical terms											
Yes	15 (9.8) [6.0 – 15.5]	15 (10.7) [6.7 – 17.2]	10 (7.4) [4.1 – 13.1]	16 (11.6) [7.3 – 18.0]	10 (8.3) [4.6 – 14.5]	0.374	1.40 (0.66-2.97)	6 (7.6) [3.5 – 15.6]	10 (8.3) [4.6 – 14.5]	0.865	0.92 (0.35-2.43)
No	138	123	125	122	111			73	111		

There was no significant difference between the face-to-face group and the control group, and the electronic group and the control group, post-intervention for the secondary outcome '*Consumer was asked if they had a question*' ($p=0.665$ and $p=0.172$, respectively). This was also the case for the secondary outcomes '*Printed/handwritten information was supplied*' ($p=0.503$ and $p=0.330$, respectively), '*Repeated any information*' ($p=0.067$ and $p=0.153$, respectively) and '*Used clinical terms*' ($p=0.374$ and $p=0.865$, respectively).

5.3.2 Measuring adoption of universal precautions with simulated patients

5.3.2.1 Simulated patient characteristics

The simulated patients selected for this study were all aged 65 or older, with one male and one female in each state, and did not have a medical or pharmacy background.

5.3.2.2 Primary outcomes

'What questions do you have?'

Within-group comparison

The change in the use of the phrase 'What questions do you have?' was statistically significant in the face-to-face group (Group 1) pre- versus post-intervention, but not

in the electronic group (Group 2). Group 1 was eight times more likely to use the phrase post-intervention than pre-intervention with an absolute *increase* of 15.16% from 2.13% to 17.29% (RR=8.17; 95%CI: 1.06-62.78; p=0.013), whereas Group 2 demonstrated an absolute *decrease* of 1.41% from 4.35% to 2.94% (RR=0.68; 95%CI: 0.69-7.16; p=0.743). There was no significant difference in the pre- and post-intervention rates of the use of the phrase in the control group (Group 3), with an absolute *increase* of 6.82% from 0% to 6.82% (RR=1.073; 95%CI: 1.00-1.16; p=0.072).

Between-group comparison

Between groups, post-intervention, there was no significant difference in the adoption of the 'What questions do you have?' phrase, in either the face-to-face group (Group 1) or the electronic group (Group 2) compared to the control group (Group 3) (17.29% vs. 6.82%, RR=2.25, 95%CI: 0.72-9.00, p=0.126; 2.94% vs. 6.82%, RR=0.41, 95%CI: 0.0047-3.97, p=0.441, respectively). There was a significant difference in the use of the phrase between Group 1 and Group 2 post-intervention (17.29% vs. 2.94%) (RR=5.91; 95%CI: 0.78-45.07; p=0.043).

Teach-back method

Within-group comparison

Within each group, changes in the use of the teach-back method were not significant pre- versus post-intervention: the face-to-face group (Group 1) increased by 0.27%,

from 12.77% to 13.04% (RR=1.02; 95%CI: 0.36-2.94; p=0.97); the electronic group (Group 2) *decreased* by 4.20%, from 13.00% to 8.80% (RR=0.95; 95%CI: 0.82-1.11; p=0.56) and the control group (Group 3) *increased* by 2.69%, from 8.69% to 11.36% (RR=1.03; 95%CI: 0.90-1.18; p=0.67).

Between-group comparison

There was no significant difference in the adoption of teach-back among the three groups post-intervention, at 13.04% in the face-to-face group (Group 1) (RR = 1.15; 95%CI: 0.38-3.49; p=0.808) and 8.80% in the electronic group (Group 2) (RR=0.78; 95%CI: 0.20-3.02; p=0.714) compared to the control group (Group 3), at 11.36%.

There was also no significant difference in the use of the teach-back method between Group 1 and Group 2 post-intervention (RR=1.48, 95%CI: 0.40-5.50, p=0.555).

5.3.2.3 Secondary outcomes

Figure 7 shows a statistically significant increase in the rate of pharmacists and pharmacy staff members in the face-to-face group (Group 1) asking consumers if they had questions (open or closed manner), compared to the control group (Group 3) (RR: 1.91; 95%CI: 1.06-3.47; p=0.025).

An awareness of the importance of repeating information to consumers was demonstrated across all three groups.

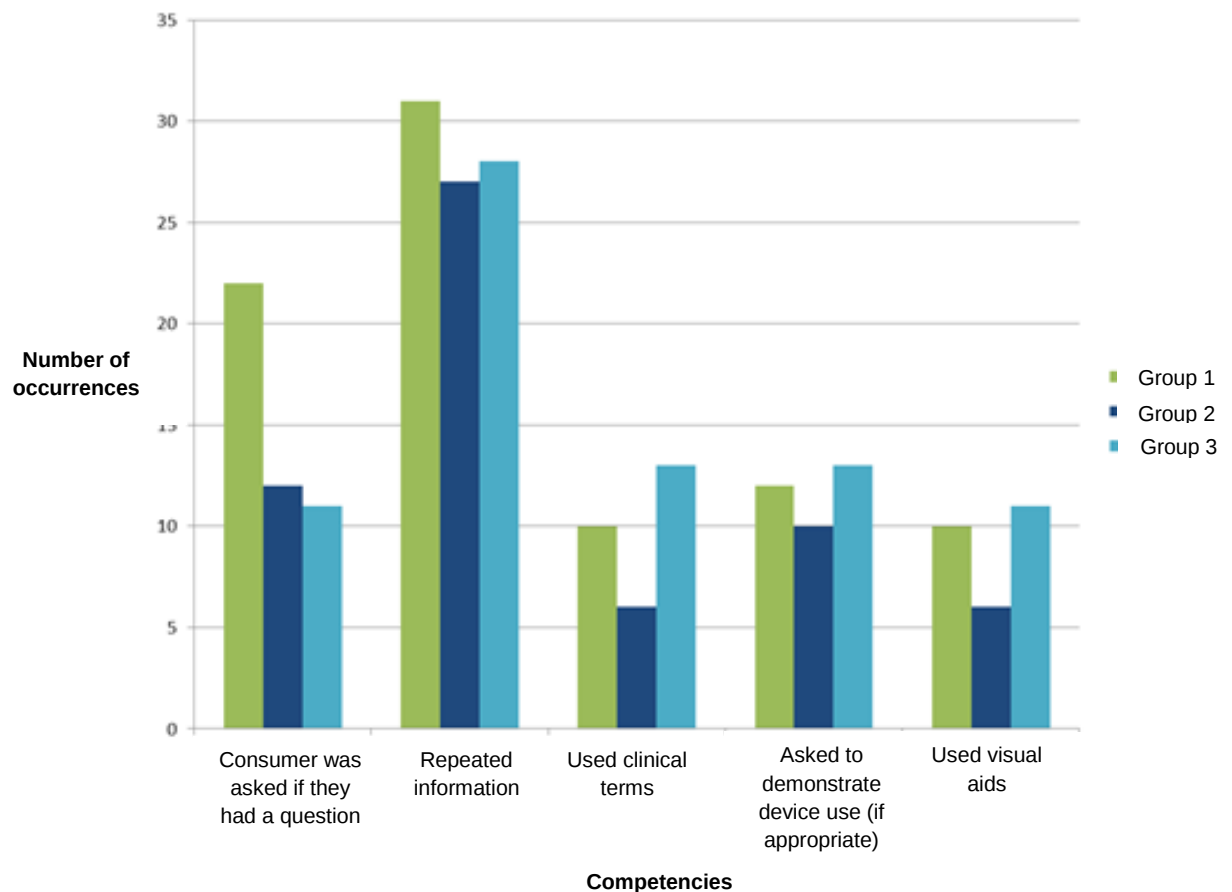


Figure 7: Secondary outcomes post-intervention in the face-to-face (Group 1), electronic (Group 2) and control group (Group 3) as measured by simulated patients (n=126)

There were no statistically significant differences in the rate of repetition of information to consumers, the use of clinical terms, whether the consumer was asked to demonstrate the use of a device if appropriate, or the use of visual aids.

Significantly less time was spent counselling in Group 2 compared to Group 3 (5.62 minutes vs. 6.64 minutes, $p=0.044$). There was also a trend towards providing less information (4.9 vs. 5.8 mean number of points) to consumers in Group 2 compared to Group 3 but this was not statistically significant. Group 1 showed no difference in

time spent counselling consumers, but demonstrated a trend to providing less information to consumers compared to Group 3 (5.0 vs. 5.8).

5.4 DISCUSSION

In the consumer survey, the use of the phrase 'What questions do you have?' was significantly higher in both intervention groups (Group 1 and 2) compared to the control group (Group 3), post-intervention based on recall data only. In contrast, the simulated patient study showed no significant increase in the use of the phrase in either Group 1 and 2 compared to Group 3 post-intervention. There was, however, a significant difference in the rate of using the phrase in Group 1 compared to Group 2 post-intervention. There was also a significant increase in pharmacists and pharmacy staff members asking simulated patients if they had questions (both open and closed format). Other secondary outcomes in both components of this phase did not show significant changes.

Other studies have shown that changing the clinical behaviours and practices of pharmacists and pharmacy staff members can be achieved with the use of education-focused interventions.^{237, 238} A British study conducted by Weiss *et al.* used simulated patients to measure community pharmacist performance in the appropriate supply of the emergency contraceptive pill (ECP). The study used student researchers as simulated patients to assess the clinical and consultation skills of pharmacists in relation to appropriate supply of the ECP.²³⁸ The study comprised 40 visits to pharmacists, and showed that pharmacists who had received

training in ECP supply scored higher than those who had not with a mean score of 76 compared to 60 when rated on performance ($p=0.005$).

There was a significant decrease in use of the phrase 'What questions do you have?' by participants in Group 3, post-intervention, using both recall data only, and when observations were included. There was no significant change within either Group 1 or Group 2, pre- versus post-intervention. This may be a result of the 'regression toward the mean' phenomenon. 'Regression toward the mean' describes the situation of when a measured variable is extreme upon its initial measurement, it will tend towards its true level upon subsequent measurements.^{239, 240} Group 3, along with Group 1 and 2, may have performed well at the initial, pre-intervention measurement as a result of being enthusiastic and motivated to perform well. As Group 3 did not receive the intervention, over the course of the project their interest to perform well may have waned, and therefore reduced towards their natural baseline level. Group 1 and 2 were encouraged by the intervention to implement universal precautions and did not exhibit this decrease.

Use of the teach-back method was met with less success, showing no statistically significant change in Group 1 and 2 compared to Group 3, post-intervention. The poor use of the teach-back method found in this and other studies may be a result of the general difficulty in using the method.^{52, 241-243} This may be further impacted in the pharmacy setting where the length of a consultation with a consumer is short and, therefore, may not be conducive to regular use of the teach-back method. A study conducted by Schwartzberg *et al.* in the USA showed that pharmacists were the least likely, when compared with physicians and nurses, to use the teach-back

method with consumers.⁵² The study suggested that simpler communication techniques might be preferred due to the ease of integrating them into the busy patient care and counselling routine.

As demonstrated by the Schwartzberg *et al.* study, pharmacists are not the only health professionals who have a low rate of use of the teach-back method. A study by Schillinger *et al.* investigating physician use of the teach-back method with patients with low health literacy and diabetes showed that physicians seldom employ the teach-back method - only 12% of the time.²⁴³ Patients who participated in the teach-back method, consequently, had better glycaemic control.

A study conducted by Jager *et al.* in the USA investigated the use of teach-back by physicians using patient self-report to measure prevalence of use.²⁴² Jager reported a much higher use of the teach-back method than the current study and other previous studies.^{52, 241}

The conflicting results seen between the Schillinger study and the Jager study may be due to differing study designs. The Schillinger study utilised direct observation of physicians' consultations with participants, providing more objective data than the Jager study, which used patient-recall. It is difficult to compare these studies to Phase 3 of this project as both were conducted in the USA using physicians, making generalisability to the Australian pharmacy context difficult. However, the Jager study provides a greater level of support to the results of Phase 3 due to a similar data collection method, namely patient-recall. All three studies, however, demonstrate that the teach-back method is under-utilised by health professionals.

There were no statistically significant changes in the secondary outcomes in the consumer survey component on Phase 3. There was a trend in Group 1 towards repeating information to consumers; however, confident conclusions cannot be made. The rate of repeating information to consumers was encouragingly high across all three groups, which may indicate an existing awareness of the importance of repeating information to consumers to improve retention.

The lack of significance in the secondary outcomes, particularly in regard to pharmacists and pharmacy staff members asking consumers if they had any questions, may result from the already high prevalence of this communication technique in all groups pre-intervention. Pharmacists and pharmacy staff members may already be aware of the importance of checking if consumers have further questions about their medicines and health, and therefore room for significant improvement in this area is limited, whereas there is much scope for changing to the open format of approaching this topic with consumers.

The mean number of items provided to simulated patients in this study (5.0, 4.9, and 5.8 in Group 1, 2 and 3, respectively) was higher than that reported in a cross-sectional study conducted in the USA.²⁴⁴ This study investigated the extent and nature of counselling in community pharmacies in eight states in the USA using simulated patients. It showed that 63% of consumers received oral information, with a mean number of 2.3 items of information provided. This difference could be attributed to a number of methodological differences between the studies or to real variation in pharmacist counselling behaviours between Australia and the USA.

5.5 LIMITATIONS

Limitations of Phase 3 relate to both the data collection tool and data collection method.

Firstly, the outcomes of the phase were measured using mainly dichotomous responses (yes or no), and therefore improvement was difficult to detect unless all the requirements of the outcome being tested were met. Pharmacists or pharmacy staff members may have scored a 'no' post-intervention even if some improvement was made from the pre-intervention period. A Likert-scale may have been a more effective scoring method to measure improvements in practice and behaviour.

The findings of this phase are limited by the inability to observe all consumer interactions with pharmacists and pharmacy staff members. A number of pharmacy study sites did not provide consent to conduct observations and, in those that did, many consumers did not provide consent for the researcher to observe the interaction. As discussed earlier, direct observation of all interactions would have provided a more accurate, objective result than relying on recall, but in many cases, was not feasible.

While simulated patients were trained to remain objective, subjective interpretation when evaluating the interaction may have affected the results. Had audio-recording been used, it may have reduced this possible effect by enabling researchers to review each interaction. Confidence in the results obtained in studies like this may be strengthened by more objective measures of data collection, including the use of

video- or audio-recording of consumer and simulated patient interactions with pharmacists and pharmacy staff members, but this may present ethical and recruitment difficulties.

When interpreting the lack of difference in the use of the teach-back method pre- and post-intervention, the results indicate that participants may have been able to more easily recall use of the teach-back method than 'What questions do you have?'.

Consumer participants may recall that there was a conversation about questions, and therefore may falsely report that the specific phrase was used. Use of the teach-back method may register as a more unusual event for consumer participants compared to the way in which they were asked questions by a pharmacist or pharmacy staff member.

Blinding of researchers when conducting consumer interviews may have reduced the possibility of bias. As the researchers were central to the implementation of the intervention into participating pharmacies, it was not possible to blind the researchers collecting the Phase 3 consumer survey data. When consumer interviews were conducted in each pharmacy, researchers may have subconsciously been more rigorous in some pharmacies and less in others depending on whether the pharmacy had received the intervention or not. Blinding can be a difficult task in educational interventions, but may reduce the risk of bias and therefore improve the reliability of the results. Independent, blinded researchers could have been used to collect consumer data from each pharmacy, possibly producing a less biased result. Although, this approach would have increased project costs.

Finally, pharmacists' and pharmacy staff members' behaviours may have been influenced by the Hawthorne effect due to the presence of an observer during the consumer interview, possibly resulting in a temporary improvement in the use of universal precautions during researcher visits.²⁴⁵

5.6 CONCLUSION

The health literacy education-focused intervention was partially effective in increasing pharmacists' and pharmacy staff members' adoption of universal precautions in practice. Use of the phrase 'What questions do you have?' was met with mixed results. Both intervention groups (Group 1 and 2) more readily used this phrase in the consumer survey study than the control group (Group 3), based on the primary analysis of post-intervention patient recall data. However, in the simulated patient study, this improvement was limited to the face-to-face group (Group 1) only. Use of the teach-back method was very low, suggesting that pharmacists and pharmacy staff members experienced difficulty using this technique.

Overall, this study has highlighted the difficulties in altering pharmacists' and pharmacy staff members' behaviours in using universal precautions with consumers. It does, however, show that practice changes in the use of universal precautions are possible for pharmacists and pharmacy staff members. Further investigation is needed on the best methods to achieve a sustained effect.

The next chapter describes the exploration of pharmacist and pharmacy staff member participants' perceptions and opinions of the health literacy education-focused intervention following implementation (Phase 4).

6 PHARMACIST AND PHARMACY STAFF MEMBER PERCEPTIONS OF THE HEALTH LITERACY EDUCATION- FOCUSED INTERVENTION

6.1 SUMMARY

This chapter describes the feedback elicited from pharmacists and pharmacy staff members on the usability, perceived effectiveness, and sustainability of the health literacy education-focused intervention (Phase 4).

6.2 METHODS

6.2.1 Choice of method

Focus groups were used due to their ability to collect a wide range of opinions from participants through the utilisation of open-ended questions in a semi-structured format. An in-depth justification for their use in the research project is included in Chapter 2, Section 2.3.1.

6.2.2 Aim and objectives

The overall aim of conducting the focus groups was to validate and refine the education-focused intervention before its wider dissemination to pharmacies. The specific objectives were to:

1. Elicit ideas for improving the content of the education-focused intervention.
2. Obtain feedback on the usability of the education-focused intervention in relation to its structure and method of delivery, including the face-to-face (Group 1), electronic (Group 2), and in-house training components.
3. Obtain feedback on the ease of integration of the education-focused intervention into the pharmacy environment.
4. Obtain feedback on the perceived effectiveness of the education-focused intervention with respect to changing pharmacists' and pharmacy staff members' behaviours and the pharmacy environment.

6.2.2.1 Development and piloting of the focus group questions and process

A two-stage process was used to develop and refine the questions for the focus groups:

1. Three broad domains needed to be examined:

- a. Usability of the education-focused intervention;
- b. Implementation of the education-focused intervention; and
- c. Effectiveness of the education-focused intervention.

2. Nine questions were drafted:

- a. I'm interested in your experiences with giving the health literacy training, including the training package⁴. Can you tell me what you thought of it?
- b. Did the training format make learning easy? Was the content interesting and appropriate?
- c. In terms of delivering the training in your pharmacy, what sort of things made it more difficult or easy? (*trainers only*)

⁴ The terms 'educational package' and 'training package' were used interchangeably in the focus group questions to refer to the health literacy education-focused intervention.

d. How did your staff respond to the training from your perspective?

(trainers only)

e. Did you feel the training prepared you adequately to change the way you interacted with clients once you finished it?

f. What were your experiences in trying to use what you've learned in practice in terms of counselling individual patients?

g. What changes have you found in how patients respond when you counsel in the manner recommended?

h. If you have made changes to the way you deal with clients, how long do you think your changes to practice will be sustained? What were the steps you have taken to make sure the changes would be implemented and sustained in your practice?

i. Would you like to do more training like this? Does the style of delivery (by staff in-house) suit your practice?

The focus group questions were piloted with two postgraduate students from the Faculty of Pharmacy and Pharmaceutical Sciences, Monash University; no changes were made to the questions.

Ethics approval was granted by the Human Research Ethics Committees of Monash University and Curtin University (Appendix 8).

6.2.2.2 Participant selection and recruitment for the focus groups

A sample of both pharmacists and pharmacy staff members was sought to capture a variety of opinions from a range of participants.

Trainer pharmacists were initially contacted by telephone following the designated trial period to inform them and their staff of the opportunity to participate in the focus groups. Those who expressed interest in participating were sent further information regarding the venue and time for the focus group, including explanatory statements and consent forms (Appendix 9).

6.2.2.3 Conducting the focus groups

The focus groups were held over a four week period, and 90 minutes was estimated to be sufficient to conduct each meeting. The focus groups were held in the following locations:

1. Victorian metropolitan (two groups) – Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, Melbourne, Victoria.
2. Victorian rural (one group) – Ararat, Victoria.

3. Western Australia metropolitan (one group) – School of Pharmacy, Curtin University, Perth, Western Australia.
4. Western Australian rural (one group) – York, Western Australia.

Focus groups were unable to be conducted in New South Wales due to lack of interest of participating pharmacists and pharmacy staff members in that state.

The timing and venues of meetings were organised to best suit the schedules of the participants. Participants were remunerated for their time.

Three types of focus groups were conducted:

1. Trainer pharmacists and pharmacy assistants only (homogenous);
2. Trained pharmacists and pharmacy assistants only (homogenous); and
3. Rural pharmacists and pharmacy assistants (both trainers and trained staff together) (heterogeneous).

The focus groups in Victoria were conducted by one of the lead investigators (G.D), with the PhD candidate acting as the observer/note-taker/audio-recorder. Two project investigators (L.E and E.E) conducted the focus groups in Western Australia.

Participants were welcomed by the facilitator, who explained the importance of their views and opinions, and the way in which these would contribute to the refinement of the education-focused intervention. Written consent was obtained (Appendix 9), and each participant was asked to introduce themselves to the group.

The questions were presented in the sequence shown above (Chapter 6, Section 6.2.2.1.). The facilitator prompted participants when necessary to elicit more specific information.

6.2.2.4 Analysis of the focus group data

Analysis of the focus group data was conducted by the PhD candidate, with assistance provided by one of the project investigators (S.H.), using thematic analysis. This process involved coding and collating the responses using NVivo 9 (NVivo qualitative data analysis software; QSR International Pty Ltd. Version 9, 2010).

Thematic coding involves pinpointing, examining and recording themes from qualitative data, and then using these themes to create conclusions and theories, or describe particular phenomena.²⁴⁶ This method of analysis was chosen due to its flexibility – it can be applied across a broad range of theoretical approaches, and is “not bound by limited variability seen in other theories, particularly conversation analysis and interpretive phenomenological analysis.”²⁴⁶

6.3 RESULTS

6.3.1 Characteristics of focus group participants

Five focus groups were conducted with 35 participants from 11 pharmacies (see Table 6.1). More pharmacy staff members participated than pharmacists.

Table 6.2 shows that most participants were from pharmacies in the face-to-face intervention group (Group 1). No pharmacies from New South Wales chose to participate, due to a lack of interest or time, or inability to attend the selected dates and/or venues.

Nine of the participating pharmacies came from metropolitan areas and two were from rural areas.

Table 6.1 Focus group characteristics: gender

	Male	Female	Total
Gender			
Pharmacists	6	8	14
Pharmacy staff members	0	21	21
Total	6	29	35

Table 6.2 Focus group characteristics: pharmacy location

	NSW		Victoria		WA		Total
Intervention group	Metro	Rural	Metro	Rural	Metro	Rural	
Face-to-face (Group 1)	0	0	3	1	4	1	9
Electronic (Group 2)	0	0	2	0	0	0	2
Total	0	0	5	1	4	1	11

Table 6.3 Focus group participants by role

	Pharmacist	Pharmacy staff members	Total
Focus group			
1	5	2	7
2	0	6	6
3	2	8	10
4	4	2	6
5	3	3	6
Total	14	21	35

6.3.2 Feedback about the usability and relevance of the education-focused intervention

Feedback about the usability and relevance of the education-focused intervention was aligned to four main themes: format, content, delivery, and relevance.

Format

Trainer pharmacist participants generally found the train-the-trainer aspect of both the face-to-face and electronic versions of the education-focused intervention too long and segmented.

They would have preferred a shorter train-the-trainer component, without segmentation into separate modules, which they thought would improve the flow.

“The five hours on the Sunday [the face-to-face train-the-trainer session], I think you could make that a fair bit shorter.” Pharmacist 1, Focus group 2.

“You can do that as one big chunk because that helps tie everything in together... but that video kept breaking up (the flow). It would’ve been a lot better in one big chunk. You’re engaging, you’re learning and then after a while, you’re just hearing the same disclosure statement and waiting for her [the voice-over] to introduce the next section. It’s repetitive, so it loses your interest for a little while.” Pharmacist 1, Focus group 1.

In relation to the in-pharmacy training component for staff, participants found the format of the education-focused intervention, on the most part, user-friendly and inviting. Having the education-focused intervention divided up into 30-minute sections enabled participants to consolidate their knowledge before moving on to the next learning module.

“I think that the half hour [session] was less scary, more user-friendly.”

Pharmacist 1, Focus group 3.

“I think it's ideal if it's in blocks. I think you remember it more...If you do it in one big block it's the things at the start and the things at the end [that you remember], but not so much the middle. But I think time, and getting everyone there, is difficult.” Pharmacist 1, Focus group 4.

One pharmacist, however, expressed concern regarding the whole process being too drawn out when undertaking the in-pharmacy delivery component of the education-focused intervention, recommending a shorter, more succinct format.

“Because that whole [in-pharmacy] training module...I feel is too long. I think the staff will get bored. It needs to be shorter and succinct. I think if you do it exactly as you suggested and go away for a week and come back...I just think...where are we going? Where are we heading? This has been going on for a while. This is going nowhere.” Pharmacist 2, Focus group 4.

Content

Participants were generally happy with the content of the education-focused intervention. The inclusion of video examples to demonstrate how to interact with consumers with limited health literacy, particularly the use of universal precautions with consumers, was well received. Participants recommended the inclusion of more videos to further demonstrate various health literacy concepts in context.

“Yeah, I think it [the content] is more than adequate. The little videos really show what situations can be like with the mother being distracted [by her children] and things like that.” Pharmacy assistant 1, Focus group 3.

“I think the scenarios you had...were really quite good because we could look at those scenarios...and say, “Oh, there’s too much [information being given] here”. The examples that you had, I think we’re all guilty of counselling like that, at some point in time.” Pharmacist 2, Focus group 4.

“I liked the little comedic sort of way of learning...It’s quite funny.” Pharmacy assistant 1, Group 3.

A number of participants said they were not sure of the relevance of some of the introductory content, and thought that some of the material was redundant and could be removed.

“There were lots of slides that were introductory or even just used as transitions from one aspect to another, which we would rather cull away completely...” Pharmacist 2, Focus group 2.

“I don’t know exactly what it was, but there was a period of time where I wasn’t quite sure what we were meant to be picking up on. Then, once universal precautions came in, then I understood what we were trying to learn and pick up on and things like that.” Pharmacist 1, Focus group 2.

“The first module was very “This is health literacy”, and if you didn’t bring it back with examples in the group session, it didn’t really make sense.”
Pharmacist 2, Focus group 1.

The inclusion of statistics to demonstrate the consequences of limited health literacy on the community and health care system was, however, viewed as beneficial to understanding the true impact of this issue.

“I found interesting the statistics about the cost, how many people it affects, and stuff like that. That was really interesting because, before I thought about it, I didn’t really notice it so much and didn’t really think about whether the customers would understand exactly what you were saying.” Pharmacy assistant 1, Focus group 4.

Delivery

Most trainer participants seemed to have diverged from the recommended delivery plan, and provided the training within the pharmacy in a fashion that best suited them. A number found the recommended delivery plan too long, and preferred to condense training into a shorter period.

“I actually just did it over a couple of days. Depending on who I was working with, I’d gather a few of them, and then I’d just run through the slides, usually at night time when it was a bit quieter.” Pharmacist 2, Focus group 3.

“We did larger chunks...we just got on a roll, really. We thought that, rather than come back and have to rehash where we left off last time and get back into it, we did it in a roll.” Pharmacist 1, Focus group 4.

“I think it’s back to an individual thing. Everybody learns differently, and retains information differently. I’m more for if I just do one big clumping and get it all over and done with, I’ll have it in my head then.” Pharmacy assistant 2, Focus group 3.

Conversely, some participants noted difficulties in condensing the large amount of training into a small period of time.

“I think two or three sessions would be hardly long enough.” Pharmacist 3, Focus group 1.

The small group learning sessions delivered in-pharmacy were well received. Participants noted their preference for this type of learning environment over larger groups. They found this method more personal and comfortable for the exchange of ideas and opinions.

“For us it was a small group as well. It was five of us. And it was good because we could discuss situations that happened in a place that we could all relate to. And it probably felt more personal and relevant to your practice, rather than going out to a lecture somewhere and getting talked at by somebody you don’t know.” Pharmacist 1, Focus group 1.

“I found that the best way to do it in this pharmacy was to actually do it with small groups of people. I couldn’t do it at a meeting because those meetings, they’re reserved for in-house business.” Pharmacist 1, Focus group 5.

“Yeah, I got more out of it than if it had been just one lecturer to 50 people.”
Pharmacy student 1, Focus group 4.

Relevance

The majority of participants found the education-focused intervention relevant to their practice. They found it useful in enhancing communication with consumers, particularly those with limited health literacy.

A conversation between the facilitator and participants in Group 3 highlighted the perceived relevance of the education-focused intervention to practice:

“,,so overall, though, you saw it as relevant to the practice?” Facilitator, Focus group 3.

“Certainly. Well, I did.” Pharmacy assistant 1, Focus group 3.

“Yes it was, always.” Pharmacist 1, Focus group 3.

Individual quotes from other groups also supported this:

“I thought it was really relevant, because I’m studying at the university and a lot of it kind of doubled up. It was easy to apply to customers that came in.”

Pharmacy student 1, Focus group 4.

“...because it was so relevant to what you do in your work. It’s the crux of what you do. So everyone was like ‘It’s good to have better tools to do what you do’.” Intern pharmacist 1, Focus group 4.

Some pharmacists and interns stated that they would have liked to have received this sort of communication training during their undergraduate course. Comment was made that undergraduate pharmacy education does not adequately prepare students to effectively communicate with consumers with limited health literacy. It was suggested that pharmacy communication training tends to focus on listing all

possible counselling points, rather than what the consumer can realistically understand and remember.

“I think it was really useful. I wish it was implemented a lot earlier in my training or even...yeah, especially my training. I’m speaking of it from a pharmacy intern’s point of view. We spent a lot of time at university learning things and reading journals which are aimed at people with high health literacy, very scientific journals. That way we learned to think in that kind of language and express ourselves in that language, so it then becomes really hard to speak to customers in a different way. So I wish, back when we were having our counselling sessions or practice counselling sessions at university, that we learned to speak to customers in that particular way. Rather than just getting marked on, “Did you mention all the ten side effects?” you know, [instead] get a mark for, “Was this clear?”” Intern pharmacist 1, Focus group 4.

“I think, even starting back at university and they had all those tutorials, and everyone was trying to counsel on something. They’re trying to impress the tutor so much; they’re using all this complex language. The tutor should’ve just said, “I have no idea what you’re talking about,” and just made them start again from scratch.” Pharmacist 1, Focus group 1.

“It depends on the patient, it depends on the situation. It’s all able to be tailored. But the bottom line is I wish I had started learning to express myself in a more health literacy friendly way earlier.” Pharmacist 1, Focus group 4.

The training was also extended to pharmacy staff members generally not involved in the pharmaceutical care process, for example, cosmetic sales assistants.

Pharmacists saw the educational content relevant for these staff members, and chose to include them in the training as well.

“I went to a really good Clarins™ girl; she’s virtually the top in Australia. I said to her, ‘You’re really good at the moment, but you could be even better. Just let me show you this video,’ and she was like, ‘Oh my God, I’m doing it so much better now.’ They come and see her and she’s incredible.” Pharmacist 3, Focus group 1.

“I think it can also apply across the board. [The] beauty girls also utilise it exactly the same way with customer skin care.” Pharmacist 2, Focus group 1.

A pharmacy assistant from one group believed the training was aimed more towards pharmacists than pharmacy assistants. They explained that they are constrained in terms of the extent of counselling they are allowed to do, thus limiting the relevance of the education-focused intervention to their work.

“Just because of the way it explains the counselling and that sort of thing, and we are limited as to what we can counsel [on], and how we counsel it. So I do believe a little it’s more aimed at the pharmacists.” Pharmacy assistant 2, Focus group 3.

6.3.3 Feedback about implementation of the education-focused intervention

Feedback about implementation of the education-focused intervention was aligned to four main themes: training, motivation of staff to undertake training, consistency of training, and evaluation and reflection.

Training

Trainer pharmacists and pharmacy assistants noted the difficulty in organising training sessions for pharmacy staff members. It was explained that training had to fit around other scheduled training sessions and staff meetings, workloads, and activities outside of work.

“It’s difficult in a pharmacy...we struggle to get all the staff together to do that, because you have to do fitting it in around customers coming in.” Pharmacist 1, Focus group 3.

“It would have meant having separate nights to do this and then trying to gather us all to do it. As you can see, we’re all from different walks of life so we’ve got activities afterwards, we’ve got kids afterwards, we’ve got other commitments, we’ve got family members you have to go see. There’s no way I was going to ask the girls to come in early either as well.” Pharmacist 1, Focus group 5.

One pharmacist devised an implementation plan in their pharmacy to aid dissemination of the training without having to organise large training sessions. They effectively conducted the training sessions with a small group of pharmacy staff members, then allocated each of those staff members another staff member who had not attended training, to educate them on what was delivered during the session.

“We made it a bit of a buddy system, so we can have them train the others. It’s having the right people at the staff meetings in the morning. We’ve got 25 staff, so not everyone can make it. We said, ‘You guys are number ones, the big buddies. We’re going to allocate you one or two people and you have to teach them.’ They were doing a train-the-trainer kind of thing, passing it on and then I’d go and check with some of the younger staff and say, ‘Do you know what I’m talking about?’ It’s pretty good to check that the message is coming out correctly from trained staff as well. That worked pretty well.”

Pharmacist 3, Focus group 1.

Motivation

Participants observed that the success of implementation and uptake of training in the pharmacy is influenced by motivating factors for pharmacists and pharmacy staff members. One intern pharmacist explained that not everyone is motivated by the same thing, and this may influence the success of implementation.

“I think it’s talking about a motivational issue. Different people will be motivated by a totally different thing. So I think you would not necessarily be able to tackle it down just one front. Personally, I’m a more self-motivated person. For me it’s personally important that I talk to the patients in an effective way. But for somebody else it might be, ‘Oh, I’m being tested on this’. Or somebody else might say, ‘I can get CPD from this’ or ‘I can do this with my friends’.” Intern pharmacist 1, Focus group 1.

Consistency

Participants explained the importance of ensuring that the education-focused intervention be implemented in a consistent manner with all staff to ensure that everyone is receiving a uniform level of training. To improve the likelihood of this, it was suggested that the training be compulsory for all staff.

A conversation between the facilitator and participants in Group 3 highlighted the importance of training consistency in use of the education-focused intervention.

“Or do you think it’s the sort of thing that each year a few staff could do and gradually build up the skill?” Facilitator, Focus group 3.

“If we were all the same page...” Pharmacist 1, Focus group 3.

“No, it should be all in the one.” Pharmacy assistant 2, Focus group 3.

Individual quotes by participants from other groups also supported this notion.

“I think if you did make it compulsory for everyone it would be better...if everyone was encouraging you to do it or holding each other accountable.”

Pharmacist 1, Focus group 4.

“Yeah, so we’ve got people that are experienced, and then people that aren’t, and if you’ve got conflicting messages, your experienced staff need to know to tell the junior staff.” Pharmacist 1, Focus group 3.

Consistency in the implementation of training was also discussed in regard to the entire profession, and it was suggested that, for the issue of health literacy to be taken seriously, all pharmacies should be trained in it.

“I don’t see how health literacy is going to be...only if universally [implemented] of course, nationally effective. So unless it becomes something that the Pharmacy Board, or something like that, enforces pharmacies to do, I don’t see that there’ll be too much uniformity coming through.” Pharmacy assistant 2, Focus group 3.

Evaluation and reflection

Participants discussed various methods of evaluating the success of implementation of the education-focused intervention in their pharmacies. Self-reflection was a popular method to evaluate the success of applying universal precautions.

"I find that, after I've counselled my patients, I think back to how I counselled them and I think, 'Oh, maybe I spent a little too long on that', or, 'That probably wasn't clear'. And I kind of summarise the whole thing for myself at the end of it, and say 'Okay, next time, I'm going to just say this, this, and this, in this sequence'." Pharmacist 1, Focus group 4.

"...you can look back [and say] 'Oh, I think there was a person like that a few days ago. I could have done this maybe a bit differently.' It's very easy, when the next customer comes in, to change how you approach that person."

Pharmacist 1, Focus group 5.

Discussions with lead pharmacy trainers were also used as an evaluation method. They allowed participants to gain feedback on areas of improvement.

"I know after we had the sessions, [pharmacy trainer] said to try to do something with the customer and then go back to him and let him know how it went. That was fine." Intern pharmacist 1, Focus group 4.

"What I found that [the] girls here would actually do after a transaction or something, they would come up to me and go 'That [example] is from that [module].' It wasn't like we waited for the next module to say, 'How did that activity go?' It was more ongoing." Pharmacist 1, Focus group 5.

6.3.4 Feedback about changes to practice as a result of the education-focused intervention

Feedback about changes to practice as a result of the education-focused intervention was aligned to five main themes: counselling, identifying consumers with limited health literacy, consumer awareness, relationships with consumers, and managing CALD consumers.

Counselling

Discussions related to changes in counselling focused on the use of universal precautions with consumers, particularly the primary outcomes: the use of ‘What questions do you have?’ and the teach-back method. Participants felt that the education-focused intervention provided them with the communication skills to tailor and enhance the delivery of health information to consumers.

“Sometimes when you say, ‘One, twice a day’ they will be like, ‘Oh?’ – they don’t really get it. ‘So that there would be one at breakfast and one at dinner’ – then they sort of get it after that.” Pharmacy assistant 3, Focus group 3.

“If they’re in a hurry and you give them too much information, like that video was saying, they’re not going to take any of it in, anyway. If you just told them those two facts before they leave, it’s better than giving them your whole spiel...” Pharmacist 1, Focus group 1.

Some participants highlighted the difficulty in asking consumers ‘What questions do you have?’

“I found that ‘What questions (do you) have for me?’ was really hard to use; it made it a bit too formal.” Pharmacist 2, Focus group 5.

Consciously thinking about what exactly you want to say to the consumer before counselling them was suggested as a way of overcoming this difficulty.

“It’s a conscious effort and still is. Because I’m less than a year out, registered, but I still have [communication] habits with people. A couple of things made their way in from this training about how I communicate things, but it’s still a very conscious effort.” Pharmacist 1, Focus group 4.

“Yeah, it’s changing, consciously changing. That’s what it is. Consciously...”
Pharmacist 1, Focus group 5.

“It’s just a matter of stopping and thinking about what you ask before you actually ask it, because a lot of it is just habit. You’ve just got to actually stop, maybe think ahead about what you’re actually going to ask before you actually ask it.” Pharmacy assistant 1, Focus group 3.

Use of the teach-back method was also met with difficulty. Participants discussed their lack of confidence and skills in being able to effectively implement this method with consumers. They described it as ‘awkward’ and confronting for the consumer.

They also noted that the busy environment of the pharmacy is not conducive to using this method.

“It’s very hard to do the teach-back thing. I personally find it hard to phrase it in such a way that people will want to do it. Because everyone’s really busy...”

Intern pharmacist, Focus group 4.

“It’s quite an awkward thing to ask. People feel thrown off by it. How do you phrase it in a way to a person normally in conversation?” Pharmacist 1, Focus group 4.

“...quite a few [pharmacy staff members] from our rural pharmacy were not comfortable asking people to teach back.” Pharmacist 1, Focus group 2.

One participant explained how they implemented the teach-back method so that it gained consumers’ attention.

“I said to her [the consumer], ‘What we’re going to...I know you’re not keen about this medicine, but I’m going to explain to you how to use it properly anyway, so that at least you’ll get benefit from it. After I’ve explained it to you, I’m going to give you a little test and you’ll have to explain it back to me, okay?’ and she went ‘Okay, all right, that’s fine.’” Pharmacist 1, Focus group 2.

Identifying consumers with limited health literacy

Overall, participants felt that they were more aware of consumers with limited health literacy following completion of the education-focused intervention. They explained that they were able to detect cues that the consumer may have a health literacy issue.

“I think it makes you think, give more thought to the fact...like we’re aware that Mr. So-and-so is probably not literate about his health, but before this program, we probably never put as much thought into it as now.” Pharmacy assistant 2, Focus group 3.

“...it never really struck me as anything before. You notice more the eye contact, looking away in a hurry, walking away on you and not asking any questions at all.” Pharmacist 2, Focus group 1.

“Yeah, I think afterwards it was kind of easy to see the signs that they weren't really listening or understanding what you were saying.” Pharmacy student 1, Focus group 4.

After detecting a health literacy issue with consumers, some participants altered the way they conducted their counselling; for example, encouraging the consumer to call the pharmacy once they are home to discuss the medicine and ask questions, instead of in the pharmacy itself.

“There’s a lot of people either with that situation or they’re not absorbing. It’s just like, ‘Yeah, take it in the morning; it will make you drowsy. Call me later and we’ll discuss it further.’ And then they’ll go home and have a think about it and maybe questions will come to them...just a follow-up chat.” Pharmacist 1, Focus group 4.

Consumer awareness

Participants discussed whether consumers were aware of pharmacists’ and pharmacy staff members’ change in communication practices and use of universal precautions in counselling following the training. They said that consumers were taken aback by the use of universal precautions, but that the technique allowed the consumer to be more open during the consultation.

“It kind of catches them off guard; they don’t expect that question from you. They’re like, ‘Oh yeah.’ And then they’ll kind of ask you in a way, ‘I wouldn’t ask you this normally, but can you help me?’ So it just brings it out of them.”
Intern pharmacist 1, Focus group 4.

Specifically, one participant expressed concern over consumer misunderstanding when pharmacy staff members, particularly younger ones, use universal precautions. They believed that this may be interpreted as rudeness.

“You don’t want to insult people.” Facilitator, Focus group 3.

“So it is going to be a fine line, particularly, I think, with some of the younger [pharmacy staff members]. Someone like [an older pharmacy staff member], they all know her, so they’re not going to worry about what she asks them, whereas with [a younger pharmacy staff member]...they’ll come back in to [the older pharmacy staff member] the next day and say, ‘That young girl was so rude yesterday’.” Pharmacy assistant 2, Focus group 3.

Relationships with consumers

The influence of the education-focused intervention on relationships and rapport building was discussed by participants. They noted that the education-focused intervention focuses on improving rapport with consumers, allowing them to be more open and honest in their discussions with pharmacists and pharmacy staff members.

“The biggest thing I think this training should highlight is building, I know we talk about building a friendly environment or safe environment where people can talk, but it’s not that one off thing. It’s rapport building and that’s where you catch your people that have difficulties understanding their medication. Then that’s where you’ll also be able to help them as well.” Pharmacist 1, Focus group 5.

Rural pharmacy staff stated that they already had well-developed relationships with their consumers compared to metropolitan pharmacies prior to receiving the training, and therefore the education-focused intervention may not have influenced this greatly.

“...I think that’s where it differs. Country pharmacists do a lot more consistent counselling, and a longer term relationship with a person helps that.”

Pharmacy assistant 2, Focus group 3.

“To get the consumer to say: ‘That’s no trouble, I’m going to give it a go and go home, and try it’; [and I’ll say] ‘Let me know how you go tomorrow. Give me a call, let me hear if it went well’ because that’s the sort of relationship we’ve got with the customers.” Pharmacist 1, Focus group 5.

CALD consumers

The education-focused intervention included a section on using universal precautions with CALD consumers (Module 3, see Chapter 1, Section 1.2.2) and the complexities of communicating health and medicines information to this population. Participants discussed their prior awareness of issues associated with CALD consumers, and seemed to be aware of the difficulties in communicating with them. Pharmacies situated in more ethnically diverse areas, or staff who had previously worked in such areas, were particularly aware of these issues.

“It is easier, and having worked in an ethnic [area], the language you can use in English communities is just so different. The English system won’t apply to ethnic groups; they just don’t even understand this.” Pharmacy assistant 1, Focus group 3.

“That being said, a lot of the cultural awareness part does already pertain to our pharmacy. It’s already standard.” Pharmacist 1, Focus group 5.

One pharmacist explained that Module 3 (Health Literacy in More Complex Situations) was the most important for her pharmacy due to its location in an ethnically diverse area.

“For us, Module 3 was very big. Module 1 and 2, yes, but 3...” Pharmacist 1, Focus group 1.

Participants discussed changes they had made in relation to managing language issues with CALD consumers, particularly limiting content and providing simpler information to enhance comprehension. One pharmacist also stated that they would collate the various resources in other languages into folders for staff to utilise when appropriate.

“Yes. I found it happened right after we had the sessions. A couple came in and they didn’t speak English very well. And that was one of things. Rather than going through everything, I just did the very simple points: when to take it, what’s it for.” Pharmacy student 1, Focus group 4.

“I think I’m going to group up all those resources, and actually just put it in a folder, put the English ones first, so all the staff know what it is, and all the

different languages behind them [and] they can copy it as they need it.”

Pharmacist 1, Focus group 4.

6.3.5 Feedback about changes to the health literacy friendliness and organisation of the pharmacy as a result of the education-focused intervention, and subsequent sustainability in practice

Feedback about changes to the health literacy friendliness and organisation of the pharmacy as a result of the education-focused intervention was aligned to three main themes: signage, support, and sustainability.

Signage

Participants were aware of the need to keep the language used in signage simple, to enhance consumer understanding.

“They’re [the signs] saying, “antihistamines,” and “anti-diarrhoeals” and things that are too big [even] to people who speak English.” Pharmacist 1, Focus group 1.

Most participants said that they had not made changes to the signage in their pharmacy, but some commented that they were planning to in the near future.

“Well I was thinking of doing a bit of an audit of the signage in our pharmacy – because with the PBS rollout thing over – and actually having a bit of a look at what we’ve got where.” Pharmacist 1, Focus group 3.

“We were discussing the signage around the new PBS, and we don’t feel we have anything, and if we do, it’s very ordinary.” Pharmacy assistant 1, Focus group 3.

One pharmacy student explained that, as a result of the training, their pharmacy had conducted a review of the signage and made alterations to improve consumer understanding.

“On your last point, I think the whole pharmacy was involved. It brought about active changes with the signage and trying to do things like that.” Pharmacy student 1, Focus group 4.

Support

Only one participant was explicit in discussing support from managers to implement and use the education-focused intervention. They explained that the positive attitude of their manager towards undertaking health literacy training made the process of implementation easier.

“Our manager is really big on improving communication with customers. That is just his thing. So I guess it would have been slightly different for us than for

some other pharmacies because he was already into that kind of thing. I think that's why he was so keen to sign on for the health literacy program. So in terms of us, there was a lot of support. Just in general, we always try to improve our communication with patients because so many problems can come from that." Intern pharmacist, Focus group 4.

Another participant suggested that it was the role of the government to ensure health literacy training was implemented and that support should be provided for this to ensure a consistent level of training for other health professionals, particularly doctors.

"I would love to see this being trained to doctors. Governments should jump on board and realise there's a gap, health literacy, there's a gap." Pharmacist 1, Focus group 5.

Sustainability

Approaches to ensuring sustainability of the education-focused intervention had been explored by some participants in their pharmacy, while others had not considered the issue.

It was suggested that, to ensure practice changes are maintained in the pharmacy, a pharmacy staff member be designated a champion or leader.

“Even if it is just one champion to be where it’s at the back of their minds all the time and they’re just monitoring how it is going...they just pick up lulls or people going back to old habits. They can just casually do whatever works.”

Pharmacist 1, Focus group 4.

Due to the relatively short amount of time between training and the focus group sessions, most pharmacy participants had not discussed methods to promote the sustainability of universal precautions and health literacy measures in their pharmacies.

A conversation between the facilitator and participants in Focus group 3 highlighted the lack of available time to consider sustainability at the time of the focus group meetings:

“In terms of that, going back to the idea of sustainability, have you guys done anything in your pharmacy that just keeps it at the front of your mind?”

Facilitator, Focus group 3.

“I don’t think we have.” Pharmacy assistant 1, Focus group 3.

“It’s inside a month.” Pharmacy assistant 2, Focus group 3.

“It’s not long enough, yeah.” Pharmacist 2, Focus group 3.

“Yeah, it’s only very new for us, so I don’t think that we are at that stage yet.”

Pharmacy assistant, Focus group 3.

6.4 DISCUSSION

The discussion below is presented a response to each study aim (Chapter 6, Section 6.2.2)

Elicit ideas for the content of the education-focused intervention that were not included in the first iteration

Overall, participants were happy with the content included in the education-focused intervention, and did not provide recommendations in relation to the inclusion of extra information. Most participants found that the content was applicable to their interactions with consumers and provided them with greater insight into health literacy principles. Some even felt that health literacy education would be useful in undergraduate or postgraduate pharmacy training. The online international survey of pharmacy academics (Chapter 3, Section 3.3) identified that health literacy education is present in the curricula of a number of universities in English speaking countries. However, a review conducted by the PhD candidate exploring learning objectives from Australian universities offering pharmacy degrees, showed that only one university explicitly lists health literacy (Chapter 1, Section 1.5.1). The integration of health literacy education into pharmacy curricula is an important step in ensuring that all pharmacists are trained in detecting and managing consumers with

health literacy issues. It must be acknowledged that the review (Chapter 1, Section 1.5.1) was conducted based on information that was publically available from university websites. To make a complete and accurate conclusion on health literacy teaching in Australian pharmacy schools, further investigations would be required.

Obtain feedback on the usability of the education-focused intervention in relation to its structure and method of delivery, including the face-to-face, computer-based, and in-house training components

In discussion with trainer pharmacists and pharmacy staff members, some felt that the train-the-trainer component for both the face-to-face and electronic delivery method was too long and segmented in nature. This may have the potential to reduce attention to content and decrease motivation to complete the training. Conversely, in-pharmacy trained participants generally agreed that the modules delivered by the trainer staff member were adequate. They commented that the shorter modules delivered in chunks were user-friendly, and enhanced the ability to remember the content.

The recommendation to shorten the train-the-trainer component, or in the case of the in-pharmacy delivered modules, keep them short, could be partly explained by the serial-position effect. The serial position effect is the tendency for individuals to be able to recall the first and last items in a series best, with recall of middle items proving more difficult.²⁴⁷⁻²⁴⁹ Items remembered at the beginning are more likely to be stored in long-term memory (the primacy effect), and items at the end are more likely to be stored in short-term memory (the recency effect).²⁴⁹ Items in the middle tend to

be displaced from short-term memory by the items at the end, and therefore not remembered.

Two recommendations can be suggested regarding the format of the education-focused intervention. Firstly, minimising the number of items to remember, and therefore keeping training short, may reduce the impact of the serial position effect on learning. Smaller chunks may be more manageable for the learner, and may aid in improving their attention and motivation to learn. Secondly, taking advantage of the primacy effect and positioning the information deemed most important at the beginning of the learning modules may increase the likelihood that this information will be stored in the learner's long-term memory.

When discussing content, participants noted the advantage of integrating videos into the education-focused intervention to aid in learning. They were able to forge associations between the examples displayed in the videos and consumers who visit their own pharmacy. Videos have been used extensively in pharmacy and medical education in the recent past and are viewed as a valuable stimulus for discussion.²⁵⁰⁻
²⁵⁵ A study conducted in The Netherlands used focus groups to gain feedback from second year medical students on the use of a video-based problem-based learning (PBL) program.²⁵⁶ Students felt that the use of video cases allowed them to better acknowledge that patients are people, and were more memorable than text-based cases. Although a number of videos were integrated into the education-focused intervention, the intervention may benefit from the inclusion of more.

The delivery method of the education-focused intervention was a discussion point for participants, both in regard to its timeline of delivery and the use of small-group learning. Many trainer participants had altered the schedule of training in their pharmacy to better suit the workload and schedules. It is important to create an education-focused intervention that has a flexible structure in terms of its delivery that allows the learner to work at their own pace.²⁵⁷ For future use, informing the trainers that the education-focused intervention can be conducted at their own pace and convenience may aid in successful in-pharmacy delivery. A downside of this is that if trainers choose to deliver the training quickly, the rapid delivery of content in large chunks may reduce the likelihood of the participants remembering the content, as discussed above.

The inclusion of small-group learning in the education-focused intervention was widely commended and adds to the limited literature on the effectiveness of this method in the pharmacy setting. The integration of an active, cooperative learning framework into education is viewed as beneficial, and may improve learning of individuals compared to didactic teaching.^{258, 259} In the USA, a study was undertaken to evaluate the effect of restructuring a large pharmacy self-care class into a small-group learning structure.²⁶⁰ The small-group learning environment was designed to promote communication and discussion of patient cases between students. Following a two-year delivery period, students' grades and course evaluations were compared to the previous structure. Students' grades had significantly improved over the two-year period, notably, the number of 'A' grades rose from 21/146 to 52/151 ($p < 0.001$). Students also recorded a higher level of satisfaction with the small-group learning format than the large class format. In particular, when asked if the course

aided the development of their verbal communication skills, there was a 51.9% increase in the affirmative over two years, from 39.7% to 91.6% ($p < 0.001$).

Obtain feedback on the ease of integration of the education-focused intervention into the pharmacy environment

Ensuring that the integration of educational programs into practice is organised and well-coordinated is essential to ensuring effective implementation and uptake.²⁶¹⁻²⁶³ Trainer pharmacists and pharmacy staff members revealed difficulties organising in-pharmacy group training sessions due to other staff commitments. This finding is similar to that of a focus group study conducted in the UK investigating the barriers to successful implementation of training in nursing practice.²⁶⁴ Participants of the UK study highlighted that lack of time to attend training is a significant barrier, compounded by local staff shortages and increasing work pressures.

While the UK study was similar in methodology to the Phase 4 focus group study reported here, participants were nursing staff involved in caring for patients with cancer, and therefore commitments would differ significantly from those of pharmacists and pharmacy staff members in community pharmacies. It does, however, highlight that time is a significant barrier to the successful implementation of training in healthcare environments.

The same UK study²⁶⁴ suggested the use of a 'link-worker scheme' to overcome the time and resource barriers associated with implementing training. A link-worker scheme is a process whereby one person in an area receives training, and is then

designated as a resource for other colleagues to refer to for information. One pharmacy reported adopting this approach in the focus groups discussed here - training a small number of key staff members and designating them a group of untrained pharmacy staff members to mentor and train at individual times. This approach may circumvent time and resource barriers associated with organising training for all staff, and may be suggested as a possible delivery approach for future use of the education-focused intervention.

It has been shown that an individual's motivation to learn influences their level of effort and commitment, focus, enthusiasm, and direction towards participating in an educational program.^{119, 265-267} During the focus group discussion, one participant highlighted the importance of acknowledging the various reasons why individuals may want to implement and undertake training in the pharmacy. In future rollouts of the education-focused intervention, participants should be asked to record motivations and then revisit them as they do the intervention and following its completion.

Ensuring that the education-focused intervention draws interest from a wide range of individuals with varying motivations is important. The UK study aforementioned also suggested that staff motivation was linked to the delivery of the education as well as different methods of training suiting different groups and personality types.²⁶⁴ Embedding various incentives to implement and undertake the training may enhance the success of the education-focused intervention in the pharmacy setting. This may include gaining accreditation to claim CPD points to fulfill registration requirements,

financial reimbursement, promoting job enrichment, an expected or realised chance of promotion, or learning to comply with pharmacy business directives.

Participants felt that all staff should receive the same level of training to ensure a uniform level of knowledge of health literacy and universal precautions. This may have the lead-on effect of promoting staff accountability when using universal precautions, due to other pharmacists and pharmacy staff members being aware of what is expected in terms of performance and use of health literacy principles. Health literacy awareness may therefore be mentioned as a competency area required of a new staff member when they are inducted into the workplace. Further, it was suggested that an expectation to implement and undertake health literacy training throughout the Australian pharmacy profession be recommended in order to achieve this goal more broadly.

Self-reflection was a commonly used method by participants in assessing their performance in the use of universal precautions with consumers. Self-reflection is viewed as key to ensuring life-long learning, and can be developed by encouraging individuals to seek formative feedback from others in regard to performance.²⁶⁸⁻²⁷⁰ To aid in the development of skills in self-reflection, preceptors and trainers should provide timely and constructive feedback that encourages individuals to develop into reflective learners.²⁷¹ The education-focused intervention already provides opportunities for pharmacy staff members to reflect on things they have tried or observed and should also encourage trainers to provide feedback to pharmacy staff members on their use of universal precautions. A Canadian study investigating self-assessment skills of 32 international pharmacy graduates trained outside of the USA

and Canada was conducted using OSCEs.²⁷² Participants, on average, overestimated their performance by 21 percentage points compared to the actual performance score (71% versus 50%, $p < 0.001$). The study suggests that adequate self-reflection and self-assessment skills are not universally well adopted by pharmacy graduates. This is of particular concern as the concept of CE relies heavily on self-assessment of performance, and thus may be compromised.

Obtain feedback on the perceived effectiveness of the education-focused intervention with respect to changing pharmacist's and pharmacy staff members' behaviours and the pharmacy environment

The education-focused intervention provided participants with the ability to tailor their communication techniques with consumers to allow for a better, more health literacy friendly way of delivering information. From the focus group discussion, while it appeared that simple changes were easy to implement in practice, universal precautions that required a more conscious effort, i.e. the teach-back method and use of the phrase 'What questions do you have?', were harder. Low adoption of the teach-back method, both pre- and post-intervention across all three groups, indicates the difficulty of employing this technique.

A study by Schwartzberg *et al.* showed that simpler communication techniques such as plain language (91.6%) and handing out printed materials (71.8%) were more commonly used by pharmacists with consumers than more involved processes.⁵² The study involved a questionnaire disseminated to nurses, physicians and pharmacists in the USA to determine the prevalence of use of various

communication techniques employed with consumers with limited health literacy. More complex techniques, e.g. the teach-back method (27.7%) and drawing pictures and diagrams (6.0%), were used less frequently than the simpler techniques mentioned above. A similar prevalence study on the use of communication techniques by physicians in the emergency department of an American hospital found the teach-back method was used the least frequently (28.4%) compared to other techniques.²⁷³

The education-focused intervention may therefore benefit from the inclusion of more video examples and role-play opportunities to help build participants' confidence in using these more complex universal precautions ('What questions do you have?' and the teach-back method) with consumers.

Participants noted that following the intervention, they were much more aware of the various cues to help them identify consumers with limited health literacy. This is a beneficial ability, as it enables a quick way of recognising consumers who may require more assistance with understanding health and medicine information. Various health literacy screening tools are available for use in practice,³⁰⁻³⁴ but may not be acceptable to consumers or conducive to the generally fast-paced environment of a community pharmacy. Therefore, the ability to identify consumers by detecting cues may be more efficient.

Consumers may react differently when unfamiliar communication techniques are used in counselling, and this in turn may influence the type of information exchanged during the consultation. Some participants noted that some consumers seemed to

wrongly interpret the use of universal precautions as prying or rudeness, especially when used by younger pharmacists and pharmacy staff members. The continued use of universal precautions in all interactions with consumers by all pharmacists and pharmacy staff members over time may slowly reduce the likelihood of consumers recognising a difference in counselling or misinterpreting their use as rudeness or an inquisition. Raising awareness amongst consumers of how a pharmacy operates and the need to ask questions in regard to one's health may help consumers understand the pharmacy's mission and goals.

Participants believed the education-focused intervention enabled them to further develop their relationships with consumers. Consumer relationships with pharmacists are influenced by the level of shared decision-making with the pharmacist, and, with the advent of the patient-centred approach to care, the need to develop relationships with consumers is essential.²⁷⁴⁻²⁷⁶ A patient-centred care approach has been shown to improve patient satisfaction as well as medication adherence.²⁷⁷ In 2012, a focus group study conducted in France with 25 consumers gained feedback on physician-patient relationships and shared decision making.²⁷⁸ Participants highlighted that trust was the determining factor in this process, allowing the development of an empathic physician-patient relationship. Extending this finding to the pharmacy environment, the development of relationships with consumers is beneficial as it may allow for a more honest and comfortable exchange of information between the consumer and the pharmacist or pharmacy staff member. The education-focused intervention appeared adequate in promoting rapport building with consumers and therefore future refinement in this area may not be required.

The prevalence of limited health literacy in CALD consumers is well documented.^{37, 44, 45} Post-intervention, participants believed they were better able to service non-English speaking consumers, utilising a variety of the tools and services included in the education-focused intervention. Encouraging pharmacists and pharmacy staff members to collate available resources for consumers from CALD backgrounds when utilising pharmacy services may help circumvent communication and medicine-related issues. This could include collecting medicines information in other languages, accessing translator services, and encouraging multi-lingual staff to undertake interpreter training. The development of a health literacy friendly pharmacy for CALD consumers may provide a comfortable environment for better health and medicine information provision. Research on pharmacists' and pharmacy staff members' perceptions of communication with CALD consumers is lacking, and thus should be addressed to create a better picture of the current state of counselling and approaches to manage CALD consumers in the pharmacy setting. Education in counselling techniques and tools available for use with CALD consumers is also minimal, and while the education-focused intervention aimed to address this shortfall, CE in this area for pharmacists and pharmacy staff members is required.

Changes to the health literacy friendliness of the pharmacy

Creating an environment for consumers that is easy to navigate is paramount to ensuring the effective utilisation of available services.²⁷⁹⁻²⁸¹ Focus group participants explained that, while they were aware of the need to create signage that could be understood by consumers with limited health literacy, they had not been able to make substantial changes to signage in the short period of time between completion

of the intervention and the focus groups. Altering signage may present as an issue for some pharmacies, particularly those belonging to a banner or chain group. Default signage requirements may be in place, which may not be modifiable by the pharmacy manager at store level. Discussions with managers at higher levels within these groups in regard to creating consumer-friendly signage is recommended to instigate change. Independently-owned pharmacies may have more freedom to change signage, but may lack the financial means to conduct such an overhaul. Research in the area of signage in pharmacy is needed to generate a more accurate snapshot of signage in pharmacies, to help initiate efforts to affect change. Future versions of the intervention may benefit from having examples of health literacy-friendly signs for community pharmacies to potentially adopt.

An individual's perceived behavioural control in regard to implementing and undertaking health literacy training may be influenced by their managers. A study conducted in the US on the provision of emergency contraceptive pill (ECP) by pharmacists found that pharmacists who had prescribed the ECP were more satisfied with their managerial support to do so, compared to those who had never supplied the ECP (3.72 ± 0.52 versus 2.91 ± 1.09 , respectively, $p < 0.001$).²⁸² Another study conducted in Canada, aimed to gain feedback from pharmacists in British Columbia following the implementation of various changes to pharmacy practice policies in that jurisdiction.²⁸³ Thirty-one pharmacists participated in semi-structured interviews; pharmacists believed that adequate managerial support was an essential factor in the successful implementation of new policies in the pharmacy. These studies highlight that managerial resistance to implementing various interventions in

the pharmacy environment may present a barrier, and approaches to overcoming this should be provided.

A possible strategy for pharmacists wanting to implement the health literacy education-focused intervention in their community pharmacy could be to provide a short presentation to pharmacy managers on health literacy, its consequences on consumer care, and subsequent benefits to consumers and the pharmacy by implementing the education-focused intervention.

Sustainability is important to ensure the continued practice of universal precautions with consumers. Encouraging the designation of a health literacy champion, or the implementation of a link-worker scheme, in the pharmacy to ensure sustained practice of universal precautions, may aid in its continued use, as discussed earlier.²⁶⁴ Continued training of pharmacy staff members, perhaps through the development and use of refresher modules, may aid in continued use of universal precautions. A systematic review of health literacy interventions showed that current studies on interventions to address health literacy issues lack sufficient data to determine their ability to create a sustained effect in practice.²⁸⁴ The review recommends that studies improve their reporting of sustainability measures in the future. Due to this lack of sustainability data for health literacy educational interventions, comparisons of the study reported here to other studies are difficult to make. Possible approaches to encouraging sustainability of the education-focused intervention in the pharmacy may be, as mentioned previously, the creation of refresher training modules and reminder systems, for example, mouse pads, alerts embedded into dispensing software, or posters.

6.5 CONCLUSION

Discussions with a number of pharmacists and pharmacy staff members provided a large amount of feedback relating to a number of facets of the education-focused intervention, including its content, usability and implementation, and its perceived effectiveness in altering communication behaviours and the pharmacy environment.

Participants were happy with the content included in the education-focused intervention, and found it interesting and informative. No recommendations for extra content were made, although some suggested removal of some information might aid memory retention.

Feedback regarding the usability of the education-focused intervention centred on its length. Some participants found the education-focused intervention too long and segmented in nature. While shortening the education-focused intervention may improve usability, major reduction would require omitting important content and is therefore not recommended.

Integration of the education-focused intervention into the pharmacy training environment was considered straight forward. Participants responded particularly well to the small-group learning format, suggesting it made their learning experience easier. No changes are therefore necessary in regard to the implementation process of the education-focused intervention.

The education-focused intervention was thought to be effective overall in altering communication practices of participants, particularly the use of universal precautions with consumers. The use of the teach-back method was considered difficult and therefore more video examples and role-play activities may aid in improving its use with consumers. Changes to the pharmacy environment were minimal at best, which may be attributed to the short time between completion of the training and the focus group meetings. Making changes to the pharmacy environment is a slow process, and therefore feedback was limited.

The next chapter summarizes the research project and its findings and provides direction for further research in this area.

7 SUMMARY, RECOMMENDATIONS AND CONCLUSION

7.1 SUMMARY

Health literacy education for Australian community pharmacists and pharmacy staff members has not been previously studied in great depth. Few health literacy educational interventions have been developed for pharmacists and pharmacy staff members to address the limitations in knowledge of health literacy, particularly in Australia, where no formal educational interventions have been developed for the pharmacy setting. The overall aim of this research project therefore was to determine the efficacy and effectiveness of a multi-modal health literacy education-focused intervention in changing communication practice and behaviours of Australian community pharmacists and pharmacy staff members to help overcome communication barriers with all consumers, specifically the use of universal precautions. This aim was successfully met following the completion of this research project.

The findings of **Phase 1** of the project highlighted the various methods of teaching health literacy to pharmacy students within schools of pharmacy in English speaking countries, with the objective for the phase sufficiently met. Small-group learning was believed to be the most effective delivery method for health literacy training. This helped inform the design and development of a health literacy education-focused intervention in the **HeLP phase** of this project. The hypothesis for Phase 1 (Chapter

1, Section 1.8.2) was not achieved due to a low survey response rate. It was not possible to determine the prevalence of health literacy education within schools of pharmacy. However, it was obvious that a variety of delivery methods are used when providing health literacy training to pharmacy students.

A multi-modal, train-the-trainer, six hour education-focused intervention in health literacy was developed in the **HeLP phase**. This is the first intervention that has used a train-the-trainer method of delivery to educate community pharmacists and pharmacy staff members in health literacy. A variety of educational strategies were used to cater for various learning styles of participants, including information delivered as text, case studies and role plays, videos and images. A reflective exercise was included following the completion of each module to promote self-reflection and group discussion amongst participants.

The education-focused intervention was delivered to two groups of community pharmacies (Group 1 and 2). Pharmacies were recruited from both metropolitan and rural New South Wales, Victoria and Western Australia. Group 1 pharmacies received the train-the-trainer component of the intervention in a face-to-face format. Group 2 received the train-the-trainer component of the intervention in an electronic, self-directed learning format. Each pharmacy was involved in a randomised controlled trial (RCT), where each intervention pharmacy implemented the health literacy education-focused intervention into their pharmacy training program. Group 3 pharmacies did not receive the intervention, and therefore acted as a control group. This was designed to provide comparison for evaluation of the intervention in relation to the use of universal precautions with consumers.

Recruitment of pharmacies for this RCT proved to be difficult, and therefore limited the number of pharmacies participating in the study. Barriers to recruitment into the RCT are consistent with previous studies investigating problems associated with encouraging pharmacists to be involved in research.

A number of pharmacies completed the entire intervention, while some partially completed the modules. Barriers to completion included time constraints, staffing changes, managerial barriers, and motivation issues. These barriers support previous research into the barriers and enablers of completing CE.

Phase 2 was a study run before the intervention was implemented into participating community pharmacies. The findings of Phase 2 highlighted the significant influence that subjective norms and perceived behavioural control (self-efficacy) have on the likelihood of pharmacists and pharmacy staff members undertaking health literacy training, with the objective successfully met. The hypothesis for this phase (Chapter 1, Section 1.8.2) was partially achieved. The majority of extracted motivational factors did have a favourable association with intentions to implement and undertake health literacy training, yet some did not.

Despite the barriers experienced by Group 1 and 2 pharmacies, the use of some universal precautions with consumers was shown to improve following the implementation of the education-focused intervention in **Phase 3**. Thus, the overall aim of the project was partially met. Use of particular universal precautions both pre- and post-intervention was shown to improve significantly, yet improvement in the use

of the teach-back method was not detected. This result supports the hypothesis for Phase 3 (Chapter 1, Section 1.8.2).

Feedback related to the education-focused intervention was collected in **Phase 4**. Participants were generally happy with the content of the education-focused intervention, yet found it to be too long and segmented, and suggested it be condensed. Small-group learning proved to be a popular method of delivery. The teach-back method was viewed as difficult to implement. Future refinement of the intervention should focus on including more examples and support in the use of the teach-back method to improve its use in the future. The hypothesis for Phase 4 (Chapter 1, Section 1.8.2) was met. The majority of the feedback provided was favourable, and provides valuable insights for future, potential refinements of the intervention.

While the generalisability of these results is limited due to the small number of pharmacies recruited, this is the first study that has used a mixture of qualitative and quantitative research methods to evaluate the efficacy and effectiveness of a nationwide health literacy education-focused intervention on community pharmacists and pharmacy staff members, and has demonstrated that community pharmacies benefit from education in health literacy.

7.2 RECOMMENDATIONS

The results of the project suggest that the lack of health literacy education for pharmacists and pharmacy staff members can be partly addressed using CE. It is

therefore recommended that the health literacy education-focused intervention be refined and disseminated to community pharmacies around Australia who are interested in developing more appropriate communication techniques to use with consumers, particularly universal precautions.

Refinement of the intervention in line with the feedback gained from Phase 4 of the project may aid in improving the success of future implementation. Shortening the overall length of the intervention may enhance the usability and ease of implementation into the busy pharmacy environment. Also, the addition of more examples of the teach-back method may improve participant confidence and self-efficacy in using this method with consumers.

The integration of this intervention into the Quality Care Pharmacy Program (QCPP), making it compulsory for all pharmacies to complete, may further encourage the use of universal precautions with consumers. It may ensure consistent use of universal precautions by all community pharmacies in Australia. The intervention may also be used in the education of pharmacy students in universities following appropriate adjustments.

Government bodies must consider limited health literacy as a major barrier to the quality use of medicines. Support must be provided to pharmacies to implement health literacy guidelines and educational interventions to better prepare staff to manage consumers with limited health literacy.

The integration of health literacy education into pharmacy curricula is as equally important. Educating pharmacy students about the importance of recognising health literacy as an important barrier to patient care, and methods to overcome these issues, is essential. An influx of young, health literacy-aware pharmacists into the workforce may even have a flow-on effect of knowledge diffusion to other, older pharmacists and pharmacy staff.

7.3 FUTURE RESEARCH DIRECTIONS

The results from the project provide key stakeholders with evidence that the issue of limited consumer health literacy can at least be partly addressed using an education-focused intervention for health professionals.

A larger research project involving more pharmacies, and other health professionals, should be conducted either more widely in Australia, or internationally. It would further support the view that improving health literacy awareness and encouraging the use of universal precautions with consumers would be beneficial. Research should also be conducted on the sustainability of health literacy education-focused interventions such as the one developed in this project.

In addition, Phase 2 was conducted only as a pre-intervention study. Future studies could be conducted to determine the impact of the implementation of a health literacy education-focused intervention on pharmacists' and pharmacy staff members' motivations and intentions. This will help determine whether interventions such as these are able to influence one's attitudes, perceived behavioural control,

subjective norms, intentions and subsequent behaviours in regard to providing health literacy centred care.

Research on health professionals' own health literacy abilities should also be conducted. It cannot be assumed that all health professionals, including pharmacists and pharmacy staff members, have adequate health literacy abilities. Research in this area would provide insight into the effect that limited health literacy of health professionals has on their provision of health information to consumers and the ability of the consumer to appropriately comprehend that information.

7.4 CONCLUSION

The research project has identified that the gap in health literacy education for community pharmacists and pharmacy staff members in Australia can be partly addressed using a multi-modal health literacy education-focused intervention. Additional interventions are required, particularly the integration of health literacy education into pharmacy curricula, and support from professional organisations and governments, to further enhance efforts to manage the issue of limited health literacy. The project has provided evidence to support the idea that communication behaviours of pharmacists and pharmacy staff members can be modified using CE. Providing Australian pharmacists and pharmacy staff members with the knowledge, self-efficacy, confidence and support to address the health literacy issues faced by consumers can help improve the health outcomes of pharmacy consumers.

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APPENDICES

Appendix 1

Ethics approval: Phase 1 (Chapter 3.3)

Appendix 1 – Ethics approval (Monash University)



Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date: 12 June 2012

Project Number: CF12/1553 – 2012000844

Project Title: International survey of health literacy education provided within pharmacy curricula

Chief Investigator: Dr Safeera Hussainy

Approved: From: 12 June 2012 To: 12 June 2017

Terms of approval

1. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. **Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.**
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.



Professor Ben Canny
Chair, MUHREC

cc: Mr Gregory Duncan, Mr Kevin McNamara, Assoc Prof Kay Stewart, Mr Glen Swinburne

Appendix 2

Phase 1 (Chapter 3) supplementary material

- Survey advertisement
- Explanatory statement
- Survey tool

Appendix 2 – Survey advertisement

Survey advertisement

Researchers at the Centre for Medicine Use and Safety at Monash University in Australia are conducting a survey on the current state of health literacy education provided to pharmacy students worldwide. If you are part of a university or academic organisation that offers pharmacy education, you are invited to participate in the survey regardless of whether your organisation does or does not currently teach health literacy.

The survey can be accessed at
https://www.surveymonkey.com/s/academic_health_literacy

Appendix 2 – Explanatory statement

Explanatory Statement

International survey of health literacy education provided within pharmacy curricula.

This online survey is being conducted by the Centre for Medicine Use and Safety at Monash University as part of PhD research by myself, **Glen Swinburne B.Pharm (Hons)**, in conjunction with my primary supervisor, **Dr. Safeera Hussainy**, a Lecturer in the Centre. We have funding from the Commonwealth of Australia as represented by the Department of Health and Ageing through the Fifth Community Pharmacy Agreement to explore educational resources and approaches in Health Literacy in professional degrees of pharmacy as part of a wider project.

Why you were chosen to participate in this survey.

It is hoped that this survey will allow a greater insight into the teaching of Health Literacy, and inform future development of Health Literacy educational resources for pharmacists and pharmacy assistants. Thus, as an academic pharmacist or non-pharmacist academic you have been asked to participate in this survey due to your expertise in this subject.

The aim/purpose of the research

The aim of this study is to collect data on the current state of health literacy education provided to pharmacy students worldwide.

Possible benefits

There may be no direct personal benefit from participating in this survey, although participation will provide researchers with valuable information regarding the current state of health literacy education that will be used to inform the development of a health literacy education package for community pharmacists and pharmacy staff. Ultimately, the intended outcome would be to reduce the burden that poor health literacy has on the individual and society in general.

How long will it take to complete the survey?

It is expected the survey will take between 15 to 30 minutes to complete, although this will be dependent on the amount of information that participants supply.

The survey is being offered through the Academic Section of the International Pharmaceutical Federation and can be accessed at:

https://www.surveymonkey.com/s/academic_health_literacy

Inconvenience/discomfort

The only foreseeable inconvenience is the time spent to complete the survey.

If you have any questions or you would like to talk to someone about the research project you are free to contact me or my supervisors on the contact details listed below.

Being in this study is voluntary and you are under no obligation to consent to participation. However, if you do consent to participate, you may withdraw from further participation at any stage but you will only be able to withdraw data before electronically submitting your response.

Confidentiality

You may choose to provide your contact details for follow-up on Health Literacy educational resources used within your institution. This information will not be publicly accessible and will only be used to contact you for more information on educational resources used. Any published information will reflect aggregate and de-identified data.

Storage of data

Data collected will be stored in accordance with Monash University regulations, kept on University premises at the Centre for Medicine Use and Safety, in a locked filing cabinet for five years. Electronic copies will be stored in a password protected environment that only research investigators can access. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Results

Outcomes of this research will be reported in academic pharmacy journal publications and presentations to professional organisations and conferences.

If you would like to contact the researchers about any aspect of this study, please contact the Supervisor:	If you have a complaint concerning the manner in which this research <insert your MUHREC project number here> is being conducted, please contact:
Glen Swinburne B.Pharm (Hons) Centre for Medicine Use and Safety Monash University 381 Royal Pde Parkville, VIC 3052	Executive Officer Monash University Human Research Ethics Committee (MUHREC) Building 3e Room 111 Research Office

Australia

[REDACTED]
[REDACTED]

Dr Safeera Hussainy

Centre for Medicine Use and Safety
Monash University
381 Royal Pde
Parkville, VIC 3052
Australia

[REDACTED]
[REDACTED]

Mr Gregory Duncan

Eastern Health Clinical School
Faculty of Medicine, Nursing and Health
Services
Monash University
5 Arnold St
Box Hill VIC 3128

[REDACTED]
[REDACTED]

Monash University VIC 3800

[REDACTED] [REDACTED]
[REDACTED]
[REDACTED]

Appendix 2 – Survey tool

Survey tool for the international survey of health literacy education within schools of pharmacy.

- 1) In which country do you work? (Required)
- 2) With which university or academic organisation do you hold this position? (Optional)
- 3) If applicable, what type of pharmacy degree do you teach within? BPharm (Bachelor of Pharmacy)/MPharm (Master of Pharmacy)/PharmD (Doctor of Pharmacy)/Other. (Required)
- 4) What is your position or role within the university or academic organisation? (Optional)
- 5) This survey explores the teaching of Health Literacy in Pharmacy Schools. As this term may not be used in all settings, a useful definition is: *Health literacy is the ability of people to obtain, understand and use health information to promote and maintain health.* Are other terms used to describe the concept of Health Literacy in your country? Please list:

- _____
- _____
- _____
- _____

- 6) Is the concept of Health Literacy explicitly taught by your university or academic organisation? Yes/No

(if you answered 'Yes', please complete Questions 7-20)

No (if you answered 'No', please go to Question 21).

- 7) In what context is Health Literacy taught?
 - Explicitly as stand-alone topic
 - Explicitly, integrated into various components (e.g. communication, counselling)
 - Not explicitly; implied in other course content

- Other: _____

8) At what stage in the pharmacist career does your university or academic organisation deliver Health Literacy training? (Select all that apply; select Not Applicable [NA] if your organisation is not involved in training at that level)

Year 1 undergraduate	☐	NA ☐
Year 2 undergraduate	☐	NA ☐
Year 3 undergraduate	☐	NA ☐
Year 4 undergraduate	☐	NA ☐
Year 5 undergraduate	☐	NA ☐
Year 6 undergraduate	☐	NA ☐
Optional undergraduate elective	☐	NA ☐
Professional internship year	☐	NA ☐
Continuing education for all pharmacists	☐	NA ☐
Postgraduate qualification	☐	NA ☐
For specialised pharmacist roles	☐	NA ☐
Pharmacy technician/pharmacy assistant training	☐	NA ☐

9) What is the main method of teaching Health Literacy in your university or academic organisation? (Select one option)

- Lectures
- Small-group learning, e.g. tutorials, workshops
- Self-directed learning (including online materials)
- Experiential learning (i.e. clinical practice; practice-based learning)
- Other: _____

10) What are the other additional methods of teaching are used to complement the main method? (Select all options that apply)

- Lectures
- Small-group learning, e.g. tutorials, workshops
- Self-directed learning (including online materials)
- Experiential learning, i.e. clinical practice, practice-based learning
- Other: _____

11) In your university or academic organisation, is Health Literacy taught

- To Pharmacy students/pharmacists separate to other professions?
- In an interprofessional learning environment (more than one profession taught together)?

12) What is/are the background(s) of the person(s) leading or coordinating Health Literacy teaching in your university or academic organisation? (Select all options that apply)

- Pharmacist academic
- Pharmacist teacher/practitioner
- Sociologist
- Psychologist
- Other social scientist
- Medical academic
- Medical practitioner
- Other: _____

13) What were the key drivers/reasons for inclusion of Health Literacy in the curriculum in your university or academic organisation? (Select all that apply)

- National/State curriculum standards dictated by an accreditation body or official organisation)
- Professional practice or competency standards
- Part of the scope of practice for pharmacists in this country

- Motivation of individual staff members
- Direction from administration/management
- Other: _____

14) Which of the following elements are included in the Health Literacy curriculum in your university or academic organisation? (Select all that apply)

- Definitions of Health Literacy [e.g.... Institute of Medicine; World Health Organisation definitions]
- Health Literacy concepts
- Awareness of Health Literacy by health professionals
- Raising awareness of Health Literacy in consumers
- How to assess Health Literacy capacity of consumers
- How to target communication to consumers' Health Literacy needs
- Assessment of Health Literacy suitability of educational materials (e.g. consumer information leaflets and other resources)
- Assessment of Health Literacy of students
- Health Literacy and culturally and linguistically-diverse consumers
- Health Literacy in special settings (schools, nursing homes, etc.)
- Health Literacy issues for pharmacy staff (including technicians and assistants)
- Other: _____

15) How does your university or academic organisation assess learning outcomes following delivery of Health Literacy education or training? (select all that apply)

- Written examination
- Oral examination (viva voce)
- Individual written assignment tasks
- Group written assignment tasks
- Presentations

- Task-oriented assessments (OSCE, practical exams)
- Experiential placement assessment by preceptor/supervisor
- Not assessed
- Other: _____

16) Do you use any textbooks or other resources to assist learners to understand the concept of Health Literacy? Yes/No

17) If you answered yes, please list the textbooks or resources.

18) Do you use any textbooks or other resources to illustrate methods or strategies that can be employed to teach the concept of Health Literacy? Yes/No

19) If you answered yes, please list textbooks or resources.

20) This project also seeks to review Health Literacy educational material and resources to assess common effective educational strategies in Health Literacy, for the purposes of developing an educational package for community pharmacists and pharmacy assistants in Australia.

With consent, we would be very grateful to have access to your curriculum or educational resources (de-identified if you wish) to be included in our review. A summary of the nature, extent and impact of various resources reviewed will be published in the pharmacy education literature. No materials created or developed by any institution or individual will be used in any way other than the summary review, without explicit permission of the appropriate person.

If you consent to be contacted regarding your curriculum, materials and resources, please provide the following contact information.

a) Title and Name

- Position
- Organisation and address
- Email address
- Brief summary of potential resources

If you answered 'Yes' to Question 6, you have now completed the questionnaire. Thank you for your participation.

21) Do you believe that dedicated Health Literacy training or education should be delivered by your university or academic organisation? Yes/No

22) Please provide reasons for your answer to Question 21

If you answered 'No' to question 21, you have now completed the questionnaire.
Thank you for your participation.

If you answered 'Yes' to Question 21, please answer questions 23-26.

23) In pharmacy practice education, at what stage do you believe Health Literacy should be delivered? (Select all that apply, select NA if not relevant to your university or academic organisation)

- | | | |
|---|--------------------------|-----------------------------|
| Year 1 Undergraduate | ☐ | NA ☐ |
| Year 2 Undergraduate | ☐ | NA ☐ |
| Year 3 Undergraduate | ☐ | NA ☐ |
| Year 4 Undergraduate | ☐ | NA ☐ |
| Year 5 Undergraduate | ☐ | NA ☐ |
| Year 6 Undergraduate | ☐ | NA ☐ |
| Optional undergraduate elective | ☐ | NA ☐ |
| Professional internship year | ☐ | NA ☐ |
| Continuing education for all pharmacists | ☐ | NA ☐ |
| Postgraduate qualification | ☐ | NA ☐ |
| For specialised pharmacist roles | ☐ | NA ☐ |
| Pharmacy technician/pharmacy assistant training | ☐ | NA ☐ |

24) If you were to introduce Health Literacy education/training, what would be your preferred method(s)? (Select all that apply)

- i) Lectures
- ii) Small-group learning, e.g. tutorials, workshops
- iii) Self-directed learning (including online materials)
- iv) Experiential learning, i.e. clinical practice, practice-based learning
- v) Other: _____

25) What elements of Health Literacy would you include in the curriculum? (Select all that apply)

- i) Definitions of Health Literacy [e.g.... Institute of Medicine; World Health Organisation definitions]
- ii) Health Literacy concepts
- iii) Awareness of Health Literacy by health professionals
- iv) Raising awareness of Health Literacy in consumers
- v) How to assess Health Literacy capacity of consumers
- vi) How to target communication to consumers' Health Literacy needs
- vii) Assessment of Health Literacy suitability of educational materials (e.g. consumer information leaflets and other resources)
- viii) Assessment of Health Literacy of students
- ix) Health Literacy and culturally and linguistically-diverse consumers
- x) Health Literacy in special settings (schools, nursing homes, etc.)
- xi) Health Literacy issues for pharmacy staff (including technicians and assistants)
- xii) Other: _____

26) How would you suggest Health Literacy be assessed within the curriculum? (Select all that apply)

- i) Written examination

- ii) Oral examination (viva voce)
- iii) Individual written assignment tasks
- iv) Group written assignment tasks
- v) Presentations
- vi) Task-oriented assessments (OSCE, practical exams)
- vii) Experiential placement assessment by preceptor/supervisor
- viii) Other: _____

Thank you for your participation

Appendix 3

Ethics approval: HeLP phase (Chapter 3)

Appendix 3 – Ethics approval (Monash University)



MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date: 29 April 2013

Project Number: CF13/479 - 2013000212

Project Title: A controlled trial of a health literacy education program in community pharmacies

Chief Investigator: Mr Gregory Duncan

Approved: From: 29 April 2013 To: 29 April 2018

Terms of approval

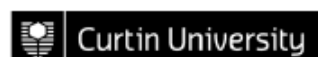
1. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. **Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.**
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.



Professor Ben Canny
Chair, MUHREC

cc: Dr Safeera Hussainy, Mr Kevin McNamara, Assoc Prof Kay Stewart, Mr Glen Swinburne

Appendix 3 – Ethics approval (Curtin University)



Memorandum

To	Lynne Emmerton, Sam Elhebir, Jeff Hughes, Moyez Jiwa, Kreshnik Hoti
From	Alison Smith, Form C Coordinator
Subject	Protocol Approval PH-18-13
Date	10 June 2013
Copy	

Office of Research and Development
Human Research Ethics Committee

Telephone 9266 2784
Facsimile 9266 3793
Email hrec@curtin.edu.au

Thank you for your "Form C Application for Approval of Research with Low Risk (Ethical Requirements)" for the project titled *"A controlled trial of health literacy education program in community pharmacies"*. On behalf of the Human Research Ethics Committee, I am authorised to inform you that the project is approved.

Approval of this project is for a period of 4 years 18/06/2013 to 18/06/2017.

Your approval has the following conditions:

- (i) Annual progress reports on the project must be submitted to the Ethics Office.
- (ii) It is your responsibility, as the researcher, to meet the conditions outlined above and to retain the necessary records demonstrating that these have been completed.

The approval number for your project is PH-18-13. Please quote this number in any future correspondence. If at any time during the approval term changes/amendments occur, or if a serious or unexpected adverse event occurs, please advise me immediately.

Sincerely,



Research & Development Support Coordinator
School of Pharmacy

Please Note: The following standard statement must be included in the information sheet to participants:
This study has been approved under Curtin University's process for lower-risk Studies (Approval Number PH-18-13). This process complies with the National Statement on Ethical Conduct in Human Research (Chapter 5.1.7 and Chapters 5.1.18-5.1.21). For further information on this study contact the researchers named above or the Curtin University Human Research Ethics Committee. c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth 6845 or by telephoning 9266 9223 or by emailing hrec@curtin.edu.au.

Appendix 3 – Ethics approval (The University of Sydney)

From: [Human Ethics](#)
To: [Betty Chaar](#)
Cc: [Kim Bellamy](#); Lynne.Emmerton@curtin.edu.au
Subject: 2013/421 - HREC application outcome
Date: Wednesday, May 22, 2013 4:56:41 PM

Dear Dr Chaar

Project Title: A controlled trial of a health literacy education program in community pharmacies

Project No: 2013/421

Under the National Statement on Ethical Conduct in Human Research (2007), institutions have the responsibility to ensure that ethical reviews are not unnecessarily duplicated.

According to the University of Sydney Procedures recognition of approval from external ethics committees is required where one or both of the following apply:

- (a) Research involves a University of Sydney student as a researcher;
- (b) Recruitment of participants and collection of data occur on a University of Sydney campus (excludes clinical campuses which are located within a NSW Health facility).

Your project does not require review by the University of Sydney Human Research Ethics Committee (HREC). The HREC acknowledges your right to proceed under the authority of Monash University Human Research Ethics Committee

Please do not hesitate to contact Research Integrity (Human Ethics) should you require further information or clarification.

Regards,
Human Ethics Administration
The University of Sydney

Appendix 4

HeLP phase (Chapter 3) supplementary material

- Letters of invitation
- Permission letters
- Explanatory statements
- Consent forms

Appendix 4 – Letter of invitation (Monash University)



February 2013

Document title: Letter of Invitation

Attention: Pharmacy owner or pharmacy manager

Re: A controlled trial of a health literacy education program in community pharmacies

Dear Pharmacy owner/manager

I am a researcher undertaking a PhD at Monash University. My supervisors are Dr Safeera Hussainy, Associate Professor Kay Stewart, Mr Kevin McNamara and Mr Gregory Duncan. I am writing to you regarding a research project being conducted by the Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, into developing and providing health literacy education resources to pharmacist and pharmacy assistants in community pharmacies in Australia. This project will form part of the research towards attainment of the degree of Doctor of Philosophy (PhD).

This project aims to develop and evaluate a health literacy educational resource to implement in Australian community pharmacies to provide education on health literacy, in particular utilising appropriate communication techniques to interact with consumers with low health literacy. The project will involve videotaping the consultation between pharmacists or pharmacy staff, and consumers in an attempt to investigate various aspects relating to communication methods used when interacting with consumers. It will also use mystery shoppers to determine in a real-life setting which communication methods are being employed when interacting with consumers, particularly those exhibiting difficulties understanding health and medication information. Information obtained will lead to the refinement of the health literacy educational resource to enhance its appropriateness and usability for wider implementation in the future.

Attached to this letter is an explanatory statement that provides further details about participating in this project. The researchers would also like to have the opportunity to further explain this project in greater detail by requesting a face-to-face meeting or telephone meeting at a time convenient to you. Please contact me on the details provided below to accept or decline this invitation.

Should you have any questions about the project in the meantime, please feel free to contact me. Additionally, my academic supervisors, Dr Safeera Hussainy and Gregory Duncan, will also be available to answer any questions you may have.

I look forward to hearing from you soon.

Sincerely,
Glen Swinburne

Mr. Glen Swinburne
Pharmacist, PhD
Candidate
Department of Pharmacy
Practice, Centre for
Medicine Use and Safety
Monash University

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Dr Safeera Hussainy
Lecturer,
Academic Supervisor
Department of Pharmacy
Practice, Centre for
Medicine Use and Safety
Monash University

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Mr. Gregory Duncan
Senior Researcher
Eastern Health Clinical
School
Faculty of Medicine,
Nursing and Health
Services
Monash University

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Appendix 4 – Letter of invitation (Curtin University)



May 2013

Document title: Letter of Invitation

Attention: Pharmacy owner or pharmacy manager

Re: A controlled trial of a health literacy education program in community pharmacies

Dear Pharmacy owner/manager

I am writing to you regarding a research project being conducted collaboratively by the Schools of Pharmacy at Curtin University, Monash University, and University of Sydney, on **developing and providing health literacy education resources to pharmacists and pharmacy assistants**. We are writing to offer your pharmacy the opportunity to receive this training, and to receive Continuing Professional Development points upon its completion.

This project aims to produce and trial an educational package that trains pharmacists and staff in how to detect and respond to consumers who are struggling to find, understand and/or use health-related information, a problem that affects around 50% of the Australian population. Following the training, if your pharmacy and clients are agreeable, a research officer will observe a limited number of in-store consultations, but only to review the communication elements: the signs of understanding and the effectiveness of techniques to improve the person's understanding. It will also use four mystery shopper visits to reflect on this without the presence of an observer. There are no 'right or wrong' scores for these parts of the project, as we will only be using the information to improve the training package.

Enclosed is an information sheet that provides further details about this project. I would also like to have the opportunity to further explain this project face-to-face or by telephone at a time convenient to you. Please contact me on the details provided below to accept or decline this invitation.

Should you have any questions about the project in the meantime, please feel free to contact me. This project has been approved by the Curtin University Human Research Ethics Committee (Approval Number: XXXX). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral

carers. Its main role is to protect participants. The Human Research Ethics Committee (Secretary) may be contacted should participants wish to make a complaint on ethical grounds. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au. I look forward to hearing from you soon.

Sincerely,

Dr Elsamaul (Sam) Elhebir
Senior Research Officer | School of
Pharmacy
Faculty of Health Science | Curtin
University

[Redacted signature block]

Associate Professor Lynne
Emmerton
Director of Research Training |
School of Pharmacy
Faculty of Health Science | Curtin
University

[Redacted signature block]

Appendix 4 – Letter of invitation (The University of Sydney)



THE UNIVERSITY OF
SYDNEY

Dr Betty Chaar
Room N508-Bldg A15
Faculty of Pharmacy
University of Sydney
NSW 2006
Australia

████████████████████
████████████████████

Letter of Invitation to Pharmacy owner/manager

A CONTROLLED TRIAL OF A HEALTH LITERACY EDUCATION PROGRAM IN
COMMUNITY PHARMACIES

Researchers: Dr Betty Chaar (University of Sydney), Mr Gregory Duncan (Monash University), Lynne Emmerton (Curtin University), Mr Glen Swinburne (Monash University), and Research Assistant Miss Kim Bellamy (University of Sydney)

Dear Pharmacy owner/manager:

We are a research team at the Faculty of Pharmacy, University of Sydney, and have acquired your contact details from the Yellow Pages. I am writing to you regarding a research project being conducted collaboratively by the Schools of Pharmacy at Sydney University, Curtin University, and Monash University, on developing and providing health literacy education resources to pharmacists and pharmacy assistants in community pharmacies in Australia. This project is being funded by the Department of Health and Ageing, through the Fifth Community Pharmacy Agreement.

This project aims to develop and evaluate a health literacy educational resource to implement in Australian community pharmacies to provide education on health literacy, in particular utilising appropriate communication techniques to interact with consumers with low health literacy. The project will involve conducting a short survey with consumers before and after a consultation with a pharmacy staff member, in an attempt to investigate various aspects relating to communication methods used by pharmacy staff when interacting with consumers. It will also use mystery shoppers to determine in a real-life setting which communication methods are being employed when interacting with consumers, particularly those exhibiting difficulties understanding health and medication information. Data collected will lead to the refinement of the health literacy educational resource to enhance its appropriateness and usability for wider implementation in the future.

The Research Assistant Kim Bellamy will contact you shortly by telephone to find out if you are interested in partaking in this study. The researchers would also like to

have the opportunity to further explain this project in greater detail by requesting a face-to-face meeting or telephone meeting at a time convenient to you.

Should you have any questions about the project in the meantime, please feel free to contact Kim Bellamy [REDACTED] Additionally Dr Betty Chaar and Gregory Duncan will also be available to answer any questions you may have.

Yours sincerely,

[REDACTED]

Kim Bellamy

Kim Bellamy
Room S303 - Building A15
Faculty of Pharmacy
University of Sydney NSW

[REDACTED]
[REDACTED]
[REDACTED]

Mr. Gregory Duncan
Eastern Health Clinical School
Faculty of Medicine, Nursing and Health
Services
Monash University Victoria

[REDACTED]
[REDACTED]

Mr. Glen Swinburne
Department of Pharmacy Practice,
Centre for Medicine Use and Safety
Monash University Victoria

[REDACTED]
[REDACTED]

Appendix 4 – Permission letter (Monash University)



Permission Letter for project: A controlled trial of a health literacy education program in community pharmacies

Date:

Glen Swinburne
Pharmacist and PhD Candidate
Department of Pharmacy Practice
Centre for Medicine Use and Safety
Faculty of Pharmacy and Pharmaceutical Sciences,
Monash University (Parkville Campus)
381 Royal Parade
Parkville VIC 3052

Dear **Glen Swinburne**

Thank you for your request to recruit participants from **<insert name of pharmacy>** for the above-named research.

I have read and understood the letter of invitation regarding the research **<insert project number>** and hereby give permission for this research to be conducted in the pharmacy premises.

<Please include any stipulations / clauses the pharmacy may have about recruitment of human participants>.

Yours Sincerely,

<insert signature of pharmacy owner/manager (Group 1 participants)>

<insert name of the above signatory>

<insert above signatory's position>

Appendix 4 – Permission letter (Curtin University)



Permission Letter for project: A controlled trial of a health literacy education program in community pharmacies

Date:

Dr Elsamaul (Sam) Elhebir
Senior Research Officer | School of
Pharmacy
Faculty of Health Science | Curtin
University

[Redacted]
[Redacted]
[Redacted]

Associate Professor Lynne Emmerton
Director of Research Training | School of
Pharmacy
Faculty of Health Science | Curtin
University

[Redacted]
[Redacted]

Dear **Sam**

Thank you for your request to recruit participants from **<insert name of pharmacy>** for the above-named research.

I have read and understood the letter of invitation regarding the research **<insert project number>** and hereby give permission for this research to be conducted in the pharmacy premises.

<Please include any stipulations / clauses the pharmacy may have about recruitment of human participants>.

Yours sincerely,

<insert signature of pharmacy owner/manager (Group 1 participants)>

<insert name of the above signatory>
<insert above signatory's position>

Appendix 4 – Permission letter (The University of Sydney)



Permission Letter for project: A Controlled Trial of a Health Literacy Education Program in Community Pharmacies

Date:

Kim Bellamy

Faculty of Pharmacy

Room N508-Building A15

University of Sydney NSW 2006

[Redacted]

[Redacted]

Dr Betty Chaar

Faculty of Pharmacy

Room N508-Building A15

University of Sydney NSW 2006

[Redacted]

[Redacted]

Dear **Kim**,

Thank you for your request to recruit participants from **<insert name of pharmacy>** for the above-named research.

I have read and understood the letter of invitation regarding the research **<insert project number>** and hereby give permission for this research to be conducted in the pharmacy premises.

<Please include any stipulations / clauses the pharmacy may have about recruitment of human participants>.

Yours Sincerely,

<insert signature of pharmacy owner/manager>

<insert name of the above signatory>

<insert above signatory's position>

Appendix 4 – Explanatory statement (Monash University)

Explanatory Statement: Pharmacy owner/manager and pharmacy staff members

Project Title: A controlled trial of a health literacy education program in community pharmacies

This information sheet is for you to keep.

My name is **Glen Swinburne B.Pharm (Hons)** and I am conducting a research project with **Dr Safeera Hussainy, Associate Professor Kay Stewart and Mr Kevin McNamara** at the Centre for Medicine Use and Safety, Department of Pharmacy Practice, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, and **Mr Gregory Duncan** at the Faculty of Medicine, Nursing and Health Sciences, Monash University. I am conducting this research project towards a Doctor of Philosophy at Monash University. This means that I will be writing a thesis which is the equivalent of a 300 page book. A report of the project may also be submitted for publication in a journal or be presented at a conference. The project is funded under the Fifth Community Pharmacy Agreement, managed by the Pharmacy Guild of Australia.

Why did you choose this particular person/group as participants?

The research project aims to develop and implement health literacy educational resources for pharmacists and pharmacy assistants. The participants for this project are pharmacists, pharmacy assistants and consumers.

The developed health literacy educational resources require evaluation within the pharmacy setting prior to wider dissemination, and thus you've been selected to participate in this evaluation. The project will also involve the use of mystery shoppers to assess the changes in behaviour and communication methods of pharmacists and pharmacy staff in a real-life simulation.

The pharmacies that have been chosen to take part in this project have been chosen at random. The details of the pharmacies have been obtained from publically available directories. The pharmacy staff member (pharmacy assistant and/or pharmacist) who will approach the mystery shopper will also be random and the identity of that pharmacy staff member will remain anonymous.

The aim/purpose of the research

The aim of the study is to assess the effectiveness of a health literacy educational resource to improve pharmacy staff knowledge of health literacy, and educate staff

on appropriate communication measures to adopt when interacting with consumers, known as universal precautions in health literacy.

This information will lead to refinement of the educational resources to maximise their usability and appropriateness for wider implementation in the future.

Possible benefits

Pharmacy staff may develop improved communication skills allowing for more effective and appropriate interactions with consumers of varying levels of health literacy. It may improve consumer understanding of medications and advice provided by pharmacy staff.

What does the research involve?

Participation in this project involves an initial training, either online or face-to-face with a researcher, where a pharmacist nominated by the pharmacy will attend the session and will receive training on health literacy and how to deliver the education program to pharmacy staff in-house. The trained pharmacist will then organise training sessions with pharmacy staff to deliver the training using the provided resources. Those undertaking training will be asked to complete a survey of knowledge and perceptions around health literacy.

Pharmacists and pharmacy staff members will be videotaped during consultations with consumers both before and after receiving the health literacy training. Demographic and health information will be collected from consumers who agree to be involved in the study, and will also be interviewed after the consultation in private to assess their understanding of the information supplied, as well as their perceptions of the consultation.

Pharmacists will also be asked to give permission to have mystery shopper visits to the pharmacy premises on four occasions, twice before training, and twice again after the in-house training. The mystery shoppers will have been trained in the case vignette that they will be required to role play. No additional involvement is required by the pharmacy or pharmacy staff. The pharmacy staff members (pharmacy assistants/pharmacists) who will serve the mystery shopper will be blinded to the mystery shopper visit and will just be required to perform the normal tasks as specified in their job description. The pharmacy will not know when the mystery shopper will be visiting and the pharmacy staff members will not know if the patient they are serving is a mystery shopper.

How much time will the research take?

The time allocated to explain this project to you is approximately 30 minutes. The initial training session for the pharmacist will take around 4-5 hours. The in-house

training of other pharmacy staff will take around 3-4 hours, and can be delivered in smaller segments over a period of time. Videotaping will take approximately 3 hours. The time allocated for the pharmacy staff members and mystery shopper visits is 5-10 minutes, however theoretically no additional time will be required by the staff members as they will be performing their work as they normally would.

Inconvenience/discomfort

There are no foreseeable risks other than the inconvenience of your time required.

If you become upset or distressed as a result of your participation in the project, the researcher is able to arrange for counselling or other appropriate support. Any counselling or support will be provided by staff who are not members of the research team and include Lifeline Australia who can be contacted on 13 11 14.

If you have any questions or you would like to talk to someone about the research project you are free to contact me or my supervisors on the contact details listed below.

Can I withdraw from the research?

Participation in this research project is voluntary and you are under no obligation to participate. If you decide to take part and later change your mind, you are free to withdraw from the project. Please notify the researchers immediately if you wish to withdraw from this research project.

Confidentiality

All the information collected from individual participants during the course of this project will be kept confidential. In any publication and/or presentation information will be provided in such a way that you cannot be identified. Details of the pharmacy staff members who speak to the mystery shoppers will not be recorded and these participants will remain anonymous.

Storage of data

Storage of the data collected will adhere to the University regulations and kept on University premises in a locked cupboard/filing cabinet for 5 years.

Use of data for other purposes

It is not intended that this data be used for any other purpose for which it is primarily obtained.

Results

If you would like to be informed of the aggregate research finding, please contact myself or my supervisors (see below). The findings will be accessible after all data is collected.

If you would like to contact the researchers about any aspect of this study, please contact the Supervisor:	If you have a complaint concerning the manner in which this research <insert your MUHREC project number here> is being conducted, please contact:
Glen Swinburne B.Pharm (Hons) Centre for Medicine Use and Safety Monash University 381 Royal Pde Parkville, VIC 3052 Australia [REDACTED] [REDACTED] Dr Safeera Hussainy Centre for Medicine Use and Safety Monash University 381 Royal Pde Parkville, VIC 3052 Australia [REDACTED] [REDACTED] Mr Gregory Duncan Eastern Health Clinical School Faculty of Medicine, Nursing and Health Services Monash University 5 Arnold St Box Hill VIC 3128 [REDACTED] [REDACTED]	Executive Officer Monash University Human Research Ethics Committee (MUHREC) Building 3e Room 111 Research Office Monash University VIC 3800 [REDACTED] [REDACTED] [REDACTED] [REDACTED]

Appendix 4 – Explanatory statement (Curtin University)



Information Sheet: Pharmacy owner/manager and pharmacy staff members

Project Title: A controlled trial of a health literacy education program in community pharmacies

This information sheet is for you to keep.

I am writing to you regarding a research project being conducted collaboratively by the Schools of Pharmacy at Curtin University, Monash University, and University of Sydney, on developing and providing health literacy education resources to pharmacist and pharmacy assistants in community pharmacies in Australia. The project has been funded by the Pharmacy Guild of Australia via the 5th Community Pharmacy Agreement

Why did we choose your pharmacy?

The research project aims to develop and implement health literacy educational resources for pharmacists and pharmacy assistants. The participants for this project are pharmacists, pharmacy assistants and consumers.

The developed health literacy educational resources require evaluation within the pharmacy setting prior to wider use, and you've been selected to participate in this evaluation. The project will also involve four mystery shopper visits to assess the changes in behaviour and communication methods of pharmacists and pharmacy staff in a real-life simulation.

The pharmacies invited to take part in this project have been chosen at random. The details of the pharmacies have been obtained from publicly available directories. The pharmacy staff member(s) (pharmacy assistant and/or pharmacist) receiving the mystery shopper visit(s) will also be random, and the identity of that staff member is not of interest to the study.

The aim/purpose of the research

This project aims to assess the effectiveness of a health literacy training package to improve how pharmacy staff detects cases of limited health literacy amongst their clients, and how these challenges are managed.

This information will help us refine the educational resources before they are offered more widely.

Possible benefits

Pharmacy staff may develop improved skills in dealing with consumers of varying levels of health literacy. This may indirectly improve consumers' understanding of medications and health advice, although this will not be measured in this project.

What does the research involve?

Participation in this project involves training, either online or face-to-face with the research team. The trained staff will be taught how to then train the rest of their staff using the provided resources. Those undertaking training will be asked to complete a survey of knowledge and perceptions around health literacy, and features of their pharmacy that help consumers with health information.

A research officer will observe and audiotape (if both staff and consumer agree) a limited number of in-store consultations before and after the health literacy training. Demographic and basic health information will be collected from consumers who agree to be involved in the study, and these consumers will also be interviewed after the consultation in private to assess their understanding of the information supplied, as well as their perceptions of the consultation.

Pharmacists will also be asked permission to receive four mystery shopper visits to the pharmacy, twice before training, and twice again after the in-house training. No additional involvement is required by the pharmacy or pharmacy staff, and there are no right or wrong scores for how the mystery shopper is dealt with; we are only interested in whether the training appears to have been effective. The staff will be notified following each mystery shopper visit.

How much time will the research take?

The initial training session will take around 4-5 hours. The in-house training of other pharmacy staff will take around 3-4 hours, and is designed to take place in smaller segments over several weeks. The complete training has been accredited for Continuing Professional Development points. The research officer will be in the pharmacy for approximately 3-4 hours.

Inconvenience/discomfort

There are no foreseeable risks other than the inconvenience of your time required.

This project has been approved by the Curtin University Human Research Ethics Committee (Approval Number: XXXX). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. The Human Research Ethics Committee (Secretary) may be contacted should participants wish to make a complaint on ethical grounds. If

needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by

Can I withdraw from the research?

Participation in this research project is voluntary, and you and your staff are under no obligation to participate. If you decide to take part and later change your mind, you are free to withdraw from the project. Please notify the researchers immediately if you wish to withdraw from this research project.

Confidentiality

All the information collected from individual participants during the course of this project will be kept confidential. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. Details of the pharmacy staff members who speak to the mystery shoppers will not be recorded and these participants will remain anonymous.

Storage of data

Storage of the data collected will adhere to the University regulations and kept on University premises in a locked cupboard/filing cabinet for 5 years.

Use of data for other purposes

It is not intended that this data be used for any other purpose for which it is primarily obtained.

Results

If you would like to be informed of the aggregate research finding, please contact myself or my supervisors (see below). The findings will be accessible after all data is collected.

Dr Elsamaul (Sam) Elhebir

Senior Research Officer | School of Pharmacy
Faculty of Health Science | Curtin University

Associate Professor Lynne Emmerton

Director of Research Training | School of Pharmacy
Faculty of Health Science | Curtin University

Professor Jeff Hughes

Head | School of Pharmacy
Faculty of Health Science | Curtin University

Dr Kreshnik Hoti

Lecturer | School of Pharmacy
Faculty of Health Science | Curtin University

Professor Moyez Jiwa

Chair Health Innovation – Chronic
Disease
Curtin Health Innovation Research
Institute (CHIRI)



Appendix 4 – Explanatory statement (The University of Sydney)



THE UNIVERSITY OF
SYDNEY

Dr Betty Chaar

Room S303-Bldg A15

Faculty of Pharmacy

University of Sydney

NSW 2006

Australia



A CONTROLLED TRIAL OF A HEALTH LITERACY EDUCATION PROGRAM IN COMMUNITY PHARMACIES

Participant Information Statement

(1) What is the study about?

Health literacy refers to the ability of individuals to obtain, understand, and apply health care information in written, spoken or digital format, and subsequently make appropriate health-related decisions.¹ Without adequate health literacy, consumers may not understand what a health care professional has told them about their condition, be able to follow written and verbal instructions, be capable of reading labels on medication packaging, or be able to understand and apply health information presented in posters or brochures.² Low health literacy is widespread in the community, with up to 60% of Australians potentially lacking the skills needed to manage their health or to navigate the health care system.³

Knowledge of how health literacy affects the community, and having the knowledge and skills to address some of those effects will put community pharmacy staff in a strong position to address some of the health effects of low health literacy. In the pharmacy setting, poor Health Literacy can be an impediment to consumers' abilities to clearly articulate the problem for which they are seeking a solution, to appreciate the potential seriousness of the problem that they have, and accept advice for referral to their doctor or another health care professional. However, the health

literacy of the pharmacy staff member engaged in the interaction with the person also has the potential to influence the outcome of the encounter, and the staff member may not be able to identify the need or persuade the person to see their doctor.

The research project aims to assess the effectiveness of a health literacy educational resource to improve pharmacy staff knowledge of health literacy, and educate staff on appropriate communication measures to adopt when interacting with consumers, known as universal precautions in health literacy.

The developed health literacy educational resources require evaluation within the pharmacy setting prior to wider distribution, and thus you've been asked to participate in this evaluation. The project will also involve the use of mystery shoppers to assess the changes in behaviour and communication methods of pharmacists and pharmacy staff in a real-life simulation.

The pharmacies that have been chosen to take part in this project have been chosen at random. The details of the pharmacies have been obtained from publically available directories. The pharmacy staff member (pharmacy assistant and/or pharmacist) who will be approached by the mystery shopper will also be random and the identity of that pharmacy staff member will remain anonymous.

(2) Who is carrying out the study?

The study is being conducted by a research team comprised of: Dr Betty Chaar (University of Sydney), Mr Gregory Duncan (Monash University), Mr Glen Swinburne (Monash University), Associate Professor Lynne Emmerton (Curtin University), and Research Assistant Miss Kim Bellamy (University of Sydney).

(3) What does the study involve?

Participation in this project involves an initial training, either online or face-to-face with a researcher, where a pharmacist nominated by the pharmacy will attend the session and will receive training on health literacy and how to deliver the education program to pharmacy staff in-house. The trained pharmacist will then organise training sessions with pharmacy staff to deliver the training using the provided

resources. Those undertaking training will be asked to complete a survey of knowledge and perceptions around health literacy.

Pharmacists and pharmacy staff members will be observed during consultations with consumers both before and after receiving the health literacy training. Demographic and health information will be collected from consumers who agree to be involved in the study, and will also be interviewed after the consultation in private to assess their understanding of the information supplied, as well as their perceptions of the consultation.

Pharmacists will also be asked to give permission to have mystery shopper visits to the pharmacy premises on four occasions, twice before training, and twice again after the in-house training. The mystery shoppers will have been trained in the case vignette that they will be required to role play. No additional involvement is required by the pharmacy or pharmacy staff. The pharmacy staff members (pharmacy assistants/pharmacists) who will serve the mystery shopper will be blinded to the mystery shopper visit and will just be required to perform the normal tasks as specified in their job description. The pharmacy will not know when the mystery shopper will be visiting and the pharmacy staff members will not know if the patient they are serving is a mystery shopper.

(4) How much time will the study take?

The time allocated to explain this project to you is approximately 30 minutes. The initial training session for the pharmacist will take around 4-5 hours. The in-house training of other pharmacy staff will take around 3-4 hours, and can be delivered in smaller segments over a period of time. The time allocated for the pharmacy staff members and mystery shopper visits is 5-10 minutes, however theoretically no additional time will be required by the staff members as they will be performing their work as they normally would.

(5) Can I withdraw from the study?

Participation in this research project is voluntary and you are under no obligation to participate. If you decide to take part and later change your mind, you are free to

withdraw from the project. Please notify the researchers immediately if you wish to withdraw from this research project.

(6) Will anyone else know the results?

All aspects of the study, including results, will be strictly confidential and only the researchers will have access to information on participants. The data collected will be stored in a secure cabinet in the Faculty of Pharmacy for 5 years.

A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

(7) Will the study benefit me?

While no direct benefit currently exists from this study, it will aid in the development of a health literacy educational package in the future that will help pharmacists and pharmacy staff members develop improved communication skills allowing for more effective and appropriate interactions with consumers of varying levels of health literacy. It may improve consumer understanding of medications and advice provided by pharmacy staff.

(8) Can I tell other people about the study?

Yes, you can tell other people about the study.

(9) What if I require further information?

When you have read this information, *Kim Bellamy* will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact *Dr Betty Chaar* [REDACTED] *Gregory Duncan* [REDACTED] [REDACTED], *Glen Swinburne* [REDACTED] *Kim Bellamy* [REDACTED]

(10) Will I be able to find out the results of the study?

If you would like to be informed of the aggregate research finding, please contact a member of the research team. The findings will be accessible after all the data is collected.

(11) What if I have a complaint or concerns?

Any person with concerns or complaints about the conduct of a research study can contact the Deputy Manager, Human Ethics Administration, University of Sydney

[REDACTED]
[REDACTED]

References

- 1) Adams R, Appleton SL, Hill CL, Dodd M, Findlay C, Wilson DH. Risks associated with low functional health literacy in an Australian population. Medical Journal of Australia 2009; 17: 257 - 9.
- 2) Keleher H, Hagger V. Health literacy in primary health care. Australian Journal of Primary Health 2007; 13(2): 24 - 34. DOI:10.1071/PY07020
- 3) Australian Bureau of Statistics. Health Literacy, Australia. Canberra 2008. Report No.: 4233.0.

Appendix 4 – Consent form (Monash University)



A controlled trial of a health literacy education program in community pharmacies
Pharmacy owner/manager consent form

NOTE: This consent form will remain with the Monash University researcher for their records

I agree for the Monash University research project specified above to be conducted in <specify pharmacy>. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records. I understand that agreeing to take part means that I am willing to:

Agree to participate in either face-to-face training or online training on the health literacy program

☐ Yes ☐ No

Agree to facilitate health literacy in-house training sessions to pharmacy staff using the educational resources provided

☐ Yes ☐ No

Agree to be videotaped during consultations with consumers at two designated time points during the study

☐ Yes ☐ No

Agree to two mystery shopper visits prior to receiving health literacy training

☐ Yes ☐ No

Agree to two mystery shopper visits after providing in-house training to pharmacy staff

☐ Yes ☐ No

Agree to not inform other pharmacy staff members of the four mystery shopper visits during the eight month data collection period

☐ Yes ☐ No

and

I understand that participation of the pharmacy is voluntary, and that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project

and

I understand that any data that the researcher extracts from the video data collection or pharmacy mystery shopper visits to use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

and

I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party

and

I understand that data from the collection periods and the mystery shopper visits will be kept in a secure storage and accessible only to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Participant's name:

Signature: _____ Date: _____

Appendix 4 – Consent form (Curtin University)



Curtin University



Curtin University

**CURTIN HEALTH INNOVATION
RESEARCH INSTITUTE**

A controlled trial of a health literacy education program in community pharmacies

Pharmacy owner/manager consent form

NOTE: This consent form will remain with Curtin University researcher for his/her records

I agree for Curtin University research project specified above to be conducted in <specify pharmacy>. I have had the project explained to me, and I have read the Information Sheet, which I keep for my records. I understand that agreeing to take part means that I am willing to:

Agree to participate in either face-to-face training or online training on the health literacy program

☐ Yes ☐ No

Agree to facilitate health literacy in-house training sessions to pharmacy staff using the educational resources provided

☐ Yes ☐ No

Agree to be audiotaped during consultations with consumers at two designated time points during the study (if the consumer also agrees)

☐ Yes ☐ No (you can still participate)

Agree to two mystery shopper visits prior to receiving health literacy training

☐ Yes ☐ No

Agree to two mystery shopper visits after providing in-house training to pharmacy staff

☐ Yes ☐ No

Agree to not inform other pharmacy staff members of the four mystery shopper visits during the eight month data collection period

☐ Yes ☐ No

and

I understand that participation of the pharmacy is voluntary, and that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project

and

I understand that any data that the researcher extracts from the data collection or pharmacy mystery shopper visits to use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

and

I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party

and

I understand that data from the collection periods and the mystery shopper visits will be kept in a secure storage and accessible only to the research team. I also understand that the data will be destroyed after 5 years unless I consent to it being used in future research.

Participant's name:

Signature: _____ Date: _____

Appendix 4 – Consent form (The University of Sydney)



Dr Betty Chaar
Lecturer in Pharmacy Practice
ABN 15 211 513 464

Faculty of Pharmacy
Room S303-Building A15
University of Sydney NSW 2006
AUSTRALIA

[REDACTED]
[REDACTED]

Miss Kim Bellamy

Faculty of Pharmacy
Room S303-Building A15
University of Sydney NSW 2006
AUSTRALIA

[REDACTED]
[REDACTED]

PARTICIPANT (PHARMACIST MANAGER/TRAINER) CONSENT FORM

I,[PRINT NAME], give consent to my participation in the research project

1. TITLE: A Controlled Trial of a Health Literacy Education Program in Community Pharmacies

I understand that agreeing to take part means that I:

Agree to participate in either face-to-face training or online training on the health literacy program

☐ Yes ☐ No

Agree to facilitate health literacy in-house training sessions to pharmacy staff using the educational resources provided

☐ Yes ☐ No

Agree to two mystery shopper visits prior to receiving health literacy training

☐ Yes ☐ No

Agree to two mystery shopper visits after providing in-house training to pharmacy staff

☐ Yes ☐ No

Agree to not inform other pharmacy staff members of the four mystery shopper visits during the eight month data collection period

☐ Yes ☐ No

In giving my consent I acknowledge that:

1. The **procedures required for the project and the time involved** have been explained to me, and any questions I have about the project have been answered to my satisfaction.

2. I have **read the Participant Information Statement** and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s.

3. I understand that **this study is completely voluntary** – I am not under any obligation to consent and I can withdraw from the study at any time without affecting my relationship with the researcher(s) or the University of Sydney now or in the future.

4. I understand that my involvement is **strictly confidential** and no information about me will be used in any way that reveals my identity.

7. I understand that data from the surveys will be kept in a **secure storage** and accessible only to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Signed:

Name:
.....

Date:

I would like to receiving feedback Yes ☐ No ☐

If you answered 'Yes' to 'Receiving Feedback'. Please provide your details below

Feedback Option:

Address:.....

.....

Email:.....

Appendix 4 – Consent form (Monash University)



*A controlled trial of a health literacy education program in community pharmacies
Employee pharmacists/pharmacy assistants*

NOTE: This consent form will remain with the Monash University researcher for their records

I agree for the Monash University research project specified above to be conducted in <specify pharmacy>. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records. I understand that agreeing to take part means that I am willing to:

Agree to participate in either face-to-face training or online training on the health literacy program if nominated

☐ Yes ☐ No

Agree to provide health literacy in-house training sessions to pharmacy staff using the educational resources provided if nominated

☐ Yes ☐ No

Agree to be videotaped during consultations with consumers at two designated time points during the study

☐ Yes ☐ No

Agree to two mystery shopper visits prior to receiving health literacy training

☐ Yes ☐ No

Agree to two mystery shopper visits after providing in-house training to pharmacy staff

☐ Yes ☐ No

and

I understand that my participation is voluntary, and that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project

and

I understand that any data that the researcher extracts from the video data collection or pharmacy mystery shopper visits to use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

and

I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party

and

I understand that data from the collection periods and the mystery shopper visits will be kept in a secure storage and accessible only to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Participant's name:

Signature: _____ Date: _____

Appendix 4 – Consent form (Curtin University)



A controlled trial of a health literacy education program in community pharmacies
Employee pharmacists/pharmacy assistants

NOTE: This consent form will remain with Curtin University researcher for his/her records

I agree for Curtin University research project specified above to be conducted in <specify pharmacy>. I have had the project explained to me, and I have read the Information Sheet, which I keep for my records. I understand that agreeing to take part means that I am willing to:

Agree to participate in either face-to-face training or online training on the health literacy program if nominated

☐ Yes ☐ No

Agree to provide health literacy in-house training sessions to pharmacy staff using the educational resources provided if nominated

☐ Yes ☐ No

Agree to be audiotaped during consultations with consumers at two designated time points during the study (if the consumer also agrees)

☐ Yes ☐ No (you can still participate)

Agree to two mystery shopper visits prior to receiving health literacy training

☐ Yes ☐ No

Agree to two mystery shopper visits after providing in-house training to pharmacy staff

☐ Yes ☐ No

and

I understand that my participation is voluntary, and that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project

and

I understand that any data that the researcher extracts from the video data collection or pharmacy mystery shopper visits to use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

and

I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party

and

I understand that data from the collection periods and the mystery shopper visits will be kept in a secure storage and accessible only to the research team. I also understand that the data will be destroyed after 5 years unless I consent to it being used in future research.

Participant's name:

Signature: _____ Date: _____

Appendix 4 – Consent form (The University of Sydney)



Dr Betty Chaar
Lecturer in Pharmacy Practice
ABN 15 211 513 464

Faculty of Pharmacy
Room N508-Building A15
University of Sydney NSW 2006
AUSTRALIA

[REDACTED]
[REDACTED]

Miss Kim Bellamy

Faculty of Pharmacy
Room N508-Building A15
University of Sydney NSW 2006
AUSTRALIA

[REDACTED]
[REDACTED]

PARTICIPANT CONSENT FORM

I,[PRINT NAME], give consent to my participation in the research project

1. TITLE: A Controlled Trial of a Health Literacy Education Program in Community Pharmacies

I understand that agreeing to take part means that I am willing to:

Agree to participate in either face-to-face training or online training on the health literacy program if nominated

☐ Yes ☐ No

Agree to provide health literacy in-house training sessions to pharmacy staff using the educational resources provided if nominated

☐ Yes ☐ No

Agree to be videotaped during consultations with consumers at two designated time points during the study

☐ Yes ☐ No

Agree to two mystery shopper visits prior to receiving health literacy training

☐ Yes ☐ No

Agree to two mystery shopper visits after providing in-house training to pharmacy staff

☐ Yes ☐ No

In giving my consent I acknowledge that:

1. The **procedures required for the project and the time involved** have been explained to me, and any questions I have about the project have been answered to my satisfaction.
2. I have **read the Participant Information Statement** and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s.
3. I understand that **this study is completely voluntary** – I am not under any obligation to consent and I can withdraw from the study at any time without affecting my relationship with the researcher(s) or the University of Sydney now or in the future.
4. I understand that my involvement is **strictly confidential** and no information about me will be used in any way that reveals my identity.
7. I understand that data from the surveys will be kept in a **secure storage** and accessible only to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Signed:

Name:
.....

Date:

I would like to receiving feedback Yes ☐ No ☐

If you answered 'Yes' to 'Receiving Feedback'. Please provide your details below

Feedback Option:

Address:.....

.....

Email:.....

Appendix 5

Ethics approval: Phase 2 (Chapter 4)

Appendix 5 – Ethics approval (Monash University)



Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date: 17 December 2012

Project Number: 2012001910

Project Title: A health literacy survey of attitudes of pharmacy staff and the pharmacy environment

Chief Investigator: Assoc Prof Kay Stewart

Approved: From: 17 December 2012 To: 17 December 2017

Terms of approval

1. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.



Professor Ben Canny
Chair, MUHREC

cc: Mr Gregory Duncan, Mr Kevin McNamara, Mr Glen Swinburne

Appendix 5 – Ethics approval (Curtin University)



Memorandum

To	Lynne Emmerton
From	Alison Smith, R&D Coordinator, School of Pharmacy
Subject	Protocol Approval PH-03-13
Date	21 January 2013
Copy	

Faculty of Health Sciences

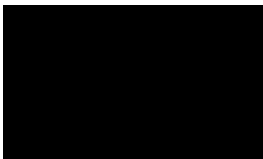
School of Pharmacy

Thank you for your "Form C Application for Approval of Research with Low Risk (Ethical Requirements)" for the project titled *"A health literacy survey of attitudes of pharmacy staff and the pharmacy environment"*. On behalf of the Human Research Ethics Committee I am authorised to inform you that the project is approved.

Approval of this project is for a period of twelve months **21/01/2013** to **21/01/2014**.

The approval number for your project is **PH-03-13**. *Please quote this number in any future correspondence.* If at any time during the twelve months changes/amendments occur, or if a serious or unexpected adverse event occurs, please advise me immediately.

Sincerely,



Research & Development Support Coordinator
School of Pharmacy

This study has been approved by the Curtin University Human Research Ethics Committee PH-03-13. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or hrec@curtin.edu.au

Appendix 5 – Ethics approval (The University of Sydney)

From: [Human Ethics](#)
To: [REDACTED]
Subject: HREC application outcome
Date: Monday, 15 April 2013 5:16:06 PM

Dear Dr Chaar

Project Title: Health Literacy in Pharmacy: the HeLP Project Stage 1: A Health Literacy Survey of Attitudes of Pharmacy Staff and the Pharmacy Environment

Project No: 2013/247

Thank you for advising the University of Sydney Human Research Ethics Committee (HREC) about your study.

Under the National Statement on Ethical Conduct in Human Research (2007), institutions have the responsibility to ensure that ethical reviews are not unnecessarily duplicated.

According to the University of Sydney Procedures recognition of approval from external ethics committees is required where one or both of the following apply:

- (a) Research involves a University of Sydney student as a researcher;
- (b) Recruitment of participants and collection of data occur on a University of Sydney campus (excludes clinical campuses which are located within a NSW Health facility).

Your project does not require review by the University of Sydney Human Research Ethics Committee (HREC). The HREC acknowledges your right to proceed under the authority of Monash University Human Research Ethics Committee.

Please do not hesitate to contact Research Integrity (Human Ethics) should you require further information or clarification.

Regards,
Human Ethics Administration
The University of Sydney

Appendix 6

Phase 2 (Chapter 4) supplementary materials

- Letters of invitation
- Permission letters
- Explanatory statements
- Consent forms
- Pharmacy trainer questionnaire: Perceptions and Activities survey – Employee (Pre-train-the-trainer)
- In-pharmacy participant questionnaire: Perceptions and Activities survey – Employee (Pre-in-house training)

Appendix 6 – Letter of invitation (Monash University)



November 2012

Document title: Letter of Invitation

Attention: Pharmacy owner or pharmacy manager

Re: A health literacy survey of attitudes of pharmacy staff and the pharmacy environment.

Dear Pharmacy owner/manager

I am a researcher undertaking a PhD at Monash University. My supervisors are Dr Safeera Hussainy, Associate Professor Kay Stewart, Mr Kevin McNamara and Mr Gregory Duncan. I am writing to you regarding a research project being conducted by the Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, on developing and providing health literacy education resources to pharmacist and pharmacy assistants in community pharmacies in Australia.

This project is being funded by the Department of Health and Ageing, through the Fifth Community Pharmacy Agreement. It aims to develop and evaluate a health literacy educational resource to implement in Australian community pharmacies to provide education on health literacy, in particular utilising appropriate communication techniques to interact with consumers with low health literacy. It will also form part of the research towards my attainment of the degree of Doctor of Philosophy (PhD).

Before this implementation can begin, the attitudes and motivational factors of pharmacists and pharmacy staff that influence the adoption of health literacy training if it were available must be determined. This will allow us to ensure the developed training package will take into account these particular factors to promote its adoption into practice. This will be conducted by providing two surveys relating to health literacy training. Secondly, a survey of the pharmacy will be conducted by the pharmacist regularly and usually in-charge using the provided survey to determine the 'health literacy friendliness' of community pharmacies in Australia.

Attached to this letter is an explanatory statement that provides further details about participating in this project. The researchers would also like to have the opportunity

to further explain this project in greater detail by requesting a face-to-face meeting or telephone meeting at a time convenient to you. Please contact me on the details provided below to accept or decline this invitation.

Should you have any questions about the project in the meantime, please feel free to contact me. Additionally, my academic supervisors, Dr Safeera Hussainy and Gregory Duncan, will also be available to answer any questions you may have.

I look forward to hearing from you soon.

Sincerely,
Glen Swinburne

Mr. Glen Swinburne
Pharmacist, PhD
Candidate
Department of Pharmacy
Practice, Centre for
Medicine Use and Safety
Monash University

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Dr Safeera Hussainy
Lecturer,
Academic Supervisor
Department of Pharmacy
Practice, Centre for
Medicine Use and Safety
Monash University

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Mr. Gregory Duncan
Senior Research Fellow
Eastern Health Clinical
School
Faculty of Medicine,
Nursing and Health
Services
Monash University

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Appendix 6 – Letter of invitation (Curtin University)



January 2013

Document title: Letter of Invitation

Attention: Pharmacy owner or pharmacy manager

Re: A health literacy survey of attitudes of pharmacy staff and the pharmacy environment

Dear Pharmacy owner/manager

I am writing to you regarding a research project being conducted collaboratively by the Schools of Pharmacy at Curtin University, Monash University, and University of Sydney, on developing and providing health literacy education resources to pharmacist and pharmacy assistants in community pharmacies in Australia.

This project is being funded by the Department of Health and Ageing, through the Fifth Community Pharmacy Agreement. It aims to develop and evaluate a health literacy educational resource to implement in Australian community pharmacies to provide education on health literacy, in particular utilising appropriate communication techniques to interact with consumers with low health literacy.

Before this implementation can begin, the attitudes and motivational factors of pharmacists and pharmacy staff that influence the adoption of health literacy training if it were available must be determined. This will allow us to ensure the developed training package will take into account these particular factors to promote its adoption into practice. This will be conducted by providing two surveys relating to health literacy training, one which will be completed by the pharmacist regularly and usually in charge, and one by all other pharmacy staff members, including pharmacists. Secondly, a survey of the pharmacy will be conducted by the pharmacist regularly and usually in-charge using the provided survey to determine the 'health literacy friendliness' of community pharmacies in Australia.

Attached to this letter is an explanatory statement that provides further details about participating in this project. The researchers would also like to have the opportunity to further explain this project in greater detail by requesting a face-to-face meeting or telephone meeting at a time convenient to you. Please contact me on the details provided below to accept or decline this invitation.

Should you have any questions about the project in the meantime, please feel free to contact me. This project has been approved by the Curtin University Human Research Ethics Committee (Approval Number: PH-03-13). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. The Human Research Ethics Committee (Secretary) may be contacted should participants wish to make a complaint on ethical grounds. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning [REDACTED]
I look forward to hearing from you soon.

Sincerely,

Dr Elsamaul Elhebir

Senior Research Officer | School of
Pharmacy

Faculty of Health Science | Curtin
University

[REDACTED]

[REDACTED]

**Associate Professor Lynne
Emmerton**

Director of Research Training | School
of Pharmacy

Faculty of Health Science | Curtin
University

[REDACTED]

[REDACTED]

Appendix 6 – Letter of invitation (The University of Sydney)



THE UNIVERSITY OF
SYDNEY

Dr Betty Chaar

Room N508-Bldg A15

Faculty of Pharmacy

University of Sydney

Letter of Invitation to Pharmacy owner/manager

A HEALTH LITERACY SURVEY OF ATTITUDES OF PHARMACY STAFF AND THE PHARMACY ENVIRONMENT

Researchers: Dr Betty Chaar, Mr Gregory Duncan, Mr Glen Swinburne, and
Research Assistant Miss Kim Bellamy

Dear Pharmacy owner/manager:

We are a research team at the Faculty of Pharmacy, University of Sydney, and have acquired your contact details from the Yellow Pages. We are writing to you regarding a research project being conducted collaboratively by the Schools of Pharmacy at Sydney University, Curtin University, and Monash University, on developing and providing health literacy education resources to pharmacists and pharmacy assistants in community pharmacies in Australia.

This project is being funded by the Department of Health and Ageing, through the Fifth Community Pharmacy Agreement. It aims to develop and evaluate a health literacy educational resource to implement in Australian community pharmacies to provide education on health literacy, in particular utilising appropriate communication techniques to interact with consumers with low health literacy.

Before this implementation can begin, the attitudes and motivational factors of pharmacists and pharmacy staff that influence the adoption of health literacy training if it were available must be determined. This will allow us to ensure the developed training package will take into account these particular factors to promote its adoption into practice. This will be conducted by providing two surveys relating to health literacy training, one which will be completed by the pharmacist in charge, and one by all other pharmacy staff members, including pharmacists. Secondly, a survey of the pharmacy will be conducted by the pharmacist in-charge using the provided survey to determine the 'health literacy friendliness' of community pharmacies in Australia.

The Research Assistant Kim Bellamy will contact you shortly by telephone to find out if you are interested in partaking in this study. The researchers would also like to have the opportunity to further explain this project in greater detail by requesting a face-to-face meeting or telephone meeting at a time convenient to you.

Should you have any questions about the project in the meantime, please feel free to contact Kim Bellamy on [REDACTED]. Additionally, Dr Betty Chaar and Gregory Duncan will also be available to answer any questions you may have.

Yours sincerely,

[REDACTED]

Kim Bellamy

Research Assistant

Kim Bellamy

Room S303 - Building A15

Faculty of Pharmacy

Mr. Gregory Duncan

Eastern Health Clinical School

Faculty of Medicine, Nursing and Health
Services

Monash University Victoria

[REDACTED]

[REDACTED]

Mr. Glen Swinburne

Department of Pharmacy Practice,
Centre for Medicine Use and
Safety

Appendix 6 – Permission letter (Monash University)



Permission Letter for project: A health literacy survey of attitudes of pharmacy staff and the pharmacy environment

Date:

Glen Swinburne
Pharmacist and PhD Candidate
Department of Pharmacy Practice
Centre for Medicine Use and Safety
Faculty of Pharmacy and Pharmaceutical Sciences,
Monash University (Parkville Campus)
381 Royal Parade
Parkville VIC 3052

Dear **Glen Swinburne**

Thank you for your request to recruit participants from **<insert name of pharmacy>** for the above-named research.

I have read and understood the letter of invitation regarding the research **<insert project number>** and hereby give permission for this research to be conducted in the pharmacy premises.

<Please include any stipulations / clauses the pharmacy may have about recruitment of human participants>.

Yours Sincerely,

<insert signature of pharmacy owner/manager>

<insert name of the above signatory>

<insert above signatory's position>

Appendix 6 – Permission letter (Curtin University)



Permission Letter for project: A health literacy survey of attitudes of pharmacy staff and the pharmacy environment

Date:

Dr Elsamaul Elhebir

Senior Research Officer | School of
Pharmacy
Faculty of Health Science | Curtin University

[Redacted signature line]
[Redacted contact information line]

Associate Professor Lynne Emmerton

Director of Research Training | School of
Pharmacy
Faculty of Health Science | Curtin University

[Redacted signature line]
[Redacted contact information line]

Dear **Elsamaul**

Thank you for your request to recruit participants from **<insert name of pharmacy>** for the above-named research.

I have read and understood the letter of invitation regarding the research **<insert project number>** and hereby give permission for this research to be conducted in the pharmacy premises.

<Please include any stipulations / clauses the pharmacy may have about recruitment of human participants>.

Yours Sincerely,

<insert signature of pharmacy owner/manager>

<insert name of the above signatory>

<insert above signatory's position>

THE UNIVERSITY OF
SYDNEY

Date:

<insert name of the above signatory>

<insert above signatory's position>

Appendix 6 – Explanatory statement (Monash University)

Explanatory Statement: Pharmacy owners/manager

Project Title: A health literacy survey of attitudes of pharmacy staff and the pharmacy environment.

This information sheet is for you to keep.

My name is **Glen Swinburne B.Pharm (Hons)** and I am conducting a research project with **Dr. Safeera Hussainy, Associate Professor Kay Stewart and Mr Kevin McNamara** at the Centre for Medicine Use and Safety, Department of Pharmacy Practice, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, and **Mr Gregory Duncan** at the Faculty of Medicine, Nursing and Health Sciences, Monash University. I am conducting this research project towards a Doctor of Philosophy at Monash University. This means that I will be writing a thesis which is the equivalent of a 300 page book. A report of the project may also be submitted for publication in a journal or be presented at a conference. The study is funded by the Department of Health and Ageing, and managed by the Pharmacy Guild of Australia through the Fifth Community Pharmacy Agreement.

Why did you choose this particular person/group as participants?

The research project aims to determine how attitudes influence the desire and perceived ability to undertake health literacy training if it were to be made available, and to assess the health literacy of the pharmacy environment and how it may influence service delivery.

Health literacy is defined by the World Health Organization as ‘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.’

The pharmacies that have been chosen to take part in this project have been chosen at random. The details of the pharmacies have been obtained from publically available directories.

The aim/purpose of the research

The aim of this study is to determine the attitudinal and motivational factors that may influence the adoption of health literacy training for pharmacists and pharmacy staff members if it were to be made available. It also aims to assess the health literacy of the pharmacy environment to determine its degree of ‘health literacy friendliness’.

This information will aid in the development of appropriate health literacy educational materials for community pharmacists and pharmacy staff in the future.

Possible benefits

While no direct benefit currently exists from this study, it will aid in the development of a health literacy educational package in the future that will help pharmacists and pharmacy staff members develop improved communication skills allowing for more effective and appropriate interactions with consumers of varying levels of health literacy. It may improve consumer understanding of medications and advice provided by pharmacy staff.

What does the research involve?

The research involves pharmacists and pharmacy staff members completing up to two surveys relating to their attitudes, desire and perceived ability in relation to the possibility of undertaking health literacy training in the future. A third survey will be completed by the pharmacist regularly and usually in-charge, and will involve an assessment of the pharmacy environment in relation to its 'health literacy friendliness'.

How much time will the research take?

The time allocated to explain this project to you is 30 minutes. Completion of the surveys should not take more than an hour.

Inconvenience/discomfort

There are no foreseeable risks other than the inconvenience of your time required.

If you become upset or distressed as a result of your participation in the project, the researcher is able to arrange for counselling or other appropriate support. Any counselling or support will be provided by staff who are not members of the research team and include Lifeline Australia who can be contacted on 13 11 14.

If you have any questions or you would like to talk to someone about the research project you are free to contact me or my supervisors on the contact details listed below.

Can I withdraw from the research?

Participation in this research project is voluntary and you are under no obligation to participate. If you decide to take part and later change your mind, you are free to withdraw from the project. Please notify the researchers immediately if you wish to withdraw from this research project.

Confidentiality

All the information collected from individual participants during the course of this project will be kept confidential. In any publication and/or presentation information will be provided in such a way that you cannot be identified.

Storage of data

Storage of the data collected will adhere to the University regulations and kept on University premises in a locked cupboard/filing cabinet for 5 years.

Use of data for other purposes

It is not intended that this data be used for any other purpose for which it is primarily obtained.

Results

If you would like to be informed of the aggregate research finding, please contact myself or my supervisors (see below). The findings will be accessible after all data is collected.

If you would like to contact the researchers about any aspect of this study, please contact the Supervisor:	If you have a complaint concerning the manner in which this research <insert your MUHREC project number here> is being conducted, please contact:
Glen Swinburne B.Pharm (Hons) Centre for Medicine Use and Safety Monash University 381 Royal Pde Parkville, VIC 3052 Australia [REDACTED] [REDACTED] Associate Prof. Kay Stewart Centre for Medicine Use and Safety Monash University 381 Royal Pde Parkville, VIC 3052 Australia [REDACTED] [REDACTED] Dr Safeera Hussainy Centre for Medicine Use and Safety	Executive Officer Monash University Human Research Ethics Committee (MUHREC) Building 3e Room 111 Research Office Monash University VIC 3800 [REDACTED] [REDACTED] [REDACTED] [REDACTED]

Monash University
381 Royal Pde
Parkville, VIC 3052
Australia

[REDACTED]

[REDACTED]

Mr Gregory Duncan

Eastern Health Clinical School
Faculty of Medicine, Nursing and Health
Services
Monash University
5 Arnold St
Box Hill VIC 3128

[REDACTED]

[REDACTED]

Mr Kevin Mc Namara

Centre for Medicine Use and Safety
Monash University
381 Royal Pde
Parkville, VIC 3052
Australia

[REDACTED]

[REDACTED]

Appendix 6 – Explanatory statement (Curtin University)



Explanatory Statement: Pharmacy owners/manager

Project Title: A health literacy survey of attitudes of pharmacy staff and the pharmacy environment

This information sheet is for you to keep.

This study is funded by the Department of Health and Ageing, and managed by the Pharmacy Guild of Australia through the Fifth Community Pharmacy Agreement.

Why did we choose you as a participant?

The research project aims to determine how attitudes influence the desire and perceived ability to undertake health literacy training if it were to be made available, and to assess the health literacy of the pharmacy environment and how it may influence service delivery.

Health literacy is defined by the World Health Organization as ‘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.’

The pharmacies that have been chosen to take part in this project have been chosen at random. The details of the pharmacies have been obtained from publically available directories.

The aim/purpose of the research

The aim of this study is to determine the attitudinal and motivational factors that may influence the adoption of health literacy training for pharmacists and pharmacy staff members if it were to be made available. It also aims to assess the health literacy of the pharmacy environment to determine its degree of ‘health literacy friendliness’.

This information will aid in the development of appropriate health literacy educational materials for community pharmacists and pharmacy staff in the future.

Possible benefits

While no direct benefit currently exists from this study, it will aid in the development of a health literacy educational package in the future that will help pharmacists and pharmacy staff members develop improved communication skills allowing for more effective and appropriate interactions with consumers of varying levels of health literacy. It may improve consumer understanding of medications and advice provided by pharmacy staff.

What does the research involve?

The research involves pharmacists and pharmacy staff members completing up to two surveys relating to their attitudes, desire and perceived ability in relation to the possibility of undertaking health literacy training in the future. A third survey will be completed by the pharmacist regularly and usually in-charge, and will involve an assessment of the pharmacy environment in relation to its 'health literacy friendliness'.

How much time will the survey take?

The time allocated to explain this project to you is 30 minutes. Completion of the surveys should not take more than 20 minutes per survey.

Inconvenience/discomfort

There are no foreseeable risks other than the inconvenience of your time required.

This project has been approved by the Curtin University Human Research Ethics Committee (Approval Number: XXXX). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. The Human Research Ethics Committee (Secretary) may be contacted should participants wish to make a complaint on ethical grounds. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by [REDACTED]

Can you withdraw from the research?

Participation in this research project is voluntary and you are under no obligation to participate. If you decide to take part and later change your mind, you are free to withdraw from the project. Please notify the researchers immediately if you wish to withdraw from this research project.

Confidentiality

All the information collected from individual participants during the course of this project will be kept confidential. In any publication and/or presentation information will be provided in such a way that you cannot be identified. Findings of this study could be presented in scientific conferences, peer reviewed journals, and a thesis.

Published results will be coded and grouped and only researchers will have access to the data.

Storage of data

Storage of the data collected will adhere to the University regulations and kept on University premises in a locked cupboard/filing cabinet for 5 years.

Use of data for other purposes

It is not intended that this data be used for any other purpose for which it is primarily obtained.

Results

If you would like to be informed of the aggregate research finding, please contact us (see below). The findings will be accessible after all data is collected.

Dr Elsamaul Elhebir

Senior Research Officer | School of
Pharmacy
Faculty of Health Science | Curtin
University

[REDACTED]
[REDACTED]

Associate Professor Lynne Emmerton

Director of Research Training | School
of Pharmacy
Faculty of Health Science | Curtin
University

[REDACTED]
[REDACTED]

Professor Jeff Hughes

Head | School of Pharmacy
Faculty of Health Science | Curtin
University

[REDACTED]

Dr Kreshnik Hoti

Lecturer | School of Pharmacy
Faculty of Health Science | Curtin
University

[REDACTED]

Professor Moyez Jiwa

Chair Health Innovation – Chronic
Disease
Curtin Health Innovation Research
Institute (CHIRI)

[REDACTED]

Appendix 6 – Explanatory statement (The University of Sydney)



THE UNIVERSITY OF
SYDNEY

Dr Betty Chaar

Room N508-Bldg A15

Faculty of Pharmacy

University of Sydney

NSW 2006

A HEALTH LITERACY SURVEY OF ATTITUDES OF PHARMACY STAFF AND THE PHARMACY ENVIRONMENT

Participant Information Statement

(1) What is the study about?

Health literacy refers to the ability of individuals to obtain, understand, and apply health care information in written, spoken or digital format, and subsequently make appropriate health-related decisions.¹ Without adequate health literacy, consumers may not understand what a health care professional has told them about their condition, be able to follow written and verbal instructions, be capable of reading labels on medication packaging, or be able to understand and apply health information presented in posters or brochures.² Low health literacy is widespread in the community, with up to 60% of Australians potentially lacking the skills needed to manage their health or to navigate the health care system.³

Knowledge of how health literacy affects the community, and having the knowledge and skills to address some of those effects will put community pharmacy staff in a strong position to address some of the health effects of low health literacy. In the pharmacy setting, poor Health Literacy can be an impediment to consumers' abilities to clearly articulate the problem for which they are seeking a solution, to appreciate the potential seriousness of the problem that they have, and accept advice for referral to their doctor or another health care professional. However, the health literacy of the pharmacy staff member engaged in the interaction with the person also has the potential to influence the outcome of the encounter, and the staff

member may not be able to identify the need or persuade the person to see their doctor.

This research project is part of an overall project aimed at improving how pharmacists and pharmacy staff counsel patients in order to accommodate the potential for low levels of health literacy. This arm of the project aims to determine the factors that influence the adoption of health literacy training for pharmacists and pharmacy staff members if it were to be made available. It also aims to assess the pharmacy environment to determine its degree of 'health literacy friendliness'.

(2) Who is carrying out the study?

The study is being conducted by a research team comprised of: Dr Betty Chaar (University of Sydney), Mr Gregory Duncan (Monash University), Mr Glen Swinburne (Monash University), Associate Professor Lynne Emmerton (Curtin University) and Research Assistant Miss Kim Bellamy (University of Sydney).

(3) What does the study involve?

The research involves pharmacists and pharmacy staff members completing up to two surveys relating to their attitudes, desire and perceived ability in relation to the possibility of undertaking health literacy training in the future. A third survey will be completed by the pharmacist in-charge, which is an assessment of the pharmacy environment in relation to its 'health literacy friendliness'.

(4) How much time will the study take?

The time allocated to explain this project to you is 30 minutes. Completion of the surveys should not take more than 20 minutes per survey.

(5) Can I withdraw from the study?

Participation in this study is completely voluntary. You are not under any obligation to consent and if you do consent you can withdraw at any time without affecting your relationship with the University of Sydney.

(6) Will anyone else know the results?

All aspects of the study, including results, will be strictly confidential and only the researchers 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.

(7) Will the study benefit me?

While no direct benefit currently exists from this study, it will aid in the development of a health literacy educational package in the future that will help pharmacists and pharmacy staff members develop improved communication skills allowing for more effective and appropriate interactions with consumers of varying levels of health literacy. It may improve consumer understanding of medications and advice provided by pharmacy staff.

(8) Can I tell other people about the study?

Yes, you can tell other people about the study.

(9) What if I require further information?

When you have read this information, the Research Assistant Kim Bellamy will discuss it with you

further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact *Dr Betty Charr* [REDACTED] *Gregory Duncan* [REDACTED] *Glen Swinburne* [REDACTED] or *Kim Bellamy* [REDACTED]

(10) Will I be able to find out the results of the study?

If you would like to be informed of the aggregate research finding, please contact a member of the research team. The findings will be accessible after all the data is collected.

(11) What if I have a complaint or concerns?

Any person with concerns or complaints about the conduct of a research study can contact the Deputy Manager, Human Ethics Administration, University of Sydney on [REDACTED]
[REDACTED]

References

- 1) Adams R, Appleton SL, Hill CL, Dodd M, Findlay C, Wilson DH. Risks associated with low functional health literacy in an Australian population. Medical Journal of Australia 2009; 17: 257 - 9.
- 2) Keleher H, Hagger V. Health literacy in primary health care. Australian Journal of Primary Health 2007; 13(2): 24 - 34. DOI:10.1071/PY07020
- 3) Australian Bureau of Statistics. Health Literacy, Australia. Canberra 2008. Report No.: 4233.0.

Appendix 6 – Consent form (Monash University)



A health literacy survey of attitudes of pharmacy staff and the pharmacy environment.

Employee pharmacist/pharmacy staff member consent form

NOTE: This consent form will remain with the Monash University researcher for their records

I agree for the Monash University research project specified above to be conducted in <specify pharmacy>. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records. I understand that agreeing to take part means that I am willing to:

Agree to participate in a survey of my attitudes relating to the possibility of undertaking health literacy training.

No ☐ Yes ☐

I understand that participation of the pharmacy is voluntary, and that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project

and

I understand that any data that the researcher extracts surveys to use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

and

I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party

and

I understand that data from the surveys will be kept in a secure storage and accessible only to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Participant's name: _____

Signature: _____ Date: _____

Appendix 6 – Consent form (Monash University)



A health literacy survey of attitudes of pharmacy staff and the pharmacy environment.

Pharmacist regularly and usually in-charge consent form

NOTE: This consent form will remain with the Monash University researcher for their records

I agree for the Monash University research project specified above to be conducted in <specify pharmacy>. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records. I understand that agreeing to take part means that I am willing to:

Agree to participate in a survey of my attitudes relating to the possibility of undertaking health literacy training.

☐ Yes ☐ No

Agree to participate in a survey of the pharmacy environment to assess its 'health literacy friendliness'.

☐ Yes ☐ No

I understand that participation of the pharmacy is voluntary, and that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project

and

I understand that any data that the researcher extracts surveys to use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

and

I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party

and

I understand that data from the surveys will be kept in a secure storage and accessible only to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Participant's name: _____

Signature: _____ Date: _____

Appendix 6 – Consent form (Curtin University)



A health literacy survey of attitudes of pharmacy staff and the pharmacy environment.

Employee pharmacist/pharmacy staff member consent form

NOTE: This consent form will remain with Curtin University researcher for their records

I agree for Curtin University research project specified above to be conducted in <specify pharmacy>. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records. I understand that agreeing to take part means that I am willing to agree to participate in a survey of my attitudes relating to the possibility of undertaking health literacy training.

☐ Yes ☐
No

I understand my participation is voluntary, and that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project

and

I understand that any data that the researcher extracts from the surveys to use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

and

I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party

and

I understand that data from the surveys will be kept in a secure storage and accessible only to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Participant's name:

Signature: _____ Date: _____

Appendix 6 – Consent form (Curtin University)



A health literacy survey of attitudes of pharmacy staff and the pharmacy environment.

Pharmacist regularly and usually in-charge consent form

NOTE: This consent form will remain with Curtin University researcher for their records

I agree for Curtin University research project specified above to be conducted in <specify pharmacy>. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records. I understand that agreeing to take part means that I am willing to:

Agree to participate in a survey of my attitudes relating to the possibility of undertaking health literacy training.

☐ Yes ☐ No

Agree to participate in a survey of the pharmacy environment to assess its 'health literacy friendliness'.

☐ Yes ☐ No

I understand that participation is voluntary, and that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project

and

I understand that any data that the researcher extracts from the surveys to use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

and

I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party

and

I understand that data from the surveys will be kept in a secure storage and accessible only to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Participant's name: _____

Signature: _____ Date: _____

Appendix 6 – Consent form (The University of Sydney)



THE UNIVERSITY OF
SYDNEY

Dr Betty Chaar
Lecturer in Pharmacy Practice
ABN 15 211 513 464

Faculty of Pharmacy
Room N508-Building A15
University of Sydney NSW 2006
AUSTRALIA



Miss Kim Bellamy

Faculty of Pharmacy
Room N508-Building A15
University of Sydney NSW 2006
AUSTRALIA



PARTICIPANT CONSENT FORM

I,[PRINT NAME], give consent to my participation in the research project

2. TITLE: A health Literacy Survey of Attitudes of Pharmacy Staff and the Pharmacy Environment

I understand that agreeing to take part means that I am willing to:

Agree to participate in a survey of my attitudes relating to the possibility of undertaking health literacy training.

☐ Yes ☐ No

Agree to participate in a survey of the pharmacy environment to assess its 'health literacy friendliness'.

☐ Yes ☐ No

In giving my consent I acknowledge that:

1. The **procedures required for the project and the time involved** have been explained to me, and any questions I have about the project have been answered to my satisfaction.
2. I have **read the Participant Information Statement** and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s.
3. I understand that **this study is completely voluntary** – I am not under any obligation to consent and I can withdraw from the study at any time without affecting my relationship with the researcher(s) or the University of Sydney now or in the future.
4. I understand that my involvement is **strictly confidential** and no information about me will be used in any way that reveals my identity.
7. I understand that data from the surveys will be kept in a **secure storage** and accessible only to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Signed:

Name:
.....

Date:

I would like to receive feedback on the project when completed

Address:.....

.....

.....

Email:.....

Appendix 6 – Pharmacy trainer questionnaire



Health Literacy in Pharmacy Study Perceptions and Activities survey – Employee (Pre-train-the-trainer)

The aim of this survey is to identify the attitudes and motivations of pharmacists with regard to the possibility of implementing and running a health literacy training program in their pharmacy in the future.

Health literacy is defined as the degree to which people are able to access, understand, appraise and communicate information to engage with the demands of different health contexts in order to promote and maintain good health across the life-course.¹

The term 'pharmacy staff' refers to all pharmacists, pharmacy interns, dispensary technicians and assistants. The term 'counselling' refers to the provision of information in relation to medications, including prescription, non-prescription and complimentary, as well as general health advice, by pharmacy staff.

1. In which state is your pharmacy located?

Victoria ☐

New South Wales ☐

Western Australia ☐

Investigator use only
Code:

2a. You are: A registered pharmacist ☐

Pharmacy intern ☐

Pharmacy assistant ☐

If you are a pharmacist, please complete 2b and 2c. If not, continue to Question 3.

2b. Are you the pharmacist in charge?

Yes ☐

No ☐

2c. Are you an owner of the pharmacy?

Yes ☐

No ☐

3. On average, how many pharmacists are on duty at one time in the pharmacy?

4. What is your age?

18-25 ☐

26-35 ☐

36-45 ☐

46-60 ☐

60+ ☐

5. Sex: Male ☐

Female ☐

1. Kanj M, Mistic W. Health literacy and health promotion. 7th Global Conference on Health Promotion; Nairobi, Kenya: World Health Organisation; 2009. p. 1-46.

Statement	1 Strongly disagree	2	3	4 Not sure	5	6	7 Strongly agree
6. I feel I am adequately prepared to address my consumers' health literacy needs.	☐	☐	☐	☐	☐	☐	☐
7. Most pharmacy staff would require additional training to fully meet the health literacy needs of their consumers.	☐	☐	☐	☐	☐	☐	☐
9. I believe that implementing a health literacy training program for pharmacy staff in my pharmacy is important.	☐	☐	☐	☐	☐	☐	☐
10. I expect my pharmacy to achieve a high standard of service delivery in this pharmacy relating to health literacy.	☐	☐	☐	☐	☐	☐	☐
11. Many of the consumers in my pharmacy have low levels of health literacy.	☐	☐	☐	☐	☐	☐	☐
12. Those consumers in my pharmacy with low levels of health literacy are likely to experience worse health outcomes than other consumers.	☐	☐	☐	☐	☐	☐	☐
13. By providing appropriate counselling, pharmacy staff can help consumers to avoid many problems associated with low levels of health literacy.	☐	☐	☐	☐	☐	☐	☐
14. A consumer should never be considered to have adequate health literacy without clear evidence.	☐	☐	☐	☐	☐	☐	☐
15. I have the right to assume that a consumer understands my advice, unless he/she indicates otherwise.	☐	☐	☐	☐	☐	☐	☐
16. It is the consumer's responsibility to ask questions if he/she is uncertain about any advice provided in my pharmacy.	☐	☐	☐	☐	☐	☐	☐
17. Suggestions provided for implementing health literacy training in the pharmacy are likely to be very helpful.	☐	☐	☐	☐	☐	☐	☐

Statement	1 Strongly disagree	2	3	4 Not sure	5	6	7 Strongly agree
20. Most of the people working in my pharmacy will encourage my efforts to apply health literacy principles to my consumer counselling.	☐	☐	☐	☐	☐	☐	☐
21. My consumers have strong expectations of me to counsel in a way that addresses their health literacy needs.	☐	☐	☐	☐	☐	☐	☐
22. Pharmacy management will be very keen to see health literacy principles applied consistently by all employees.	☐	☐	☐	☐	☐	☐	☐
23. The employees in my pharmacy will be very keen to see that health literacy principles are applied consistently to all consumer counselling.	☐	☐	☐	☐	☐	☐	☐
24. If I work towards achieving a high standard of service delivery in the pharmacy relating to health literacy, my managers and colleagues would be impressed.	☐	☐	☐	☐	☐	☐	☐
25. It would be easy for me to apply the counselling principles outlined in a health literacy training program for all consumers when providing health information.	☐	☐	☐	☐	☐	☐	☐
26. The concepts described in health literacy training are logical and reasonable.	☐	☐	☐	☐	☐	☐	☐
27. I am confident that I could use effective communication techniques for all consumers when providing health information.	☐	☐	☐	☐	☐	☐	☐
28. I am confident I have the skills to run a health literacy training program for my staff.	☐	☐	☐	☐	☐	☐	☐
29. The ability for me to run the health literacy training session for the pharmacy staff is beyond my control.	☐	☐	☐	☐	☐	☐	☐

Statement	1 Strongly disagree	2	3	4 Not sure	5	6	7 Strongly agree
30. Whether I can run the health literacy training session for the pharmacy staff is not entirely up to me.	☐	☐	☐	☐	☐	☐	☐
31. Whether or not I can achieve a high level of service delivery relating to health literacy in this pharmacy is beyond my control.	☐	☐	☐	☐	☐	☐	☐
32. Whether or not a high level of service delivery relating to health literacy in this pharmacy can be achieved is not entirely up to me.	☐	☐	☐	☐	☐	☐	☐
33. I have a clear vision of how to implement health literacy counselling into all counselling in the pharmacy	☐	☐	☐	☐	☐	☐	☐
34. Implementing health literacy counselling in the pharmacy seems like a complicated process	☐	☐	☐	☐	☐	☐	☐
35. I anticipate that my pharmacy would provide sufficient practical support for the implementation of a health literacy program	☐	☐	☐	☐	☐	☐	☐
36. In the past, my pharmacy has provided reasonable support to implement professional programs.	☐	☐	☐	☐	☐	☐	☐
37. I intend to understand the concepts and skills required to implement health literacy counselling.	☐	☐	☐	☐	☐	☐	☐
38. I intend to apply the principles of healthy literacy counselling to how I communicate with all of my consumers.	☐	☐	☐	☐	☐	☐	☐
39. I have already successfully incorporated and sustained changes to the way I counsel consumers in everyday practice.	☐	☐	☐	☐	☐	☐	☐
40. I will implement health literacy training sessions for pharmacy staff in my pharmacy.	☐	☐	☐	☐	☐	☐	☐
41. I will work to achieve a high standard of service delivery in the pharmacy relating to health literacy.	☐	☐	☐	☐	☐	☐	☐

Please seal the completed survey in the provided envelope.
Thank you for your participation.

Appendix 6 – In-pharmacy questionnaire



Health Literacy in Pharmacy Study Perceptions and Activities Survey – Employee (Pre-in-house training)

The aim of this survey is to identify the attitudes and motivations of pharmacy staff with regard to the possibility of receiving health literacy training in the future.

Health literacy is defined as the degree to which people are able to access, understand, appraise and communicate information to engage with the demands of different health contexts in order to promote and maintain good health across the life-course.¹

The term 'pharmacy staff' refers to all pharmacists, pharmacy interns, dispensary technicians and assistants. The term 'counselling' refers to the provision of information in relation to medications, including prescription, non-prescription and complimentary, as well as general health advice, by pharmacy staff.

1. In which state is your pharmacy located?

Victoria ☐

New South Wales ☐

Western Australia ☐

Investigator use only
Code:

2a. You are: A registered pharmacist ☐

Pharmacy intern ☐

Pharmacy assistant ☐

If you are a pharmacist, please complete 2b and 2c. If not, continue to Question 3.

2b. Are you the pharmacist in charge?

Yes ☐

No ☐

2c. Are you an owner of the pharmacy?

Yes ☐

No ☐

3. On average, how many pharmacists are on duty at one time in the pharmacy?

4. What is your age?

18-25 ☐

26-35 ☐

36-45 ☐

46-60 ☐

60+ ☐

5. Sex: Male ☐

Female ☐

1. Kanj M, Mitic W. Health literacy and health promotion. 7th Global Conference on Health Promotion; Nairobi, Kenya: World Health Organisation; 2009. p. 1-46.

Statement	1 Strongly disagree	2	3	4 Not sure	5	6	7 Strongly agree
6. I feel I am adequately prepared to address my patients' health literacy needs.	☐	☐	☐	☐	☐	☐	☐
7. Most pharmacy staff would require additional training to fully meet the health literacy needs of their patients.	☐	☐	☐	☐	☐	☐	☐
8. Most other pharmacy staff would require additional training to fully meet the health literacy needs of their patients.	☐	☐	☐	☐	☐	☐	☐
9. Many of the consumers in my pharmacy have low levels of health literacy.	☐	☐	☐	☐	☐	☐	☐
10. Those consumers in my pharmacy with low levels of health literacy are likely to experience worse health outcomes than other consumers.	☐	☐	☐	☐	☐	☐	☐
11. By providing appropriate counselling, pharmacy staff can help consumers to avoid many problems associated with low levels of health literacy.	☐	☐	☐	☐	☐	☐	☐
12. A consumer should never be considered to have adequate health literacy without clear evidence.	☐	☐	☐	☐	☐	☐	☐
13. I have the right to assume that a consumer understands my advice, unless he/she indicates otherwise.	☐	☐	☐	☐	☐	☐	☐
14. It is the patient's responsibility to ask questions if he/she is uncertain about any advice provided in my pharmacy.	☐	☐	☐	☐	☐	☐	☐

Statement	1 Strongly disagree	2	3	4 Not sure	5	6	7 Strongly agree
15. It is essential to counsel all consumers in a manner that assumes they have limited health literacy, unless proven otherwise.	☐	☐	☐	☐	☐	☐	☐
<i>If you are the manager, skip this question.</i>							
16. Following completion of the training, my managers will expect me to counsel consumers in a way that addresses their health literacy needs.	☐	☐	☐	☐	☐	☐	☐
17. Most of the people working in my pharmacy will encourage my efforts to apply health literacy principles to my consumer counselling.	☐	☐	☐	☐	☐	☐	☐
18. My consumers have strong expectations of me to counsel in a way that addresses their health literacy needs.	☐	☐	☐	☐	☐	☐	☐
19. Pharmacy management will be very keen to see health literacy principles applied consistently by all employees.	☐	☐	☐	☐	☐	☐	☐
20. The employees in my pharmacy will be very keen to see that health literacy principles are applied consistently to all consumer counselling.	☐	☐	☐	☐	☐	☐	☐
21. If I work towards achieving a high standard of service delivery in the pharmacy relating to health literacy, my managers and colleagues would be impressed.	☐	☐	☐	☐	☐	☐	☐
22. I am confident that I could use effective communication techniques for all consumers when providing health information.	☐	☐	☐	☐	☐	☐	☐
23. Whether or not I can achieve a high level of service delivery relating to health literacy in this pharmacy is beyond my control.	☐	☐	☐	☐	☐	☐	☐

Statement	1 Strongly disagree	2	3	4 Not sure	5	6	7 Strongly agree
24. Whether or not a high level of service delivery relating to health literacy in this pharmacy can be achieved is not entirely up to me.	☐	☐	☐	☐	☐	☐	☐
25. I have a clear vision of how to implement health literacy counselling into all counselling in the pharmacy.	☐	☐	☐	☐	☐	☐	☐
26. Implementing health literacy counselling in the pharmacy seems like a complicated process.	☐	☐	☐	☐	☐	☐	☐
27. I anticipate that my pharmacy would provide sufficient practical support for the implementation of a health literacy program.	☐	☐	☐	☐	☐	☐	☐
28. In the past, my pharmacy has provided reasonable support to implement professional programs.	☐	☐	☐	☐	☐	☐	☐
29. I intend to understand the concepts and skills required to implement health literacy counselling.	☐	☐	☐	☐	☐	☐	☐
30. I intend to apply the principles of healthy literacy counselling to how I communicate with all of my patients.	☐	☐	☐	☐	☐	☐	☐
31. I expect my pharmacy to achieve a high standard of service delivery in this pharmacy relating to health literacy.	☐	☐	☐	☐	☐	☐	☐
32. I have already successfully incorporated and sustained changes to the way I counsel patients in everyday practice.	☐	☐	☐	☐	☐	☐	☐
31. I will work to achieve a high standard of service delivery in the pharmacy relating to health literacy.	☐	☐	☐	☐	☐	☐	☐

Please seal the completed survey in the provided envelope.
Thank you for your participation.

Appendix 7

Phase 3 (Chapter 5) supplementary materials:

- Explanatory statements
- Consent forms
- Consumer data collection tool
- Simulated patient case vignettes
- Simulated patient data collection tool

Appendix 7 – Explanatory statement (Monash University)

Explanatory Statement: Consumers

Project Title: A controlled trial of a health literacy education program in community pharmacies

This information sheet is for you to keep.

My name is **Glen Swinburne B.Pharm (Hons)** and I am conducting a research project with **Dr Safeera Hussainy, Associate Professor Kay Stewart and Mr Kevin McNamara** at the Centre for Medicine Use and Safety, Department of Pharmacy Practice, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, and **Mr Gregory Duncan** at the Faculty of Medicine, Nursing and Health Sciences, Monash University. I am conducting this research project towards a Doctor of Philosophy at Monash University. This means that I will be writing a thesis which is the equivalent of a 300 page book. A report of the project may also be submitted for publication in a journal or be presented at a conference. The project is funded under the Fifth Community Pharmacy Agreement, managed by the Pharmacy Guild of Australia.

Why did you choose this particular person/group as participants?

The research project aims to develop and implement health literacy educational resources for pharmacists and pharmacy assistants, which hopes to improve the communication between the pharmacist and pharmacy assistant with the consumer. The participants for this project are pharmacists, pharmacy assistants and consumers.

Health literacy can be defined as one's ability to access, read, understand and use health information, either written or verbal, in a way that improves health.

The developed health literacy educational resources require evaluation within the pharmacy setting prior to wider distribution, and thus you've been selected to participate in this evaluation.

The consumers selected as a part of this study have been selected at random upon entering the pharmacies involved in the study.

Consumers are eligible to partake in the study if they are 18 years or over.

Consumers who are receiving opioid substitution therapy or the emergency contraception pill, or do not speak at an adequate English level, will be excluded from this study.

The aim/purpose of the research

The aim of the study is to assess the effectiveness of a health literacy educational resource to improve pharmacy staff knowledge of health literacy, and educate staff on appropriate communication measures to adopt when interacting with consumers, called universal precautions in health literacy.

This information will lead to refinement of the educational resources to maximise their usability and appropriateness for wider distribution in the future.

Possible benefits

Pharmacy staff may develop improved communication skills allowing for more effective and appropriate consultations with consumers of varying levels of health literacy. It may improve consumer understanding of medications and advice provided by pharmacy staff.

What does the research involve?

The study will involve collecting data about yourself, including your age, gender, reasons for visiting the pharmacy today, and other health conditions that you may have. During the consultation with the pharmacist or pharmacy assistant, the pharmacist will be videotaped to record the types of communication techniques they used when explaining the information to you. After the consultation, you will be interviewed again to provide feedback about the interaction with the pharmacist or pharmacy staff member, and how comfortable you feel managing the new medication or health condition once you leave the pharmacy.

How much time will the research take?

The research is not believed to take longer than 20 minutes, which includes the time associated with the consultation with the pharmacist or pharmacy staff member.

Inconvenience/discomfort

There are no foreseeable risks other than the inconvenience of your time required.

If you become upset or distressed as a result of your participation in the project, the researcher is able to arrange for counselling or other appropriate support. Any counselling or support will be provided by staff who are not members of the research team and include Lifeline Australia who can be contacted on 13 11 14.

If you have any questions or you would like to talk to someone about the research project you are free to contact me or my supervisors on the contact details listed below.

Can I withdraw from the research?

Participation in this research project is voluntary and you are under no obligation to participate. If you decide to take part and later change your mind, you are free to

withdraw from the project. Please notify the researchers immediately if you wish to withdraw from this research project.

Confidentiality

All the information collected from individual participants during the course of this project will be kept confidential. In any publication and/or presentation information will be provided in such a way that you cannot be identified. Details of the pharmacy staff members who speak to the mystery shoppers will not be recorded and these participants will remain anonymous.

Storage of data

Storage of the data collected will adhere to the University regulations and kept on University premises in a locked cupboard/filing cabinet for 5 years.

Use of data for other purposes

It is not intended that this data be used for any other purpose for which it is primarily obtained.

Results

If you would like to be informed of the aggregate research finding, please contact myself or my supervisors (see below). The findings will be accessible after all data is collected.

If you would like to contact the researchers about any aspect of this study, please contact the Supervisor:	If you have a complaint concerning the manner in which this research <insert your MUHREC project number here> is being conducted, please contact:
Glen Swinburne B.Pharm (Hons) Centre for Medicine Use and Safety Monash University 381 Royal Pde Parkville, VIC 3052 Australia [REDACTED] [REDACTED] Dr Safeera Hussainy Centre for Medicine Use and Safety	Executive Officer Monash University Human Research Ethics Committee (MUHREC) Building 3e Room 111 Research Office Monash University VIC 3800 [REDACTED] [REDACTED] [REDACTED] [REDACTED]

Monash University
381 Royal Pde
Parkville, VIC 3052
Australia

[REDACTED]

[REDACTED]

Mr Gregory Duncan

Eastern Health Clinical School
Faculty of Medicine, Nursing and Health
Services
Monash University
5 Arnold St
Box Hill VIC 3128

[REDACTED]

[REDACTED]

Appendix 7 – Explanatory statement (Curtin University)



Information Sheet: Consumers

Project Title: A controlled trial of a health literacy education program in community pharmacies

This information sheet is for you to keep.

This information is about a research project being run by the Schools of Pharmacy at Curtin University, Monash University, and University of Sydney. The project is about developing a training package for pharmacy staff on how to better deal with the health information needs of people like yourself. Some people like more health information, others only want a small amount of simple information, and some need certain things explained differently to make sure they get the best out of their medicines. We are training pharmacy staff to better adjust their health language and the instructions they give, to meet different people's health information needs.

Why did we choose you as a participant?

The people involved in this project are pharmacists and pharmacy assistants, who receive our training, and people like yourself, who deal with the pharmacy staff in your everyday lives. The staff in this pharmacy are participating in our training, and we want to involve people like yourself to check whether the staff are using what they've learned.

You are eligible to be involved if you are 18 years old or over. You won't be needed for this project if you came into the pharmacy for a dose of Methadone (or similar), or for the emergency contraception pill, or if you don't understand English very well.

Possible benefits

We hope that pharmacy staff who finish our training will be better at talking with people like yourself about health issues and medicines, and will be better at picking up when you might be confused about something they or another health professional have said or written. In the long run, our project intends to make pharmacy staff better communicators, and in turn, make health information easier for everyone to understand.

What does the research involve?

The study will involve collecting data about yourself, including your age, sex, reasons for visiting the pharmacy today, and other health conditions that you may have. During your talk with the pharmacist or pharmacy assistant, and only if you agree,

we would like to tape your discussion with the staff member. This is only to later listen to how the staff member is talking and responding to you. The observer would also like to talk with you in private after you have finished, to ask how you felt about talking with the staff member.

How much time will the research take?

The research should take up to 20 minutes, which includes your time with the staff member.

Inconvenience/discomfort

We don't need anything from you other than your time on this one occasion, and won't be making you do anything embarrassing or hurtful.

This project has been approved by the Curtin University Human Research Ethics Committee (Approval Number: XXXX). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. The Human Research Ethics Committee (Secretary) may be contacted should participants wish to make a complaint on ethical grounds. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning [REDACTED]

Can I withdraw from the research?

You can say no to this request if you want to. If you decide to take part and later change your mind, you are free to pull out. This won't affect the way that the pharmacy staff deal with you in the future.

Confidentiality

All the information collected from all people involved in this project will be kept confidential. Nobody will be named or identified in any reports that we write from this project.

Storage of data

Our universities require us to store the project information for 5 years, but it will be in a locked cupboard, and then destroyed after this time.

Use of data for other purposes

We won't be using any information that you give us for any other purpose. There will be no follow-up contact after today.

Results

If you would like to learn about what we find from our project, we are happy to share a copy at the end; please let us know.

Dr Elsamaul (Sam) Elhebir

Senior Research Officer | School of Pharmacy
Faculty of Health Science | Curtin University

[REDACTED]
[REDACTED]

Associate Professor Lynne Emmerton

Director of Research Training | School of Pharmacy
Faculty of Health Science | Curtin University

[REDACTED]
[REDACTED]

Professor Jeff Hughes

Head | School of Pharmacy
Faculty of Health Science | Curtin University

[REDACTED]

Dr Kreshnik Hoti

Lecturer | School of Pharmacy
Faculty of Health Science | Curtin University

[REDACTED]

Professor Moyez Jiwa

Chair Health Innovation – Chronic Disease
Curtin Health Innovation Research Institute
(CHIRI)

[REDACTED]

Appendix 7 – Explanatory statement (The University of Sydney)



A CONTROLLED TRIAL OF A HEALTH LITERACY EDUCATION PROGRAM IN COMMUNITY PHARMACIES

Participant Information Statement

(1) What is the study about?

Health literacy refers to the ability of individuals to obtain, understand, and apply health care information in written, spoken or digital format, and subsequently make appropriate health-related decisions.¹ Knowledge of how health literacy affects the community, and having the knowledge and skills to address some of those effects will put community pharmacy staff in a strong position to address some of the health effects of low health literacy. In the pharmacy setting, poor Health Literacy can be an impediment to consumers' abilities to clearly articulate the problem for which they are seeking a solution, to appreciate the potential seriousness of the problem that they have, and accept advice for referral to their doctor or another health care professional. However, the health literacy of the pharmacy staff member engaged in the interaction with the person also has the potential to influence the outcome of the encounter, and the staff member may not be able to identify the need or persuade the person to see their doctor.

The research project aims to assess the effectiveness of a health literacy educational resource to improve pharmacy staff knowledge of health literacy, and educate staff on appropriate communication measures to adopt when interacting with consumers, called universal precautions in health literacy. The developed health literacy educational resources require evaluation within the pharmacy setting prior to wider distribution, and thus you've been selected to participate in this evaluation.

The consumers selected as a part of this study have been selected at random upon entering the pharmacies involved in the study. Consumers are eligible to partake in

the study if they are 18 years or over. Consumers who are receiving opioid substitution therapy or the emergency contraception pill, or do not speak at an adequate English level, will be excluded from this study.

(2) Who is carrying out the study?

The study is being conducted by a research team comprised of: Dr Betty Chaar (University of Sydney), Mr Gregory Duncan (Monash University), Mr Glen Swinburne (Monash University), Associate Professor Lynne Emmerton (Curtin University), and Research Assistant Miss Kim Bellamy (University of Sydney).

(3) What does the study involve?

The study will involve collecting data about yourself, including your age, gender, reasons for visiting the pharmacy today, and other health conditions that you may have. During the consultation with the pharmacist or pharmacy assistant, the pharmacist will be videotaped to record the types of communication techniques they used when explaining the information to you. After the consultation, you will be interviewed again to provide feedback about the interaction with the pharmacist or pharmacy staff member, and how comfortable you feel managing the new medication or health condition once you leave the pharmacy.

(4) How much time will the study take?

The research is not believed to take longer than 20 minutes, which includes the time associated with the consultation with the pharmacist or pharmacy staff member.

(5) Can I withdraw from the study?

Participation in this research project is voluntary and you are under no obligation to participate. If you decide to take part and later change your mind, you are free to withdraw from the project. Please notify the researchers immediately if you wish to withdraw from this research project.

(6) Will anyone else know the results?

All the information collected from individual participants during the course of this project will be kept confidential. In any publication and/or presentation information will be provided in such a way that you cannot be identified. Details of the pharmacy

staff members who speak to the mystery shoppers will not be recorded and these participants will remain anonymous.

(7) Will the study benefit me?

Pharmacy staff may develop improved communication skills allowing for more effective and appropriate consultations with consumers of varying levels of health literacy. It may improve consumer understanding of medications and advice provided by pharmacy staff.

(8) Can I tell other people about the study?

Yes, you can tell other people about the study.

(9) What if I require further information?

When you have read this information, the Research Assistant Kim Bellamy will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact *Dr Betty Chaar* (+61 2 90367101), *Gregory Duncan* (+61 412040320), *Glen Swinburne* (+61 9903 9025) or *Kim Bellamy* (+61 451610529).

(10) What if I have a complaint or concerns?

Any person with concerns or complaints about the conduct of a research study can contact the Deputy Manager, Human Ethics Administration, University of Sydney on [REDACTED]
[REDACTED]

References

- 1) Adams R, Appleton SL, Hill CL, Dodd M, Findlay C, Wilson DH. Risks associated with low functional health literacy in an Australian population. Medical Journal of Australia 2009; 17: 257 - 9.

Appendix 7 – Consent form (Monash University)



A controlled trial of a health literacy education program in community pharmacies
Consumer consent form

NOTE: This consent form will remain with the Monash University researcher for their records

I agree for the Monash University research project specified above to be conducted in <specify pharmacy>. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records. I understand that agreeing to take part means that I am willing to:

Agree to supply personal and health information before the consultation with the pharmacist or pharmacy assistant

☐ Yes ☐ No

Agree to be videotaped during consultations with the pharmacist or pharmacy assistant

☐ Yes ☐ No

Agree to be interviewed at the conclusion of the consultation by a research assistant to gain feedback regarding the consultation with the pharmacist or pharmacy assistant

☐ Yes ☐ No

and

I understand that participation is voluntary, and that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project

and

I understand that any data that the researcher extracts from the video data collection or interviews to use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

and

I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party

and

I understand that data from the videotaping and interviews will be kept in a secure storage and accessible only to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Participant's name:

Signature: _____ Date: _____

Appendix 7 – Consent form (Curtin University)



A controlled trial of a health literacy education program in community pharmacies **Consumer consent form**

NOTE: This consent form will remain with Curtin University researcher for his/her records.

I agree for Curtin University research project specified above to be conducted in <specify pharmacy>. I have had the project explained to me, and I have read the Information Sheet, which I keep for my records. I understand that agreeing to take part means that I am willing to:

Agree to supply personal and health information before the consultation with the pharmacist or pharmacy assistant (only what I am comfortable with)

☐ Yes ☐ No

Agree to be audiotaped during my talk with the pharmacist or pharmacy assistant

☐ Yes ☐ No (you may still participate)

Agree to be interviewed afterwards by the researcher about how I felt talking with the pharmacist or pharmacy assistant

☐ Yes ☐ No

and

I understand that participation is voluntary, and that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project

and

I understand that my name, or any other identifying details, will not appear in any reports from this project

and

I understand that my tape-recorded talk and my comments to the researcher will be kept in a locked cupboard at Curtin University, and accessible only to the research team. I also understand that this information will be destroyed after 5 years unless I agree to it being used in future research.

Participant's name: _____

Signature: _____ Date: _____

Appendix 7 – Consent form (The University of Sydney)



Dr Betty Chaar
Lecturer in Pharmacy Practice
ABN 15 211 513 464

Faculty of Pharmacy
Room N508-Building A15
University of Sydney NSW 2006
AUSTRALIA

[REDACTED]
[REDACTED]

Miss Kim Bellamy

Faculty of Pharmacy
Room N508-Building A15
University of Sydney NSW 2006
AUSTRALIA

[REDACTED]
[REDACTED]

PARTICIPANT CONSENT FORM

I,[PRINT NAME], give consent to my participation in the research project

1. TITLE: A Controlled Trial of a Health Literacy Education Program in Community Pharmacies

I understand that agreeing to take part means that I am willing to:

Agree to supply personal and health information before the consultation with the pharmacist or pharmacy assistant

☐ Yes ☐ No

Agree to be videotaped during consultations with the pharmacist or pharmacy assistant

☐ Yes ☐ No

Agree to be interviewed at the conclusion of the consultation by a research assistant to gain feedback regarding the consultation with the pharmacist or pharmacy assistant

☐ Yes ☐ No

In giving my consent I acknowledge that:

1. The **procedures required for the project and the time involved** have been explained to me, and any questions I have about the project have been answered to my satisfaction.
2. I have **read the Participant Information Statement** and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s.
3. I understand that **this study is completely voluntary** – I am not under any obligation to consent and I can withdraw from the study at any time without affecting my relationship with the researcher(s) or the University of Sydney now or in the future.
4. I understand that my involvement is **strictly confidential** and no information about me will be used in any way that reveals my identity.
7. I understand that data from the surveys will be kept in a **secure storage** and accessible only to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Signed:

Name:

Date:

I would like to receiving feedback Yes ☐ No ☐

If you answered 'Yes' to 'Receiving Feedback'. Please provide your details below

Feedback Option:

Address:.....

.....

Email:.....

Appendix 7 – Consumer data collection form



HEALTH LITERACY IN PHARMACY PROJECT CONSUMER DATA COLLECTION FORM (PRE-CONSULTATION)

Investigator use only
Code:

DEMOGRAPHICS					
Gender				Male ☐	Female ☐
Age	18-30 ☐	31-50 ☐	50-64 ☐	65-74 ☐	75+ ☐
State interaction is occurring within			Victoria ☐	W.A. ☐	N.S.W. ☐
Highest level of education achieved		Not completed high school ☐	Completed high school ☐	Higher level of education (e.g. university/technical school) ☐	
What language do you speak most often at home?					

LEVEL OF MEDICATION MANAGEMENT ASSISTANCE REQUIRED					
Did you come in to the pharmacy today for yourself or for someone else?		Myself ☐		Someone else ☐	
If for yourself, do you need assistance with managing your medicines or health?		Yes ☐	No ☐	NA ☐	
If you answered yes to the previous question, was this assistance on advice by your doctor or other health professional?		Yes ☐	No ☐	NA ☐	

HEARING AND VISION			
Do you (or the person who manages these medicines) wear glasses to read or have any other vision problems?		Yes ☐	No ☐
Do you (or the person who manages these medicines) use a hearing aid or have any other hearing problems?		Yes ☐	No ☐

HEALTH STATUS
Please tell us what health conditions you currently have (even if it is minor or not being treated) and roughly how long you have had them for. List below.

WHAT IS YOUR REASON FOR VISITING THE PHARMACY TODAY? (Tick all that apply)	
New prescription ☐	Repeat prescription ☐
Primary care ☐	General health advice ☐
Other (please specify):	

OTHER COMMENTS
Please provide any other comments that you feel are important regarding the consumer:

CONSUMER DATA COLLECTION FORM (POST-CONSULTATION)

Please tick "Yes" for every item that has been asked by the pharmacy staff member. For every item that was not asked please tick "No". For questions that require a written response please write the answers in the spaces that have been provided.

PHARMACY INFORMATION		
Pharmacy name:		
Duration of consultation: Start time:	End time:	Time taken to be attended to:
Did the pharmacy staff member approach you or did you ask for assistance?	☐ Yes ☐ No	
Who spoke to you about your medicine(s) or health query today?	☐ Pharmacist ☐ Assistant	

Please answer Yes or No to the following statements about the service provided by the person who helped you: PROCESS STRATEGIES		
They used clinical terms/complex words in the counselling session	☐ Yes ☐ No	
They clarified the meaning of all clinical terms/complex words, if they were used.	☐ Yes ☐ No	
They spoke in a way that was very clear (e.g. was there an issue with the way the pharmacist or staff member pronounced words?)	☐ Yes ☐ No	
They always spoke at an appropriate pace	☐ Yes ☐ No	
They always spoke at a volume level that I could hear properly	☐ Yes ☐ No	
They repeated all essential information delivered in the counselling session	☐ Yes ☐ No	

CONTENT STRATEGIES USED BY THE PHARMACIST OR STAFF MEMBER		
How many points of information about the medicine did the pharmacy staff member provide? (Answer below)		
☐ 0	☐ 1	☐ 2 ☐ 3 ☐ 4-5 ☐ 6-8 ☐ 9 or more
Did you fully understand everything the pharmacist or pharmacy staff member said?		☐ Yes ☐ No

Please answer Yes or No to indicate: ENGAGEMENT STRATEGIES		
You were given the opportunity to ask questions	☐ Yes ☐ No	
Did the pharmacist or staff member ask the question "What questions do you have?" or similar? <i>[Note to data collector – if not exactly this, check if it was an open question; otherwise answer 'No']</i>	☐ Yes ☐ No	
Were you asked to explain the information back (e.g. teach –back)	☐ Yes ☐ No	
Were you asked to demonstrate device use, if appropriate?	☐ Yes ☐ No	
Were any visual aids used, such as information sheets or diagrams, to help with counseling?	☐ Yes ☐ No	
Were you given printed/handwritten information (please specify below) ask to see if any uncertainty	☐ Yes ☐ No	
An official product information sheet ('CMI') ☐	Information leaflet ☐	
Other printed information ☐	PSA Self-care card ☐	
Was the purpose of the written materials explained?	☐ Yes ☐ No	
Was the content of the written materials explained?	☐ Yes ☐ No	
Were the materials you were given easy to read?	☐ Yes ☐ No	

I feel fully capable with managing my medicines or health with the information I was supplied with today				
☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree

OTHER COMMENTS
Please provide any other comments that you feel are important regarding the consumer consultation

Appendix 7 – Simulated patient case vignettes

1. Heartburn

- a. Patient characteristics: simple, use plain language, don't ask questions.
- b. "I have been having some burning in my chest, and a yucky taste at the back of my throat"
 - "Any other symptoms?" No.
 - "Have you used anything?" No
 - "Any foods that bring it on? Causes?" Not sure. Never thought about that.
 - "Worse at night?" Yes
 - "Had it before?" Yes, a few times. Happens on and off.
 - "How long has it been going on for? Duration?" Had it last night.
 - "Do you have any radiating pain in chest/arms?" No
 - "Any heart problems?" No
 - "Any other medications?" No
 - "Allergies?" No
 - "Pregnant/BF?" No

Assume the pharmacy staff member will take them to the gastro area. If not, MS can ask them to show them what they have available. Can point Mylanta and say that they have seen that at home, I think someone at home uses it. If asked "Do you know how to use it?" say I've never used it before.

If asked "Do you have any questions?" say No.

If asked "What questions do you have?" can ask "Why is it called heart burn? Is it to do with my heart?"

2. Asthma

- a. Patient Characteristics: : simple, use plain language, has ventolin inhaler (unboxed)

"I had difficulty breathing this morning while running. This happened before and got this puffer from my GP, but I haven't used it and I am not sure what to do"

"When did you get the puffer/see the Dr?" 6 months ago

"How long did you have shortness of breath?" A few hours

"Do you have asthma? My doctor mentioned it, but I am not sure"

"Is it only during exercise?" Yes

"Any allergies?" No

Pregnant/BF? No

"Do you know how to use it?" No, the doctor didn't explain it

"Any other conditions?" No

"Do you use any medication/preventer?" No

If asked "Do you have any questions?" say No.

If asked "What questions do you have?" can ask "Should I avoid exercise?"

3. Allergy

a. Patient characteristics: simple, plain language, don't ask questions.

"My partner has red, itchy eyes, runny nose and sneezing"

"Is anything coming out of the eyes?" Yes, just tears.

"Any other symptoms/cough/sore throat/fever?" No

"Had it before?" Yes, maybe a year ago.

"Does anything bring it on?" I don't know.

"Have they tried anything for it before?" Yes, Phenergen, but it made them quite tired so maybe not that.

"Any other medicines?" No.

Pregnant/BF? No

Take in a used strip of Zyrtec and Codral, and say they had this in their medicine box that they used for a runny nose a few months ago, wondering if any of these could be useful for their partner.

If asked "Do you have any questions?" say No.

If asked "What questions do you have?" can ask "Can I catch it?"

Appendix 7 – Simulated patient data collection form



Investigator use only
Code:

MYSTERY SHOPPER DATA COLLECTION FORM

Please tick "Yes" for every item that has been asked by the pharmacy staff member. For every item that was not been asked please tick "No". For questions that require a written response please write the answers in the spaces that have been provided.

PHARMACY INFORMATION		
Pharmacy name:		
Duration of consultation: Start time:	End time:	Time taken to be attended to:
Did the pharmacy staff member approach you?	☐ Yes ☐ No	
Did you speak to a pharmacy assistant?	☐ Yes ☐ No	
Did you speak to the pharmacist?	☐ Yes ☐ No	

SCENARIO:

PROCESS STRATEGIES		
Utilised clinical terms/complex words in the counselling session	☐ Yes ☐ No	
Clarified the meaning of clinical terms/complex words, if they were used.	☐ Yes ☐ No	
Heard what the pharmacist or pharmacy staff member said	☐ Yes ☐ No	
Spoke at an appropriate pace	☐ Yes ☐ No	
Spoke at a volume level that I could hear properly	☐ Yes ☐ No	
Repeated any information delivered in the counselling session	☐ Yes ☐ No	

CONTENT STRATEGIES		
Provided the following information:		
Brand name of the medicine ☐	Common side effects ☐	Contraindications ☐
Dosage ☐	Dosage form ☐	Drug name of the medicine ☐
Duration of therapy ☐	Interactions with drugs or food ☐	Number of repeats (if appropriate) ☐
Proper storage ☐	Purpose of the medicine ☐	Route of administration ☐
Self-monitoring advice ☐	Severe side effects ☐	Special directions ☐
What to do if missed dose ☐		

ENGAGEMENT STRATEGIES		
Provided the opportunity to ask questions	☐ Yes ☐ No	
Utilised the phrase "What questions do you have?"	☐ Yes ☐ No	
Asked you to explain the information back to them (e.g. teach-back)	☐ Yes ☐ No	
Asked you to demonstrate device use, if appropriate.	☐ Yes ☐ No	
Used visual aids to complement counselling	☐ Yes ☐ No	
Supplied printed/handwritten information	☐ Yes ☐ No	
CMI ☐	Information leaflet ☐	
Other printed information ☐	PSA Self-care card ☐	
Explained the purpose of the written materials	☐ Yes ☐ No	
Explained the content of the written materials	☐ Yes ☐ No	
Provided materials that were legible?	☐ Yes ☐ No	

OTHER COMMENTS
Please provide any other comments that you feel are important regarding the mystery shopper – pharmacist/pharmacy staff member consultation and visit including where the consultation was done.

Appendix 8

Ethics approval for Phase 4 (Chapter 6)

Appendix 8 – Ethics approval (Monash University)



MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

This is to certify that the project below was considered by the Monash University Human Research Ethics Committee. The Committee was satisfied that the proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* and has granted approval.

Project Number: CF13/3475 - 2013001778

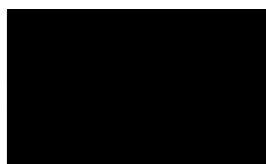
Project Title: The Usability of a Health Literacy Education Package - Views of Pharmacists And Pharmacy Assistants

Chief Investigator: Dr Safeera Hussainy

Approved: From: 21 November 2013 To: 21 November 2018

Terms of approval - Failure to comply with the terms below is in breach of your approval and the Australian Code for the Responsible Conduct of Research.

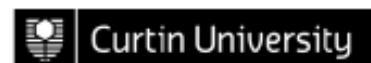
1. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, before any data collection can occur at the specified organisation.
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must include your project number.
6. Amendments to the approved project (including changes in personnel): Require the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. Future correspondence: Please quote the project number and project title above in any further correspondence.
8. Annual reports: Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. Final report: A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. Monitoring: Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. Retention and storage of data: The Chief investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.



Professor Nip Thomson
Chair, MUHREC

cc: Mr Gregory Duncan, Dr Kevin McNamara, Assoc Prof Kay Stewart, Mr Glen Swinburne

Appendix 8 – Ethics approval (Curtin University)



Memorandum

To	Lynne Emmerton
From	Alison Smith, Form C Coordinator
Subject	Protocol Approval PH-26-13
Date	14 th January 2014
Copy	Elsamaul Elhebir, Jeff Hughes, Moyez Jiwa, Kreshnik Hoti

Faculty of Health Sciences

School of Pharmacy

Thank you for your "Form C Application for Approval of Research with Low Risk (Ethical Requirements)" for the project titled *"The usability of a health literacy education package - views of pharmacists and pharmacy assistants"*. On behalf of the Human Research Ethics Committee, I am authorised to inform you that the project is approved.

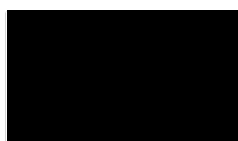
Approval of this project is for a period of 4 years **14/01/2014 to 14/01/2018**.

Your approval has the following conditions:

- (i) **Annual progress reports** on the project must be submitted to the Ethics Office.
- (ii) It is your responsibility, as the researcher, to **meet the conditions** outlined and to retain the necessary records demonstrating that these have been completed.
- (iii) It is the investigator's responsibility to complete **Risk Assessments** as appropriate to the research activities, prior to commencement of this research. The Curtin University Risk Assessment form is [available here](#).

The approval number for your project is **PH-26-13**. Please quote this number in any future correspondence. If at any time during the approval term changes/amendments occur, or if a serious or unexpected adverse event occurs, please advise me immediately.

Sincerely,



Research & Development Support Coordinator
School of Pharmacy

Please Note: The following standard statement must be included in the information sheet to participants:
This study has been approved under Curtin University's process for lower-risk Studies (Approval Number PH-26-13). This process complies with the National Statement on Ethical Conduct in Human Research (Chapter 5.1.7 and Chapters 5.1.18-5.1.21). For further information on this study contact the researchers named above or the Curtin University Human Research Ethics Committee. c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth 6845 or by telephoning 9266 9223 or by emailing hrec@curtin.edu.au.

Appendix 9

Phase 4 (Chapter 6) supplementary materials:

- Explanatory statements
- Consent forms
- HeLP focus group question guide

Appendix 9 – Explanatory statement (Monash University)



EXPLANATORY STATEMENT

Pharmacy staff members (Pharmacists and pharmacy assistants)

Project: The usability of a health literacy education package – views of pharmacists and pharmacy assistants.

Dr. Safeera Hussainy

Mr. Glen Swinburne

Centre for Medicine Use and Safety

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

Dear <Title/name>,

My name is Glen Swinburne B.Pharm (Hons) GCPharmPrac and I am conducting a research project with Dr. Safeera Hussainy, Mr Gregory Duncan, Dr. Kevin Mc Namara and Associate Professor Kay Stewart at the Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University. I am conducting this research project towards a Doctor of Philosophy at Monash University. This means that I will be writing a thesis which is the equivalent of a 300 page book. A report of the project may also be submitted for publication in a journal or be presented at a conference. The study is funded by the Department of Health and Ageing, and managed by the Pharmacy Guild of Australia through the Fifth Community Pharmacy Agreement.

What does the research involve?

The aim of this study is to elicit your views on the design, effectiveness and usability of the health literacy educational program that you have been using since August 2013.

We are inviting you to participate in a group discussion, which is known as a focus group, so that the researchers can refine the health literacy educational program prior to wider dissemination to other pharmacists and pharmacy assistants.

Participation in this study involves a group discussion (a focus group) with other <pharmacists> OR <pharmacy assistants>. Ten < pharmacists> OR <pharmacy assistants> will be invited for discussion, which will last approximately two hours. The group discussion will take place at a place and time convenient for all the participants. I will be moderating the group discussion. Another member of the research team will also be present to take some written notes of the discussion. All participants will be asked to sign a confidentiality statement prior to the commencement of the group discussion to ensure all material discussed amongst group remains private. The discussion will be audio-recorded to make sure that we do not miss any valuable information provided by the participants. If you prefer for you input not to be recorded, the recording will be ceased while you speak, and recommenced when you have finished. You will be identified only by a unique code in the transcript; any personal information that could reveal the identity of individual participants will be removed from the transcript.

Why were you chosen for this research?

You have been chosen for the study due to your prior participation in the health literacy educational program implementation and training in your pharmacy.

Participants must be aged 18 years or over to take part in this study.

Possible benefits from this study

While no direct benefit currently exists from this study, it will aid in the refinement a health literacy educational package that will help pharmacists and pharmacy staff members develop improved communication skills allowing for more effective and appropriate interactions with consumers of varying levels of health literacy. It may improve consumer understanding of medications and advice provided by pharmacy staff.

Consenting to participate in the project and withdrawing from the research
Participating in this study is voluntary, it is up to you to decide whether to take part or not. If you choose not to take part, this will not affect your relationship with Monash University, the researchers or other stakeholders. However, your taking part will be very useful for us. Even if you consent to participate, you may withdraw at any time prior to the group discussion. Once the group discussion has been conducted, any information provided by you during the discussion will be utilised in a way that will make you unidentifiable, in the study results.

Possible inconvenience or discomfort

There are no foreseeable risks other than the inconvenience of your time required to attend the group discussion or potential discomfort while answering questions during the group discussion. The moderator during the group discussion will not ask you any personal or sensitive questions. You will also be given a copy of the questions that will be asked in the group discussion prior to attending. If you have any concerns about the questions you can contact the researchers on the details provided below prior to the group discussion. If you become upset or distressed during or after the group discussion, please notify the moderator or the researchers immediately and they will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by staff who are not members of the research team and include Lifeline Australia who can be contacted on 13 11 14.

Confidentiality

All the information collected from individual participants throughout the course of this study will be kept confidential. To ensure your participation remains anonymous and confidential, we will ask all participants in the group discussion to sign a confidentiality declaration form.

Storage of data

Storage of the information will adhere to the Monash University's regulations. Audiotapes and transcripts will be kept in the University premises in a locked cabinet for 5 years and electronic data or files will be stored in a password protected computer.

Results

If you would like to be informed of the study findings or would like to obtain a copy of the study report, please contact Glen Swinburne [REDACTED]
[REDACTED] The findings will be accessible after all data is collected.

Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the

**Executive Officer, Monash University Human Research
Ethics (MUHREC):**

**Executive Officer
Monash University Human Research Ethics Committee
(MUHREC)
Room 111, Building 3e
Research Office
Monash University VIC 3800**

**[REDACTED] [REDACTED]
[REDACTED]**

**If you would like to contact the researchers about any aspect of this study,
please contact one of the investigators below:**

Dr. Safeera Hussainy B.Pharm (Hons) PhD GCHE
(Chief investigator)
Lecturer, Academic supervisor
Centre for Medicine Use and Safety,
Monash University

[REDACTED]

[REDACTED]

Glen Swinburne B.Pharm(Hons) GCPharmPrac
(Student researcher)
PhD candidate
Centre for Medicine Use and Safety,
Monash University.

[REDACTED]

[REDACTED]

Appendix 9 – Explanatory statement (Curtin University)



EXPLANATORY STATEMENT

Pharmacy staff members (Pharmacists and pharmacy assistants)

Project: The usability of a health literacy education package – views of pharmacists and pharmacy assistants.

Dr Elsamaul (Sam) Elhebir
Senior Research Officer | School of
Pharmacy
Faculty of Health Science | Curtin
University

[Redacted contact information]

Associate Professor Lynne Emmerton
Director of Research Training | School
of Pharmacy
Faculty of Health Science | Curtin
University

[Redacted contact information]

Dear <Title/name>,

I am writing to you regarding a research project being conducted collaboratively by the Schools of Pharmacy at Curtin University, Monash University, and The University of Sydney. Since your pharmacy has participated in the research project and received our health literacy training, we would like to invite you to participate in our focus groups.

What does the research involve?

The aim of this study is to elicit your views on the design, effectiveness and usability of the health literacy educational program that you have been using since August 2013.

We are inviting you to participate in a group discussion, which is known as a focus group, so that the researchers can refine the health literacy educational program prior to wider dissemination to other pharmacists and pharmacy assistants.

Participation in this study involves a group discussion (a focus group) with other pharmacists and pharmacy assistants, with up to 10 participants per group. Each focus group will last up to two hours. The group discussion will take place at a place and time convenient for all participants. I will be moderating the group discussion. Another member of the research team will also be present to take some written notes of the discussion. All participants will be asked to sign a confidentiality statement prior to the commencement of the group discussion to ensure all material discussed amongst group remains private. The discussion will be audio-recorded to

make sure that we do not miss any valuable information provided by the participants. If you prefer for your input not to be recorded, the recording will be ceased while you speak, and recommenced when you have finished. You will be identified only by a unique code in the transcript; any personal information that could reveal the identity of individual participants will be removed from the transcript.

Why were you chosen for this research?

You have been chosen for the study due to your prior participation in the health literacy educational program implementation and training in your pharmacy.

Participants must be aged 18 years or over to take part in this study.

Possible benefits from this study

While no direct benefit currently exists from this study, it will aid in the refinement of the health literacy educational package to help pharmacists and pharmacy staff members develop improved communication skills, allowing for more effective and appropriate interactions with consumers of varying levels of health literacy. It may improve consumer understanding of medications and advice provided by pharmacy staff.

Consenting to participate in the project and withdrawing from the research
Participating in this study is voluntary; it is up to you to decide whether to take part or not. If you choose not to take part, this will not affect your relationship with any of the researchers or other stakeholders. However, your taking part will be very useful for us. Even if you consent to participate, you may withdraw at any time prior to the group discussion. Once the group discussion has been conducted, any information provided by you during the discussion will be utilised in a way that will make you unidentifiable in the study results.

Possible inconvenience or discomfort

There are no foreseeable risks other than the inconvenience of your time required to attend the group discussion or potential discomfort while answering questions during the group discussion. The moderator during the group discussion will not ask you any personal or sensitive questions. You will also be given a copy of the questions that will be asked in the group discussion prior to attending. If you have any concerns about the questions you can contact the researchers on the details provided below prior to the group discussion. Should you have any questions about the project in the meantime, please feel free to contact me.

Confidentiality

All the information collected from individual participants throughout the course of this study will be kept confidential. To ensure your participation remains anonymous and

confidential, we will ask all participants in the group discussion to sign a confidentiality declaration form.

Storage of data

Storage of the data collected will adhere to the University regulations and kept on University premises in a locked cupboard/filing cabinet for 5 years.

Results

If you would like to be informed of the aggregate research finding, please contact me (see below). The findings will be accessible after all data are collected.

If you would like to contact the researchers about any aspect of this study, please contact one of the investigators below:

Dr Elsamaul (Sam) Elhebir
Senior Research Officer | School of
Pharmacy
Faculty of Health Science | Curtin
University

[REDACTED]
[REDACTED]

Professor Jeff Hughes
Head | School of Pharmacy
Faculty of Health Science | Curtin
University

[REDACTED]

Professor Moyez Jiwa
Chair Health Innovation – Chronic
Disease
Curtin Health Innovation Research
Institute (CHIRI)

[REDACTED]

Associate Professor Lynne Emmerton
Director of Research Training | School
of Pharmacy
Faculty of Health Science | Curtin
University

[REDACTED]
[REDACTED]

Dr Kreshnik Hoti
Lecturer | School of Pharmacy
Faculty of Health Science | Curtin
University

[REDACTED]

This project has been approved by the Curtin University Human Research Ethics Committee (Approval Number: PH-26-13). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. The Human Research Ethics Committee (Secretary) may be contacted should participants wish to make a complaint on ethical grounds. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning [REDACTED]

Thank you,
Dr Sam Elhebir

Appendix 9 – Consent form (Monash University)



CONSENT FORM

Pharmacy staff members (Pharmacists and pharmacy assistants)

Project: The usability of a health literacy education package – views of pharmacists and pharmacy assistants.

Chief Investigator: Safeera Hussainy

I have been asked to take part in the Monash University research project specified above. I have read and understood the Explanatory Statement and I hereby consent to participate in this project.

I consent to the following:	Yes	No
I agree to be involved in a focus group (group discussion) of up to 10 people	☐	☐
I agree to allow the interview to be audio-taped	☐	☐
I agree for any information provided by me in this research project to be utilised in a way that keeps me anonymous	☐	☐

- 1. I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project prior to the commencement of the group discussion without being penalised or disadvantaged in any way.**
- 2. I understand that I will be offer the opportunity to view a transcript of data concerning me for my approval before it is included in the write up of the research.**
- 3. I understand that I may ask at any time/prior to giving final consent and commencement of the group discussion (focus group session) for my data to be withdrawn from the project.**

4. I understand that no information I have provided that could lead to the identification of any other individual will be disclosed in any reports on the project, or to any other party.
5. I understand that data from the group interview (focus group) will be kept in secure storage and accessible to the research team. I also understand that the data will be destroyed after a five year period unless I consent to it being used in future research.

Name	of
Participant	
Participant	
Signature	Date

Please return the consent form in the reply paid envelope to:

Glen Swinburne
Department of Pharmacy Practice
Monash University
381 Royal Parade
Parkville VIC 3052



Thank you for your participation

Appendix 9 – Consent form (Curtin University)



CONSENT FORM

Pharmacy staff members (Pharmacists and pharmacy assistants)

Project: The usability of a health literacy education package – views of pharmacists and pharmacy assistants.

I have been asked to take part in Curtin University research project specified above. I have read and understood the Explanatory Statement and I hereby

I consent to the following:	Yes	No
I agree to be involved in a focus group (group discussion) of up to 10 people	☐	☐
I agree to allow the interview to be audio-taped	☐	☐
I agree for any information provided by me in this research project to be utilised in a way that keeps me anonymous	☐	☐

consent to participate in this project.

- 1. I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project prior to the commencement of the group discussion without being penalised or disadvantaged in any way.**
- 2. I understand that I will be offered the opportunity to view a transcript of data concerning me for my approval before it is included in the write up of the research.**
- 3. I understand that I may ask at any time/prior to giving final consent and commencement of the group discussion (focus group session) for my data to be withdrawn from the project.**
- 4. I understand that no information I have provided that could lead to the identification of any other individual will be disclosed in any reports on the project, or to any other party.**

5. I understand that data from the group interview (focus group) will be kept in secure storage and accessible to the research team. I also understand that the data will be destroyed after a five year period unless I consent to it being used in future research.

Name of Participant _____

Participant Signature _____

Date _____

Please return the consent form to:

**Dr Elsamaul (Sam) Elhebir, Senior Research Officer | School of Pharmacy,
Faculty of Health Science | Curtin University.** [REDACTED]
[REDACTED]

Thank you for your participation

Appendix 9 – HeLP focus group question guide

HeLP focus group questions

Trainer group questions (GROUPS 1 AND 3)

1. I'm interested in your experiences with giving the health literacy training, including the training package. Can you tell me what you thought of it?

- Prompts
 - Type of training – was it convenient?
 - Was it user friendly?
 - Was it practical?
 - What did you think of the length of the training package?
 - How did you find the detail in the package?
 - Was it clear in your mind how the training would improve practice?
 - Did the training build on your previous knowledge?
 - Did you enjoy doing the health literacy training? What was it that you liked? What was it that you disliked?

2. Did the training format make learning easy? Was the content interesting and appropriate?

- Layout, sequence, activities provided.

3. In terms of delivering the training in your pharmacy, what sort of things made it more difficult or easy?

- Prompts
 - Time taken to deliver the training
 - Skill level *and perceived ability to influence implementation (self-efficacy)*
 - Dedication (*attitudes*)
 - Person driving it
 - Peer pressure among staff or managers (*subjective norms*)
 - Consumer need (*subjective norms*)
 - Rewards

- What would make it better or more effective?

4. How did your staff respond to the training from your perspective?

- Did it change the way other staff may look to you for support or advice in regards to communication with consumers, or health literacy?
- Was this type of training (train-the-trainer) effective over other methods you've previously used?

5. Did you feel the training prepared you adequately to change the way you interacted with clients once you finished it?

- Was the training relevant to your everyday practice?

- Did it extend what you already know and practice in this area?

6. What were your experiences in trying to use what you've learned in practice in terms of counselling individual patients?

- Prompts
 - If you assumed that a person had limited health literacy until proven otherwise.
 - In looking/listening for clues of person's health literacy ability
 - If you attempted to ask "What questions do you have for me?" or similar phrasing.

7. What changes have you found in how patients respond when you counsel in the manner recommended?

- Prompts
 - Different aspects of universal precautions
 - Tell me about how you counselled clients as a result of training.
 - What other changes have happened in your pharmacy overall as a result of the training?
 - Environment
 - Management approaches (training, staff performance reviews, policy etc.)
 - Other staff changing practice, plus their reactions to changes.
 - If changes occurred, how did clients react to these? Did they give any feedback or say anything about this new way of explaining things to them about their medicines?

8. If you have made changes to the way you deal with clients, how long do you think your changes to practice will be sustained? What were the steps you have taken to make sure the changes would be implemented and sustained in your practice?

- Prompts
 - Have you developed new habits? (e.g. reminder systems)
 - Did you feel unnatural or uncomfortable? If so, how long did that last?
 - Have environmental changes in the pharmacy become 'permanent'?

9. Would you like to do more training like this? Does the style of delivery (by staff in-house) suit your practice?

Training participant group questions (GROUPS 2, 4 AND 5)

USABILITY OF THE TRAINING PACKAGE

1. I'm interested in your experiences with receiving the health literacy training. Can you tell me what you thought of it?

- Prompts

- Type of training – was it convenient?
 - Was it user friendly?
 - Was it practical?
 - What did you think of the length of the training package?
 - How did you find the detail?
 - Was it clear in your mind how this would improve practice?
 - Did the training build on your previous knowledge?
 - Did you enjoy doing the health literacy training? What was it that you liked? What was it that you disliked?
2. Did the format make learning easy? Was the content interesting and appropriate?
- Did you find it challenging?
 - Layout, sequence, activities provided.
3. In terms of delivering the training in your pharmacy, what sort of thing made it more difficult or easy?
- Prompts
 - Time taken to deliver the training
 - Skill level (*self-efficacy*)
 - Dedication (*attitudes*)
 - Person driving it
 - Peer pressure among staff or managers (*subjective norms*)
 - Consumer need (*subjective norms*)
 - Rewards
 - What would make it better or more effective?
4. Did you feel the training prepared you adequately to change the way you interacted with clients once you finished it?
- Was the training relevant to everyday practice?
 - Did it extend what you already know and practice in this area?
5. What were your experiences in trying to use what you'd learned in practice in terms of counseling individual patients?
- Prompts
 - If you assumed that a person had limited health literacy until proven otherwise.
 - In looking/listening for clues of person's health literacy ability
 - If you attempted to ask "What questions do you have for me?" or similar phrasing.
6. What changes have you found in how patients respond when you counsel in the manner recommended?
- Prompts
 - Different aspects of universal precautions
 - Tell me about how you counselled clients as a result of training.

- What other changes have happened in your pharmacy overall as a result of the training?
 - Environment
 - Management approaches (training, staff performance reviews, policy etc.)
 - Other staff changing practice, plus their reactions to changes.
- If changes occurred, how did clients react to these? Did they give any feedback or say anything about this new way of explaining things to them about their medicines?

7. If you have made changes to the way you deal with clients, how long do you think your changes to practice will be sustained? What were the steps you have taken to make sure this would be implemented and sustained in your practice?

- Prompts

- Have you developed new habits? (e.g. reminder systems)
- Did you feel unnatural or uncomfortable? If so, how long did that last?
- Have environmental changes in the pharmacy become 'permanent'?

8. Would you like to do more training like this? Does the style of delivery (by staff in-house) suit your practice?