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HeLP: Health Literacy in Pharmacy project

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Research & Development

FULL FINAL REPORT

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Acronyms

Acronym	Explanation
5CPA	Fifth Community Pharmacy Agreement
ABS	Australian Bureau of Statistics
AHRQ	Agency for Healthcare Research and Quality
CALD	Culturally and Linguistically Diverse
CMI	Consumer Medicine Information
FECCA	Federation of Ethnic Communities' Councils of Australia
HCPs	Health Care Professionals
HREC	Human Research Ethics Committee
N/A	Not applicable
NSW	New South Wales, Australia
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
S2	Pharmacy Only Medicine
S3	Pharmacist Only Medicine
S4	Prescription Only Medicine

TAFE	Technical and Further Education
TPB	Theory of Planned Behaviour
UK	United Kingdom
US	United States
VIC	Victoria, Australia
WA	Western Australia, Australia
WHO	World Health Organization

Project Team

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Abstract

Evidence from published research suggests that the concept of **health literacy** has gained little traction in community pharmacy practice, despite the daily involvement of pharmacy staff with consumers who may have limited understanding of their medicines or the healthcare system, and limited ability to navigate through these challenges. Conversely, pharmacy services should also address the needs of consumers with greater capacity for information and health-related skills.

This project aimed to design, develop, implement and evaluate a health literacy educational package for community pharmacy staff in Australia. The purpose of the educational package was to improve the ability of pharmacy staff to detect and resolve issues related to consumers' health literacy. In doing so, staff were trained in more effective provision of advice and medicines information, with a view to improving the quality use of medicines.

The educational package was developed with assistance by professionals in the fields of health literacy, pharmacy and educational design, and reference to relevant literature and an online survey of health literacy education in English-speaking countries to inform the content and format of the package. The package was produced in two formats, for face-to-face or electronic delivery to a nominated staff member(s) in each participating pharmacy (a 'train-the-trainer' approach). This staff member(s) then managed the training of the remaining staff. The principle of "Universal Precautions" formed the foundation of the training, encouraging pharmacists and staff to assume that a consumer has limited health literacy until cues or clues from the consumer indicate otherwise. Two key elements of the training were adoption of the "teach-back method" during counselling to ensure consumers' understanding of instructions, and routine use of "What questions do you have?" to encourage questions.

A randomised controlled trial was conducted from May to November 2013 to evaluate the uptake and implementation of the educational package. In total, 77 pharmacies were recruited, sampled by geographical location across three states in Australia; at least partial data were obtained from 71, with 63 pharmacies remaining at the conclusion of the trial. Pharmacies either received the training face-to-face (in a workshop held in each state), by electronic means, or were allocated to a control group where no training was received. Key elements of the training (collectively, the Universal Precautions approach) were monitored before and after the training using simulated patients, researcher observation and consumer recall following consultations. Pharmacists and pharmacy staff members were also surveyed before and after the training regarding their attitudes and motivations towards health literacy training, and a survey of the 'health-literacy friendliness' of the pharmacy environment was undertaken. Finally, feedback on the training and its implementation was obtained via focus groups or interviews with 17 pharmacists and 22 pharmacy staff from 11 of the participating pharmacies.

A simulated patient study was undertaken to gain objective feedback regaridng the use of Universal Precautions by pharmacies. There was a significant increase in the use of the phrase "What questions do you have?" in the face-to-face group post-intervention when compared to the rate detected in this group pre-intervention. There was no significant improvement in the use of the teach back-method post-intervention in both the face-to-face and electronic group compared to the control group. The researchers recruited 440 consumers pre-intervention, and 338 post-intervention, from 77 pharmacies. Based on the combination of both consumer recall and researcher observations, pharmacies in the two intervention groups (face-to-face and electronic) were 7.9 and 5.0 times more likely, respectively, to exhibit the primary outcome of "What questions do you have?" than control group pharmacies. Not all interactions were able to be observed by researchers. There was no significant change in the use of the teach-back method post-intervention in both the face-to-face and electronic group compared to the control group. There was also a significant improvement in pharmacists' and pharmacy staff

members' attitudes and intentions in the face-to-face and electronic group combined when compared to the control group post-intervention, and a significant improvement in the perceived behavioural control in the face-to-face and electronic group combined post-intervention compared to the combined intervention group pre-intervention in regards to undertaking health literacy training. Feedback from participating pharmacists and pharmacy staff requested greater flexibility around the training materials and delivery modes, and suggested alternative communication and consumer engagement techniques used in their pharmacies. The majority of feedback related to the introductory and techniques-focussed modules.

The educational package was demonstrated effective in improving some aspects of communication by pharmacists and pharmacy staff with consumers, but also highlights the relative difficulty in attempting to make changes to practice behaviours, particularly in relation to communication techniques. The study provided scope for the refinement of the educational package before wider dissemination. The refined training package, comprising four modules, is available for wider implementation. The researchers welcome further feedback on all components, but in particular, the applied module relating to 'outreach' initiatives to the carers and teachers of at-risk sectors of the community, when these service models are more widely delivered.

1 Key Findings

Key findings summary

The findings of this project describe an issue that has profound personal and service impact, and presents significant burden to the health system. Health literacy is a term used to describe the cognitive and social skills that determine the motivation and ability of individuals to gain access to, understand and use information in ways that promote and maintain good health. In the pharmacy setting, people with limited health literacy have increased risk of medication misadventure, may misunderstand warning labels and directions, and may not access their entitlements. In a broader perspective, it is estimated that 56% of Australian adults have limited health literacy, and in the United States, the consequences cost over $200 billion each year (Vernon et al., 2007).

There has been limited success in addressing the issues and impact of low health literacy, particularly in the pharmacy setting. There is limited research in the community pharmacy context. Very few interventions exist to manage the issue of limited health literacy and ever fewer are successful in improving consumer health literacy. The focus needs to broaden to include health professionals and their skills and abilities to reduce the impact of limited health literacy.

An evidence-based educational package for community pharmacies, the *HeLP (Health Literacy in Pharmacy)* program, was developed for, and trialled by, pharmacy staff. The program, designed for pharmacists and support staff, applies adult learning principles, educational tools and resources to enhance delivery. The constituent modules are illustrated in Figure 1. Our 'Universal Precautions' strategy encourages staff to assume a consumer has limited health literacy unless there are indications of higher engagement. A 'train-the-trainer' approach (using two delivery modes – face-to-face training and electronic/self-directed learning) was used for dissemination within the pharmacies. A randomised-controlled trial was conducted with 77 pharmacies from three states to evaluate the impact of the program and guide its refinement. Significant improvements were detected in the key outcome: the use of the phrase, 'What questions do you have?' Greater adoption of teach-back techniques was not evident, although focus group feedback indicated reasons for this, which informed enhancement of the educational package. There was measured improvement in attitudes and intentions in regard to implementing and using the package in the pharmacy. Some organisational barriers may hinder confidence in implementing the package and applying Universal Precautions in counselling. Overcoming these barriers is vital in promoting sustainability of the educational package in the pharmacy.

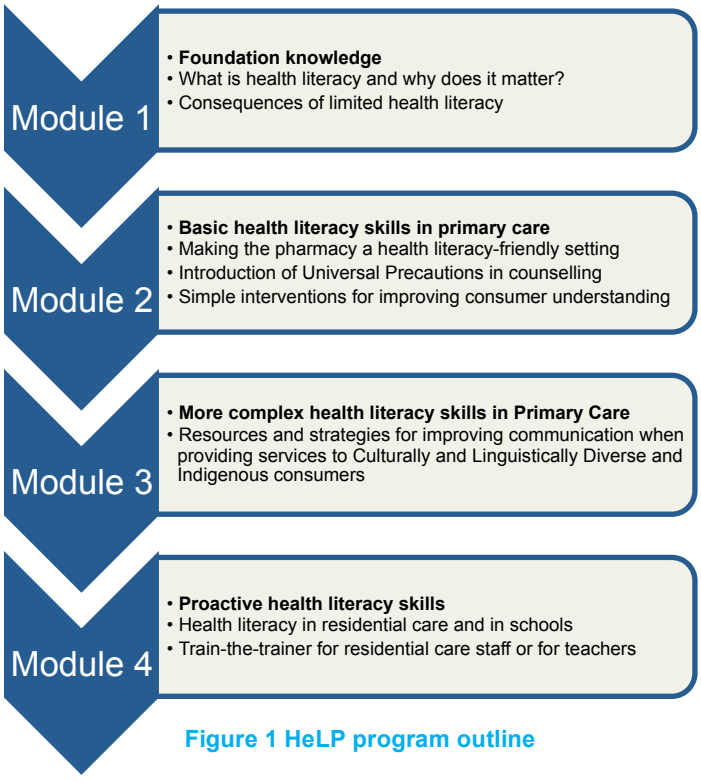

Figure 1 HeLP program outline

The HeLP education program is accessible, useful and meaningful to pharmacy staff. It is recommended that it be made widely available for community pharmacies as well as pharmacy schools to improve consumer services and health outcomes. Ongoing monitoring and review should be part of an implementation strategy.

Key findings in detail for each objective

Objective 1: Review literature relating to health literacy and health literacy educational interventions for health-care professionals, specifically pharmacists

- There is a limited body of health literacy research in a community pharmacy context.

  Limited health literacy in the elderly has been associated with poor health outcomes and higher all-cause mortality, reflecting previous findings.

- There are very few interventions to address the effects of limited health literacy.

- Interventions to improve health literacy of consumers have not been successful, but the potential to mitigate against the adverse effects of health literacy has been demonstrated for a number of health conditions.

- The link between health literacy and adherence to medications is not well supported in the available literature. This contrasts with earlier findings. Understanding this discrepancy was central to designing a successful intervention, and suggests that people with limited health literacy do, in the right circumstances, have the capacity to adhere to a medication regimen.

- Multiple strategies to overcome low health literacy are more effective than implementing a single strategy.

- Improving the readability of information and using best-practice document design and self-management instruction improves knowledge. This has been identified in numerous studies across a range of health contexts and primary care settings.

- Video guidance helps people read and understand medication labels.

- Improving children's general reading ability may reduce hospitalisation rates in children with asthma.

- The health literacy of the carer is not always a factor in the use of health services by children. This finding had not been reported elsewhere, and is not what would be expected, given what is known of health literacy and its effects in other contexts. This finding is, however, supported across a range of settings.

- Pharmacists agree that more continuing education and professional development in health literacy is needed in the community pharmacy context. This is a new finding that supports the goals of this project.

- Formal health literacy training significantly improves pharmacists' health literacy practices.

- The use of family and friends in medication management is important for those with limited health literacy, although having family or friends collect medication at the pharmacy can have negative consequences for health literacy.

- People with better health literacy are more likely to understand the importance of asking questions about medications.

- Ancillary labels may be confusing, and use of icons may not improve understanding.

Objective 2: Investigate how health literacy education is delivered in Pharmacy curricula from English-speaking countries

- Health literacy training is included in Pharmacy curricula in a number of universities in English-speaking countries.
- Delivery, assessment and drivers for inclusion into the curriculum are common among responding institutions.
- Small-group learning is the most common mode of delivery for health literacy curricula.
- The most common driver for teaching health literacy was its inclusion in the pharmacists' scope of practice.
- Most respondents believed oral assessment was the most effective way of assessing competency in health literacy education.

Objective 3: Design, develop and implement a multi-modal health literacy education package for community pharmacies

- While some educational resources for community pharmacy in Health Literacy exist, they did not meet the needs for Australian community pharmacy nor did they take a Universal Precautions approach.
- An adult learning model was employed in the development and delivery or the package. The package contained varied educational tools and resources to enhance delivery. This includes the use of video vignettes to demonstrate points and stimulate discussions, small group shared experiences, role-play and more traditional didactic components. A step-wise approach was taken to establish an understanding of each element before moving on to the next.
- Locally relevant and developed multimedia resources and examples were preferred for implementation in this package.
- Community pharmacy specific multimedia resources and examples were preferred for implementation in this package.
- This model was integrated into a "train-the-trainer" approach by which one pharmacist and/or pharmacy assistant from each participating pharmacy was to be trained to deliver the educational package in their own pharmacy.
- The focus of the package varied from the RFT with approval of the advisory panel to take a Universal Precautions approach.
- Pharmacy staff do not need to screen the health literacy capacity of consumers.
- Pharmacy staff modify counselling behaviours to address limited health literacy of consumers unless there are indications of a higher level of consumer engagement.
- The educational package was well received.
- The educational package was implemented in various ways to meet local pharmacy needs and logistics.
- Revisions were made to the package based on feedback and evaluation to facilitate wider implementation. No significant changes to the structure or content were necessary. The focus of refinements included:

- Combining two sessions from Module 1 into a single session.
- Revising structure of four sessions for Module 2 so that they can be delivered as individual sessions or combined together to meet the practical delivery needs of an individual pharmacy.
- Enhancing the "teach-back" components of the package with more examples, interaction and resources around this element.
- Combining Modules 4 and 5 into a single module as the same process is used across the two settings discussed – avoiding repetition.

- The educational package meets accreditation requirements for Group 2 and Group 3 CPD recognition.

Objective 4: Evaluate the impact of the package on pharmacists' and pharmacy staff members' practice and behaviour

- Pharmacists and pharmacy staff members demonstrated a significant increase in the use of "What questions do you have?" in both the face-to-face groups and electronic groups compared to the control group in the consumer survey study post-intervention, as well as in the intervention groups compared pre- and post-intervention.
- This difference was not observed in the simulated patient study.
- Teach-back had a very low level of use across all three groups in both the consumer survey and simulated patient studies pre- and post-intervention.
- Pharmacists and pharmacy staff members were aware of the importance of encouraging questions from consumers regarding their medicines or health.

Objective 5: Identify motivational factors and attitudes of pharmacists that may influence the uptake and success of the health literacy educational package in the pharmacy and how these may change over time

- Health literacy training can influence the attitudes, intentions and perceived behavioural control of pharmacists and pharmacy staff with regard to undertaking training and use of communication techniques to engage consumers.
- Organisational barriers may hinder the confidence of pharmacists and pharmacy staff in undertaking training and employing health literacy techniques, suggesting that support and encouragement from management is vital.
- Pharmacists and pharmacy staff acknowledge that consumers and managers expect them to counsel with health literacy in mind. Our training did not change this.

Objective 6: Measure the change in the health literacy of the pharmacy environment over the course of the training

- The implementation of changes to improve the 'health-literacy friendliness' of a pharmacy is a time-consuming process, and difficult to measure within the constraints of a research trial.
- Pharmacists are aware of the importance of clear verbal communication with consumers.

- Pharmacies developed an increased awareness of resources available to manage consumers who do not speak English, including interpreter services for medicines provision.

- Prior to training, pharmacy managers lacked awareness of health literacy, and therefore did not have policies in place to manage health literacy issues of consumers. Improvement in this area was detected post-training.

- Health literacy-related policies are recommended to promote sustainability and consistency of staff training.

2 Executive Summary

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 concept of health literacy and its effect on the Quality Use of Medicines is relatively new to pharmacy practice, especially in Australia. Interventions to bridge the educational gap for practising pharmacists and pharmacy staff regarding health literacy communication techniques to use with consumers in Australia are very limited. This is despite the fact that up to 60% of Australians between the ages of 15 and 74 have limited health literacy.

2.1 Aims and objectives

The overall aim of the proposed research was to increase Australian community pharmacists' and pharmacy staff members' knowledge of health literacy, and ability to detect and respond to consumers' health literacy issues. This was to be achieved through the delivery of an education package that used a variety of methods to help overcome communication barriers regardless of consumers' perceived health literacy ability. The literature suggests that measurement of consumers' health literacy is impractical in a healthcare setting such as a community pharmacy; thus, this project focussed instead on **building capacity in community pharmacy to communicate and engage effectively with consumers to improve their use of medicines and healthcare resources**.

The specific research objectives were:

- To undertake a review of the literature relating to health literacy and health literacy educational interventions for healthcare professionals, specifically pharmacists.
- To investigate how health literacy education is delivered in pharmacy curricula in English-speaking countries to inform the development of the educational package trialled in this study.
- To design, develop and implement a multi-modal health literacy education package for community pharmacies in New South Wales, Victoria and Western Australia.
- To evaluate the impact of the package on pharmacists' and pharmacy staff members' knowledge and practice.
- To identify motivational factors and attitudes of pharmacists that may influence the uptake and success of the health literacy educational package in the pharmacy and how these may change over time.
- To measure the change in the health literacy friendliness of the pharmacy environment over the course of the trial.

2.2 Overview

This project was undertaken from October 2011 to February 2014, and involved the contribution of health literacy and pharmacy practice experts from around Australia, including Monash University, Curtin University, The University of Sydney, University of Technology Sydney, The University of Queensland and the Pharmaceutical Society of Australia.

The first phase of the project was a review of literature to November 2011, relating to health literacy in pharmacy practice. Twenty-two original research articles and five reviews were identified as suitable for inclusion in the literature review from 5,182 possibly-relevant articles. The review concluded that health literacy has demonstrated relationships in a number of pharmacy-related contexts, yet research directly in community pharmacy is relatively rare, and effects in this context are less clear-cut. Even less common are interventions with pharmacy staff, rather than consumers. A 'grey-literature' search was conducted to collect possibly-relevant health literacy resources including videos, online courses, presentations and manuals. Forty-two resources were collected and reviewed, with the majority deemed unsuitable for informing either the content or format of the educational package.

To supplement the literature reviews, an international survey of pharmacy academics was conducted to collect information regarding methods in which health literacy is taught to students, as well as the content included in pharmacy curricula. The survey, distributed online, demonstrated a low response rate of 5%. Available data indicate that small-group learning was viewed as the most popular form of teaching in this area, and that oral-based assessment is the most prevalent form of evaluation.

The health literacy educational package was developed with assistance by professionals in the fields of health literacy, pharmacy and educational design, and reference to relevant literature and an online survey of health literacy education in English-speaking countries to inform the content and format of the package. The package was produced in two formats, for face-to-face or electronic delivery to a nominated staff member(s) in each participating pharmacy (a 'train-the-trainer' approach). This staff member(s) then managed the training of the remaining staff. The principle of "Universal Precautions" formed the foundation of the training, encouraging pharmacists and staff to assume that a consumer has limited health literacy until cues or clues from the consumer indicate otherwise. Central to the training was skills development for pharmacists and pharmacy staff to encourage questions from consumers, and ensure consumers' understanding of instructions and techniques. Two specific elements were use of the phrase "What questions do you have" and use of the "teach-back" method.

A randomised controlled trial method was used to evaluate the implementation of the educational package, with pharmacies block randomised into three groups: a group receiving training face-to-face, a group receiving training electronically, and a group receiving no training (control). A total of 77 pharmacies agreed to participate in this project, sampled by geographical region in New South Wales, Victoria and Western Australia. 63 pharmacies remained at the conclusion of the trial. After completion of the randomised control trial, control group pharmacies will receive the educational package to conduct training. This is to occur beginning June 2014 and continue throughout July 2014. Final approval for the refined package had not been provided at the time of publishing of this report, and therefore control group pharmacies had not been provided with training.

Pre-intervention, a number of evaluations were undertaken within each pharmacy. Firstly, a researcher-delivered survey was conducted in-pharmacy with consumers. This survey involved researchers observing consultations for key elements of the Universal Precautions training, followed by a brief interview with the observed consumers regarding their recall of these elements. Secondly, two simulated patients visited each pharmacy before and after the training, with a standardised request for either a product or advice, and documented the use of Universal Precautions by pharmacists and pharmacy staff members. Pre-intervention data identified little use of Universal Precautions, specifically the primary outcome, which was the use of the phrase "What questions do you have?". Observational data combined with consumer recall showed that pharmacies in the face-to-face group used the phrase 7.8% of the time, electronic group pharmacies used the phrase 4.5% of time, and control group pharmacies used the phrase 11.8% of the time. However, on the interactions that were observed by researchers pre-intervention, there was no use of this phrase. Consumer recall was relied upon for all interactions that could not be observed, and thus inaccurate recall may have led to a higher reported rate of use of this phrase.

Attitudinal and motivational data were also collected to assess pharmacists' and pharmacy staff members' attitudes, motivations and potential barriers to implementing the health literacy educational package. Pre-intervention median scores were determined for the intervention and control groups in the tested domains. The intervention and control groups scored the same median scores for all four domains pre-intervention on a scale of 1 to 7, where 1 is the lowest score and 7 the highest. These scores were: 5 for perceived behavioural control, 6 for attitudes, 6 for intentions, and 6 for subjective norms. An environmental survey of the 'health-literacy friendliness' of the pharmacy was also undertaken by the managing pharmacist or pharmacist-in-charge. Pre-intervention, face-to-face, electronic and control group pharmacies scored generally quite poorly in the area of 'health literacy policies', with mean scores of 1.45, 2.03 and 1.35 out of 3, respectively. Pharmacies performed better in areas related to the promotion of services, printed materials and clear verbal communication, pre-intervention.

One or two senior staff members from each pharmacy in the *face-to-face* training groups attended a workshop (conducted locally) that aimed to develop their capacity to then train their remaining staff using the educational package. The *electronic* training group received the materials on a USB drive, along with hard-copy training materials, and a key staff member was then responsible for self-directed learning, then training of the remaining staff. Participants were allocated from August 2013 to November 2013 to complete their in-pharmacy training. Post-intervention evaluations were then conducted with all pharmacies to measure the implementation of the educational package.

Post-intervention, consumer recall, researcher observation, and simulated patient data collectively demonstrated a significant increase in use of the phrase 'What questions do you have?'. Specifically,, there was a significant increase in the use of the phrase "What questions do you have?" by pharmacists and pharmacy staff members in both intervention groups, with the face-to-face and electronic groups 6.14 and 4.29 times, respectively, more likely to use the phrase than the control group using consumer recall. There was no change in the use of the teach-back method.

There was a significant improvement in attitudes and intentions of pharmacists and pharmacy staff of the intervention groups regarding undertaking health literacy training in comparison to the control group, as well as a significant improvement in perceived behavioural control (people's perceptions of their ability to perform certain tasks) of pharmacists and pharmacy staff in the intervention groups when compared pre- and post-intervention.

There was some improvement in environmental and organisational aspects of the pharmacy, particularly in relation to the implementation of health literacy policies and management of health literacy issues for consumers from culturally and linguistically diverse (CALD) backgrounds.

Following this, focus groups and individual telephone interviews were conducted with 17 pharmacists and 22 pharmacy assistants from 11 pharmacies to collect feedback in relation to the perceived effectiveness, usability and sustainability of the educational package to aid in the refinement of the package before wider dissemination to community pharmacies in the future. Participants offered generally positive feedback in regards to the usability and perceived effectiveness of the package, yet reported difficulty using the teach-back method with consumers, due a lack of examples and practice.

A revised version of the educational package is presented within this report, along with recommendations relating to ongoing evaluation and methods to ensure its sustainability in pharmacy. The package, comprising four modules, is recommended for wider implementation, including to Schools of Pharmacy for inclusion in Pharmacy curricula. The researchers welcome further feedback on all components, but in particular, the applied module relating to 'outreach' initiatives to the carers and teachers of at-risk sectors of the community, when these service models become more widely trialled.

2.3 Findings versus project objectives

The literature review identified the gaps in knowledge and paucity of educational interventions in relation to health literacy in community pharmacies, especially in Australia.

The survey of academic pharmacists, an additional objective to supplement the literature review, confirmed the original concept of small-group learning as an effective delivery mode, supplemented with role-plays. A low response rate limited the ability to generalise these findings more widely.

The educational package was successfully designed in a train-the-trainer format and implemented in 77 pharmacies in Australia, 63 pharmacies remained at the conclusion of the project. Withdrawing pharmacies cited perceived commitment for training of pharmacy staff and lack of managerial support as issues. Partial data collected pre-intervention was able to be used from eight pharmacies before withdrawal. This withdrawal rate is comparable to other trials involving community pharmacies.

All three evaluation methods, researcher observation, consumer recall and simulated patient documentation, demonstrated improvement in some elements of the Universal Precautions approach with consumers. The element proving more challenging was the use of the teach-back method. Feedback from participants identified the need for flexibility in this approach, along with alternative techniques to encourage questions from consumers. Attitudes and intentions towards using the educational package were positive, and showed improvement in the intervention pharmacies following the training. Environmental change was detected, but may require more time for pharmacists and pharmacy staff to implement for significant change to be observed.

3 Introduction

3.1 Background to Health Literacy

Healthcare in Australia, and in particular, pharmacy, has over the past number of years, fostered the idea of patient-centred care, a process whereby consumers work hand-in-hand with healthcare professionals (HCPs) to make shared decisions regarding their health care and treatment. For consumers to be actively involved in this process, and achieve a certain level of self-empowerment in their health care journey, they must first be able to access, understand and use effectively both the information associated with their care, and the healthcare system.

This ability is termed 'health literacy'. Health literacy is most adequately 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" (Kanj and Mitic 2009). Health literacy influences many processes in the consumer's journey through the healthcare system, including, specifically in the pharmacy context, the ability to understand medication labelling and directions. Those with limited health literacy may face problems associated with medication misadventure, and under utilise entitlements available through health insurers and the government (Lindquist et al.2011 ; Davis et al. 2006; Mårtensson et al. 2011).

In 2006, the Australian Bureau of Statistics estimated that up to 60% of the Australian population aged between 15 and 74 years fell below the level of health literacy deemed the "minimum required for individuals to meet the complex demands of everyday life and work in the emerging knowledge-based economy", or what will be termed in this report, *limited health literacy* (Australian Bureau of Statistics 2006). Those particularly vulnerable are older adult consumers and culturally and linguistically diverse (CALD) consumers (Fiscella, Franks et al. 2002; Wilson, Chen et al. 2005; Hawkins 2010). Given the complexity of the healthcare system, requiring one to understand prescription medication information, and recognise when to seek acute care and preventative medicine, inadequacies in consumers' health literacy ability may result in poorer health outcomes.

On a larger scale, the effects of limited health literacy on the health care system and economy is significant. In the United States (US), the estimated cost associated with this problem is US$200 billion per annum (Vernon, Trujillo et al. 2007). In the absence of Australian estimates, we assume that the 'cost per head' of limited health literacy is similar locally.

The Australian Commission on Safety and Quality in Health Care has included health literacy into 16 of their National Safety and Quality Health Services Standards, recognising it as an important influence on consumer care and health outcomes (Australian Commission on Safety and Quality in Health Care 2012). In the pharmacy context, pharmacists, under the Pharmaceutical Society of Australia's *Code of Ethics*, are required to "recognise consumers who are particularly vulnerable and tailor the provision of care accordingly" (Pharmaceutical Society of Australia 2011). It can be argued that consumers with limited health literacy are 'particularly vulnerable', and pharmacists are required to pay particular attention to these consumers when providing care, and tailor information provision accordingly.

Improving pharmacist and pharmacy staff education in relation to health literacy is essential in bridging the knowledge gap and improving consumer understanding of medicines and health

information, in the effort to reduce medication misadventure with consumers, and limit preventable costs to the healthcare system.

3.2 Request for Tender

In 2010 the Commonwealth of Australia through the Department of Health and Ageing and the Pharmacy Guild of Australia, released a Request for Tender with a Health Literacy education focus for Australian community pharmacies:

"The purpose of this project is to develop, pilot and refine an educational package for pharmacists and pharmacy assistants around health literacy, in order for them to better tailor information to consumers, thereby facilitating improved health outcomes for those consumers."

Key elements of development and delivery of this educational package were:

- Undertake a literature review of both Australian and international literature regarding health literacy.
- Collate and review existing resources/tools specific to facilitating the communication of health information to differing health literacy levels.
- Develop an educational package for community pharmacy staff, including:
    - Strategies for pharmacists and pharmacy assistants to assist consumers improve their health literacy and self-management capabilities;
    - Strategies specific to indigenous populations; and
    - Strategies specific to Culturally and Linguistically Diverse (CALD) populations.
- Pilot and evaluate the educational package.
- Based on the findings of the pilot, refine the educational package.

3.3 Summary of proposal

Our response to the Request For Tender involved a multi-disciplinary consortium of academics and professional leaders from around Australia. The scope of this project required design and planning input from diverse perspectives. The Consortium, led by Monash University, comprised The University of Queensland, The University of Sydney, Curtin University, University of Technology Sydney and the Pharmaceutical Society of Australia (Victorian Branch). The depth and breadth of expertise in this consortium provided the essential skills and knowledge that were required for successful execution of the project, including significant research experience, particularly with projects funded under previous Community Pharmacy Agreements, internationally recognised expertise in the field of health literacy, and depth of experience and skill in curriculum design, development and delivery.

This project has a solid foundation in the framework of themes for the 5CPA Research and Development Program. Naturally, the driving theme for this project on health literacy was the *Quality Use of Medicines*. Improved engagement of pharmacy staff with consumers and a consequent positive change in the way consumers use medicines and medicines resources has dramatic effects both for the individuals involved and the wider community, reducing the burden that arises from medication misadventure. This was also a *collaborative* project in many ways – a multi-faceted project team came together with expertise in a number of areas, including health literacy, pharmacy services and policy, educational design and delivery – and represented the health disciplines of pharmacy and medicine. The scope for stakeholder involvement was wide, and the project team actively sought input and participation from relevant stakeholders, including those listed in the tender as well as others that were identified in the iterative project process. The *consumer focus* of the project was reflected in the objectives – improving the engagement of consumers with pharmacy staff to improve health outcomes through enhanced communication processes. A particular focus was on groups where there

may be a number of factors affecting health literacy, including cultural and linguistic diversity (incorporating Indigenous communities). Finally, this was intended to be a practical and meaningful project. The goal was the development of an educational package that could be delivered to pharmacists and pharmacy assistants across Australia to help them recognise the Health Literacy levels of customers and adopt appropriate communication strategies to suit these levels, contribute to their professional development, and enhance their interaction with consumers, with a consequent improvement in therapeutic outcomes.

3.4 Systematic review

3.4.1 Introduction

Health literacy refers to key personal and interpersonal competencies that people need in order to stay healthy or to become healthy. A national survey suggests that health literacy levels across the Australian population are low[1], with as many as 60% of people lacking the skills to manage their health (Australian Bureau of Statistics 2008). International research suggests that low health literacy has important consequences for mortality, health status, use of health services, medication adherence and disease knowledge (Bush, Boyle et al. 2009).

Community pharmacy has a pivotal role in supporting health practices in the community beyond its important role in providing medicines. This role extends into such areas as preventive health, disease management, and facilitating health system navigation (e.g. triage for minor ailments, use of Safety Net, etc.). Poor health literacy can be an impediment to pharmacy 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. Consequently, a pharmacist's ability to accommodate for poor health literacy during patient encounters will have a direct influence on their ability to provide adequate support to all patients' health and wellbeing

This review aimed to identify and report on the findings of high quality evidence for the role of health literacy in a pharmacy context. This included how low health literacy affects people's use of pharmacy services and efforts to improve or accommodate low health literacy both in pharmacy staff and customers. The review informed the development and delivery of a subsequent health literacy intervention in community pharmacy settings. Figure 2 outlines the database search and article appraisal results. Refer to Appendices 1-5 for a complete version of the systematic review and appraisal tools.

[1] While the terms 'low' and 'poor' health literacy has been widely reported in the literature, out research has adopted the term '**limited**' health literacy to minimise the negative connotation associated with a consumer's capacity to manage his or her health.

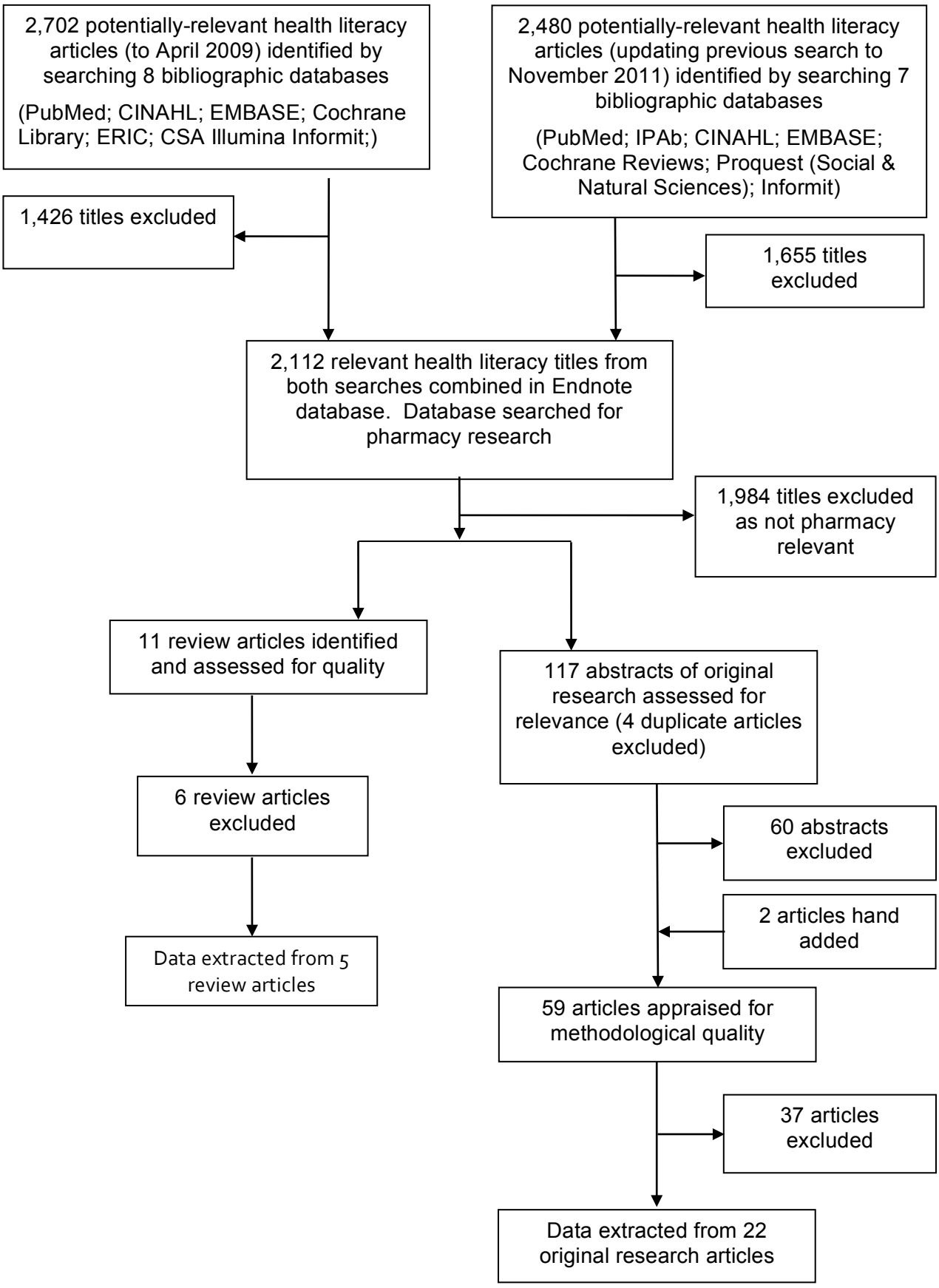

Figure 2 Diagram of database search and article appraisal process outcomes

3.4.2 Key points

Following are the key findings from this systematic review of pharmacy health literacy:

- There is a limited body of health literacy research in a community pharmacy context.
- Limited health literacy in the elderly has been associated with poor health outcomes and higher all-cause mortality, reflecting previous findings.
- There are very few interventions to address the effects of limited health literacy.
- Interventions to improve health literacy of consumers have not been successful, but the potential to mitigate against the adverse effects of health literacy has been demonstrated for a number of health conditions.
- The link between health literacy and adherence to medications is not well supported in the available literature. This contrasts with earlier findings. Understanding this discrepancy was central to designing a successful intervention, and suggests that people with limited health literacy do, in the right circumstances, have the capacity to adhere to a medication regimen.
- Multiple strategies to overcome low health literacy are more effective than implementing a single strategy.
- Improving the readability of information and using best-practice document design and self-management instruction improves knowledge. This has been identified in numerous studies across a range of health contexts and primary care settings.
- Video guidance helps people read and understand medication labels.
- Improving children's general reading ability may reduce hospitalisation rates in children with asthma.
- The health literacy of the carer is not always a factor in the use of health services by children. This finding had not been reported elsewhere, and is not what would be expected given what is known of health literacy and its effects in other contexts. This finding is, however supported across a range of settings.
- Pharmacists agree that more continuing education and professional development in health literacy is needed in the community pharmacy context. This is a new finding that supports the goals of this project.
- Formal health literacy training significantly improves pharmacists' health literacy practices.
- The use of family and friends in medication management is important for those with limited health literacy, although having family or friends collect medication at the pharmacy can have negative consequences for health literacy.
- People with better health literacy are more likely to understand the importance of asking questions about medications.
- Ancillary labels may be confusing, and use of icons may not improve understanding

3.4.3 Conclusions

This review reveals that health literacy has demonstrated relationships in a number of pharmacy contexts. Research in community pharmacy contexts is relatively rare, however, and effects in this context are less clear-cut. Even less common are interventions with pharmacy staff rather than consumers.

Our review suggests that health literacy in the pharmacy research context mirrors broader health literacy research in that there are still few intervention studies. Most research is still cross-sectional, investigating the association between health literacy on health, without yet demonstrating effective ways to use this knowledge to improve people's health. Even where intervention studies have been conducted, very little of this research has been with primary care providers (Bush, Boyle et al. 2009) (a rare example is described in Seligman, Wang et al. 2005). This review strongly suggests that there is a need for intervention research to address the challenges of limited health literacy in community pharmacy contexts. The implementation and evaluation of this project, considering the effects of a health literacy intervention for pharmacy staff, would directly target a sizeable gap in what is known about improving health literacy in primary care settings.

Even though medication adherence has been associated with health literacy (DeWalt, Berkman et al. 2004; Osborn, Paasche-Orlow et al. 2007; Gordon and Wolf 2009), changes in adherence as a consequence of a health literacy intervention are difficult to demonstrate. This may be a methodological issue, or a consequence of an, as yet, poorly understood, complex relationship between adherence and health literacy. Since adherence is also not a good single indicator of good community pharmacy practice, we conclude that it would not be a suitable outcome for our community pharmacy health literacy intervention. What this work does suggest is that even consumers with limited health literacy have the capacity for medication adherence, so the enhanced engagement planned for this project is very relevant for this high-risk group.

Similarly, while medication labels are an important part of a health literacy supporting community pharmacy, they represent a level of practice that is too specific to be the focus of our intervention. Instead, our review suggests that a valuable focus for our intervention would be to provide formal health literacy training that conveys the nature and scope of the problem of limited health literacy, together with information about how to provide clear verbal and written information. This information should take the form of a multifaceted training program for pharmacists and pharmacy assistants that is flexible, does not impose a heavy time burden, and is engaging (e.g. uses multimedia techniques).

3.4.4 Implications for the Health Literacy in Pharmacy Project

Specific interventions that may be wholly implemented in this project are not obvious. Equally there is not a simple screening tool to help identify patients with low levels of health literacy in the pharmacy setting. There are however other informative outcomes from this review. Firstly, the finding that formal health literacy training significantly improves pharmacist health literacy practices indicates that the focus of Module 1 of the educational package (education in health literacy concepts, impacts, and issues) will be critical to the success of the project. Furthermore, as the extent of limited literacy amongst Australian consumers is so widespread, a "Universal Precautions" approach, whereby limited health literacy is assumed until indicated otherwise, appears warranted. This approach becomes even more appropriate when we reflect on the notion that pharmacy consumers, as a specific group, tend to be older and sicker than the general population, and so would be expected to have even higher rates of

limited health literacy than the population prevalence quoted previously. Finally, peripheral discussions in the literature identified a number of potential barriers to consumer engagement and the implementation of our proposed project, enabling strategic planning for implementation to address and overcome these issues.

This review has, in general, identified that a limited number of well-established strategies is available to guide a health literacy intervention. Despite the limited guidance, it still provides a useful basis for moving forward. It has also provided a reminder that there are significant gaps in knowledge and research in the field of health literacy in the pharmacy setting. The execution of this project, which included evaluation of all aspects around structure, process and outcome, not only allowed for delivery for a sound, high quality product at the project conclusion, but also contributed to filling gaps in this field that may enhance future work.

Given the important role of health literacy in primary care setting, including community pharmacies, and the demonstrated value of formal health literacy training, this project proceeded to the design and implementation of a randomised controlled trial (RCT) to *build capacity within community pharmacy to detect and respond to the needs of consumers with limited health literacy*. Because strong evidence on the design of effective interventions of this type was not available in the pharmacy health literacy literature, we recommended that methods that have been shown to be efficacious in training primary care staff in their work settings (e.g. 'train-the-trainer') be identified and used in the implementation of the RCT.

3.5 Collection and review of 'grey literature' resources

3.5.1 Survey of pharmacy educators internationally

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

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 (Appendix 6). 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 US to identify relevant pharmacy academics. They were contacted directly via email with an invitation to be involved in the study. Participants were provided with an explanatory statement (Appendix 7), and informed consent was received upon completion of the survey.

The questionnaire was specifically designed to assess the current state of health literacy within pharmacy curricula. Topics to investigate were initially informed by the literature, and then 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 practice, institution in which they teach, type of pharmacy degree into which they teach, position they hold 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;
4. Opinion on the importance of health literacy education in pharmacy curricula;
5. Opinion on how health literacy should be taught and assessed; and
5. Materials and textbooks used to teach health literacy.

The questionnaire comprised of 25 questions, of which four allowed the respondent to enter free text (Appendix 8).

Ethics approval was granted for this phase by the Monash University Human Ethics Research Committee (Appendix 9).

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. The country of origin of respondents is listed in Table 1.

Table 1: Countries of Employment of Respondents

Country	*n*
Australia	7
United Kingdom	6
United States of America	4
New Zealand	2
South Africa	1
Canada	1
Total	21

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 2. 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 2 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
Total	21

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) and self-directed learning (n=6) were the most common responses, whereas lectures were selected by three respondents, complementing the planned delivery method of the education package.

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 country (

Table 3).

Table 3 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	47*
* Total frequency is larger than 21 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 was methods to target communication to consumers of varying health literacy needs (n=17), followed by health literacy concepts (n=15) and

awareness of health literacy by health professionals (n=13). Definitions of health literacy were included in 12 of the 21 curricula.

In regards to assessment, the highest responses were for oral examinations (n=5), OSCEs (n=5), and experiential placement assessment by a preceptor or supervisor (n=5). Only one respondent selected written examinations as their desired method of assessment.

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. The same can be said for dealing with 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 (Weinick and Krauss 2000; Fiscella, Franks et al. 2002; Wilson, Chen 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 skills training. On the other hand, techniques for communicating with consumers with limited health literacy and assessment of the suitability of educational materials for consumers were taught in the majority of pharmacy curricula, confirming these as important concepts in health literacy education.

Limited information was gained from this survey, but this was considered in the development of the educational package, as part of a broad approach to designing and developing this resource. Eight respondents reported that small-group learning formed a part of health literacy education within their pharmacy curricula, the highest reported method of delivery, along with lectures, although it was not possible to determine the exact methods used in these small-group learning sessions. Respondents also indicated that small-group learning was the best method of teaching health literacy. There is evidence 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 and Schmidt 1992; Schwartz 1997).

The majority (n=16) 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 to define professional expectations and reinforce these expectations in practice.

Regarding assessment, the majority (n=12) of respondents reported that health literacy knowledge was assessed via written examination, yet when respondents were asked to provide their opinions regarding the best way to measure the health literacy knowledge of students, oral examination and OSCEs were selected as the most preferred method. 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 the andragogy 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 generalisability 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 drawn. 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.

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

The inclusion of health literacy definitions and the effects of limited health literacy on CALD consumers into the health literacy education package is important as foundation knowledge for our study participants, who have not received university training on health literacy.

Delivery of the educational package as a small-group learning activity seems most reasonable. Assessment of competencies following completion of the training should be assessed orally by a role-play in an academic setting, or potentially using simulated patients in an authentic practice setting.

3.5.2 Collection and review of grey literature resources

Following completion of the review of the formal literature relating to health literacy, the research team collected and collated other materials and information relating to health literacy and health literacy education to complement the education package.

Various search terms were entered into search engines to generate results leading to further materials on the internet. These materials were grouped into five categories: Videos, Manuals, Slide shows, Resources, and Other. Collected resources were reviewed for their:

- Year of creation
- URL
- Country
- Mode(s)
- Content
- Evidence of evaluation
- Target audience
- Useful aspects and other comments.

A total of 17 videos, four manuals, five slideshows, 14 resources, and two 'other' materials were reviewed for relevance for informing the content of the education package, and for possible inclusion as an extra resource. Refer to Appendix 10 for a complete list of resources collected.

Videos

All videos reviewed as a part of this phase originated from the US, and involved patient consultations with doctors rather than pharmacists. The focus of the videos was the effect of limited health literacy on American society, with many videos featuring patients explaining their limitations and associated emotions. Some videos included communication training for doctors.

It was concluded that these videos were not suitable for inclusion into the educational package due to their lack of relevance to pharmacy in the Australian setting. Videos for the educational package were therefore created specifically for use in the package.

Manuals

The manuals reviewed for this phase were all produced by the Health Literacy Studies group in the Department of Society, Human Development, and Health from the Harvard School of Public Health.

The resources were not deemed useful for the development of the educational package due to their American context and minimal relevance to the pharmacy setting.

Slideshows

As with the videos and manuals, all the slideshows reviewed were created in the United States. One slideshow from the Agency for Healthcare Research and Quality (AHRQ) entitled 'Strategies to Improve Communication Between Pharmacy Staff and Patients: A Training Program for Pharmacy Staff' (Emory University 2007) proved useful in providing ideas for both content and format in regards to the development of the educational package.

Resources

The majority of resources (including online courses and toolkits) were created in the US. Two resources provided excellent guidance in the development of the educational package. Firstly, the Health Resources and Services Administration of the Department of Health and Human Services in the United States provides a short online course on health literacy for health professionals, covering both general knowledge on the problem surrounding health literacy, as well as possible techniques to overcome problems consumers may face when attempting to understand health information. This resource provided some guidance on possible formatting of the educational package in regards to layout and sequence.

The second resource was from the AHRQ in the US entitled 'Health Literacy Universal Precautions Toolkit' (DeWalt, Callahan et al. 2010). This package contained information regarding ways to implement Universal Precautions into practice and methods to evaluate their effectiveness. Although useful, the toolkit was created for the American healthcare system, and was determined to be unsuitable in the Australian setting given the differences in access to, funding of and provision of medicines and other pharmacy services. It provided some guidance on content for inclusion into the educational package, particularly around Universal Precautions.

3.5.3 Key findings

This phase of the study was useful in determining the current resources that exist in the field of health literacy, and provided some insight into ways the educational package could be developed, particularly in relation to its content, format and method of delivery. The majority of the resources were created in the US and focused on the American healthcare system. While they provided much insight, it was deemed appropriate to develop specific resources for the Australian setting for inclusion into the educational package, particularly video examples with consumers and pharmacists.

Some resources were included in the package if deemed appropriate for further reading for participants.

4 Aims, objectives and hypotheses

The overall aim of this research was to increase Australian community pharmacists' and pharmacy staff members' knowledge of health literacy, and ability to detect and respond to consumers' health literacy issues. This was to be achieved through the delivery of an education package that used a variety of methods to help overcome communication barriers regardless of consumers' perceived health literacy ability. The literature suggests that measurement of consumers' health literacy is impractical in a healthcare setting such as community pharmacy; thus, this project focussed instead on **building capacity in community pharmacy to communicate and engage effectively with consumers to improve their use of medicines and healthcare resources**.

The specific research objectives were:

- To undertake a review of the literature relating to health literacy and health literacy educational interventions for healthcare professionals, specifically pharmacists (addressed above).
- To investigate how health literacy education is delivered in pharmacy curricula in English-speaking countries, to inform the development of the educational package trialled in this study (addressed above).
- To design, develop and implement a multi-modal health literacy education package for community pharmacies in New South Wales, Victoria and Western Australia.
- To evaluate the impact of the package on pharmacists' and pharmacy staff members' knowledge and practice.
- To identify motivational factors and attitudes of pharmacists that may influence the uptake and success of the health literacy educational package in the pharmacy and how these may change over time.
- To measure the change in the 'health literacy friendliness' of the pharmacy environment over the course of the trial.

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

- The health literacy education package will improve Australian community pharmacists' and pharmacy staff members' practice in relation to using Universal Precautions for all consumers, regardless of their perceived health literacy abilities.
- The method of delivery, being face-to-face and electronic, will show similar rates of success in regards to implementation.

- The attitudes and motivations of pharmacists and pharmacy staff in regard to health literacy will be influenced by the implementation and ongoing use of the package.

- The health literacy of the pharmacy environment will change to be more conducive to acknowledging health literacy as a barrier to information provision.

5 Design and development of the Health Literacy Educational Package

The proposal submitted in response the RFT for this project described in broad terms the nature of the package that would be provided with a proposed outline. This would be further informed by the outcomes of both the literature review and review of other resources available. Figure 3 shows the original proposal outline. The proposal described a train-the-trainer approach in which one pharmacist from each pharmacy would complete training and then deliver the educational package to their staff in their own pharmacy. The train-the-trainer would be offered both face-to-face and electronically to test if it worked in both contexts to inform final delivery.

The acronym 'HeLP' (Health Literacy in Pharmacy) was adopted for this project.

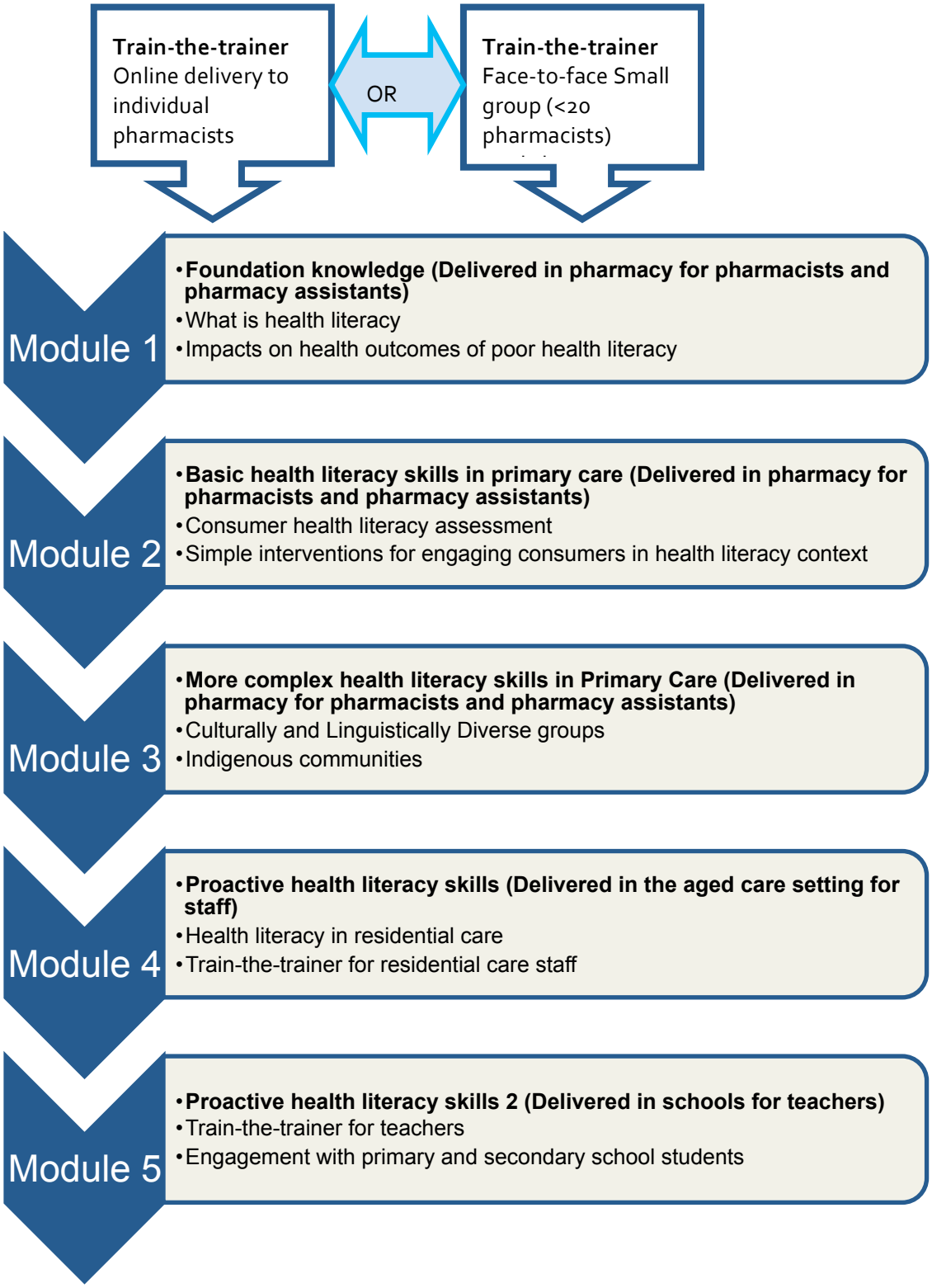

Figure 3: Original educational package proposal

5.1 Educational theory for the HeLP Package

An adult learning approach is the foundation for this educational package. Staff will be learning with and from each other and drawing on their own experiences and observations to give meaning and relevance to theory being presented. As described, a step-wise approach will be taken, building knowledge and skill, allowing time for these to be consolidated before moving on to the next step, In many clinical settings this approach to adult learning is used and often described using Miller's Pyramid (Miller 1990).

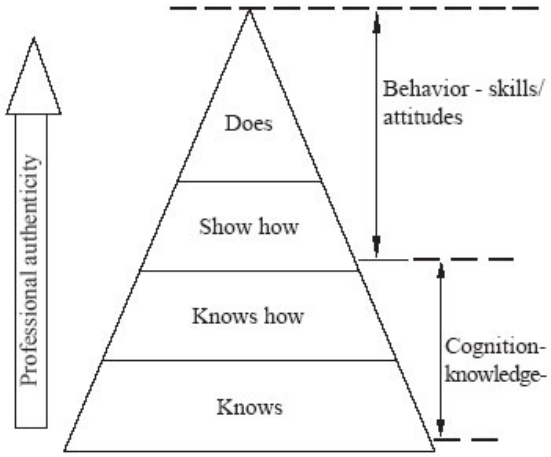

Figure 4 Miller's Pyramid

This model identifies the process of building knowledge from a basic remembering of it, through to an understanding (the knowledge or cognitive aspect) and then once these steps have been completed and the learning consolidated, moving on to the behavioural/skills aspects where practical application of the knowledge is first shown and then done by the learner. This process, whether known by name or not, is familiar to many who have received clinical learning in the workplace, and for those who have not, it is a sensible and accessible process. It indicates that learning does not have to happen in a single event, and therefore may be less intimidating to those who have not taken part in formal learning for some time. At the behavioural end of the pyramid, it is not only the trainer who will develop the higher levels of skill, but the reflective and practice nature of the modules means that eventually all staff will participate at this level. This gradual building of knowledge and skills occurs in an active learning environment using interaction between participants to explore issues, practice skills and enhance understanding and knowledge. Structured reflections on a staff member's own experiences in a number of contexts helps build the understanding and relevance to themselves. Group discussions then share the experiences of others further consolidating meaning. As skills and strategies are explored they are demonstrated in videos and then put into action in a safe environment through role-plays and other forms of interaction before moving on to the pharmacy and its consumers. Once back in the pharmacy, further reflection is required to consider and review implementation of skills and changes that may be made to make communication more effective. Much reflection occurs both within sessions and between them to consider both previous experience and then the effect behavioural change has on current service delivery. The overall package is a shared learning experience rather than a taught one. Participants learn with and from each other and then have the capacity to give on-going support and feedback to each other in the pharmacy setting.

5.2 Package content

As can be seen from the outcomes of the literature review and a review of the grey literature and other resources, a variation to the original educational package plan was made. Rather than incorporating a consumer assessment or screening process for their health literacy capacity the overwhelming evidence was that a Universal Precautions approach should be taken. Simply put, this means engaging with a consumer assuming they have limited health literacy unless there are indications to suggest

otherwise (demonstrated in general by the consumer's engagement). This was approved by the project advisory panel and then became the main focus of the package. Three of the four sessions in Module 2 were designed to provide strategies and resources for taking a Universal Precautions approach to consumer counselling and information provision. This also includes detecting signals that consumers are engaged and understand which then means that the usual good communication skills and strategies are applied. The package is not designed as a general communication in pharmacy activity so refers staff to use other resources to enhance those general communication skills.

A further enhancement to the package from the completed reviews was the identification and consequent inclusion of information and resources on the pharmacy as a health literacy friendly setting. This helps change the environment in a number of ways to support activities for consumers with limited health literacy.

A reference group, acknowledged at the beginning of this report, was established in October 2012 to provide input on the educational package which allowed for relevant, specific aspects to be enhanced and existing materials to be endorsed or amended.

For Module 3, input from FECCA indicated that the content was appropriate – focussed on the use of interpreters and directing to resources for specific communities. Input from Indigenous Health Programs at the University of Sydney enhanced the broad recommendations for providing services to indigenous consumers. The recommendations for cultural competence training were endorsed and some simple engagement strategies added to could be important to indigenous people, such as making sure there is space to join the conversation if more than one person attends, that all are acknowledged and greeted, and that conversations are inclusive and recognise the potential wider participation in discussions by others in the community. An experienced manager from a large residential care group provided insight into that setting. There has been a move to brief "tool box" learning sessions that meet logistical needs in a busy residential care setting and this short focussed education that could be provided to their staff would fit in well, especially as it could be broken into smaller chunks. It could also reduce risk of medication errors and improve not only residents and their families asking questions but staff as well who may not have high levels of training or confidence. Similarly for schools, this was considered a useful enhancement to preparing children for a future as a consumer. It was recognised that changing the overall health literacy of a society starts at a young age and so it would be important to assist teachers with information and resources. It was appreciated that it was explicitly about content and not process or "how to teach".

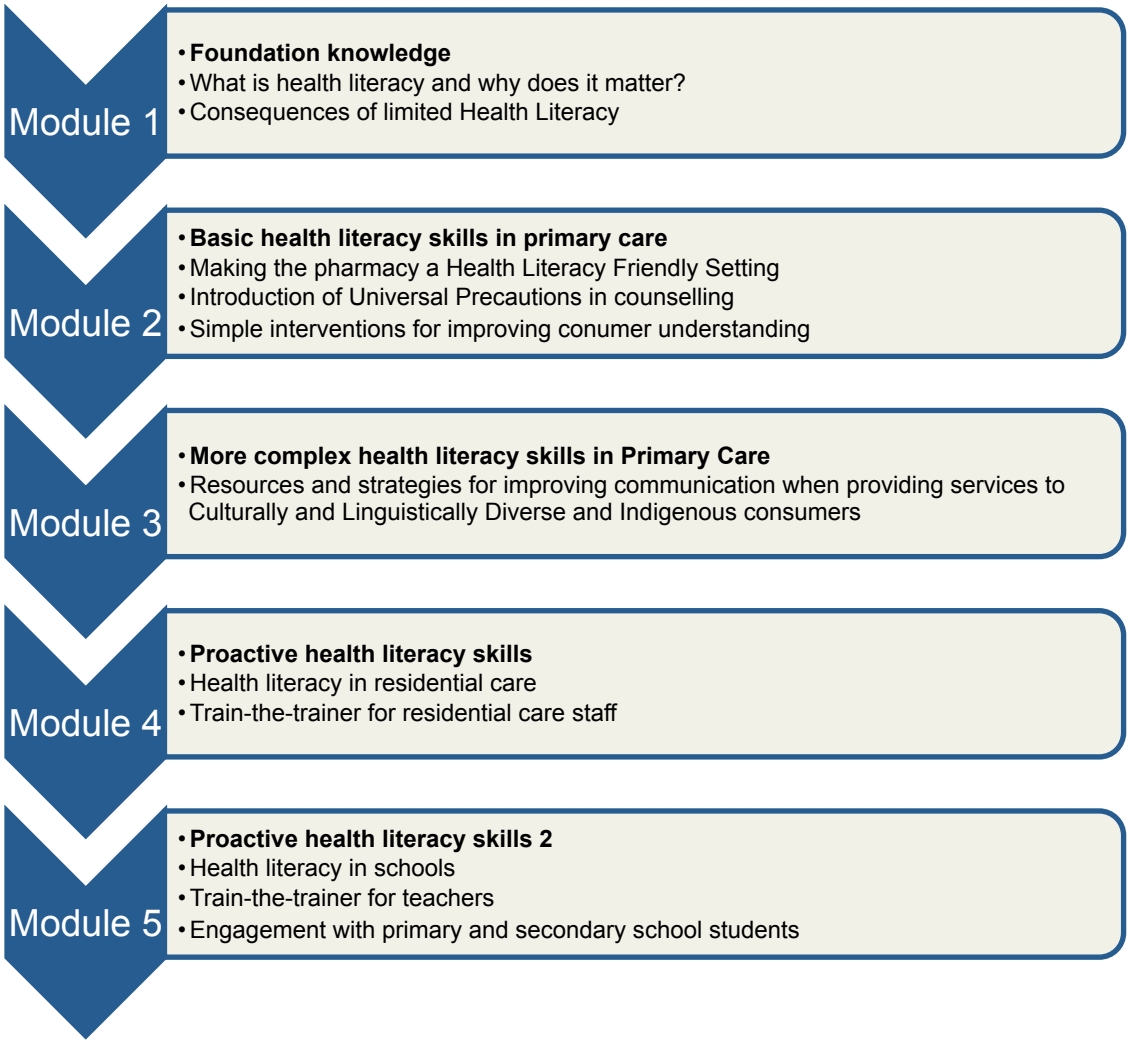

Figure 5 Revised plan for educational package after literature reviews and reflection on outcomes

5.3 Multimedia development

Review of available multimedia resources did not produce anything suitable for use in this package. It was either aimed at different healthcare settings (predominantly nursing and medicine), countries with divergent health systems from ours, or were culturally or socially inappropriate. Given these factors, a series of short video vignettes and still images were produced as part of the project. This enabled us to have specific examples of Health Literacy issues being discussed shown in an Australian context. This allowed for a more meaningful description of signals for limited health literacy using both verbal descriptions as well as visual images, demonstrating strategies and skills for improved engagement, showing varied approaches to the same scenario to stimulate discussion, etc. Green screen technology (i.e. the filming activity against a plain green backdrop which can then be replaced digitally with any image) was employed to streamline the process and allowed for a range of pharmacy images to be used as the setting for various scenarios. Once the aspects of the package that would benefit from video enhancement were identified, scripts were written by project team and staff and reviewed by other pharmacists, interns and students.

5.4 Train-the-Trainer

The train-the-trainer element of the package contains the complete set of educational package materials described as well as a short presentation to introduce the nature of the educational package, how it is structured and what it involves, as well as how to deliver the package in-pharmacy to the staff. To enhance this, a Trainer Guide has been produced that walks the trainer through the process of delivery on a slide by slide basis. Each page of the guide has the information for a single slide including:

- The exact content of the slide
- The aim or purpose of the slide
- Trainer notes on effective delivery, for example, some questions to stimulate discussion in group activity, extra examples if needed to make certain points, etc.
- Space for trainer's own notes.

Emphasis in the Train-the-trainer sessions is on:

- As the trainer, you will guide the learning, rather than teach it
- Trainers will be trained in the techniques, knowledge and skills around Health Literacy to pass this to staff
- Learning will come from reflection, observation, some explanation by the trainer

This trainer guide is used in each format of the Train-the-Trainer as the template for delivery of the package and supports the activities in both formats.

Each trainer is to be provided with:

- PowerPoint presentations to show the rest of the staff for each training session
- Trainer's guide to go with PowerPoint (cheat sheet)
- Participant notes – handouts for staff to focus on key issues
- Short quizzes to evaluate learning and for CPD
- Extra readings and links to resources for those keen

5.4.1 Face-to-face Train-the-trainer delivery

This initial training for the pharmacy trainers is designed to be delivered flexibly as a single session or a series of smaller sessions. In total the training takes approximately 4-5 hours. It may be delivered by one or two facilitators. If using two facilitators, it is to be delivered with one taking the lead in teaching the Health Literacy elements (i.e. delivering the content itself, modelling the process) while the other provides the Train-the-Trainer element (i.e. how to deliver the content).

5.4.2 Electronic Train-the-trainer delivery

This element was produced as a series of videos for the introduction to the package and then one for each module. The video element was the PowerPoint slides of the package so to make it clear what was the Health Literacy educational and what was the "how to deliver it" training one male and one female voice were used for the voice-overs, each addressing one aspect. The electronic training package with pauses for activities should take 4-5 hours to complete. One advantage of this package is that the trainer can review materials as often as needed and certainly immediately before delivering their own training to give them more confidence with the process.

6 Method overview

For this project, a randomised controlled trial method was used to evaluate the efficacy of the health literacy educational package (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), an electronic group (intervention), and a control group, who did not receive any health literacy training. Figure 6 demonstrates the process of block randomisation using Victorian pharmacies as an example.

Code	**Pharmacy**	**Group allocated to**
Block 1		
F	Vic4	Face-to-face
C	Vic15	Control
E	Vic12	Electronic
Block 2		
E	Vic10	Electronic
F	Vic9	Face-to-face
C	Vic21	Control

Figure 6 Example of block randomisation and allocation of pharmacies to study groups.

The unit of randomisation was the pharmacy. Metropolitan and rural pharmacies were randomised separately, as was each state.

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 educational package.

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 educational package.

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 training package (to be provided following completion of the project).

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. This involved one or two key staff members from each pharmacy receiving training and guidelines for then training 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.

The recruitment process involved contacting 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 study. An e-bulletin was also distributed through the NSW Branch of the Pharmaceutical Society of Australia, advertising the project. Those pharmacies who registered their interest in participating were forwarded a Letter of Invitation (Appendices 11-16), an Explanatory Statement (Appendices 17-22), a Consent Form (Appendices 23-32), and a Permission Letter (Appendices 33-38) to complete prior to enrolment.

The sample represented a mix of both metropolitan and rural pharmacies, the latter of which was required to be PhARIA 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.

Pharmacists in Group 1 were notified of training venues and dates for the train-the-trainer portion of the package. 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 were provided with the education package 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 were supplied the education package in-person or via mail in the form of a USB drive and Trainer Guide. Control group pharmacies did not receive the education package 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[2].

Pharmacists were offered 25 CPD points for completion and delivery of all five modules of the educational package, and 10 points if they completed only core modules 1 and 2.

A total of 77 pharmacies from New South Wales, Victoria and Western Australia initially consented to being involved in the project. Table 4 provides a breakdown of the pharmacies by state and location.

[2] The original Module 5 has been merged with Module 4 in the version submitted with this report.

Table 4. Location of recruited pharmacies at beginning of the project

	State			
	NSW	**Victoria**	**WA**	**Total**
Metropolitan	19	21	20	60
Rural*	4	4	9	17
Total	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 5. Reasons for withdrawals, where given, predominantly related to workload and staffing changes.

Table 5. 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
Total	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, electronic delivery, and the deferred (control) group resulted in the distribution reported in Table 6.

Table 6. Allocation of pharmacies to exposure and control groups

	State			
	NSW	**Victoria**	**WA**	**Total**
Face-to-face	8	8	10	26
Electronic	8	9	9	26
Control (deferred)	7	8	10	25
Total	23	25	29	77

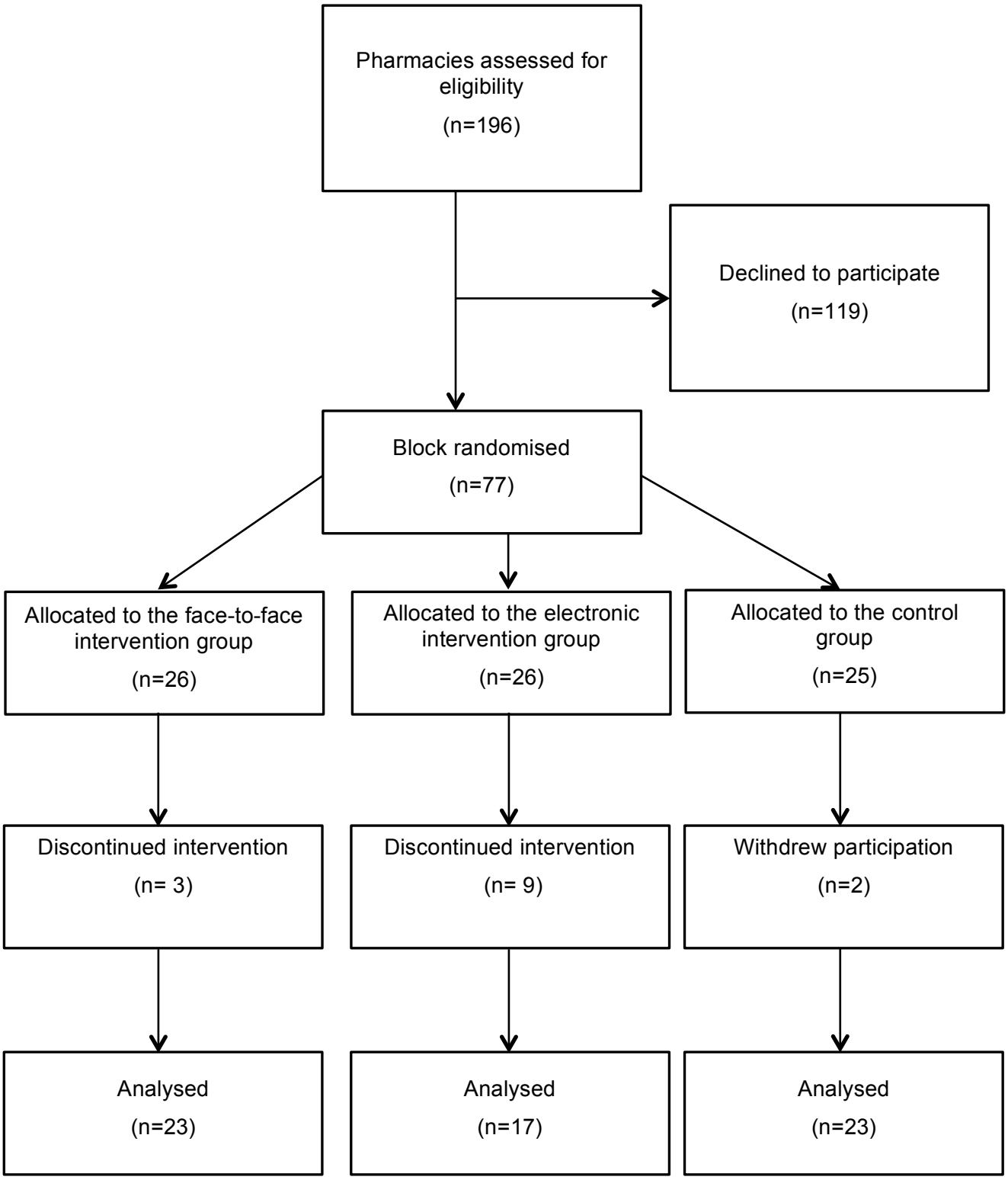

Figure 7 CONSORT diagram of the recruitment and allocation process of pharmacies

7 Evaluation framework

The objective of the evaluation was to determine the effect of the education package on the practice behaviours and attitudes of pharmacists and pharmacy staff relating to health literacy, and their use of particular communication and engagement techniques with pharmacy consumers. The evaluation also determined whether any organisational or environmental changes were made in the pharmacy as a result of the training.

Four methods to evaluate the effectiveness and usability of the educational package were selected. These are outlined below, explained in more detail in Sections 7.1-7.5, and the key findings are presented in Sections 8-12. Sections 8-11 are supported by relevant quotations from the focus groups to allow them to be read as 'stand-alone' sub-studies. Section 12 presents the remaining focus group findings relevant to revision of the educational package and its delivery. The evaluation methods (sub-studies) were:

Method 1: Mailed survey to evaluate the impact of the health literacy educational package on the environmental and organisational aspects of the pharmacy.

Method 2: Documentation of health literacy interventions with consumers before and after the educational intervention. This took place using researcher observation of consultations, followed by consumer recall of elements (rather than content) of his/her consultation.

Method 3: Mailed survey before and after training to evaluate the impact of the health literacy educational package on the attitudes and motivations of pharmacists and pharmacy assistants in Group 1 and 2, and how these changed following completion of the program, compared to those in Group 3.

Method 4: Use of simulated patients (mystery shoppers) to assess health literacy interventions both before and after the educational intervention.

7.1 Environmental and organisational survey

A questionnaire was developed to evaluate the impact the educational program had on the organisational and environmental aspects of the pharmacy, and how these may have changed over the period of the training. The questionnaire used was based on the Agency for Healthcare Research and Quality Pharmacy Health Literacy Assessment Tool (Appendix 39). Changes were made to questions, as well as extra questions added, to suit the Australian pharmacy setting.

The questionnaire was completed by the pharmacist in-charge or manager before and after the educational intervention.

7.2 Documentation of health literacy interventions

A survey tool was developed to identify the impact of the educational package on pharmacists' and pharmacy staff members' use of health literacy communication techniques, specifically Universal Precautions, with consumers (Appendices 40-41). Consumers were invited by a research officer to take part in the study in-store after consulting with a pharmacist or pharmacy staff member, and were asked a series of questions by the research officer relating to their demographics, personal health status, and the consultation with the pharmacist or pharmacy staff member. Consumers were eligible for inclusion if they presented with a new prescription or over-the-counter request, and were 18 years

or older. Consumers presenting with repeat prescriptions, for opioid replacement therapy or emergency contraception were excluded. Consumers with repeat prescriptions were excluded due to the reduced counselling generally provided on resupply of a continuing medicine. Researchers also observed the counselling session within earshot, but not in a manner that impeded on the pharmacist-consumer interaction before conducting the consumer recall survey. Disparities between consumer recall and researcher observations were documented. This was conducted before any training was conducted with pharmacists and pharmacy staff members, and again one to three weeks following the completion of training. These consumer questionnaires were also conducted in Group 3 pharmacies, those in which staff did not receive any training during the project.

The sample size was calculated based on an increase in the use of Universal Precautions by pharmacists and pharmacy assistants from 5% to 15%. 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. The final sample size was inflated by 10% to account for attrition, with the final sample size being 528 consumers. Research officers allocated a single block of time of 3.5 hours to each pharmacy to administer the surveys. Some pharmacies were visited twice in the event of a poor consumer response rate, or the length of time spent was extended if possible.

7.3 Attitudinal and behavioural surveys

Four questionnaires were developed to evaluate the impact of the educational program on attitudes and behaviours of pharmacists and pharmacy staff regarding learning about health literacy. Two pre-intervention questionnaires were developed, one for the lead training pharmacist (Appendix 42) and one for all other pharmacists and pharmacy staff who were scheduled to receive in-pharmacy training from the lead training pharmacist (Appendix 43). The pre-intervention questionnaires were completed by all groups of pharmacists and pharmacy staff to determine their baseline attitudes and motivations to implementing and using the health literacy program prior to Group 1 and 2 receiving the educational program. The post-intervention questionnaires were completed by the lead training pharmacists (Appendix 44) and all other pharmacists and pharmacy staff (Appendix 45) in Group 1 and 2 following completion of the educational program, as well as by Group 3 pharmacies.

The questionnaires were designed based on the Theory of Planned Behaviour (TPB)(Ajzen 1985; Francis, Eccles et al. 2004). The TPB was developed in an attempt to model the various factors that dictate intentional human actions. The theory explains behaviour as a result of an individual's intentions, which are determined and dictated by three variables: attitudes (whether or not the individual wants to do the action), subjective norms (the influence of social pressures on whether the individual should do the action), and perceived behavioural control (how capable the individual feels in doing the action). Analysis was carried out following statistical advice in line with the response characteristics and research questions.

7.4 Simulated patients

Various methods exist to assess the communication skills of pharmacists and pharmacy staff members, with simulated patients being a widely used and reliable method to derive outcome measures in pharmacy practice research (Watson, Skelton et al. 2004; Watson, Norris et al. 2006). Simulated patients, also known as mystery shoppers, are used in pharmacy to assess and evaluate current practice, or to measure outcomes when involved in research. 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" (Watson, Norris et al. 2006). When assessing simulated patients as a method for evaluating communication behaviour by pharmacists, a systematic review found that the simulated patient were superior to both consumer-assessed and observational-type studies in

detecting counselling rates (Puspitasari, Aslani et al. 2009). The review concluded that the simulated-patient method appeared to be a more reliable research design when evaluating the counselling practice of pharmacists.

All pharmacies were visited by two simulated patients twice during the study period: prior to receiving the health literacy educational package, and following the completion of the in-house training component. The 10 simulated patients were a mix of professional actors and lay members of the public. All received training in case vignettes developed for this study and were provided with relevant props for authenticity. Three case vignettes were developed for this component of the study (Appendix 46), along with a data collection form to objectively evaluate the pharmacist and pharmacy staff performance, the process for which is described in the following sections.

The simulated patients were instructed to enter each pharmacy at separate times to minimise the chance of their identity and purpose being revealed. The simulated patient was instructed to wait to be approached by a pharmacist or pharmacy staff member for assistance, yet in the case of a lengthy waiting period, they approached the nearest available staff member. The pharmacy manager was instructed before the visits to not inform any other pharmacy staff, including other pharmacists that simulated patient visits were to occur.

Following the consultation in the pharmacy, the simulated patient completed a data collection tool (Appendix 47) as soon as possible after leaving the pharmacy. This documentation featured 'yes/no' indications of whether key behaviours or communication techniques were experienced during the consultation, and could be annotated with further detail. In accordance with the ethical approval, consultations were not recorded, and no feedback was provided to individual pharmacies or their staff. Missing data were excluded from analysis.

7.5 Focus groups

The overall aim of this phase was to validate, add to, and refine the education package before its wider dissemination to pharmacies in the future, if deemed suitable. This phase was carried out in the form of focus groups, supplemented with telephone interviews where deemed more practical.

The specific aims were to:

- Elicit new ideas for the content of the educational package that were not included in the trial version.
- Seek feedback on the usability of the educational package in relation to its structure and method of delivery, including the face-to-face, computer-based, and in-house training components.
- Seek feedback on the ease of integration of the educational package into the pharmacy.
- Seek feedback on the perceived effectiveness of the educational package on changing pharmacy staff behaviours and the pharmacy environment.

Three broad domains to examine were decided upon:

1. Usability of the training package
2. Implementation
3. Effectiveness of the training package.

A semi-structured interview guide that addressed the above domains and allowed for free-flowing conversation between participants was developed and piloted for use in the focus group meetings (Appendix 48). A sample of both pharmacists and pharmacy assistants was sought to capture the views of a variety of pharmacy staff members. Trainer pharmacists were initially contacted by telephone following the end of the designated trial period, to inform them of the opportunity for themselves and their staff to participate in the focus groups. Those who registered interest in participating were sent further information regarding the venue and time for the meeting.

The timing and venues of meetings were organised for the convenience of the participating pharmacy staff members. All participants provided signed consent for the discussion to be audio-recorded. Remuneration for participants' time was provided.

A total of five focus groups were conducted: two in Melbourne, one in rural Victoria, one in Perth and one in rural Western Australia. One pharmacist in Sydney and four pharmacists in Western Australia (two metropolitan and two rural) were interviewed by telephone.

Focus group recordings were transcribed. Two researchers independently read each transcript and noted emerging themes, which were compared for similarities. The key themes were decided upon and used in the grouping and analysis of the feedback from the focus groups. Quotations of interest, supporting these themes, were identified.

The five focus groups comprised groups of trainer pharmacists and pharmacy assistants only (one group), trained pharmacists and pharmacy assistants only (one group), and pharmacists and pharmacy assistants (both trainers and trained staff together) (three groups, two of which were in a rural location). In Victoria, GD facilitated the discussion and GS was the observer/note-taker/audio-recorder. In Western Australia, LE facilitated the discussion and EE was the observer/note-taker/audio-recorder. GS and EE conducted telephone interviews.

8 Organisational and environmental survey

8.1 Foreword

> *"It was taking that whole program that you'd given us, and just giving us a platform for conversation, and that came across in so many different ways." (Pharmacist 1, focus group 1)*

Health literacy is a multi-dimensional concept that involves not only the health professional and the consumer, but also the environment and organisational health literacy 'friendliness' of the pharmacy. To allow for effective use of the services offered by the pharmacy to the consumer, the pharmacy must ensure the environment allows for ease of navigation.

The aim of this survey was to measure the changes in both the environment and organisational structure of the pharmacy before and after the intervention.

8.2 Method

The survey tool used for this phase of the project was a modified version of the Universal Precautions Toolkit for Pharmacy by the Agency for Healthcare Research and Quality (AHRQ) in the United States (DeWalt, Callahan et al. 2010). The original survey was designed for use in the American setting, and was thus not deemed entirely appropriate for use in this study. Questions were modified slightly in

language, structure and content, and further questions were added to elicit information relevant to this study. The survey was assessed for face and content validity by five team members.

The survey was separated into four domains: 1) promotion of services; 2) printed materials; 3) health literacy policies; and 4) clear verbal communication. Each question response was measured categorically with five options (Appendix 39).

Ethic approval was obtained from Monash University and Curtin University. Reciprocal ethic approval was granted by The University of Sydney (Appendices 49-52).

One copy of the survey was sent by mail or e-mail to all participating pharmacies before and after the intervention, and was completed by the pharmacist in-charge or the managing pharmacist.

The data were analysed using SPSS® version 19.0 (SPSS Statistics Inc. 2010) and summarised using descriptive statistics. Significance values were to be calculated where permitted by the sample size. Scoring for this survey ranges from 1 to 3. A mean score between 1.00 and 1.99 indicates that the pharmacy does not appear to be performing in the particular item within the domain. A mean score of 2.00 to 2.99 indicates that the pharmacy is performing the item to some extent, but could make some improvements in the area, while a score of 3.00 indicates that the pharmacy is performing well in that item.

8.3 Results

A total of 43 surveys were returned from the lead pharmacists in each pharmacy before health literacy training was implemented. Following the training period, 23 post-intervention surveys were returned.

Table 7 illustrates scores for each domain before and after training. Refer to Appendices 53 and 54 for the breakdown of responses by individual item.

Table 7. Mean scores for the environmental survey for all three groups before and after training (n=42 pre-intervention, n=23 post-intervention).[3]

Domain	Face-to-face (mean)		Electronic (mean)		Control (mean)	
	Before	After	Before	After	Before	After
Promotion of services	2.32	2.48	2.38	2.73	2.38	2.26
Printed materials	2.02	2.50	2.30	2.66	1.96	2.21
Health literacy policies	1.45	2.33	2.03	2.25	1.35	1.59
Clear verbal communication	2.09	2.65	2.42	2.74	2.24	2.52

Pharmacies in the face-to-face and electronic groups both showed an increase in scores in the **promotion of services domain** (2.48 and 2.73, respectively), whereas the control group scored lower

[3] Scores are an average out of a maximum score of 3. Statistical significance was not measured due the low sample size.

post-training (2.26). In each of the intervention groups, there was an increase in scores associated with providing clear signage to distinguish prescription-in and prescription-out areas (Question/item 3), and displaying pamphlets and educational brochures in a way that makes consumers able to find information (Question/item 5). The increase in scores for both intervention groups in this domain following training indicated that the health literacy educational package was effective at improving staff awareness and knowledge in regards to how consumers access pharmacy services, and ways in which changes can be made to the pharmacy environment to make this easier for consumers.

There was an overall increase in means scores for all three groups in the **printed materials domain** following training, although the intervention group pharmacies both recorded a greater improvement than the control group. Pharmacies again showed a sound awareness of the importance of limiting medical jargon and terminology in printed materials. All groups recorded an increase in the use of blank space in printed materials to provide relief from printed text (Question/item 7), in the use of visual graphics and illustrations to decrease dependence on text for comprehension (Question/item 9), and the use of a font size of 12 or higher in printed materials (Question/item 10). The most dramatic improvement was in relation to providing written materials in languages other than English (Question/item 11). Both the face-to-face and electronic groups recorded an improvement in this area, with the control group recording no change. This highlighted the effectiveness of Module 3 in the educational package, specifically in relation to providing appropriate materials to consumers from CALD backgrounds.

Both intervention groups scored higher in the domain associated with **health literacy policies**, with the face-to-face group and electronic group scoring 2.33 and 2.25, respectively. The control group made a small improvement, but scored 1.59, indicating that the development and implementation of health literacy policies was generally not adopted in this group of pharmacies. Specifically, pharmacies in the intervention group made improvements in ensuring that all staff are trained in health literacy (Question/item 15), with the face-to-face group improving from 1.31 to 2.22 and the electronic group improving from 1.83 to 2.33. This change indicated the success of the educational package in promoting health literacy as an important consideration in relation to consumer care, and one which requires a policy framework for pharmacies- in particular, training requirements for staff.

All groups scored higher in the **clear verbal communication domain**. The face-to-face group noted the largest improvement from 2.09 to 2.65 in this area. In the area of securing language assistance for speakers of languages other than English (Question/item 17), the face-to-face group scored highest at 2.80, improving from 1.82 pre-training; while the electronic group improved from 2.00 to 2.50. The control group scored 2.00 post-training on this question/item. This again highlighted the effectiveness of Module 3 in informing staff on the services available to consumers from CALD backgrounds and how these can be accessed. Possibly most importantly in this domain, both intervention groups improved on their recognition of the importance of pharmacy leadership to promote commitment to health literacy and clear communication (Question/item 20). The face-to-face group improved on this question from 2.11 to 2.75, the electronic group improved from 2.62 to 2.83 and the control group remained unchanged at 2.40. The educational package aimed to encourage staff to demonstrate both leadership and ownership towards improving the health literacy friendliness of the pharmacy environment to improve consumer care, with this change reflected in the scores for this question.

Qualitative feedback

Focus groups provided insightful feedback into the various challenges associated with the health literacy friendliness of the pharmacy as an organisation. A number mentioned that signage was an aspect of the pharmacy that required attention:

"We recently made some changes with our signage. It looks pretty consumer friendly, I think. But inside the pharmacy, I think next time I think we want to try and make them a bit bigger so you can see it a bit more clearly" (Pharmacist, Interview 1)

"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. The problem we have is our front door is covered in community notices. There are a whole lot of things that you have to put up there. I really felt that our poor old self-care cards have been removed from the wall, and one lot's been shoved in the lockers…" (Pharmacist 1, focus group 3)

"[Our signs are] saying, "antihistamines," and "anti-diarrhoeals" and things that are big to people who speak English" (Pharmacist 2, focus group 1)

"I think the whole pharmacy was involved. It brought about active changes with the signage and trying to do things like that" (Pharmacy assistant 1, focus group 2)

The provision of written information to consumers and the acknowledgement that this may not always be in an appropriate format, especially for those who do not speak English, was also mentioned in these group discussions.

"…we have pamphlets and things that we provide in different languages. Our signs are very, they're like quite simple. Our pharmacy is not a very big pharmacy. We try and lay things out that it's quite clear. I think that we will probably be looking at other ways of improving health literacy…" (Pharmacist, interview 1)

"I think Module Three was more important than the other ones". "…those information sheets in other languages … 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 knows what it is, and all the different languages behind them they can copy it as they need it" (Pharmacist 3, focus group 1)

Some also noted the difficulties in regards to size and location of the pharmacy when wanting to make change:

"It's harder for us because in a way, the pharmacy that we find ourselves in, we are constrained by our location and the size of the building. There are a huge number of retail kinds of things because it's a chain". (Pharmacist 1, focus group 2)

The results of this phase supported the hypothesis to an extent, as some aspects of the pharmacy changed, yet others remained similar pre- and post-intervention.

8.4 Key findings

A number of improvements in relation to the health literacy friendliness of the pharmacy environment were made in both the face-to-face and electronic group pharmacies as a result of the health literacy training. A dramatic improvement was seen in the consideration of health literacy in CALD consumers and measures that can be taken to improve their understanding of medicine and health information, highlighting the success of Module 3 in educating pharmacy staff in this area.

This area remains an important aspect of health literacy friendliness in pharmacy, and requires leadership from both staff and managers to initiate and implement changes both physically in the pharmacy in relation to signage and printed materials, but also within the structural framework of the pharmacies' operations to ensure that any changes that are made are sustainable and long-lasting.

9 Evaluation of behavioural and practice change

9.1 Foreword

The educational package primarily aimed to encourage behavioural change in the use of Universal Precautions by pharmacists and pharmacy staff. Measuring consumer experience is important in measuring communication and service delivered in the pharmacy, and therefore surveying consumers was an appropriate approach for detecting changes The primary outcomes for this study were the use of the question "What questions do you have?" and the use of the teach-back method with consumers.

9.2 Method

All pharmacies were visited by the research officers before and after the intervention to conduct researcher-administered consumer surveys.

A survey tool was developed to identify the impact of the educational package on pharmacists' and pharmacy staff members' use of health literacy communication techniques, specifically Universal Precautions, with consumers. The survey tool was divided two sections. The first section collected demographic data of consumers, education level, vision or hearing impairments, reason for visiting and any short or long-term medical conditions. The second section collected data in relation to the use of Universal Precautions by pharmacists and pharmacy staff with consumers. Responses were collected using a combination of both dichotomous and categorical options. The survey tool was assessed for face and content validity by five team members, and piloted with ten consumers. Small adjustments were made (Appendix 40-41).

The sample size was calculated based on the assumption that there would be an increase in the use of Universal Precautions by pharmacists and pharmacy assistants from 5% to 15%. With an alpha value of 0.05 and power of 0.8, the required sample size per group was 160 consumers i.e.480 consumers across the three groups (2 intervention and one control). The final sample size was inflated by 10% to 528 to account for attrition.

Consumers were invited to take part in the study by a research assistant in-store, after consulting with a pharmacist or pharmacy staff member. Consumers were eligible for the inclusion if they were 18 years or older, and were English-speaking. The survey was conducted both before and after the intervention. Researchers visited each pharmacy until 10 interviews were conducted or for five hours, whichever occurred first. Consumers were excluded from the study if they were receiving a repeat prescription, opioid replacement therapy or the emergency contraception pill. Consumers were provided with an Explanatory Statement (Appendices 54-56) and Consent Form (Appendices 57-59).

As per the protocol, consumers were invited to take part in the study prior to (whenever possible) or after the consultation with a pharmacist or pharmacy staff member. When possible, the researchers observed and documented consultations. Audio-recording was viewed negatively by both pharmacy managers and consumers. Many pharmacy managers explained that they would not participate in the program if audio-recording was utilised, and thus was not employed. Privacy was explained as a major drawback of audio-recording, as well as the experience potentially being confronting for consumers.

Ethics approval was obtained from the human research ethics committees of Monash University and Curtin University. Reciprocal ethics approval was granted by The University of Sydney (Appendices 49-52).

9.3 Results and Discussion

Data cleaning to remove incorrectly collected data resulted in 14 surveys from two pharmacies being removed from the pre-intervention sample.

Demographics

Tables 8 and 9 display demographic data of consumers recruited pre- and post-intervention, respectively.

Table 8. Demographics of consumers surveyed prior to training

Variable	Face-to-face (n=153) Frequency (%)	Electronic (n=138) Frequency (%)	Control (n=149) Frequency (%)
Gender			
Male	48 (31.4)	54 (39.1)	59 (39.6)
Female	105 (68.6)	84 (60.9)	90 (60.4)
Age			
18-30	32 (20.9)	26 (18.8)	18 (12.1)
31-50	32 (20.9)	29 (21.0)	42 (28.2)
50-64	32 (20.9)	29 (21.0)	31 (20.8)
65-74	20 (13.1)	19 (13.8)	30 (20.1)
75+	37 (24.2)	35 (25.4)	28 (18.8)
Education			
Not completed high school	23 (15.0)	11 (8.0)	17 (11.4)
Completed high school	56 (36.6)	53 (38.4)	53 (35.6)
Higher level of education	74 (48.4)	73 (52.9)	79 (53.0)
Not reported	0	1 (0.7)	0
Visual impairment			
Yes	98 (64.1)	85 (61.6)	99 (66.4)
No	55 (35.9)	53 (38.4)	50 (33.6)
Hearing impairment			
Yes	14 (9.2)	9 (6.5)	12 (8.1)
No	139 (90.8)	129 (93.5)	137 (91.9)
Reason for visiting			
New prescription	87 (56.9)	74 (53.6)	84 (56.4)
Primary care	50 (32.7)	46 (33.3)	50 (33.6)
Combination of above	11 (7.2)	6 (4.3)	3 (2.0)
Not reported	5 (3.3)	12 (8.7)	12 (8.1)
Who is the visit regarding?			
Myself	131 (85.6)	113 (81.9)	125 (83.9)
Someone else	22 (14.4)	24 (18.1)	24 (16.1)
Not reported	0	1 (0.7)	0

Baseline demographic data showed that a higher proportion of females participated in the pre-training survey than males, and that participants represented a broad age range. In regard to education, the majority of participants across the three groups had completed a higher level of education (e.g. university or technical school/TAFE), with the smallest group being participants who had not completed high school. The majority of participants stated that they had vision problems, but only a small number reported having a hearing disability.

The majority of participants reported their reason for attending the pharmacy as presentation of a new prescription, followed by primary care, with most attending the pharmacy on their own behalf.

Table 9. Demographics of consumers surveyed after training

Variable	Face-to-face (n=138) Frequency (%)	Electronic (n=79) Frequency (%)	Control (n=121) Frequency (%)
Gender			
Male	49 (35.5)	37 (46.8)	37 (30.6)
Female	89 (64.5)	42 (53.2)	84 (69.4)
Age			
18-30	18 (13.0)	11 (13.9)	9 (7.4)
31-50	27 (19.6)	30 (38.0)	24 (19.8)
50-64	35 (25.4)	17 (21.5)	32 (26.4)
65-74	30 (21.7)	13 (16.5)	32 (26.4)
75+	28 (20.3)	8 (10.1)	24 (19.8)
Education			
Not completed high school	22 (15.9)	8 (10.1)	22 (18.2)
Completed high school	48 (34.8)	28 (35.4)	45 (37.2)
Higher level of education	68 (49.3)	42 (53.2)	54 (44.6)
Not reported	0	1 (1.3)	0
Visual impairment			
Yes	93 (67.4)	41 (51.9)	82 (67.8)
No	45 (32.6)	38 (48.1)	39 (32.2)
Hearing impairment			
Yes	9 (6.5)	8 (10.1)	7 (5.8)
No	129 (93.5)	71 (89.9)	114 (94.2)
Reason for visiting			
New prescription	88 (63.8)	53 (67.1)	79 (65.3)
Primary care	35 (25.4)	21 (26.6)	25 (20.7)
Combination of above	15 (10.9)	5 (6.3)	16 (13.2)
Not reported	0	0	1 (0.8)
Who is the visit regarding?			
Myself	114 (82.6)	66 (83.5)	99 (81.8)
Someone else	24 (17.4)	13 (16.5)	22 (18.2)

Consumers interviewed after the training showed similar demographic characteristics to the pre-training consumers.

Primary outcome – use of 'What questions do you have?'

Post-training, there were significant improvements in the use of 'What questions do you have?', in both the face-to-face group and electronic group, with the face-to-face group being 6.14 times and the electronic group 4.29 times more likely to use this question than the control group (Figure 8)

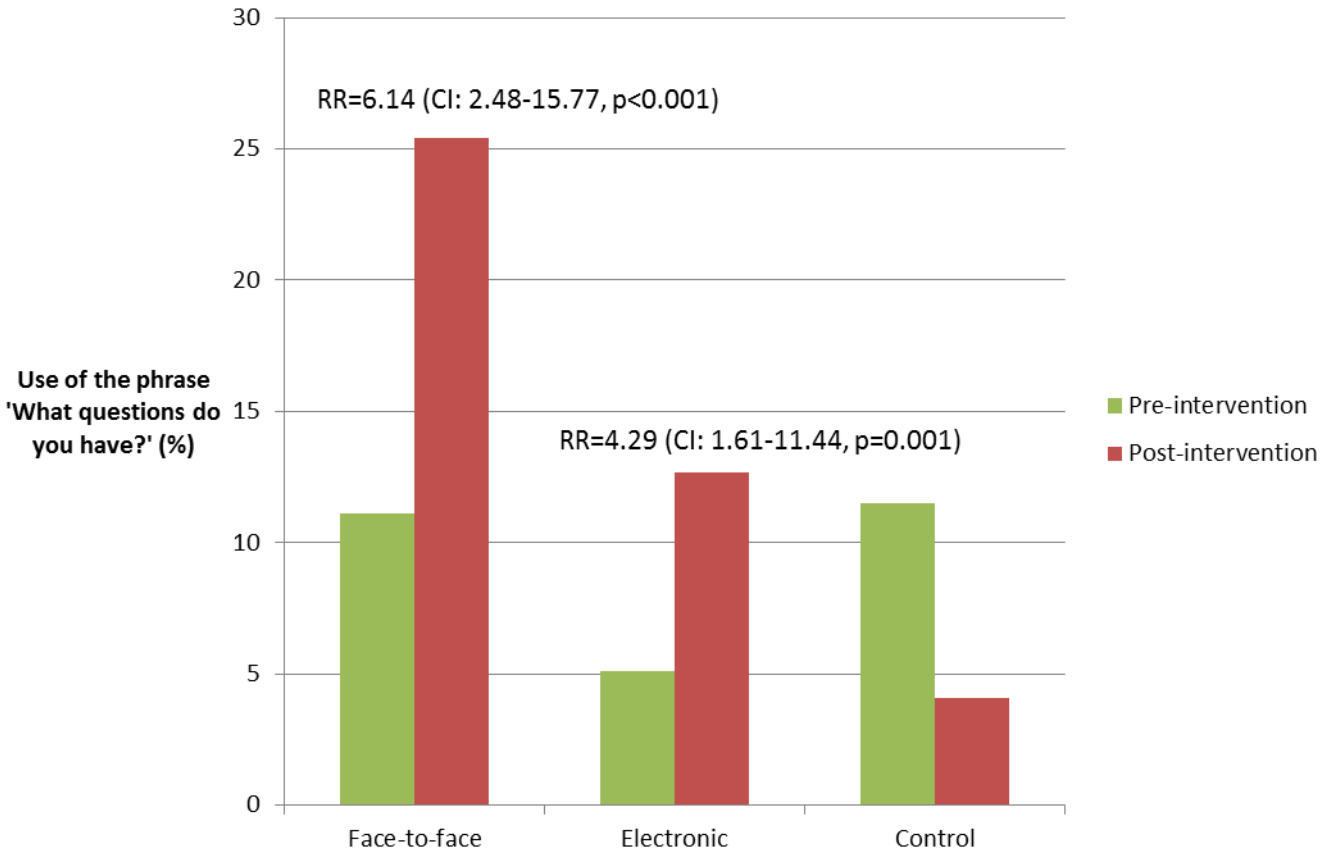

Figure 8. Use of 'What questions do you have?' among groups post-intervention (including observations)

With researcher observations removed, i.e. relying completely on consumer recall, the effect was slightly smaller, yet still significant. Post-intervention, the face-to-face group were 4.89 times more likely to use 'What questions do you have?' than the control group (CI: 2.27-10.52, p<0.001), and 3.06 times more likely in the electronic group than the control group (CI: 1.29-7.25, p=0.007)

With regard to changes within groups, The face-to-face group improved by 17.5% with a rate ratio of 3.83 (CI: 1.94-7.4, p=0.0001), while in the electronic group, the improvement was 14.4% with a rate ratio of 4.16 (CI: 1.67-10.37, p=0.0022).

When analysed separately, pharmacists in both the face-to-face and electronic groups were significantly more likely to use the question than pharmacists in the control group when post-training rates were compared. Face-to-face group pharmacists were 1.68 times more likely to use the question than the control group (CI: 1.35-2.10, p=0.001), and the electronic group pharmacists were 1.99 times more likely to use the question than the control group (CI: 1.43-2.75, p=0.002). Difference in the rate of use of the question between the face-to-face and electronic group when compared post-training, although not statistically significant, suggests a trend towards the face-to-face group pharmacists performing better than those in the electronic group (RR = 1.91, CI: 1.44-2.54, p=0.065).

Pharmacy staff members in the face-to-face group were significantly more likely to use the question than those in the control group when post-training results were compared, with a rate ratio of 2.17 (CI: 1.61-2.94, p=0.038), Whereas pharmacy staff members in the electronic group were not significantly more likely to use the question than those in the control group, post-training. There was also no statistically significant difference in the rate of use of the question between the face-to-face and electronic groups when compared post-training (RR = 1.02, CI: 0.76-1.37, p=0.901).

This increase in the use of the 'What questions do you have?' question suggests that the training was effective in creating awareness among pharmacists and pharmacy staff members in the usefulness and importance of using open-ended phrasing when asking questions to consumers to elicit more information, and to promote a judgment-free environment for the consumer. The use of this question has the roll on effect of possibly reducing medication misadventure among consumers as clarification is sought on particular issues or confusion the consumer may have with their medicines.

Primary outcome – use of the teach-back method

There was no significant difference in the use of teach-back among the three groups, but there was a slight trend towards the intervention groups being more likely than the control group to use teach-back post-intervention 3.6%, electronic group 2.5%, control group 1.7%) (Figure 9). This result did not change when researchers' observations were removed.

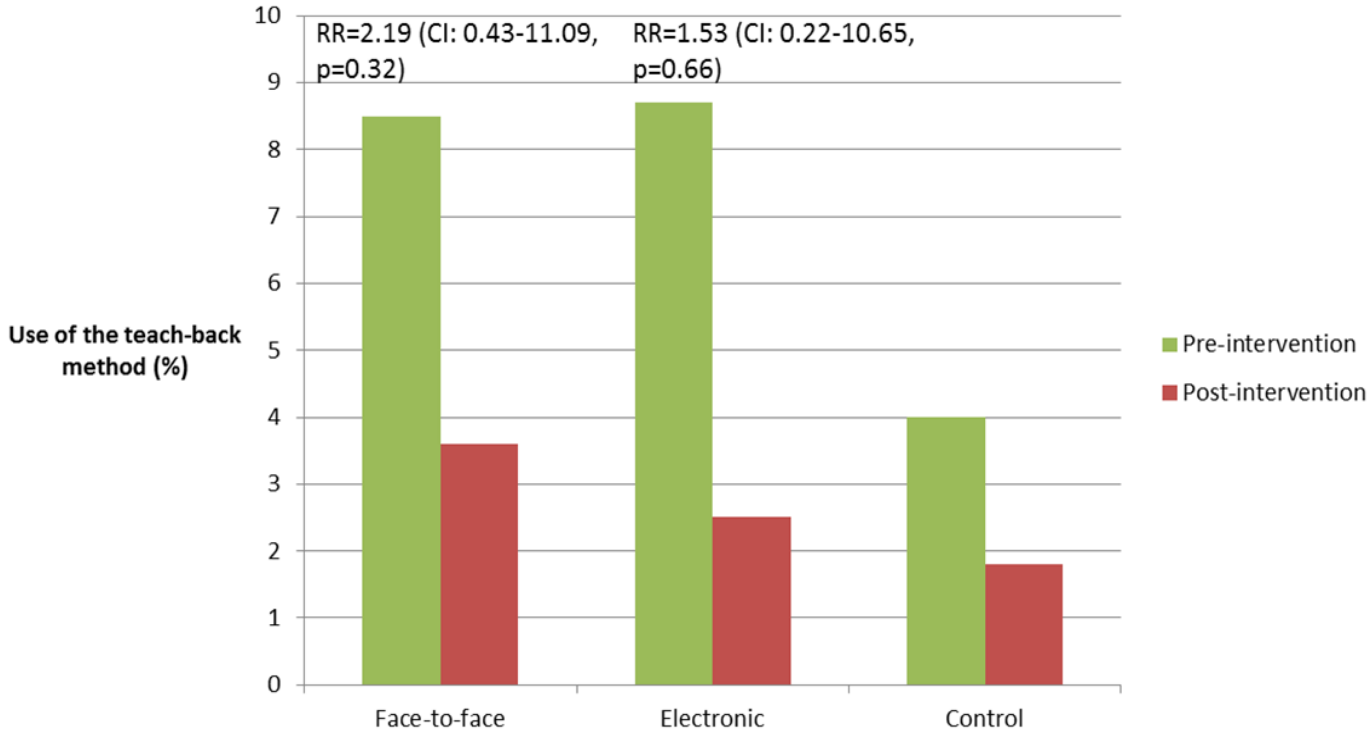

Figure 9. Use of teach-back among groups with consumers post-intervention (including observations)

When pharmacists and pharmacy staff members were analysed separately in their use of the teach-back method, there was no significant difference when compared between groups post-training, and within groups pre- versus post-training.

Little improvement occurred in the use of teach-back, with similar rates of use being seen both pre-training and post-training. Pharmacists and pharmacy staff members provided feedback in regard to

the use of the teach-back method and described it as a difficult method of counselling, and felt it would require more training on its application before feeling more confident in using it in practice.

Secondary outcomes

There were no statistically significant differences in the secondary outcomes between the face-to-face and control groups, and electronic and control groups (Tables 11 and 12), although the results suggested a trend towards the face-to-face group being more likely to repeat information to consumers compared to the control group (RR=1.38).

Table 10. Secondary outcomes pre-training among groups.

Outcome	Face-to-face (n=153) Frequency (%)	Electronic (n=138) Frequency (%)	Control (n = 135) Frequency (%)
Consumer was asked if they had a question.	142 (92.8)	120 (87.0)	123 (91.1)
Printed/handwritten information was supplied	33 (21.6)	17 (12.3)	32 (23.7)
Any information repeated	88 (57.5)	60 (43.5)	73 (54.1)
Used clinical terms	15 (9.8)	15 (10.7)	10 (7.4)

Table 11. Comparison of secondary outcomes post -training in the face-to-face training group versus the control group.

Outcome	Face-to-face (n=138) Frequency (%)	Control (n = 121) Frequency (%)	P value	Rate ratio (CI)
Consumer was asked if they had a question.	122 (88.4)	109 (90.1)	0.665	0.98 (0.90-1.07)
Printed/handwritten information was supplied	24 (17.4)	25 (20.7)	0.503	0.84 (0.51-1.39)
Any information repeated	61 (44.2)	40 (33.1)	0.067	1.38 (0.98-1.83)
Used clinical terms	16 (11.6)	10 (8.3)	0.374	1.40 (0.66-2.97)

Table 12.Comparison of secondary outcomes post-training in the electronic training group versus the control group.

Outcome	Electronic (n=79) Frequency (%)	Control (n = 121) Frequency (%)	P value	Rate ratio (CI)
Consumer was asked if they had a question.	66 (83.5)	109 (90.1)	0.172	0.93 (0.83-1.04)
Printed/handwritten information was supplied	12 (15.2)	25 (20.7)	0.330	0.74 (0.39-1.38)
Any information repeated	34 (43.0)	40 (33.1)	0.153	1.30 (0.91-1.86)
Used clinical terms	6 (7.6)	10 (8.3)	0.865	0.92 (0.35-2.43)

Pharmacists and pharmacy staff members tended to be good at asking consumers if they had any questions, in both a closed and open format. The rate was high both pre-training and post-training, around 85-90% across the groups, highlighting pharmacists' and pharmacy staffs' awareness of the importance of checking if consumers require any more information regarding their medicine.

Qualitative feedback

Constructive feedback was provided about the use of the primary outcomes, and any difficulties associated with this. In regards to teach-back, most participants noted the difficulties of implementing the method with consumers, yet some found it useful in certain circumstances

> *"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…I personally felt quite unsure of how to do it effectively." (Pharmacist 2, focus group 2)*

> *"Then I asked him if he would show me, because there was a puffer as well. Then he did the puffer completely wrong [sic]. That's when I used teach-back, so he totally handled it wrong [sic]. We did it again, and he got it right" (Pharmacist 1, focus group 4)*

Use of 'What questions do you have?' was met with more acceptance by participants than teach-back, but some issues and difficulties were raised.

> *"It actually did increase my knowledge a lot. In the way I ask the question after I've done everything, I've done the counselling and then I close it off. It's made me more aware of looking out for little details - people not making eye contact or looking kind of overwhelmed of your speaking - and then also asking the closing question…" (Pharmacist, interview 2)*

> *"You know, it was difficult for us to change how we spoke to customers and saying, "What questions do you have?" It was a bit difficult. It didn't come out automatically. You had to think about it or you went back and asked just, you know, what you normally asked. "You have any questions?" It was more difficult in the beginning" (Pharmacist, interview 1)*

> *"I don't ask them very often because I feel like they might ask me a question I'm not going to know the answer to, because I'm still learning. So that's one reason I just get put off by asking them" (Pharmacy assistant 1, focus group 2)*

Some participants also commented on consumers' reactions to using the question, many stating that it surprised the consumer but also that it resulted in opening up the medicines conversation.

> *"…some of them looked at us like, you know, "What are you talking about?" They sort of didn't know what that was supposed to say. Then we sort of went on with a bit of conversation and some of them came up with questions. It did open up more conversation and discussion with them about their medication and hopefully it would have improved their treatment and the outcomes of their medication" (Pharmacist, interview 1)*

> *"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 of, "I wouldn't ask you this normally, but can you help me?" kind of thing. And some things you can answer for them, so it just brings it out of them" (Pharmacist 3, focus group 1)*

Pharmacists suggested variations to this question that would serve the same purpose, such as the use of open-ended questions throughout the consultation such as "What issues do you have with this?", and the use of pauses after each key point to prompt questions throughout the consultation, rather than at the end.

The hypothesis that the use of Universal Precautions would be improved by the educational package was supported to some degree in that the use of Universal Precautions was improved by some pharmacists and pharmacy staff members. The study did not support the null hypothesis thatthe face-to-face and electronic methods of delivery would have a similar impact, as the face-to-face group performed better in regard to the primary outcomes.

9.4 Key findings

The effectiveness of achieving the primary outcomes was mixed. The use of 'What questions do you have?' was successful, but other outcomes demonstrated no significant change after the intervention. Teach-back was not well adopted.

The results may have been influenced by the Hawthorne effect during the short observation period. The use of simulated patients was an attempt to negate this effect.

Separate analysis of pharmacists and pharmacy staff members demonstrates that the package is suitable for both pharmacists and pharmacy staff members. These results may encourage greater participation by all pharmacy staff, possibly even those not involved in the supply of professional services. The results highlight the difficulties in altering pharmacists' and pharmacy staff members' behaviours in regards to communication with consumers, and provide scope for refining the health literacy educational package to increase the likelihood of effecting change after a wider dissemination to community pharmacies in the future.

10 Attitudes and motivations of pharmacists and pharmacy staff

10.1 Foreword

Successful implementation of this educational package relies on the attitudes, motivations, intentions and perceived self-efficacy of pharmacists and pharmacy staff. This study aimed to determine whether these factors changed after the intervention was introduced.

10.2 Method

Four questionnaires were used to evaluate the impact of the educational program on pharmacist and pharmacy staff attitudes and behaviours in regards to learning about health literacy. Two pre-intervention questionnaires were developed, one for the lead training pharmacist (Appendix 42) and one for all other pharmacists and pharmacy staff who planned to receive the in-pharmacy training (Appendix 43). Two post-intervention questionnaires were developed for the same two groups (Appendices 44-45).

The questionnaires were based on the Theory of Planned Behaviour (TPB) (Ajzen 1985; Francis, Eccles et al. 2004). The TPB was developed in an attempt to model the various factors that dictate intentional human actions. The theory explains behaviour as a result of an individual's intentions, which are determined and dictated by three variables: attitudes (whether or not the individual wants to do the action), subjective norms (the influence of social pressures on whether the individual should do the action), and perceived behavioural control (how capable the individual feels in doing the action). A toolkit developed by the Centre for Health Services Research at the University of Newcastle in the United Kingdom was used to guide the construction of these questionnaires (Francis, Eccles et al. 2004). Responses were measured on a Likert scale from one to seven, with one being strongly disagree, and seven being strongly agree.

The pre-intervention questionnaires were completed by all pharmacists and pharmacy staff to determine their baseline attitudes and motivations to implementing the health literacy program prior to Group 1 and 2 receiving the educational program.

Ethics approval was obtained from Monash University and Curtin University. Reciprocal ethics approval was granted by The University of Sydney (Appendices 49-52).

10.3 Results and Discussion

The pre-intervention questionnaire was completed by 216 participants, 71 (33%) of which were pharmacists, 8 (4%) were pharmacy interns, and 137 (63%) were pharmacy assistants from across the two intervention groups and control group. The post training survey was completed by 78 participants, 31 (40%) of which were pharmacists, 3 (4%) were pharmacy interns, and 44 (56%) were pharmacy assistants across the two intervention groups and control group. The significant decrease in questionnaires returned post-intervention was a result of both the attrition of 14 pharmacies from the study, as well the questionnaires being delivered to pharmacies towards the end of the year, a time generally viewed as busy for pharmacies in terms of business volume.

The median responses for each of the four domains surveyed pre- and post-intervention are shown in the table below. The Mann-Whitney U test was selected as the measure of comparison as data were not normally distributed and therefore a non-parametric analysis was required.

Table 13. Comparison of attitudes and behaviours between intervention and control groups pre- and post-intervention

Variable	**Intervention Median (Mean rank)**		**P value (Pre-intervention vs. post-intervention)**	**Control Median**	
	Before	**After**		**Before**	**After**
Perceived behavioural control over undertaking health literacy training	5 (1415.2)	6 (1544.5)	<0.001	5	5
Attitudes toward health literacy training	6 (682.3)	6 (806.0)	<0.001	6	6
Intentions to change behaviours	6 (505.4)	6 (500.9)	0.805	6	6
Subjective norm (influence of others on changing behaviours)	6 (713.1)	6 (672.7)	0.603	6	6

The medians of the intervention group were compared pre- and post-intervention for each of the four domains. As mentioned, a Mann-Whitney's U test was conducted to evaluate the difference in the responses of the 7-Likert scale questions.

There was a significant improvement in both perceived behavioural control and attitudes in the intervention group post-intervention when compared to the pre-intervention data, with a p value of <0.001 for both domains and a higher mean rank score (Table 13). There was no significant change in intentions or subjective norm in the intervention group post-intervention compared to pre-intervention. There were no significant differences between the control group pre- and post-intervention.

Table 14. Comparison of attitudes and behaviours between intervention and control groups post-intervention for study variables

Variable	Intervention median	Intervention mean rank	Control median	Control mean rank	P value
Perceived behavioural control over undertaking health literacy training	6	528.1	5	460.7	0.063
Attitudes toward health literacy training	6	301.3	6	219.6	0.004
Intentions to change behaviours	6	171.0	6	98.3	<0.001
Subjective norm (influence of others on changing behaviours)	6	235.3	6	238.3	0.603

Following the intervention, it was seen that there was a significant improvement in the intervention groups' attitudes towards undertaking health literacy training, as well as intentions to undertake health literacy training and employ the use of health literacy Universal Precautions with consumers when compared to the control group post-intervention (Table 14). When the intervention group was compared pre- and post-intervention, there was also a significant change in perceived behavioural control in regards to undertaking health literacy training, as well as attitudes and intentions. There was no change the influence of subjective norms in regards to undertaking health literacy training.

These findings may suggest that attitudes of pharmacists and pharmacy staff, their intentions to undertake health literacy training and implement it into practice, and their perceived behavioural control and self-efficacy can be modified by undertaking an in-house health literacy training program. Changes to pharmacist and pharmacy staff attitudes may result from an increased knowledge and awareness of health literacy as a result of the training. A poor attitude towards wanting to learn about health literacy may simply come from this unawareness of the concept, which may be modified by training. Similarly, an improvement in intentions of pharmacists and pharmacy staff may result from an increased awareness of health literacy and the possible negative consequences of not considering a consumer's ability to understand and use health information. Improvements in the perceived behavioural control of pharmacists and pharmacy staff may result from an increased confidence in using the skills obtained through use of the training package. Self-empowering staff and liaising with management may further minimise the barrier this may place on the implementation of health literacy training in the pharmacy.

There was no significant change on the influence of the expectations of others on participants' likelihood to undertake the health literacy training (subjective norm), but both the intervention and control groups scored highly in this area, possibly indicating that pharmacists and pharmacy staff already feel an expectation by consumers and their managers to consider consumers' health literacy ability when counselling, and to use health literacy techniques when appropriate.

This phase of the project was limited by a lower response rate post-training in comparison to pre-training which may affect both the results obtained and the generalisability of the results to the wider population. It is possible that the post-intervention questionnaires were returned by mostly motivated participants, which in turn may have biased the post-intervention results.

The results of this phase support the hypothesis that the health literacy educational package can alter pharmacist and pharmacy staff attitudes and motivations to health literacy training.

10.4 Key findings

From the results above, it can be suggested that the attitudes, intentions and perceived behavioural control of pharmacists and pharmacy staff towards undertaking health literacy training and using health literacy principles in the pharmacy environment are modifiable through training. Pharmacists and pharmacy staff may already acknowledge that consumers and managers currently expect them to keep the health literacy ability of consumers in mind when counselling.

11 Simulated patient surveys

11.1 Foreword

The objective of this phase of the study was to measure the change in the practices and behaviours of pharmacists and pharmacy staff in regards to the use of Universal Precautions in a real-life setting using simulated patients, limiting the effect of bias and the Hawthorne effect.

Various methods exist to assess the communication skills of pharmacists and pharmacy staff members, with simulated patients being a widely used and reliable method to derive outcome measures in pharmacy practice research(Watson, Skelton et al. 2004; Watson, Norris et al. 2006). Simulated patients, also known as mystery shoppers, are used in pharmacy to assess and evaluate current practice, or to measure outcomes when involved in research. 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"(Watson, Norris et al. 2006).

11.2 Method

All pharmacies were visited by two simulated patient twice during the study period: prior to receiving the health literacy educational package and one week following the completion of the in-house training component. Simulated patients were a mix of both professional actors and lay people. All simulated patients received training in role playing the case vignettes developed for this study. This method was utilised to objectively measure the uptake of health literacy techniques post-intervention in everyday practice, without the possible effect or influence of a researcher's presence. Three case vignettes were developed for this component of the study (Appendix 46), along with a standardised data collection form to objectively evaluate the performance of pharmacist and pharmacy staff.

The three case vignettes were developed by three research officers, who are also pharmacists, based on typical real-life scenarios in pharmacy practice. The first case was the presentation of a consumer with an asthma inhaler (used in visits both pre- and post-intervention intervention). The second case was heartburn, which was used pre- intervention, and the third case was seasonal allergies, which was used -post-intervention. The last two cases were used only once as the nature of the scenario may be remembered by some pharmacy staff who attend to the 'consumer'.

Visits were conducted before the intervention, and immediately after the completion of at least core modules 1 and 2 of in-pharmacy training. The simulated patients were instructed to enter each pharmacy at separate times to avoid any chance of their identity and purpose being revealed. They were instructed to wait to be approached by a pharmacist or pharmacy staff member for assistance, or in the case of a lengthy waiting period, they approached the nearest available staff member.

Following delivery of the case vignettes in the pharmacy, the simulated patient completed the standardised data collection form as soon as possible after leaving the premises.

The data collection tool for the evaluation of the pharmacist and pharmacy staff members' performance was developed alongside the consumer questionnaire (Appendix 47). As both components of the study aimed to evaluate the use of Universal Precautions during consultation with a pharmacist or pharmacy staff member, both tools bare many similarities. The nine themes and skills identified as underpinning Universal Precautions in health literacy were used to formulate the objective assessments on the data collection form. The form was created in a fashion similar to that used in an objective-structured clinical examination (OSCE). Each evaluation point describes a skill that the assesse must demonstrate to be considered competent. Each skill begins with an action verb, for example, 'heard', 'spoke', 'utilised', etc.

The final data collection tool collected information regarding:

1. Length of interaction with pharmacist or pharmacy staff member

2. Who the simulated patient consulted (pharmacist or pharmacy assistant)

3. Process strategies used by the pharmacist or pharmacy staff member (for example, use of medical terms, clarity, volume and pace of speech, and whether information was repeated)

4. Content strategies used by the pharmacist of pharmacy staff member (for example, number of pieces of information given, and whether the consumer understood everything that was said).

5. Engagement strategies used by the pharmacist or pharmacy staff member (for example, opportunity to ask questions, whether "What questions do you have for me?" or 'teach-back' was employed, or whether written information was supplied and in what form).

The questionnaire comprised 42 questions, of which one allowed the simulated patient to provide free-text comments. The data collection tool was evaluated for face and content validity by five pharmacy academics from the Faculty of Pharmacy and Pharmaceutical Sciences, Monash University and the School of Pharmacy, Curtin University.

Ethics approval was obtained from Monash University and Curtin University. Reciprocal ethics approval was granted by The University of Sydney (Appendices 49-52).

11.3 Results and Discussion

A total of 72 pharmacies were visited by two simulated patients pre-intervention, totalling 143 individual visits, and 63 pharmacies were visited post-intervention twice by simulated patients, totalling 126 individual visits. 9 pharmacies withdrew from the study before post-training data collection was conducted.

Data was analysed using SPSS version 19.0 and summarized using descriptive statistics. Multiple response questions were assigned codes 'yes' or 'no' for each response. To determine any significant

relationships between variables, Pearson's Chi squared test was used. The significance level was set at $p<0.05$.

The primary outcomes for this phase were use of the phrase 'What questions do you have?' and use of the teach-back method. There was no significant change in the use of the phrase 'What questions do you have?' or the teach-back method between both the face-to-face group and electronic group, compared to the control group post-intervention. When pharmacists and pharmacy staff members were analysed separately, there was also no statistically significant differences in use of either of the primary outcomes. There was a statistically significant improvement in the face-to-face group when compared to pre- and post-intervention, with a rate ratio of 8.17 (CI: 1.06-62.78, p=0.013), meaning that the face-to-face group were more than eight times more likely to use the phrase following training as they were before undertaking training. There was no statistically significant change in the electronic or control groups pre- and post-intervention.

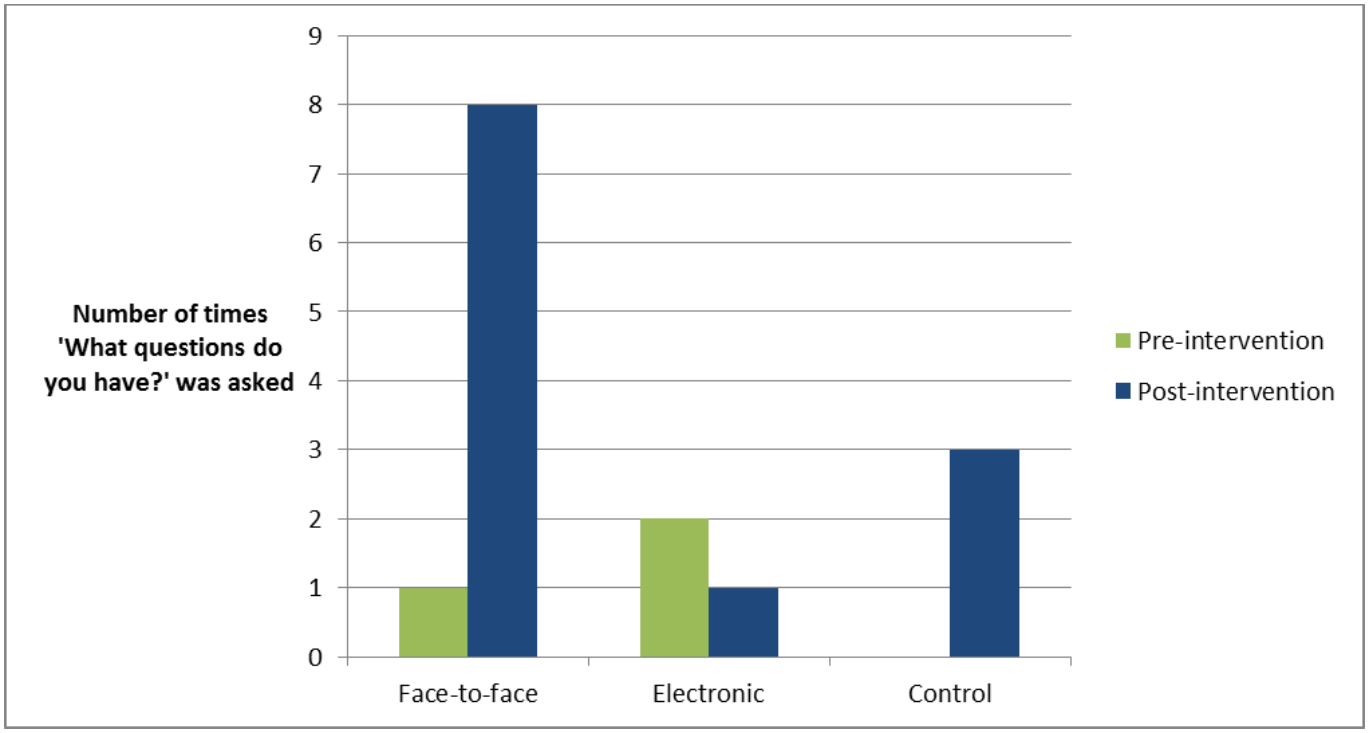

Figure 10. Comparison of the face-to-face, electronic and control groups pre- and post-intervention in regard to using the phrase 'What questions do you have?' with simulated patients (n=143 pre-intervention, n=126 post-intervention)

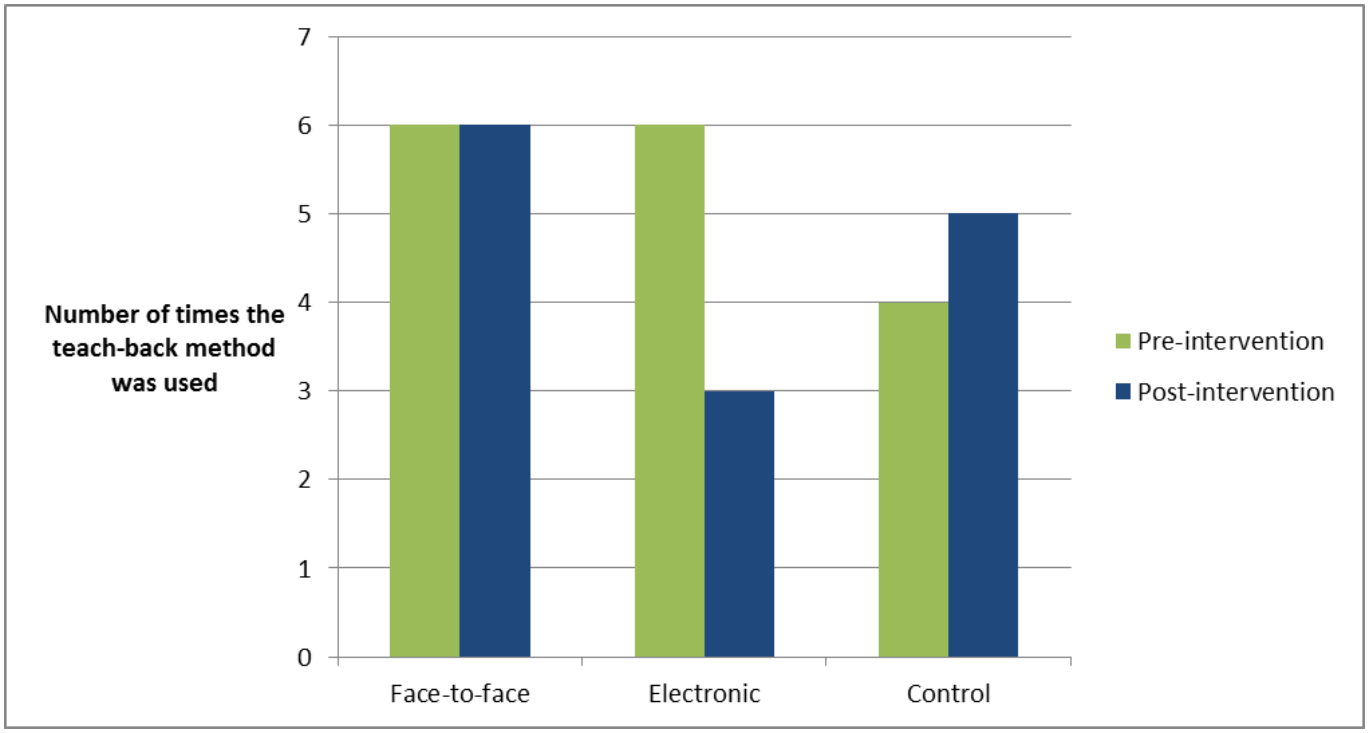

Figure 11. Comparison of the face-to-face, electronic and control groups pre- and post-intervention in regard to using the teach-back method with simulated patients (n=143 pre-intervention, n=126 post-intervention)

The low use of the teach-back method was again reflected in the simulated patient surveys as was first observed in the consumer surveys. This may have resulted from a lack of confidence or self-efficacy in relation to using the method in practice. The package may therefore benefit from more examples and role-play scenarios demonstrating the use of the teach-back method.

Regarding the secondary outcomes, the face-to-face group were almost twice as likely to ask consumers if they had questions compared to the control group following training (RR: 1.91, CI: 1.06-3.47, p=0.025) (see Figure 8). This may highlight the educational package's value in reminding pharmacists and pharmacy staff members to be aware that consumers may have questions, and that it is only when they are prompted, do they ask these. It would be preferable if pharmacists and pharmacy staff members phrased this question in an open-ended format to create a more conducive lead-in for the consumer to ask questions. Pharmacists and pharmacy assistants across all three groups also demonstrated an awareness of the importance of repeating information to consumers as shown in Figure 8.

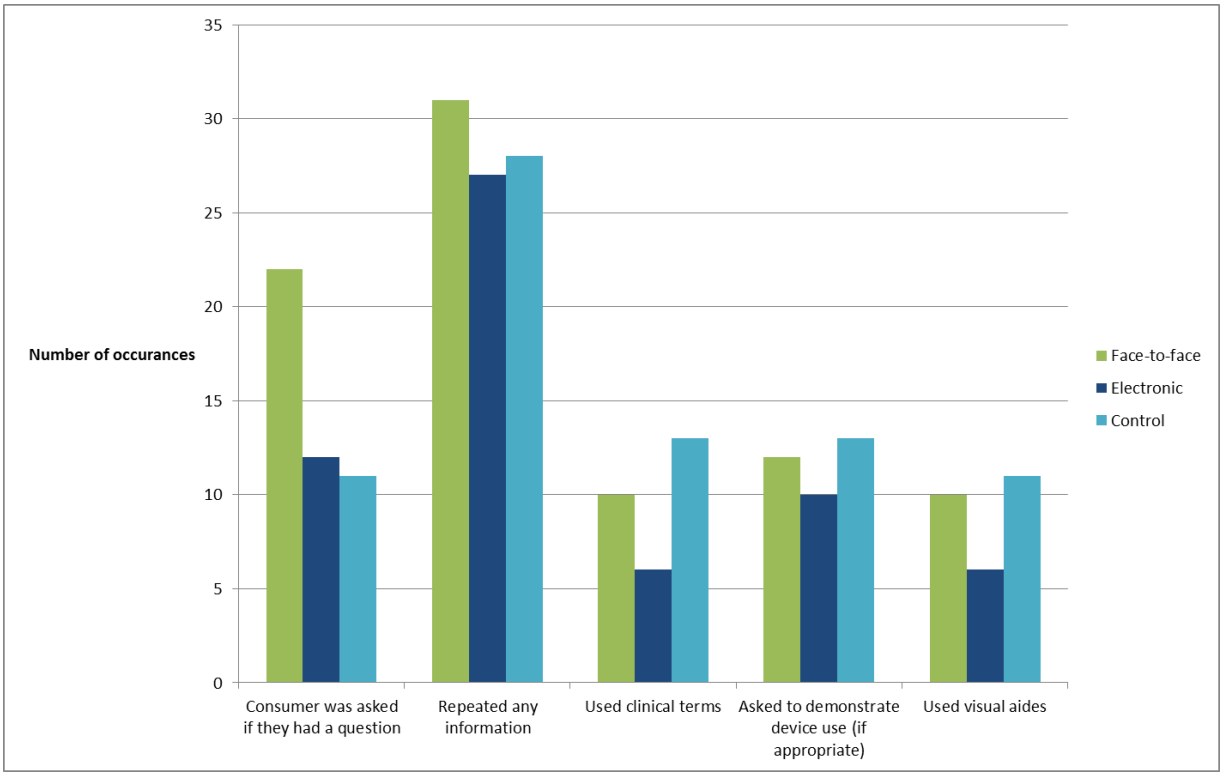

Figure 12. Secondary outcomes post-training in the face-to-face, electronic and control groups as measured by a simulated patient (n=126)

There was also no statistically significant difference in the provision of printed materials or their subsequent explanation by pharmacists and pharmacy staff members post-intervention across the three groups (Figure 13).

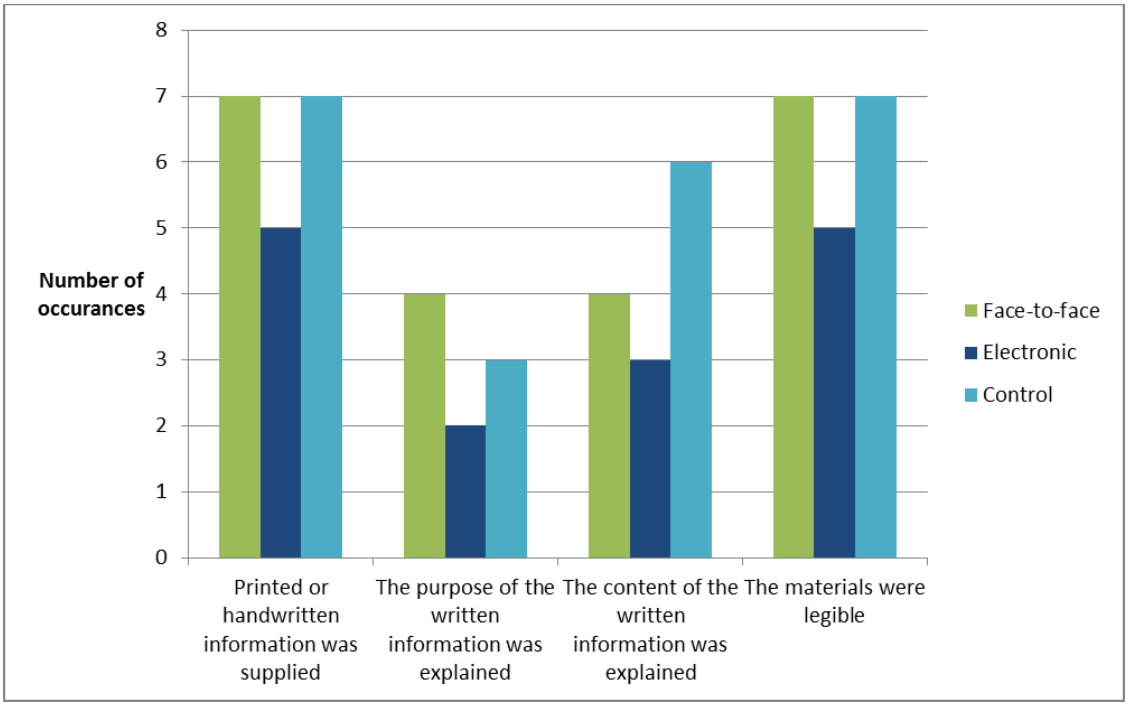

Figure 13. Secondary outcomes related to printed information post-training in the face-to-face, electronic and control groups as measured by a simulated patient (n=126)

Figure 13 also shows that pharmacists and pharmacy staff members did not always explain the purpose and content of printed information provided to consumers. This is an important step in ensuring that consumers understand how to retrieve important and useful aspects of printed information.

There was also a statistically significant decrease in the time spent counselling in the electronic group compared to the control group (5.62 minutes vs. 6.64 minutes, p=0.044). The educational package encouraged short and succinct counselling sessions to reduce the risk of consumers becoming confused and overwhelmed with information. There was also a trend in a decrease in the mean number of points of information supplied to consumers in this group compared to the control group (4.9 vs. 5.8), but this was not statistically significant, and therefore further assumptions cannot be made. The face-to-face group showed no difference in time spent counselling consumers, but also demonstrated a trend to provide less information to consumers compared to the control group (5.0 vs. 5.8). Once again, this difference was not statistically significant. These trends may be interpreted as demonstrating pharmacists' and pharmacy staff members' awareness of the need to provide less information to consumers to reduce confusion, but also that they may require extra training on effective ways to prioritise important information..

There were no other statistically significant differences in secondary outcomes post-training. Pharmacists and pharmacy staff members demonstrated their awareness of the importance and benefit of repeating information to consumers.

The hypothesis was supported in some aspects as the educational package did improve the use of some, but not all, Universal Precautions by pharmacists and pharmacy staff members.

11.4 Key findings

This phase of the study demonstrated that the educational package was effective in increasing the use of 'What questions do you have?' but may benefit from the implementation of a reminder system in pharmacies to improve its use. It also showed that the rate of using the teach-back method remained low post-intervention and therefore suggested that more examples of its use in the educational package may be of benefit. The study also demonstrated that more emphasis on prioritising and reducing content with consumers may be of benefit in the refinement of the package. Otherwise, pharmacists and pharmacy assistants appeared competent in most other areas when communicating with consumers and in understanding the importance of delivering information in a manner that consumers comprehend.

A possible limitation of the study may relate to the construction of the data collection form. Outcomes were mainly measured using 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' even if improvement was made from the pre-intervention period as they may not have met all the requirements to score a 'yes'. A scale may have been a more effective scoring method to measure improvements in practice and behaviour.

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12 Qualitative feedback

12.1 Foreword

The aim of this phase of the study was to gather feedback regarding the health literacy education package from intervention pharmacies. Focus groups provided a method of gathering qualitative feedback in regards to a particular topic, in this case, the usability, perceived effectiveness and sustainability of the health literacy educational package. Discussions were held in three states, and were conducted as focus groups (n=5) and phone interviews (n=4) .The overall aim of this phase was to validate, add to, and refine the education package before its wider dissemination to pharmacies in the future. .

The specific aims were to:

- Elicit new ideas for the content of the educational package that had not been included in the first edition.
- Seek feedback on the usability of the educational package in relation to its structure and method of delivery, including the face-to-face, computer-based, and in-house training components.
- Seek feedback on the ease of integration of the educational package within a pharmacy context.
- Seek feedback on the perceived effectiveness of the educational package on changing the behaviors of pharmacy staff and the pharmacy environment.

Three broad domains of the training package were explored:

1. Usability
2. Implementation
3. Effectiveness

12.2 Method

Nine broad, exploratory research questions were developed for use in the focus group meetings (Appendix 46). Questions were examined for face and content validity by five pharmacy academics, and two independent postgraduate students. A sample of both pharmacists and pharmacy assistants was recruited to capture the views of a variety of pharmacy staff members. Trainer pharmacists were initially contacted by phone to invite them and their staff to participate in the focus groups. Those who expressed an interest in participating were provided with information regarding the venue and time for the meeting. Participants received an Explanatory Statement and Consent form before participation (Appendices 61-64), and a $100 reimbursement in the form of a shopping voucher.

The time of the group discussions and venues for the meetings were organised to best suit the schedules of the participating pharmacy staff members. Remuneration for participation was provided.

A total of five focus groups were conducted: two in Melbourne, one in rural Victoria, one in Perth and one in rural Western Australia. Individual interviews were also conducted, one with a pharmacist in Sydney and four with pharmacists in Western Australia (two metropolitan and two rural).

Various group compositions were sued: trainer pharmacists and pharmacy assistants only, trained pharmacists and pharmacy assistants only, and rural pharmacists and pharmacy assistants (both trainers and trained staff together). G.D. and G.S. conducted the focus groups and interviews in Victoria, where G.D. facilitated the process and G.S. was the observer/note-taker/audio-recorder. L.E.

and E.E. conducted the focus groups and interviews in Western Australia: L.E. facilitated the process and E.E. was the observer/note-taker/audio-recorder.

Focus group discussions were audio-recorded and transcribed verbatim. Two researchers independently read the transcripts; neither person had participated in the focus group discussions or the interviews. During this phase of initial coding, descriptive codes (or raw meaning units) were identified. In phase two of the analysis, an iterative process of coding and thematic analysis will be undertaken until consensus is reached between the research team.

Ethics approval was obtained from Monash University and Curtin University. Reciprocal ethics approval was granted by The University of Sydney (Appendices 60-61).

12.3 Results and Discussion

The discussions were audio-recorded and transcribed verbatim. Preliminary descriptive analysis identified a range of meaning units (i.e. quotes or raw data). These were constructive (positive and negative feedback) and thoughtful, and showed a degree of reflection by the participants.

Overall, the participants found the following aspects of the education package useful: the train -the-trainer approach, understand and implementing the concept of Universal Precautions, the video clips (of which they requested more examples) and flexibility of the modular approach. Constructive criticism included reducing the length of training for the trainer, refinement to reduce duplication, and the challenges of using the teach-back technique. The small-group peer-learning process was considered an acceptable, constructive mode of learning.

The preliminary findings are summarised below and are supported by quotations from participants.

Although some of the participants had been aware of the concept of health literacy, they were not aware of the wider effects on the consumer and the community:

> *"I heard of health literacy more in the context of people having information or access to health information, or access to good quality health information. But not in this sort of sense." (Pharmacist 1, focus group 2)*

> *"I'd never heard of it in terms of services. You know, when you're eligible for certain cards. I always just thought of it as the information or the education of your meds or your condition, whatever. That side of it. So it broadened my view." (Pharmacist 2, focus group 2)*

The inclusion of statistics in the education package and the effect of health literacy on the healthcare system were well-received by participants and helped them to understand the extensive impact of limited health literacy.

> *"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 2, focus group 2)*

Various reasons for undertaking the HeLP training became apparent during the focus group discussions, and ranged from self-directed learning to a requirement in the workplace, or an assessment activity for Continuing Professional Development.

"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 somebody else it might be, oh, I'm being tested on this. Or somebody else might be I can get CPD from this, or I can do this with my friends." (Pharmacist 2, focus group 2)

The effectiveness of the package regarding staff training was highlighted; some participants mentioned that staff took ownership of the program, and trained other staff members who may have been younger or less experienced.

"They tell you their own take on the program. Everyone at my shift at work got more into it at that moment. Instead of just telling them something, "This is what we're doing," they take initiative and go train some other younger staff and get more involved. I thought it was a cool process for us." (Pharmacy assistant 1, focus group 1)

"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." (Pharmacist 1, focus group 1)

"I couldn't stop them talking. It was something different. Most of the time when you mention training…It's just me talking…it's information overload." (Pharmacist 1, focus group 4)

Discussion about education package, especially the slides and videos, would often extend beyond the training session*:*

"The girls here after a transaction would come up to me and say 'that reminds me of that'"(Pharmacist 1, focus group 5)

Some mention was made of the education package being more suited for and targeted towards pharmacists than pharmacy assistants, and it was suggested that some refinement of the package could be undertaken to reduce this perception:

"So I do believe a little it's more aimed at the pharmacists." (Pharmacy assistant 1, focus group 3)

Pharmacy assistants noted the difficulty in deciding when it is appropriate to refer consumers with health literacy issues to the pharmacist, or up to what level they are able to assist the consumer, and thus referral in relation to health literacy issues was raised:

"… there is still that uncertainty from the pharmacy assistant's point of view…where is that line between: Do they go to counsel him? Do they refer? Because the Guild is so stringent about when to refer to the pharmacist." (Pharmacist 1, focus group 3)

"We would always get…the pharmacist if we felt they didn't understand, we'd always go and get backup." (Pharmacy assistant 1, focus group 3)

One pharmacist had extended the health literacy training to include areas of the pharmacy which were unrelated to medicines:

"I went to a really good Clarin's 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 go to this video," and she was like, "Oh my God, I'm doing so much better now." I just want to make it simpler, and take care of all those

other people that get washed over, maybe, they come and see her and she's incredible." (Pharmacist 4, focus group 1)

Module 1 (Introduction to Health Literacy) was perceived by some as being "fairly self-explanatory" and perhaps this module could be suitably revised

There was a general feeling among many participants that the content of the education package should be reduced to key points that facilitated small group discussion. For example, participants appeared perceptive in detecting when clients were in a hurry, but less skilled in detecting whether the advice they provided was understood. One pharmacist recalled a consultation with a client from a different ethnic and cultural background:

> *"I was going through this thing and getting all the nods and smiles … we were having this great conversation, I was 100% sure we were doing really well…but we were totally on two different paths." (Pharmacist 2, focus group 4)*

The use of polite nodding and lack of comprehension is addressed in the education package in the 'cues and clues' sections.

Pharmacists also commented on clients' limited ability to retain information:

> *"The written information is crucial for some people who are in a bad emotional state … There was a lady … who had to be started, of all things, on a Webster-Pak with warfarin … she'd just come out of hospital … then all this stuff was happening … by the time she … reached the pharmacy with all her scripts … I was trying to explain how to use the Webster-Pak and counsel her on warfarin … I could tell she wasn't taking anything in because she was nodding her head … she just wanted to go home … you've got to give her the written info … we organised for her to come back in a couple of days' time when the dust had settled." (Pharmacist 3, focus group 4)*

Participants noted the importance of integrating health literacy training into guidelines for practice to ensure consistency across pharmacy practice in Australia.

> *"I think that if it's put into Quality Care, and it has this neat health literacy standards kit at the end…I think that's where the baton is going." (Pharmacist 1, focus group 3)*

> *"…I think it's pretty worthwhile to incorporate it more into the pharmacy degree…or into the Pharmacy Guild training…" (Pharmacist, interview 1)*

When asked about the sustainability of the educational package and the methods they were implementing to ensure that the skills they acquired could continue to be used in practice, suggestions ranged from reminders to broader issues such as self-motivation:

> *"…I think reminders can help. We've got a place where we've got it set up okay."(Pharmacist 1, focus group 2)*

> *"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 more a self-motivated person. For me it's personally important that I talk to patients in an effective way. But somebody else it might be "Oh, I'm being tested on this" or somebody else might be "I can get CPD from this" or "I can do this with my friends". (Pharmacist 2, focus group 2)*

There were many suggestions for revision of and refinements to the health literacy educational package, particularly an increase in the number of videos and a change to the structure and delivery of the train-the-trainer section of the electronic package:

> *"I think the train-the-trainer video could've been more in-depth. You can do it as one big chunk because that helps tie everything in together…but that video kept breaking up…The different modules were okay to get broken up…but within the module, there was a closing statement and then an introduction again. That could've just been omitted and just given as one."(Pharmacist 2, focus group 1)*

> *"It was good, except the videos didn't work on the Mac. We got another video player and did it like that. That was fine but that might be an issue." (Pharmacist 3, focus group 1)*

> *"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 1, focus group 1)*

> *"I found it very intense sometimes like it was quite repetitive in some aspects…but then I guess that's also reiterating something so it's also sticking it into that person's mind" (Pharmacist 1, focus group 5)*

12.4 Key findings

The health literacy educational package was well received and most participants found the training useful and engaging. Various methods of delivery and training were used which reflect the flexibility of the package for use in different workplace environments and contexts.

The use of universal precautions, as introduced and incorporated in the education package, was met with mixed opinions and varied success. Many found the concept of prompting further questioning to be useful, such as the term 'What questions do you have?' However, variations in the wording would have been easier to incorporate into everyday conversation with consumers. Teach-back was considered difficult to use and implement and it did not 'feel natural' for many participants.

Participant feedback provided valuable information in relation to the benefits of the educational package and how it improved both awareness of health literacy in the pharmacy context, and counselling consumers, although it raised areas that require revision and refinement before wider dissemination of the education package.

Improved guidance for pharmacy staff members regarding the level of assistance and intervention they could provide to consumers with limited health literacy and the point at which it would be appropriate to refer these consumers to the pharmacist, would be of value. Both pharmacists and other pharmacy staff felt that this guidance may be provided through pharmacy organisations such as the Pharmacy Guild of Australia.

Changes to the formatting and presentation of the education package may improve usability, particularly in the electronic train-the-trainer section and it is perceived that this would facilitate learning by making the process more fluid. In addition, adapting the modules to facilitate flexible delivery (i.e. as single modules or as components of a module) may improve the acceptability for pharmacists and pharmacy staff.

The use of a reminder system may improve the sustainability of implementing the Universal Precautions in the community practice setting. Participants noted the benefits of using reminders to maintain a focus on health literacy, such as posters, stickers or add-ons in computer programs.

The challenges experienced with the use of the teach-back technique were raised in the focus groups and were also reflected in the consumer surveys and in the surveys associated with the simulated patients. Participants suggested that more examples of effective use of the technique may be beneficial, particularly in the form of videos and role-play scenarios.

In general, the package received mostly positive feedback. The benefits of recognising health literacy as a potential issue among pharmacy consumers was evident in feedback provided by participants during the focus groups. The feedback also highlighted that refinement of the educational package was required before it could be considered for implementation to a wider audience in community pharmacy.

13 The revised educational package

Based on the outcomes of the research, feedback from focus groups and input from the project reference group, adjustments were made to the package to enhance its flexibility, focus, and usability. Overall, the package was well received and no major changes to either content or structure were necessary.

Flexibility in delivery of the package was observed as an issue to be considered. This was evident not only from the feedback in focus groups but also from observations of implementation in pharmacies during the trial period where many variations were used. This included running all sessions together, combining some sessions and having staff read materials from some sessions while working as a group with others. It was clear that the capacity to join or separate various aspects of the package would be important to meet the varied needs of individual pharmacies and their services.

The major focus of refinements to the package included:

- Combining two sessions from Module 1 into a single session. Feedback here suggested that the materials were a little drawn out while the key concepts of this were easily grasped. Participants understood what Health Literacy was and recognised how and why limited Health Literacy was a significant issue. A more focussed introduction in a single module then allows for staff to work on the various strategies to address the issues in Modules 2 and 3.

- Revising structure of four sessions for Module 2 so that they can be delivered as individual sessions or combined together to meet the practical delivery needs of an individual pharmacy.

- Enhancing the "teach-back" components of the package with more examples, interaction and resources around this element. It was clear from the evaluation that teach-back was not well adopted, yet focus group feedback indicated that staff recognised it was important and useful but they were often afraid to use it for fear of upsetting consumers or "getting it wrong". To help address this, more examples have been included as well as enhanced activities to practice the skill, resources for individuals to use to help them grasp key phrases to use, as well as an activity for the group to try and identify reminders to use in the pharmacy that may help them approach "teach-back" more confidently.

- Combining Modules 4 and 5 into a single module as the same process is used across the two settings discussed. While the settings of residential care and schools may seem to be very different, the approach used in these modules was based on the same content and strategies. The modules were redesigned so that a focus on either setting could be made, with direction in the trainer guide to ignore (or even delete) content about the other setting. In both settings the focus is on providing knowledge and resources to staff to enhance the work they do. This includes a basic understanding of what Health Literacy is and the consequences of limited Health Literacy. Basic

skills to share with their charges (students, residents, families) in particular "Ask Me Three" and resources to help make this sustainable. An important message that comes through this session is building a culture that it is OK to ask questions of health providers and that questions are normal and, importantly, expected.

Minor amendments of language and presentation were made as well.

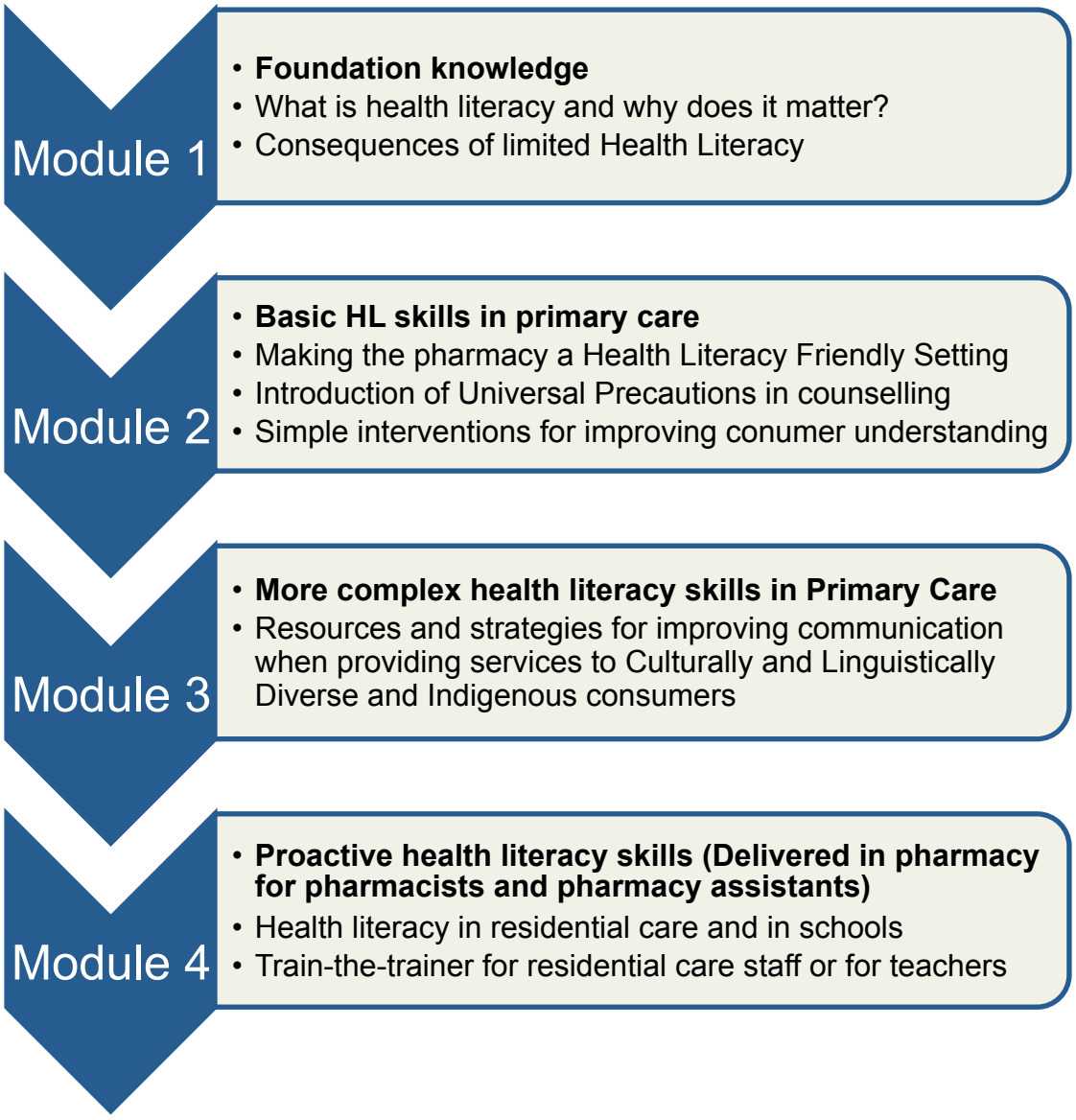

Figure 14 Outline of revised educational package

The supporting trainer guide was also amended to reflect the changes to the modules described. Focus groups and other anecdotal feedback did not produce any significant issues with using the guide for delivering the package (in fact it was quite well received). Input from the project team suggested some minor enhancements that would make the trainer guide even more useful, including:

- Clearer and more detailed direction for managing group activities
- Adding the duration of videos to the trainer guide to make keeping to time easier

- Changing slide number formatting
- Enhanced descriptions of some video to make it clearer how they inform the next activity

Train-the-Trainer

Face-to-face training was preferred for trainers and supported timely delivery of the package but the flexibility of the electronic version of the package was appealing to those who saw the obstacles of distance and time affecting their opportunity to participate in the project. It is a recommendation of the project team that the educational package be made available in both formats rather than focussing on just one.

14 CPD accreditation

The PGA has accredited this educational package for both Group 2 and Group 3 CPD recognition. Participants in the Train-the-trainer sessions and those who participate in the in-pharmacy trainer will be able to claim Group 2 CPD for their participation on completion of assessments. For the pharmacists who deliver the in-pharmacy training, the will be able to claim up to Group 3 recognition for their work if conditions are met.

15 Summary of key findings

Health literacy is a major issue in the delivery of healthcare in Australia, particularly in the pharmacy setting. This educational package intended for the community pharmacies proved effective at increasing awareness of health literacy as an issue, and ways in which these issues can be overcome, or at least minimised to improve consumer use of medicines, and reduce the risk of medication misadventure and poor health outcomes.

The uptake of Universal Precautions was met with mixed results. The use of the phrase "What questions do you have?" with consumers showed significant improvement among pharmacists and pharmacy assistants, yet the use of teach-back was met with poor results. This highlights the relative difficulties faced when attempting to affect practice change with pharmacists and pharmacy assistants in the area of communication, particularly when specific communication methods have been engrained in practice and used for years.

Pharmacists and pharmacy assistants did show positive attitudes, intentions and perceived behavioural control towards acknowledging health literacy as an issue, although difficulties in implementing the package were highlighted in the attitudes and motivations of pharmacists and pharmacy staff members, which showed that a lack of organisation support may prevent uptake of the training. Organisational support may come in the form of support from managers to implement the educational package in the pharmacy, for example, financial incentives or time during working hours allocated to preparing and implementing the package for both pharmacists and pharmacy staff members. This may highlight the need to liaise with managers or organisations to ensure the creation of a supportive environment for staff to undertake training and use the communication techniques in practice.

Environmental changes were difficult to measure, but did highlight some improvements as a result of the package, particularly in the area of implementing health literacy related policies into the pharmacy structure, for example, in the area of training new staff.

Further refinement of the educational package is warranted to further increase the likelihood of success in changing both practice behaviours and illicit organisational and environment changes of the pharmacy.

16 Summary discussion

The overall aim of the proposed research was to increase Australian community pharmacists' and pharmacy staff members' knowledge of health literacy, and ability to detect and respond to consumers' health literacy issues. This was to be achieved through the delivery of an education package that used a variety of methods to help overcome communication barriers regardless of consumers' perceived health literacy ability. The literature suggests that measurement of consumers' health literacy is impractical in a healthcare setting such as community pharmacy; thus, this project focussed instead on **building capacity in community pharmacy to communicate and engage effectively with consumers to improve their use of medicines and healthcare resources**.

Effectively, this is a risk reduction strategy to assist consumers get the basics of medication use right, particularly if they are at risk of confusion or misunderstanding when too much or too complex information is presented to them.

While there are strengths and weaknesses to the research outcomes, overall the package was well received and did have an impact. The issues of sustainability of changes and addressing the challenges of implementing "teach back" more effectively are of concern. Wide distribution of this package to Australian community pharmacies has the potential to contribute to better medicines use and reduced negative consequences of medication misadventure. The following important effects should be observed from wide dissemination:

- The health literacy education package will increase Australian community pharmacists' and pharmacy staff members' awareness of the concept of health literacy.
- The health literacy education package will improve Australian community pharmacists' and pharmacy staff members' practice in relation to using Universal Precautions for all consumers, regardless of their perceived health literacy capacity.
- The method of delivery, being face-to-face and electronic, will show similar rates of success in regards to implementation. While face-to-face was preferred, having the option was popular to enhance flexibility and access.
- The attitudes and motivational reasons behind implementing the health literacy educational package in the pharmacy will influence the success of implementation and on-going use of the package.
- The health literacy "friendliness" of the pharmacy environment will change to be more conducive to acknowledging and addressing health literacy as a barrier to information provision.

17 Recommendations

The project team makes the following recommendations as a result of this study to capitalise on the work done in this projected supported by the PGA to maintain a leadership role in enhancing medicines use and safety for consumers in Australia. The leadership at a professional level in this field through the funding and support of this project is a model for other health professions.

- It is recommended that the Pharmacy Guild of Australia make this health literacy educational tool available by open access (e.g. under a creative commons licence, etc). This would allow for the package to be used in a wide variety of areas related to patient care and health practitioner education. Health literacy principles apply not only to pharmacists and pharmacy staff, but also many other professions where patient-focused care is involved. Consideration of a 'roadshow' to raise the profile of the health literacy educational package and increase dissemination of the training into community pharmacies may be beneficial. A national roll out, as well as inclusion into the annual APP conference could also be considered.

- The educational package is made available to Schools of Pharmacy for integration into Bachelor/Master of Pharmacy curricula to ensure that pharmacy students are equipped with the necessary skills to manage consumers with limited health literacy, and understand its importance for both pharmacy practice and the health care system. An added benefit to this is that new pharmacists who enter the workforce may be familiar with the content and format of the educational package and thus may be in a better position to lead training for other pharmacy staff.

- Invest in further research to incorporate the needs of Indigenous and CALD consumers.

- To more specifically trial Module 4 (schools and aged care) – this was outside the scope of this project.

- To invest in further research to develop methods to measure effectiveness and sustainability of this intervention (staged approach to full roll-out).

- To incorporate organisation/structure and support elements of the educational package into QCPP. Qualitative feedback from study participants suggested that the incorporation of this educational package into the QCPP framework by improve uptake and consistency of training and knowledge of pharmacists and pharmacy staff members in Australia. Compulsory implementation into community pharmacies in Australia may increase the use of Universal Precautions with consumers, and therefore may improve health outcomes related to medication misadventure.

- To invest in reminders (pop-ups, gimmicks, laminated card, slogans) to encourage routine/habitual use of the PUPPY principles.

- That the findings be used to enhance the evidence surrounding pharmacists' time spent in patient consultation.

- That Universal Precautions and health literacy should be a consideration in any patient-focused policy.

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21 Appendices

Appendix 1: Health Literacy in Pharmacies – Review of Academic Literature

Health literacy refers to key personal and interpersonal competencies that people need in order to stay healthy or to become healthy. A national survey suggests that health literacy levels across the Australian population are low, with as many as 60% of people lacking the skills to manage their health (Australian Bureau of Statistics 2008). International research suggests that low health literacy has important consequences for mortality, health status, use of health services, medication adherence and disease knowledge (Bush, Boyle et al. 2009).

Community pharmacy has a pivotal role in supporting health practices in the community beyond its important role in providing medicines. This role extends into such areas as supporting preventive health practices and facilitation health system navigation. Knowledge of how health literacy affects the community, and having the knowledge and skills to address some of those effects puts 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. People with a potentially life-limiting illness (e.g. bowel cancer, lung cancer) may come to a pharmacy to seek over-the-counter (OTC) medicines to manage their symptoms, when in fact they should be consulting their doctor, and should be directed so by the pharmacy staff. 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 for that person to see their doctor.

This review aims to identify and report on the findings of high quality evidence for the role of health literacy in a pharmacy context. This includes how low health literacy affects people's use of pharmacy services and efforts to improve or accommodate low health literacy both in pharmacy staff and customers. The review will inform the development and delivery of a subsequent health literacy intervention in community pharmacy settings.

METHOD

This review builds on an earlier comprehensive review of health literacy in primary care settings (Bush, Boyle et al. 2009). The current review updates the search results from the previous review and focuses on research that is conducted in a pharmacy context.

This review used a systematic review methodology including an *a priori* design; comprehensive search strategy; duplicate article selection, evaluation, and data extraction; and the use of formal tools for quality appraisal and data extraction. A 6-item tool for appraising research quality was used to evaluate original research articles. This tool has been used in previous systematic reviews and is designed to be sufficiently flexible to enable the evaluation of articles using a range of different methodologies. A copy of this tool is provided in Appendix I. The AMSTAR tool (Shea, Grimshaw et al. 2007; Shea, Hamel et al. 2009) was used to appraise the quality of the review articles that were included in the current systematic review. The AMSTAR tool is a published evaluation tool specifically designed to evaluate the adherence of review articles to QUOROM (QUality Of Reporting Of Meta-analyses) Statement principles (Moher, Cook et al. 1999). A copy of the AMSTAR tool is also provided in Appendix I.

Separate data extraction forms were used for abstracting data from review articles and from original research articles. These tools were again modified versions of tools used in previous systematic reviews. Copies of these tools are provided in Appendix II. As with the quality evaluation tool, the data extraction tool for original research articles was designed to be sufficiently flexible as to allow relevant data to be obtained from research using a range of different methodologies.

Search protocol

The search strategy focussed on the PubMed database as the most comprehensive repository of health research using an updated (2011) version of the National Library of Medicine (NLM) Health Literacy search protocol. The updated search added terms to capture research on numeracy as it relates to health. The NLM Health Literacy search protocol uses a sophisticated combination of Medical Subject Headings (MeSH terms) to produce a search that combines high sensitivity with good specificity. That is, the protocol is designed to identify as many relevant publications as possible while limiting the amount of extraneous material that is picked up by the search. The NLM search protocol was amended to include terms that drew

more on population health literature, to complement the clinical focus of the NLM protocol. The modified search protocol is shown in Appendix III. This search protocol produced the majority of the search results for this review.

The comprehensiveness of the search protocol was bolstered by abstract and keyword searches in other bibliographical databases of health and social science literature including CINAHL, EMBASE, Cochrane Reviews, International Pharmaceutical Abstracts (IPAb), Proquest (Social and Natural Sciences), and Informit. These databases were searched using Keyword, Title, Abstract, or a combination of these fields, as appropriate to the specific database, using the terms "Health literacy", "Health literate", and "Medical literacy". These searches were tailored to accommodate the different characteristics of each database, using different search fields and drawing on relevant subject terms (e.g., EMTREE) where appropriate. Searches were limited to English language publications and research on humans. The results of searching the bibliographic databases and the results of the article appraisal process are outlined schematically in Figure 1.

Review process

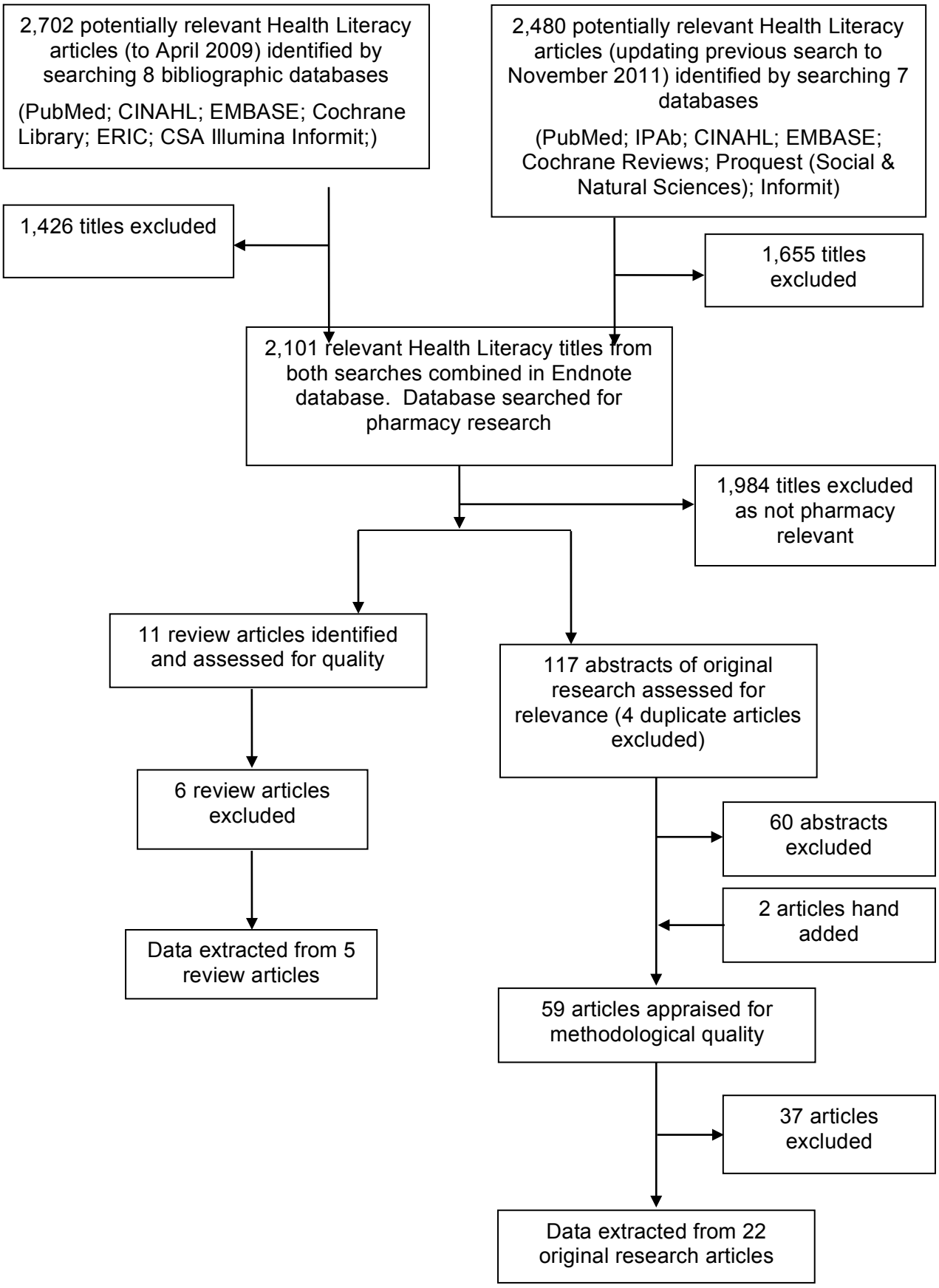
The bibliographic database search returned 2480 unique results. A scan of article titles for relevance (health literacy research) resulted in 825 articles being retained. Eleven of these articles were identified as review articles.

The records of the 825 relevant articles from our update search were then combined with the 1276 title relevant, health literacy articles from the earlier review. The combined results were searched for pharmacy research. A keyword and abstract search for "Pharmacy", "Medicines", or "Drugs" identified 117 pharmacy and health literacy relevant articles.

Four articles were identified as duplicates. Two researchers (JS, RO) independently conducted an abstract scan of the remaining 113 pharmacy health literacy research articles to confirm relevance and to specifically identify reports of original research. A third reviewer (FB) resolved any differences in evaluations. Fifty-seven relevant, original research articles were identified in this way. Two further articles were identified as relevant through the professional network of the research team and added to the review at this point. Two reviewers (JS, RO) evaluated these 59 articles for methodological quality using our formal, 6-item appraisal tool

(Appendix I). Differences in quality appraisal between reviewers were resolved by consensus. Twenty-two higher quality original research articles were identified in this way.

Figure 1. Diagram of database search and article appraisal process outcomes



At the same time, two reviewers (JS, RO) evaluated the quality of the 11 review articles that our search identified using the AMSTAR tool (Appendix I). Five higher quality reviews were identified in this way.

One reviewer (RB) extracted data from the higher quality review articles using a formal data extraction tool Appendix II). Three reviewers (JS, FB, & RO) used a different tool (Appendix II) to extract data from the original research articles.

RESULTS

In this section we present the results of our review. Results are presented separately for review articles and original research articles.

REVIEW ARTICLES

Eleven new published reviews of health literacy research were identified through our search and abstract scanning process. Five of these review articles were appraised as being of higher quality, with one focussed on medication use (Keller, Wright et al. 2008). The Keller et al. review investigated evidence for the effect of health literacy on disease state control and medication adherence in an ambulatory care setting. They identified only eight good quality studies and of these only one showed a relationship between health literacy and disease control while only one other found a relationship between health literacy and adherence. The most methodologically sound study in this review did not find a relationship between health literacy and medication adherence. The study in the Keller et al. review that showed a relationship between disease state control and health literacy found that glycaemic control was better among patients with greater health literacy, in a lower SES, US ethnic minority sample.

Intervention research

Only one of the five higher quality reviews included in our project focussed solely on intervention studies (Sheridan, Halpern et al. 2011). The Sheridan et al. review assessed evidence for the effect of health literacy interventions on improved outcomes in health care service use, health outcomes and disparities, and costs of care. Results from interventions to improve knowledge about hospital quality showed that providing information up front and using pictorial representations improved comprehension, while a traffic light system did not. Multimedia presentation of information had mixed results, failing to improve hospital quality comprehension but successfully improving behavioural intentions to choose higher quality hospitals. Multiple health literacy strategies to improve cancer screening rates were successful, particularly among those with low health literacy. Similarly, multiple strategies to improve asthma self-management resulted in reduced emergency department admissions. There was also some evidence for reductions in hospitalisations for heart failure among those with low health literacy when multiple strategies were used. The Sheridan et al. review

suggests that multiple strategies are more effective than single strategies, and that the biggest gains may be among those with the lowest health literacy.

In terms of health outcomes, the Sheridan et al. review found that improving readability and using best practice document design and self-management instruction does improve knowledge, while the use of video guidance helps people to read and understand medication labels. Presenting numerical information in simple tables was also more effective than including it in text. It was also found that giving special attention to low health literacy patients can improve health behaviours.

Review updates

Two of the reviews we included were updates of earlier reviews that the authors had conducted (DeWalt and Hink 2009; Berkman, Sheridan et al. 2011). The DeWalt & Hink review focussed on child health; specifically the relationship between carer and child health literacy and outcomes such as knowledge, health behaviours, service use and health status. This update included some intervention studies. They showed that improving the general reading ability of children with asthma improved hospitalisation rates. The reviewed interventions also showed that well designed written materials combined with interpersonal or video content can improve intervention outcomes across the spectrum of health literacy but that the gap between high and low health literacy remained.

Studies of association between health literacy and health outcomes in the DeWalt and Hink (2009) review found that where carers had lower health literacy, their knowledge about health outcomes, behaviours and services was poorer. Use of health services was not always related to health literacy and the links between health literacy and health outcomes varied depending on the specific disease under investigation.

The Berkman et al. (2011) review update found that the majority of studies were still of low quality overall. With respect to the relationship between health literacy and health outcomes this review found moderate evidence for increased emergency department use and hospital admissions among those with low health literacy, although not among children. Low health literacy was associated with lack of medication compliance among coronary patients and HIV patients as well as with greater misunderstanding of medication label instructions in primary care settings. This review found the evidence for associations with mental health literacy to be

too poor to draw conclusions. In contrast, low health literacy among the elderly was found to be associated with poor health outcomes and there was strong evidence for higher all-cause mortality among those with lower health literacy.

This review (Berkman, Sheridan et al. 2011) suggests possible moderators for the effects of health literacy including knowledge, self-efficacy, and stigma. The review concluded that sound population-based studies of health literacy prevalence and associations remained rare.

The final review that met our quality appraisal criteria focussed on the impact of health literacy on emergency department outcomes (Herndon, Chaney et al. 2011). This review found that the readability level of materials in emergency departments was too high for many patients and demonstrated a lack of attention to readability. Evidence collated in this review suggested that emergency department visits were often associated with low health literacy – except for children's attendance at emergency departments where the health literacy levels of children's carers was not associated with emergency department visits. The Herndon et al. review also noted the difficulty of distinguishing between variables that might mediate the impact of health literacy from those that act as confounders.

ORIGINAL RESEARCH ARTICLES

Twenty of the 22 original research studies in this review involved quantitative data collection and analysis. Four of these studies also included qualitative data collection and analysis, in a mixed-method design. Two further studies used purely qualitative designs. Table 1 describes some of the features of the studies in this review. It shows that a large majority of the studies treat health literacy as a risk factor for poor health; investigated functional health literacy rather than its communicative or critical aspects; and were conducted in the primary care clinic setting. The studies in this review address five of the seven areas pertinent to the development of our intervention. These are Professional development research, Train-the-training research, Educational programs, the Health literacy needs of CALD groups, and Assessing the health literacy needs of consumers. While a large majority of the studies involved assessing consumer health literacy, rarely was this the focus of the study and rarely did this occur in a community pharmacy setting. From that perspective, much of this research is of limited value in guiding the design of our intervention program.

Table 1: Descriptive Characteristics of Studies Tallied by Research Type

	Types of Research			
	Experimental	**Non-Experimental**	**Qualitative**	**Total†**
HL as a Risk Factor	2	17	6	24
HL as an Asset	0	1	0	1
Functional HL	1	17	5	22
Communicative HL	0	1	1	2
Critical HL	0	0	0	0
Assessing the health literacy needs of consumers	1	15	4	19
Health literacy needs of CALD groups	0	0	1	1
Train-the-trainer research	1	0	0	1
Education programs	1	1	1	3
Professional development research	0	2	1	3
Community	0	5	3	8
Primary care clinic	1	11	4	15
Hospital outpatient	1	2	0	3
Total Studies	2	18	6*	22

† Categories are not mutually exclusive so study tallies may not sum to 22
* Includes four mixed-method studies

The research reported in 19 of the studies was conducted in the United States of America, two studies reported Australian research and one study reported on research conducted in South Africa.

Qualitative research

The six studies that involved qualitative research, investigated a range of pharmacy-related health literacy issues. In four of the studies, the qualitative research was part of a mixed-

methods design, supporting and elaborating results obtained in the quantitative component of those studies.

Pharmacist needs

In a study with one of the simplest mixed-method designs, 113 pharmacists completed an online survey, which concluded with a free response item asking them to describe "in their own words" what would need to occur at their practice setting for them to be able to better communicate with patients with limited health literacy skills (Bradley-Baker, Mullins et al. 2011). The most common response (n=35) indicated a need for more ongoing professional education and training on this issue. Almost as many respondents (n=27) suggested a need for quick tips and resources that would equip them to be better able to recognise and communicate with low health literacy patients. Fifteen respondents described a need for methods to increase the amount of time available to communicate with patients – such as technical support staff and better workflow. Curiously, seven respondents indicated that the issue was not relevant to their practice. Six respondents described a need for more information on communicating with patients from other cultures.

Role of social support

A mixed-method study on the role of social support in helping people to take their medicines correctly interviewed seven pharmacists and conducted focus groups with 26 pharmacy patients (Johnson, Jacobson et al. 2010). Focus groups were composed of people with similar levels of health literacy.

Pharmacist interviews identified three themes. The first was around how pharmacists identified and helped limited health literacy patients by learning to identify the signs of low literacy since patients rarely say that they cannot read. A second theme emerged around pharmacist interactions with patient's family and friends, suggesting that low health literacy patients typically collected medicines on their own and that relatives do not always listen to pharmacists. The final theme indicated that one of the biggest challenges for pharmacists was the reluctance of patients with limited health literacy to ask questions.

These themes from pharmacist interviews were reflected in some of the themes from patient focus groups (Johnson, Jacobson et al. 2010). Both limited and adequate health literacy groups discussed the importance of medicines and taking them as directed for health. Both groups

also identified how family and friends help with medicines. Only adequate health literacy focus groups indicated wanting to be independent and responsible for their health. A difference also emerged around asking questions of pharmacists. Adequate health literacy groups indicated this as something that they do while limited health literacy groups indicated that they understood what pharmacists told them and so did not need to ask questions.

How pharmacies deal with low health literacy

The third mixed-method study conducted a telephone survey of 30 pharmacies in which they asked how pharmacies dealt with problems of low health literacy in their patients (Praska, Kripalani et al. 2005). Only two pharmacies indicated that they attempted to identify the health literacy needs of their patients. One of these pharmacies reported providing more detailed verbal counselling when low health literacy was identified. The other pharmacy reported that, when faced with patients with low health literacy, they tried to involve family members, provide verbal counselling, and use the teach-back method in order to help patients take their medications correctly.

Evaluating medication warning labels

In the final mixed-method study, 85 adults participated in 10 discussion groups designed to elicit feedback on ways to improve the language, content and icons associated with the 10 most commonly used warning labels (Webb, Davis et al. 2008). Most warning label instructions were found to be confusing. Study participants suggested making instructions shorter and more practical, using simple language. Five icons were not understood by a minimum of 80% of participants and were revised. Most participants considered icons to be important in aiding comprehension of warning labels.

Qualitative evaluation of a health literacy RCT

One study that only reported qualitative results investigated how well a pharmacy health literacy intervention (the PILL study) was delivered and received by patients and pharmacists (Blake, McMorris et al. 2010). The intervention itself involved the use of a card with images of the dose forms a patient took and dosage details with written and pictorial representations of dosage schedules to assist adherence. Quantitative analyses of this intervention are reported elsewhere in this review (Gatti, Jacobson et al. 2009; Gazmararian, Jacobson et al. 2010; Johnson, Jacobson et al. 2010). The qualitative analysis of the intervention involved interviews

with seven pharmacists, one month after the intervention began and again at the end of the six month long intervention (Blake, McMorris et al. 2010). Focus groups were composed of people with similar levels of health literacy (adequate or limited) and half were conducted one month after the start of the intervention and half at the end of the intervention. Overall, patients and pharmacists viewed the intervention favourably. Specifically, pharmacists were pleased with the training session on clear communication, although they had problems with the Picture Rx software – including logistic problems such as running out of paper – and they were not sure whether the automated telephone reminder system was working. Patients had few difficulties with the intervention and reported regularly using the Picture Rx cards. They also reported satisfaction with the automated reminder system.

Verifying patient comprehension

In the final qualitative study included in this review, 26 cross-cultural pharmacist-patient interactions in an antiretroviral pharmacy were analysed using conversation analysis (Watermeyer and Penn 2009). Following the interactions, patients and pharmacists were interviewed with a semi-structured interview, the results of which were analysed using thematic content analysis. The goal of this research was to identify practical ways to verify patient comprehension of a complex medication regimen. Analysis indicated four ways that pharmacists verified patient understanding. One practical method was to have patients demonstrate understanding by showing how their medications should be taken (or have been taken for returning patients) using pill container props where necessary. Pharmacists also asked specific questions about the timing, dosage and name of the medication to build patient knowledge. Patients were also specifically asked for responses to instructions – particularly on those occasions when none was spontaneously forthcoming. Pharmacists also monitored patient responses, both verbal and non-verbal (e.g., eye gaze, nodding) to verify understanding.

Post interaction interviews indicated that patients did comprehend the medication-taking instructions of the pharmacists although this was hindered by the language barrier in some cases. Pharmacists suggested that the most reliable way to identify misunderstandings was through repeated verification over multiple visits.

Quantitative research

Experimental studies

We have separated the quantitative research in this review into experimental and non-experimental research, to distinguish between work that tests interventions to improve health and more descriptive studies that document evidence around health literacy prevalence and associations. Table 2 lists details of the two experimental studies identified by this review. One study was an RCT (Muir, Ventura et al. 2011) while the other implemented a controlled before and after design (Gazmararian, Jacobson et al. 2010). Both studies investigate interventions to address low literacy in patients, in an attempt to ensure that patients took their medications as often as prescribed. One study implemented an intervention that included pharmacist training, pictorial prescription instructions, and refill reminders in a hospital outpatient setting (Gazmararian, Jacobson et al. 2010). The other study used a patient education intervention that aimed to match the literacy level of an informational video with the health literacy of patients in a veteran's medical centre setting (Muir, Ventura et al. 2011). Both studies had modest sample sizes and neither intervention was found to be effective in improving patient medication taking congruence with its prescribed frequency.

Non-Experimental studies

The bulk of studies accepted for inclusion in this review were non-experimental studies. The details of these 18 studies are listed in Table 3. Three of these studies used purely descriptive methods. One tabulated the health literacy practices of 30 pharmacies in the United States (Praska, Kripalani et al. 2005). It found that two pharmacies attempted to identify the health literacy needs of their patients while three pharmacies were not concerned about health literacy because they did not perceive it as a problem for their patient demographic. Nevertheless, a number of health literacy supporting practices were implemented by various pharmacies, with a majority of pharmacies providing written or verbal prescription counselling.

The second study tabulated the results from a survey of pharmacist's mental health literacy. It showed that a large majority of responding pharmacists could identify depression and schizophrenia symptoms (O'Reilly, Bell et al. 2010).

The third purely descriptive study investigated how well 10 of the most common warning labels were understood (Webb, Davis et al. 2008). Using the International Symbols

Organisation standard, this study showed that five of the warning labels were understood by more than 80% of the sample.

Risk factors for health literacy

The remaining 15 studies are differentiated by whether they treated health literacy as a risk factor for health outcomes or whether they investigated factors that put people at risk for low health literacy.

Pharmacist and pharmacy characteristics One study that investigated risk factors for health literacy found few demographic associations with health literacy, among pharmacists having direct contact with patients (Bradley-Baker, Mullins et al. 2011). This study did however, show that formal health literacy training significantly improved pharmacist health literacy practices, and that health literacy practices were significantly associated with practice setting. Chain pharmacies were strongly associated with strong print health literacy practices, while independent community pharmacies were strongly associated with health literacy sensitivity and verbal health literacy practices.

Medication label characteristics A second study of health literacy risk factors found that the presence of medication label features that demonstrated good health literacy principles varied by type of practice (Wolf, Shekelle et al. 2009). In particular, providing indication for use on a prescription medication label was significantly more common at chain pharmacies than at grocery store or independent pharmacies.

Gender A study investigating gender as a risk factor for metal health literacy among a Chinese population in Australia found that women demonstrated better health literacy, although the difference was not statistically tested (Wong, Lam et al. 2011).

Health literacy as a risk factor

Twelve studies in this review investigated health literacy as a risk factor for various health outcomes.

Medication knowledge Two of these studies investigated medication knowledge as their outcome variable (Marks, Schectman et al. 2010; Backes and Kuo 2011). Knowledge of medication name and dosage were associated with health literacy in both studies. One study also found that knowledge of potential side-effects was associated with health literacy (Marks, Schectman et al. 2010) while the second study identified a relationship between health literacy

and correct reporting of medication use frequency (Backes and Kuo 2011). The two studies diverged in their findings on the relationship between health literacy and knowledge of medication indication with only the Marks (2010) study finding such a relationship. This study also showed that health literacy provided an 8% greater explanation of medication knowledge than demographic variables alone.

Self-efficacy One study investigated medication use self-efficacy and found that this outcome was predicted by health literacy (Cameron, Ross et al. 2010). Similarly, health literacy was found to be related to overall medication management ability (Kripalani, Henderson et al. 2006) – although this relationship was largely the result of a strong relationship between health literacy and the a single sub-scale of the outcome measure used in this study (i.e., ability to identify medications). A single study also reported the relationship between health service usage and the use of medication labels based on health literacy principles (Shrank, Patrick et al. 2009). This study found no difference in outpatient visit rates or inpatient and emergency department visit rates between people using the redesigned medication labels and a matched sample of patients using standard medication labels.

Adherence Two reports emanating from the PILL Study used different analysis methods to show that health literacy was not associated with medication adherence (Gatti, Jacobson et al. 2009; Johnson, Jacobson et al. 2010). The Johnson et al. report did find that greater social support is associated with better medication adherence but only for people with adequate health literacy.

Medication labels The outcome most often investigated in the studies included in this review was patient's attention to and understanding of medication labels, both instruction and warning labels. This outcome has been investigated in five separate studies (Davis, Wolf et al. 2006; Davis, Federman et al. 2009; Wolf, Davis et al. 2010; Wolf, Curtis et al. 2011; Wolf, Davis et al. 2011). Research has shown that low health literacy patients make more errors in their understanding of medication label instructions, even after adjusting for the effect of demographic variables, the number of medications that the patients are taking, frequency of use, and dose complexity (Davis, Wolf et al. 2006; Davis, Federman et al. 2009). More specific instructions about when to take medications were less likely to be misinterpreted than instructions worded as the number of times in a day that the medicine should be taken (Davis, Federman et al. 2009).

In other research, health literacy was not associated with the misinterpretation of medicine instruction labels generally (Wolf, Davis et al. 2011) but simplified labels and patient-centred labels were found to improve low health literacy patients' attention to warning labels, and interpretation of medication instructions (Wolf, Davis et al. 2010; Wolf, Davis et al. 2011). The addition of icons to simplified text improved attention to warning labels (Wolf, Davis et al. 2010) but did not affect the correct interpretation of instruction labels (Wolf, Davis et al. 2011).

Key Points

Following are the key findings from this systematic review of pharmacy health literacy:

- There is a limited amount of health literacy research in a community pharmacy context.
- There are very few interventions to address the effects of low health literacy.
- Interventions to improve health literacy were not successful, but the potential to mitigate against the adverse effects of health literacy has been demonstrated for a number of health conditions. Understanding why this might be will be important for the process of developing our intervention later in this project.
- The link between health literacy and adherence to medications is not well supported in the available literature. This contrasts with earlier findings. Understanding this discrepancy will be central to designing a successful intervention but does suggest that people with limited health literacy do have the capacity to adhere to a medication regimen in the right circumstances.
- Multiple strategies to overcome low health literacy are more effective than implementing a single strategy.
- Improving the readability of information and using best practice document design and self-management instruction improves knowledge. This finding supports review findings across a range of health contexts and primary care settings.
- Video guidance helps people read and understand medication labels.
- Improving children's general reading ability may reduce hospitalisation rates in asthmatics.

- The health literacy of the carer was not always a factor in the use of health services by children. This finding has not previously been identified and is not what would be expected given what is known of health literacy and its effects in other contexts. This finding is, however supported across a range of settings.
- Low health literacy in the elderly was associated with poor health outcomes and higher all-cause mortality, reflecting previous findings.
- Pharmacists agree that more continuing education and professional development in health literacy is needed in the community pharmacy context. This is a new finding that supports the goals of this project.
- Formal health literacy training significantly improves pharmacist health literacy practices
- The use of family and friends in medication management was important for those with low health literacy, although having family or friends collect medication at the pharmacy can have negative health literacy consequences.
- People with better health literacy are more likely to understand the importance of asking questions about medications.
- Ancillary labels were found to be confusing, and use of icons may not improve understanding.

Conclusions

The results of this review show that health literacy has demonstrated relationships in a number of pharmacy contexts. Research in community pharmacy contexts is relatively rare however, and effects in that context are less clear-cut. Even less common are interventions with pharmacy staff rather than consumers.

Our review suggests that health literacy in the pharmacy research context mirrors broader health literacy research in that there are still few intervention studies. Most research is still cross-sectional, investigating the influence of health literacy on health, without yet demonstrating effective ways to use this knowledge to improve people's health. Even where intervention studies have been conducted, very little of this research has been with primary care providers (Bush et al., 2009; see for a rare example, Seligman et al. 2005). This review strongly suggests that there is a clear need for intervention research to address the challenges of low health literacy in community pharmacy contexts. *The implementation and evaluation of this project considering the effects of a health literacy intervention for pharmacy staff would directly target a sizeable gap in what is known about improving health literacy in primary care settings.*

Even though medication adherence has previously been associated with health literacy (Dewalt, Berkman et al. 2004; Osborn, Paasche-Orlow et al. 2007; Gordon and Wolf 2009), changes in adherence as a consequence of a health literacy intervention are difficult to demonstrate. This may be a methodological issue, or a consequence of an, as yet, poorly understood, complex relationship between adherence and health literacy. Since adherence is also not a good single indicator of good community pharmacy practice, we conclude that it would not be a suitable outcome for our community pharmacy health literacy intervention. What this work does suggest is that even consumers with limited health literacy have the capacity for medication adherence, so the enhanced engagement planned for this project is very relevant for this high-risk group.

Similarly, while medication labels are an important part of a health literacy supporting community pharmacy, they represent a level of practice that is too specific to be the focus of our intervention. Instead, our review suggests that a valuable focus for our intervention would be to provide formal health literacy training that conveys the nature and scope of the problem of low health literacy, together with information about how to provide clear verbal and written

information. This information should take the form of a multifaceted training programme for pharmacists and pharmacy assistants that is flexible, does not impose a heavy time burden, and is engaging (e.g., uses multimedia techniques).

Implications for Health Literacy in Pharmacy Project

While specific interventions that may be of use in this project are not obvious and there is not a simple screening tool for determining if a consumer has limited health literacy or somehow determine the level of health literacy of a consumer that could be used in the pharmacy setting, there are other informative outcomes from this review. Firstly, the fact that formal health literacy training significantly improves pharmacist health literacy practices indicates that the plan for Module 1 of the educational package, (education in health literacy concepts, impacts, and issues) will be critical to the success of the project. Furthermore, as the extent of limited literacy amongst Australian consumers is so widespread, a "universal precautions" approach should be taken in which limited health literacy is assumed until demonstrated otherwise. This approach becomes even more appropriate when we reflect on the fact that pharmacy consumers as a specific group, will be older and sicker than the general population and so would be expected to have even higher rates of limited health literacy than the prevalence studies have shown. Finally, peripheral discussions in papers reviewed identified limited potential barriers to consumer engagement and the implementation of our proposed project, enabling strategic planning for implementation to address and overcome these issues.

This review has, in general, identified the limited number of well-established strategies available to guide a health literacy intervention. Although limited evidence is available, it still provides a useful basis for moving forward. It has also provided a reminder that there are significant gaps in knowledge and research in the field of health literacy in the pharmacy setting. The execution of this project, which includes evaluation of all aspects around structure, process and outcome, will not only allow for delivery for a sound, high quality product at the project conclusion but also contribute to filling some of the many gaps in the knowledge in the field that may enhance any future work.

Given the important role of health literacy in primary care setting, including community pharmacies, and the demonstrated value of formal health literacy training, we recommend that this project move forward to designing and implementing a randomised controlled trial (RCT) to improve the health literacy of pharmacy staff. Because strong evidence on the design

of effective interventions of this type is not yet available in the pharmacy health literacy literature, we recommend that methods that have been shown to be efficacious in training primary care staff in their work settings (e.g., train-the-trainer) in other settings or on other topics be identified and used in the implementation of the RCT.

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Table 2. Characteristics of Original Research and Results for Main Outcomes – Experimental and Quasi Experimental Studies

Reference; Health issue; Country of study	Design; Sample size; Population; Literacy assessment	Intervention	Control	Primary outcome	Results
Gazmararian, Jacobson et al. (2010); No specific health issue; USA	Controlled Before and After; N=275; Indigent, minority population, predominantly low literacy; (PILL Study) REALM	3-part; (1) automated telephone refill reminders, (2) pictorial prescription representation; (3) training for pharmacists on clear communication and the use of pictorial prescriptions	Control site continuing with usual prescription filling practices	Medication adherence as measured by Cumulative Medication Gap (CMG)	There was no significant difference in pre- and post-intervention CMG between the control and experimental groups
Muir, Ventura et al. (2011); Glaucoma; USA	RCT; N=127; Military veterans, all but one are male; TOFHLA	Educational intervention showing an informational video where the language of the video varied according to subject HL	Usual care	Days without medication (DWM)	There was no significant difference in DWM between the interventions and the control groups, although the effect of the intervention was larger for lower literacy participants than for those with higher health literacy

Table 3. Characteristics of Original Research and Results for Main Outcomes – Non-Experimental studies

Reference; Health issue; Country of study	Design; Sample size; Population; Literacy assessment	Treatment variables	Primary outcome	Results
Descriptive features of Health Literacy				
Praska, Kripalani et al . (2005); No specific health issue; USA	Descriptive study; N=30 pharmacies; Pharmacies in urban Atlanta – average education level <12 years; Respondent's own understanding of health literacy	None	Pharmacy health literacy practices	3 (10%) pharmacies noted a lack of concern regarding health literacy because they were located in a middle-class neighbourhood and did not serve many Medicaid recipients; 2 (7%) pharmacies attempted to identify the health literacy needs of patients; 22 (73%) provided written or verbal counselling; 8 (27%) provided packaging or organisational aids such as pill bottles; 5 (17%) provided a refill service; and 4 (13%) provide graphical or multimedia aids for patients
O'Reilly, Bell et al. (2010); Mental health; Australia	Cross-sectional; 391; Registered pharmacists (19% response rate); Jorm mental health vignette protocol	None	Mental health literacy	92% of pharmacists could identify depression and 79% could identify schizophrenia from the symptoms in the vignette
Webb, Davis et al. (2008); No specific health issue; USA	Cross-sectional; N=85; Primary care patients (45) and members of adult education classes (40); REALM	None	Percentage of people able to match a warning label with its corresponding icon	Five of 10 common prescription drug warning labels were understood by greater than 80% of the sample (Range: 82-96%)

Risk Factors for Health Literacy

Bradley-Baker, Mullins et al. (2011); No specific health issue; USA	Cross-sectional; N=113; Pharmacists in direct contact with patients; AHRQ Pharmacy Health Literacy Assessment Tool	Demographic variables including age, gender, race, years since graduation, average script volume, and time at current practice; Formal Health Literacy Training; Pharmacy practice setting; chain, independent, or hospital	Health Literacy	Only occasional marginally significant relationships found for demographic variables; print and verbal health literacy practices as well as health literacy sensitivity were significantly correlated with formal health literacy training (r=0.34, 0.24, and 0.39; p=0.009, p=0.025, and p<0.0001 respectively); print and verbal health literacy practices as well as health literacy sensitivity also significantly correlated with practice setting (r=0.42, 0.31, and 0.53; p<0.001, p=0.002, and p<0.0001 respectively)
Wolf, Shekelle et al. (2009); No specific health issue; USA	Cross-sectional; N=96 prescriptions (from 24 community pharmacies); Chain, grocery store and independent pharmacies across the United States; No specific health literacy measure	Type of pharmacy	Medication label features that demonstrate health literacy principles	6% of prescriptions omitted dose frequency; 2% gave precise timing of administration; and 38% had indications for use transcribed on to the label; The provision of indication for use differed by type of pharmacy being provided by 56%, 20% and 28% of Chain, Grocery store, and Independent pharmacies respectively (chi-square statistic not provided, p<0.05)
Wong, Lam et al. (2011); Mental health;	Cross-sectional; N=200; Chinese population of	Gender	Health Literacy	25% of men and 75% of women correctly identified depression; 24% of men and 76% of women correctly identified schizophrenia in the

Australia	Melbourne; Jorm mental health vignette protocol			vignettes. These differences were not statistically tested
Health Literacy as a Risk Factor				
Backes and Kuo (2011); No specific health issue; USA	Cross-sectional; N=79; University hospital outpatients; S-TOFHLA	Health Literacy	Medication knowledge	Patients with adequate health literacy correctly reported the names of their medications more often than those with inadequate health literacy (84% vs 60%, p<0.001); correctly reported medication dosage more often (83% vs 71%, p=0.03); and correctly reported the frequency of their medications more often (85% vs 62%, p<0.001); there was no difference between the health literacy proficiency groups in the correct reporting of medication indication
Cameron, Ross et al. (2010); No specific health issue; USA	Cross-sectional; N=267; Primary care patients; REALM	Health Literacy	Medication use self efficacy (MUSE score)	Health literacy predicted medication use self-efficacy. Mean MUSE scores were 28.7 (4.3); 28.5 (3.7); and 29.1 (3.7) respectively for Inadequate, Marginal, and Adequate health literacy (p<0.001)
Davis, Wolf et al. (2006); No specific health issue; USA	Cross-sectional; N=395; Indigent and clinically underserved populations; REALM	Health Literacy	Errors in medication label understanding; Misunderstanding medication labels	More participants in the Low health literacy group made 1 or more errors in their understanding of medication labels than participants in the Marginal or Adequate health literacy groups (62.7%, 51.3%, and 37.7% respectively; p<0.001); Adjusting for demographic variables and number of medications, Low health literacy patients were more likely to misunderstand medication labels (ARR 2.32: CI 1.26-4.28) than Adequate health

				literacy patients. This was also true for Marginal health literacy patients (ARR 1.94: CI 1.14-3.27)
Davis, Federman et al. (2009); No specific health issue; USA;	Cross-sectional; N=359; Indigent and clinically underserved populations; REALM	Health Literacy	Incorrect interpretation of medication label instructions	Low and Marginal health literacy respondents were more likely to misinterpret one or more label instructions, adjusting for demographic factors, number of medications, frequency of use and dose complexity (ARR Low HL: 1.66, CI 1.18-2.32; Marginal HL: 2.70, CI 1,81-4.03); Instructions that gave time periods (e.g., morning, evening) or specific times (e.g., 8:00am, 5:00pm) were less likely to be misinterpreted than instructions that indicated how often in a day medications should be taken (ARR Time period: 0.42, CI 0.34-0.52; Specific times: 0.60, CI 0.49-0.74)
Gatti, Jacobson et al. (2009); No specific health issue; USA	Cross-sectional; N=275; Indigent, minority population, predominantly low literacy (PILL Study) REALM	Health Literacy	Morisky 8-item Medication Adherence Scale (MMAS-8)	Health literacy did not significantly predict medication adherence as measured by the MMAS-8
Johnson, Jacobson et al. (2010); No specific health issue; USA	Cross-sectional; N=275; Indigent, minority population, predominantly low literacy (PILL Study) REALM	Health Literacy	Morisky 8-item Medication Adherence Scale (MMAS-8)	This report investigated the relationship between MMAS and HL using Chi-square analysis but as with Gatti et al. (2009) found that health literacy was not related to MMAS-8 scores; Analysis of social support found that greater social support is associated with better medication adherence but only for people with

				adequate health literacy
Kripalani, Henderson et al. (2006); Coronary heart disease; USA	Cross-sectional; N=152; Indigent, minority population, predominantly low literacy; REALM	Health Literacy	Medication management capacity as assessed by the Drug Regiment Unassisted Grading Scale (DRUGS)	Overall ability to manage medication was significantly associated with low health literacy (chi-square test result not provided, p<0.001); this result is largely due to low health literacy's association with patient's scores on the *Ability to identify medications* sub-scale of the DRUGS measure (test statistic not provided, p<0.001); this result held in multivariate analysis adjusting for demographic factors and cognitive function (AOR 10.93, CI 2.09-51.54)
Marks, Schectman et al. (2010); No specific health issue; USA	Cross-sectional; N=100; Socio-economically disadvantaged group; REALM	Health Literacy	Medication knowledge	Health literacy was associated with knowledge of Medication name (Rho=0.69, p<0.001); Dosage (Rho=0.22, p=0.02); Purpose (Rho=0.42, p<0.001); and Potential side-effect (Rho=0.31, p<0.001); In multivariate analysis, health literacy provided an additional 8% explanation of medication knowledge over and above that provided by demographic variables (p<0.001)
Shrank, Patrick et al. (2009); No specific health issue; USA	Cohort study; N=127,153; Blue Cross Blue Shield administrative claims database; No specific measure of health literacy	Medication labels designed for Target pharmacies based on health literacy principles	Health service utilization	New users of the redesigned Target medication labels did not differ significantly from a matched sample of patients using standard (non-Target) labels in outpatient visit rates or inpatient visits and emergency department visits
Wolf, Davis et al.	Cross-sectional;	Modified drug	Attention to	Low health literacy patients were more likely to

(2010); No specific health issue; USA	N=500; Predominantly minority patients REALM	warning labels using simplified text and icons	warning labels	attend to simplified text labels than standard labels (AOR 1.60, CI 1.09-2.33); Low and Marginal health literacy patients were more likely to attend to simplified text plus icons than simplified text only labels (AOR Low HL 3.22, CI 1.39-7.50; AOR Marginal HL 2.59, CI 1.24-5.44)
Wolf, Curtis et al. (2011); No specific health issue; USA	Cross-sectional; N=464; Older patients; NVS	Health Literacy	Patient reports of how often throughout a day they would take a standard set of medications	Low health literacy was the only independent predictor of taking medications more often – given a standardised setting (Beta=0.67, p=0.02); patients with low health literacy and no chronic conditions dosed more than any other combination of literacy and chronic condition (test statistic not provided, p=0.005)
Wolf, Davis et al. (2011); No specific health issue; USA	Cross-sectional; N=500; Predominantly minority patients REALM	Health Literacy	Correct interpretation of prescription medication label instructions	Health literacy was not significantly related to correct label interpretation across different types of labels; Low health literacy patients correctly interpreted the patient-centred label more often than the standard label (RR 1.39. CI 1.14-1.68);

CI: 95% confidence interval; RR: Risk Ratio; ARR: Adjusted Risk Ratio; AOR: Adjusted odds ratio

Appendix 2: Tool for evaluating the quality of original research articles.

PHARMACY HEALTH LITERACY
FORM A1: CRITICAL APPRAISAL OF EVIDENCE OF EFFECTIVENESS

Reviewer: _____ **Date**: _____

Author: _____ **Year**: _____ **Record Number**: _____

SCREENING QUESTIONS

I. Is the study one of the following quantitative designs?

Experimental/Quasi-Experimental. Includes treatment/intervention

RCT ☐ Controlled Trial ☐ Controlled Before and After ☐ Interrupted Time Series ☐ Pre-post study ☐

Non-experimental. No treatment/intervention

Cohort study ☐ Case Control ☐ Case study or case series ☐ Cross-sectional survey ☐

II. Is the study one of the following qualitative designs?

Generalisable studies ☐ Conceptual studies ☐ Descriptive studies ☐ Single case studies ☐

III. If the study does not include data collection and analysis: **STOP NOW** ☐

If the study is an empirical study and not exclusively conducted in a hospital inpatient setting, appraise the quality of the reported research using the questions below.

APPRAISAL QUESTIONS

Q No.	Appraisal Question	Yes	No	Can't tell or Mixed response
1	Is the purpose of the study clear and well defined?	2	0	1
2	Is the population well defined and properly selected?	2	0	1
3	Are the methods clearly described and appropriate for the type of study reported?	2	0	1
4	Are the results presented in a clear and understandable format?	2	0	1
5	Does the interpretation of the results seem consistent with the results presented?	2	0	1
6	Are there any other explanations that could account for these results?	0	2	1
	Total score:			*(Maximum of 12)*

RECOMMENDATION: Include ☐ Exclude ☐ Seek further information ☐

Comments (including reasons for exclusions): _____

(Questions derived from Oxman & Guyatt, 1994; JBI Criteria;)

Tool for evaluating the quality of review articles.

ADVANCING HEALTH LITERACY
FORM A1: CRITICAL APPRAISAL OF EVIDENCE OF EFFECTIVENESS – REVIEWS

Reviewer: _____ **Date**: _____

Author: _____ **Year**: _____ **Record Number**: _____

SCREENING QUESTIONS

IV. Is the research focused on Health Literacy research?

Yes ☐ Continue screening No ☐ **STOP NOW**

V. Is the publication a **review** of Health Literacy literature?

Yes ☐ Continue with article appraisal No ☐ **STOP NOW**

TOPIC CATEGORISATION

This review Includes/Focuses on Health Literacy in a *Pharmacy* context.

Yes ☐ No ☐

This review Includes/Focuses on Health Literacy interventions.

Yes ☐ No ☐

APPRAISAL QUESTIONS

1. Was an "a priori" design provided?
The research question and inclusion criteria should be established before the conduct of the review.

☐ Yes
☐ No
☐ Can't answer
☐ Not applicable

2. Was there duplicate study selection and data extraction?
There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.

☐ Yes
☐ No
☐ Can't answer
☐ Not applicable

3. Was a comprehensive literature search performed?
At least two electronic sources should be searched. The report must include years and databases used (e.g., Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated, and where feasible, the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.

☐ Yes
☐ No
☐ Can't answer
☐ Not applicable

4. Was the status of publication (i.e., grey literature) used as an inclusion criterion?

The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.[a]

- ☐ Yes
- ☐ No
- ☐ Can't answer
- ☐ Not applicable

5. Was a list of studies (included and excluded) provided?

A list of included and excluded studies should be provided.

- ☐ Yes
- ☐ No
- ☐ Can't answer
- ☐ Not applicable

6. Were the characteristics of the included studies provided?

In an aggregated form, such as a table, data from the original studies should be provided on the participants, interventions, and outcomes. The ranges of characteristics in all the studies analysed, e.g., age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.

- ☐ Yes
- ☐ No
- ☐ Can't answer
- ☐ Not applicable

7. Was the scientific quality of the included studies assessed and documented?

"A priori" methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo-controlled studies, or allocation concealment as inclusion criteria); for other types of studies, alternative items will be relevant.

- ☐ Yes
- ☐ No
- ☐ Can't answer
- ☐ Not applicable

8. Was the scientific quality of the included studies used appropriately in formulating conclusions?

The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.

- ☐ Yes
- ☐ No
- ☐ Can't answer
- ☐ Not applicable

9. Were the methods used to combine the findings of studies appropriate?

For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e., Chi-squared test for homogeneity, I2). If heterogeneity exists, a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e., is it sensible to combine?).

- ☐ Yes
- ☐ No
- ☐ Can't answer
- ☐ Not applicable

10. Was the likelihood of publication bias assessed?

An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/ or statistical tests (e.g., Egger regression test).

- ☐ Yes
- ☐ No
- ☐ Can't answer
- ☐ Not applicable

11. Was the conflict of interest included?

Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.

- ☐ Yes
- ☐ No
- ☐ Can't answer
- ☐ Not applicable

Total Score (*Tally 1 for each question answered "Yes"*)

"Can't answer" is chosen when the item is relevant but not described by the authors; "not applicable" is used when the item is not relevant, such as when a meta-analysis has not been possible or was not attempted by the authors.

[a] The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.

RECOMMENDATION:	Include ☐	Exclude ☐	Seek further information ☐

Comments (including reasons for exclusions): _____

(Form based on: A measurement tool to assess systematic reviews (AMSTAR) by B.J. Shea et al. Journal of Clinical Epidemiology (2009).

Appendix 3: Form for extracting data from original research articles.

PHARMACY HEALTH LITERACY
FORM A2: ORIGINAL RESEARCH ARTICLE FINDINGS – DATA COLLECTION TEMPLATE

This information sheet is to collect results from original research on health literacy

Reviewer: _____ **Date**: _____

Author: _____ **Year**: _____

Journal/Report Source: _____

KEY RESEARCH QUESTIONS *(Indicate which key question(s) the study addresses)*

☐	1. Assessing the health literacy needs of consumers
☐	2. Health literacy needs of CALD groups
☐	3. Health literacy in residential care groups
☐	4. Health literacy in schools
☐	5. Train-the-trainer research
☐	6. Educational programs
☐	7. Professional development research

BASIS FOR INVESTIGATION _____

_____

_____

(*e.g., Study background, quality of literature; perceived clinical need – reasons given for doing study*)

STUDY SETTING **Country of Study:** _____

☐ Community ☐ Primary Care Clinic ☐ Hospital outpatient ☐ Emergency Department ☐ Other

HEALTH LITERACY CHARACTERISTICS

☐ Health Literacy as a Risk factor
☐ Health Literacy as an Asset
☐ Functional Health Literacy
☐ Communicative Health Literacy
☐ Critical Health Literacy
☐ Other: _____

Measure of Health Literacy:

- ☐ REALM
- ☐ TOFHLA (or variation)
- ☐ Other available measure: _____
- ☐ Study specific operationalisation

STUDY PARTICIPANTS

Sample drawn from: ☐ Specific/clinical group ☐ Whole Population

Health Care Provider Characteristics: *(if study is in a clinical context)*

(e.g., age, gender, specialisation)

_____

Patient Characteristics:

Sample Size _____

Clinical problem (*if clinical sample*) _____

Other characteristics as relevant (e.g., age, gender, ethnicity, geography)

_____

STUDY TREATMENT (*Indicate what the study was investigating and how it did so*)

TYPE OF TREATMENT (QUANTITATIVE) *(Choose all that apply)*

- ☐ Association (e.g., Correlation, regression)
- ☐ Group differences (e.g., t-Test, ANOVA)
- ☐ Interventions (e.g., before and after comparisons, with or without controls)
- ☐ Other: _____

ROLE OF HEALTH LITERACY IN TREATMENT

- ☐ Health Literacy is the Dependant Variable/Criterion
- ☐ Health Literacy is the Independent Variable/Predictor

TREATMENT EFFECT (*could be health professional, patient or economic outcomes*)

Outcome Description* *(e.g., DV; Criterion operationalisation)*	**Variable/Measure** *(e.g., explanatory variable/score)*	**Size of Result** *(e.g., test statistic value)*	**Significance**

* Types of outcomes could include:
- Health literacy
- Health outcome
- Use of health services
- Costs of healthcare
- Disparities in health outcomes
- Disparities in health service use

TYPE OF TREATMENT (QUALITATIVE) (*Only use section if mixed method or not quantitative*)

(How is health literacy investigated?)

- ☐ Interviews
- ☐ Focus groups
- ☐ Other data source
- ☐ Participant observation
- ☐ Self-evaluation
- ☐ Content analysis
- ☐ Discourse/literature-based analysis
- ☐ Ethnography/observational
- ☐ Other analysis: _____

What concepts/variables are being investigated?

What are the study findings?

RESULTS

Treatment Significance *(Overall conclusion where multiple treatments)*
(Did the variable(s) of interest/intervention affect HL – or did HL affect the variable(s) of interest – in a statistically significant or qualitatively important way?)

Author(s) Conclusion: ☐ Significant/important ☐ Not Significant/important

Reasons *(optional)*

Reviewer's Conclusion: ☐ Significant/important ☐ Not Significant/important

Result Evaluated: ☐ Clinical effect ☐ Statistical effect (quant only)

Reasons *(optional)*

OTHER RELEVANT COMMENTS *(Aspects of the project not identified above which may have influenced the effects on or of health literacy)*

Form for extracting data from review articles.

ADVANCING HEALTH LITERACY
FORM R2: REVIEW ARTICLE FINDINGS – SUMMARY TEMPLATE

This form is to collect information on what has been found in reviews of health literacy research

Reviewer: _____ **Date**: _____

Author: _____ **Year**: _____

Journal/Report Source: _____

REVIEW BACKGROUND (*Brief – 1 paragraph – summary of review topic area. From article.*)

STUDY INCLUSION INFORMATION

Search period: _____

Number of studies reviewed: _____

Design(s) of studies reviewed: _____

STUDY CHARACTERISTICS

Target Population: _____

Intervention(s): _____

Setting: _____

Participant characteristics – as relevant: (age, gender, ethnicity, geography, condition)

_____

Health Literacy Outcomes: _____

Other outcomes: _____

REVIEW QUALITY: _____

TABLE OF RESULTS

Comparison *(One row for each type covered in the review)*	**Outcome**	**N** *(No. of studies)*	**Analysis** *(How study results combined)*	**Results** *(Effect of comparisons)*

RESULTS – OVERALL

RESULTS – RELATED TO KEY RESEARCH QUESTIONS *(Note findings where the review article addresses a question only)*

OVERALL CONCLUSIONS

Appendix 4: Modified National Library of health literacy search protocol.

"health literacy" OR
“health literate” OR
“medical literacy” OR
(health [ti] AND
literacy [ti]) OR
(functional [tw] AND
health [tw] AND
literacy [tw]) OR
((low-literate [ti] OR
low-literacy[ti] OR
literacy[ti] OR
illiteracy[ti] OR
literate[ti] OR
illiterate[ti] OR
reading [mh] OR
comprehension [mh]) AND
(health promotion [major] OR
health education [major] OR
patient education [major] OR
communication barriers [major] OR
communication [major:noexp] OR
health knowledge, attitudes, practice [major] OR
attitude to health[major] OR
"population characteristics"[MeSH Major Topic])) OR
(comprehension [major] AND
educational status [major])OR
(family [ti] AND
literacy [ti])OR
(("drug labeling"
OR Prescriptions, drug [mh])
AND "comprehension"))OR numeracy

OR ((cancer[ti] OR diabetes[ti] OR genetic[ti]) AND (literacy[ti] OR comprehension[ti]))
OR “adult literacy” OR
“limited literacy” OR
“patient literacy” OR
“patient understanding”[ti] OR
(self care [major] AND perception[mh]) OR
(comprehension AND food labeling[mh])
AND English [la]

Appendix 5: List of pharmacy relevant, health literacy publications identified.

New AHRQ tools help pharmacies better serve patients with limited health literacy. (2007). *AHRQ Research Activities*(328), 19-19.

Top drawer. New health literacy tool helps consumers make sense of prescription labels. (2007). *CIN: Computers, Informatics, Nursing, 25*(2), 65-65.

Medication therapy management in pharmacy practice: core elements of an MTM service model (version 2.0). (2008). *J Am Pharm Assoc (2003), 48*(3), 341-353.

Anonymous. (2006). Health Literacy - Solving a complex patient care puzzle. *Journal of the Pharmacy Society of Wisconsin*.

Assemi, M., Mutha, S., & Hudmon, K. S. (2007). Evaluation of a train-the-trainer program for cultural competence. *American Journal of Pharmaceutical Education, 71*(6).

Bailey, S. C., Pandit, A. U., Curtis, L., & Wolf, M. S. (2009). Availability of Spanish prescription labels: a multi-state pharmacy survey. *Med Care, 47*(6), 707-710.

Bastianelli, K. M., & Conway, J. M. (2008). Pharmaceutical care lab activity promotes literacy awareness in pharmacy students. *American Association of Colleges of Pharmacy Annual Meeting, 72*(3).

Beniwal, S., Sharma, B. B., & Singh, V. (2011). What we can say: disease illiteracy. *J Assoc Physicians India, 59*, 360-364.

Berger, D., Inkelas, M., Myhre, S., & Mishler, A. (1994). Developing health education materials for inner-city low literacy parents. *Public Health Rep, 109*(2), 168-172.

Bjorn, E., Rossel, P., & Holm, S. (1999). Can the written information to research subjects be improved?--an empirical study. *J Med Ethics, 25*(3), 263-267.

Blake, S. C., McMorris, K., Jacobson, K. L., Gazmararian, J. A., & Kripalani, S. (2010). A qualitative evaluation of a health literacy intervention to improve medication adherence for underserved pharmacy patients. *J Health Care Poor Underserved, 21*(2), 559-567.

Bloodworth, L., & Ross, L. (2011). Delta Pharmacy Patient Care Management Project: Implementation of medication therapy management services in an underserved region. *Journal of the American Pharmacists Association, 51*(2), 257.

Bradley-Baker, L. R., Mullins, C. D., & Baquet, C. R. (2011). Pharmacists' assessment of facets of health literacy in pharmacy practice settings. *Journal of Pharmacy Technology, 27*(2), 55-62.

Brahm, N., & Palmer, T. (2008). The OU-Tulsa Bedlam Community Health Clinic: integrating MTMS concepts into a unique service-learning model. *American Association of Colleges of Pharmacy Annual Meeting, 72*(3).

Buchbinder, R., Hall, S., Grant, G., Mylvaganam, A., & Patrick, M. R. (2001). Readability and content of supplementary written drug information for patients used by Australian rheumatologists. *Med J Aust, 174*(11), 575-578.

Byrns, J., Gates, A., & Helmlinger, K. (2011). Apha-asp project chance: A student pharmacist led initiative to increase medication compliance and health literacy in an uninsured population of North Carolina. *Journal of the American Pharmacists Association, 51*(2), 256.

Cameron, K. A., Ross, E. L., Clayman, M. L., Bergeron, A. R., Federman, A. D., Bailey, S. C., et al. (2010). Measuring patients' self-efficacy in understanding and using prescription medication. *Patient Educ Couns, 80*(3), 372-376.

Capehart, K. D. (2008). Development and implementation of a health literacy elective in a pharmacy curriculum. *American Association of Colleges of Pharmacy Annual Meeting, 72*(3).

Carlisle, A., Jacobson, K. L., Di Francesco, L., & Parker, R. M. (2011). Health Literacy in the Pharmacy Practical Strategies to Improve Communication With Patients. *P and T, 36*(9), 576-580.

Chen, H., Parker, G., Kua, J., Jorm, A., & Loh, J. (2000). Mental health literacy in Singapore: a comparative survey of psychiatrists and primary health professionals. *Ann Acad Med Singapore, 29*(4), 467-473.

Chovil, N., & Panagiotopoulos, C. (2010). Engaging families in research to determine health literacy needs related to the use of second-generation antipsychotics in children and adolescents. *J Can Acad Child Adolesc Psychiatry, 19*(3), 201-208.

Chuang, M. H., Lin, C. L., Wang, Y. F., & Cham, T. M. (2010). Development of pictographs depicting medication use instructions for low-literacy medical clinic ambulatory patients. *J Manag Care Pharm, 16*(5), 337-345.

Compton, L., Riche, D., Ellis, A., Ross, L., & Cross, J. (2010). Health literacy as it relates to medication safety in the Mississippi Delta. *Journal of the American Pharmacists Association, 50*(2), 231.

Costa, F. A., Duggan, C., & Bates, I. (2007). A systematic approach to cross-cultural adaptation of survey tools. *Pharmacy Practice, 5*(3), 115-124.

Davis, T. C., Federman, A. D., Bass, P. F., 3rd, Jackson, R. H., Middlebrooks, M., Parker, R. M., et al. (2009). Improving patient understanding of prescription drug label instructions. *J Gen Intern Med, 24*(1), 57-62.

Davis, T. C., Wolf, M. S., Bass, P. F., Thompson, J. A., Parker, R. M., & et al. (2006). Literacy and misunderstanding prescription drug labels. *Annals of Internal Medicine, 145*(12), 887-894.

Dawson, S., Heidrick, J., Katz, A., Murray, M., Ferreri, S., & Marciniak, M. (2010). Evaluating the impact of community pharmacist-provided education on A1C levels. *Journal of the American Pharmacists Association, 50*(2), 227-228.

Devrai, R., & Gupchup, G. (2011). Components of Illinois pharmacists' attitudes and barriers toward health literacy: A factor analytic approach. *Journal of the American Pharmacists Association, 51*(2), 234.

Devraj, R., Butler, L. M., Gupchup, G. V., & Poirier, T. I. (2010). Active-learning strategies to develop health literacy knowledge and skills. *Am J Pharm Educ, 74*(8), 137.

Devraj, R., & Gupchup, G. (2010). Assessment of Illinois pharmacists' knowledge and attitudes towards health literacy: Preliminary results. *Journal of the American Pharmacists Association, 50*(2), 272.

Dolinsky, D., Dhing, C., Lonie, J., Mihm, D., & Thakkar, B. (2001). Counseling patients with low health literacy. *American Association of Colleges of Pharmacy Annual Meeting, 102*(Jul).

Drummond, M., & Smith, J. (2006). Ageing men's understanding of nutrition: Implications for health. *Journal of Men's Health & Gender, 3*(1), 56-60.

Dulcan, M. K. (2003). "Talking to Families about ADHD": Editor's Comment. *Journal of the American Academy of Child & Adolescent Psychiatry, 42*(12), 1386-1387.

Emmerton, L. M., Mampallil, L., Kairuz, T., McKauge, L. M., & Bush, R. A. (2010). Exploring health literacy competencies in community pharmacy. *Health Expect*.

Fagerlin, A., Sepucha, K. R., Couper, M. P., Levin, C. A., Singer, E., & Zikmund-Fisher, B. J. (2010). Patients' knowledge about 9 common health conditions: the DECISIONS survey. *Med Decis Making, 30*(5 Suppl), 35S-52S.

Field, S., & Tworek, C. (2010). Over-the-counter medications: A study of attitudes, perceptions, and utilization to promote health literacy among adults. *Journal of the American Pharmacists Association, 50*(2), 301.

Fitzsimmons, D. S. (2005). Cultural competency and the patient encounter. *ASHP Midyear Clinical Meeting, 40*(137).

Gardner, P. H., McMillan, B., Raynor, D. K., Woolf, E., & Knapp, P. (2011). The effect of numeracy on the comprehension of information about medicines in users of a patient information website. *Patient Educ Couns, 83*(3), 398-403.

Gatti, M. E., Jacobson, K. L., Gazmararian, J. A., Schmotzer, B., & Kripalani, S. (2009). Relationships between beliefs about medications and adherence. *Am J Health Syst Pharm, 66*(7), 657-664.

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Soller, R. W. (2006). An integrated approach to teaching health literacy in the clinical pharmacy curriculum. *Journal of Pharmacy Teaching, 13*(1), 17-28.
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Appendix 6: Survey advertisement for the international survey of health literacy education provided within pharmacy curricula.

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 7: Explanatory statement - International survey of health literacy education provided within pharmacy curricula.

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 Australia Tel: +61 3 9903 9025 Email: glen.swinburne@monash.edu **Dr Safeera Hussainy** Centre for Medicine Use and Safety Monash University 381 Royal Pde Parkville, VIC 3052 Australia Tel: +61 3 9903 9176 Email: safeera.hussainy@monash.edu **Mr Gregory Duncan** Eastern Health Clinical School Faculty of Medicine, Nursing and Health Services Monash University 5 Arnold St Box Hill VIC 3128 Tel: +61412040320 Email: gregory.duncan@monash.edu	**Executive Officer** **Monash University Human Research Ethics Committee (MUHREC)** **Building 3e Room 111** **Research Office** **Monash University VIC 3800** **Tel: +61 3 9905 2052 Fax: +61 3 9905 3831** **Email: muhrec@monash.edu**

Appendix 8: Questionnaire for the 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:

_____

_____

_____

_____

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 9: Monash University Human Ethics Approval for the international survey of health literacy education provided within pharmacy curricula.

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 stewrtg, Mr Glen Swinburne

Appendix 10: Grey literature resources reviewed.

Organisation	Titles of resource	URL
WebMD	Helping patients with low health literacy	http://www.webmd.com/a-to-z-guides/video/low-health-literacy
Harvard University	In Plain Language	http://www.hsph.harvard.edu/healthliteracy/overview/#Video
ALMA	TV 411 videos - need to pay though	http://www.hsph.harvard.edu/healthliteracy/practice/tv-411/index.html
Academy for Educational Development	A prescription to end confusion	http://hospitals.unm.edu/health_literacy/index.html
Cnet	Improving your Health literacy	http://cnettv.cnet.com/improving-your-health-literacy/9742-1_53-50020656.html
AMA	Health literacy and patient safety: help patients understand	http://classes.kumc.edu/general/amaliteracy/AMA_NEW3.html
American College of Physicians	Health Literacy video	http://www.acpfoundation.org/materials-and-guides/video/videos-for-patients/health-literacy-video.html
American College of Physicians	Lots of patient focused videos on common health conditions	http://www.acpfoundation.org/materials-and-guides/video/
AHRQ	Questions are the answer	http://www.ahrq.gov/questions/pcvideos.htm
AHRQ	Health Literacy podcast	http://healthcare411.ahrq.gov/radiocastseg.aspx?id=709&type=seg
AHRQ	Health literacy and understanding health information podcast	http://healthcare411.ahrq.gov/featureAudio.aspx?id=711
AHRQ	Health literacy limited for many Americans podcast	http://healthcare411.ahrq.gov/radiocastseg.aspx?id=801&type=seg
AHRQ	Tools designed to help pharmacists communicate better with patients	http://healthcare411.ahrq.gov/featureAudio.aspx?id=712
Health Literacy Out Loud	Podcasts	http://www.healthliteracyoutloud.com/
Family and Community Medicines, University of Arizona	Health Literacy	http://healthlit.fcm.arizona.edu/HealthLitPlayer.html

NEA Academy	Health Literacy program	http://ondemand.neaacademy.org/
AED	Health Literacy practice	http://healthliteracy.aed.org/
Harvard University	The health literacy environment of hospitals and health centers - partners for action: making your healthcare facility literacy-friendly	http://www.hsph.harvard.edu/healthliteracy/files/healthliteracyenvironment.pdf
Harvard University	The health literacy environment activity packet: first impressions and a walking interview	http://www.hsph.harvard.edu/healthliteracy/files/activitypacket.pdf
Harvard University	Health literacy in adult basic education	http://www.hsph.harvard.edu/healthliteracy/files/healthliteracyinadulteducation.pdf
Harvard University	Assessing Health Materials - Eliminating barriers, increasing access: tools for workshop facilitators	http://www.hsph.harvard.edu/healthliteracy/files/eliminating_barriers_assessing.pdf
AMA	Health literacy and patient safety: help patients understand - manual for clinicians	http://www.ama-assn.org/resources/doc/ama-foundation/healthlitclinicians.pdf
AHRQ	A pharmacy health literacy assessment tool user's guide	http://www.ahrq.gov/qual/pharmlit/pharmlit.pdf
The Rhode Island Health Literacy Project	Health Literacy Toolkit	http://www.rihlp.org/pubs/Complete_toolkit_224pgs.pdf
Health Literacy Now	Health Literacy Manual	http://www.healthliteracynow.org/health-literacy-manual.html
NCSALL	Teaching and Training materials	http://www.ncsall.net/index.php?id=25
Harvard University	Health & Literacy	http://www.hsph.harvard.edu/healthliteracy/files/overview_slides.pdf
HLSD		http://healthliteracysd.org/healthcare-professionals/training.aspx
AHRQ	Strategies to improve communication between pharmacy staff and patients: a training program for pharmacy staff	http://www.ahrq.gov/qual/pharmlit/pharmtrain.pdf
AHRQ	How to create a pill card	http://www.ahrq.gov/qual/pillcard/pillcard.pdf
World Education	Health Literacy: New Fields and New Opportunities	http://healthliteracy.worlded.org/docs/tutorial/SWF/flashcheck/main.htm
Literacy and Health in America	Health Activities, Materials and Tasks	http://www.hsph.harvard.edu/healthliteracy/files/health_actvities_materials_tasks_chart.pdf

AHRQ	Health literacy universal precautions toolkit	http://www.ahrq.gov/qual/literacy/healthliteracytoolkit.pdf
NYNJ PHTC	Health Literacy and Public health training course	http://www.nynj-phtc.org/phLit/Home/phlit-login.cfm
HRSA	Health Literacy course	http://www.hrsa.gov/publichealth/healthliteracy/
Medscape	Assuring Quality Care for People With Limited Health Literacy CE Activity	http://www.medscape.org/viewprogram/8603
American College of Physicians	e-Health TiPS (Downloadable - for different diseases)	http://www.acpfoundation.org/materials-and-guides/health-tips/
University of Michigan	Plain Language medical dictionary	http://www.lib.umich.edu/plain-language-dictionary
AHRQ	Your Medicine: Be Smart. Be Safe	http://www.ahrq.gov/consumer/safemeds/yourmeds.htm
Australian Indigenous HealthInfo Net	Foundations in Health Literacy - a train the trainer resources (DVD)	http://www.healthinfonet.ecu.edu.au/key-resources/promotion-resources?lid=18900
AAAS Science Net Links	Health Literacy	http://sciencenetlinks.com/collections/health-literacy/
National Institute for Literacy	Health Literacy Materials and Instruction Guide	http://healthliteracynetwork.org/materials/instr_guide.html
ACP Foundation	Health Literacy and Medication Safety	http://www.fda.gov/downloads/Drugs/DrugSafety/UCM173471.pdf
CDC	Health Literacy for Public Health Professionals	http://www.cdc.gov/healthliteracy/training/index.html
University of Minnesota	Culture and Health Literacy Modules	http://cpheo1.sph.umn.edu/healthlit/#a

Appendix 11: Letter of Invitation - A health literacy survey of attitudes of pharmacy staff and the pharmacy environment (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
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Appendix 12: Letter of Invitation - A health literacy survey of attitudes of pharmacy staff and the pharmacy environment (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: 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 Elhebir

Senior Research Officer | School of Pharmacy

Faculty of Health Science | Curtin University

Tel: 08 9266 7726 | Fax: 08 9266 2769

Email: E.Elhebir@curtin.edu.au

Associate Professor Lynne Emmerton

Director of Research Training | School of Pharmacy

Faculty of Health Science | Curtin University

Tel: 08 9266 7352 | Fax: 08 9266 2769

Email: Lynne.Emmerton@curtin.edu.au

Appendix 13: Letter of invitation – A health literacy survey of attitudes of pharmacy staff and the pharmacy environment (The University of Sydney)

Dr Betty Chaar
Room N508-Bldg A15
Faculty of Pharmacy
University of Sydney
NSW 2006

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 0451610529 or email xxx. Additionally, Dr Betty Chaar and Gregory Duncan will also be available to answer any questions you may have.

Yours sincerely,

Kim Bellamy

Research Assistant

Kim Bellamy
Room S303 - Building A15
Faculty of Pharmacy
University of Sydney NSW

Mr. Gregory Duncan
Eastern Health Clinical School
Faculty of Medicine, Nursing and Health Services
Monash University Victoria
Telephone: +61 412040320
Email: gregory.duncan@monash.edu

Mr. Glen Swinburne
Department of Pharmacy Practice, Centre for Medicine Use and Safety
Monash University Victoria

Appendix 14: Letter of invitation- A controlled trial of a health literacy education program in community pharmacies (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
Telephone: 9903 9025
Email: glen.swinburne@monash.edu

Dr Safeera Hussainy
Lecturer,
Academic Supervisor
Department of Pharmacy Practice, Centre for Medicine Use and Safety
Monash University
Telephone: 9903 9176
Fax: 9903 9629
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Mr. Gregory Duncan
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Eastern Health Clinical School
Faculty of Medicine, Nursing and Health Services
Monash University
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Appendix 15: Letter of invitation - A controlled trial of a health literacy education program in community pharmacies (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
Tel: 08 9266 2535 | Fax: 08 9266 2769
Email: E.Elhebir@curtin.edu.au

Associate Professor Lynne Emmerton
Director of Research Training | School of Pharmacy
Faculty of Health Science | Curtin University
Tel: 08 9266 7352 | Fax: 08 9266 2769
Email: Lynne.Emmerton@curtin.edu.au

Appendix 16: Letter of invitation – A controlled trial of a health literacy education program in community pharmacies (The University of Sydney)

Dr Betty Chaar
Room N508-Bldg A15
Faculty of Pharmacy
University of Sydney
NSW 2006
Australia
Telephone: +61 2 90367101
Email: betty.chaar@sydney.edu.au

Letter of Invitation to Pharmacy owner/manager

A CONTROLLED TRIAL OF A HEALTH LITERACY EDUCATION PROGRAM IN COMMUNITY PHARMACIES

Researchers: Dr Betty Chaar (Uinversity 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 on 0451610529 or email 1905kim@gmail.com. Additionally Dr Betty Chaar and Gregory Duncan will also be available to answer any questions you may have.

Yours sincerely,

Kim Bellamy

Kim Bellamy
Room S303 - Building A15
Faculty of Pharmacy
University of Sydney NSW
Telephone: +61 451610529
Email:
kim.bellamy@sydney.au.edu

Mr. Gregory Duncan
Eastern Health Clinical School
Faculty of Medicine, Nursing and Health Services
Monash University Victoria
Telephone: +61 412040320
Email: gregory.duncan@monash.edu

Mr. Glen Swinburne
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Centre for Medicine Use and Safety
Monash University Victoria
Telephone: +61 9903 9025
Email: glen.swinburne@monash.edu

Appendix 17: Explanatory Statement– A health literacy survey of pharmacy staff and the pharmacy environment (Pharmacy owners/manager) (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 Tel: +61 3 9903 9025 Email: glen.swinburne@monash.edu **Associate Prof. Kay Stewart** Centre for Medicine Use and Safety Monash University 381 Royal Pde Parkville, VIC 3052 Australia Tel: +61 3 9903 9176	**Executive Officer** **Monash University Human Research Ethics Committee (MUHREC)** **Building 3e Room 111** **Research Office** **Monash University VIC 3800** **Tel: +61 3 9905 2052 Fax: +61 3 9905 3831** **Email: muhrec@monash.edu**

Email: kay.stewart@monash.edu

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Appendix 18: Explanatory Statement – A health literacy survey of pharmacy staff and the pharmacy environment (Pharmacy owners/manager) (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 telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

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 Tel: 08 9266 7726 | Fax: 08 9266 2769 Email: E.Elhebir@curtin.edu.au	**Associate Professor Lynne Emmerton** Director of Research Training | School of Pharmacy Faculty of Health Science | Curtin University Tel: 08 9266 7352 | Fax: 08 9266 2769 Email: Lynne.Emmerton@curtin.edu.au
Professor Jeff Hughes Head | School of Pharmacy Faculty of Health Science | Curtin University Email: J.D.Hughes@curtin.edu.au	**Dr Kreshnik Hoti** Lecturer | School of Pharmacy Faculty of Health Science | Curtin University Email: Kreshnik.Hoti@curtin.edu.au
Professor Moyez Jiwa Chair Health Innovation – Chronic Disease Curtin Health Innovation Research Institute (CHIRI) Email: M.Jiwa@curtin.edu.au	

Appendix 19: Explanatory statement – A health literacy survey of attitudes of pharmacy staff and the pharmacy environment (The University of Sydney)

THE UNIVERSITY OF SYDNEY

Dr Betty Chaar
Room N508-Bldg A15
Faculty of Pharmacy
University of Sydney
NSW 2006
Australia
Telephone: +61 2 90367101

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 Chaar (+61 2 90367101), Gregory Duncan (+61 412040320), Glen Swinburne (+61 9903 9025) or Kim Bellamy (+61 451610529).*

(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 (02) 8627 8176 (Telephone); (02) 8627 7177 (Facsimile) or human.ethics@usyd.edu.au (Email)

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.

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 Tel: +61 3 9903 9025 Email: glen.swinburne@monash.edu **Dr Safeera Hussainy** Centre for Medicine Use and Safety Monash University 381 Royal Pde Parkville, VIC 3052 Australia Tel: +61 3 9903 9176 Email: safeera.hussainy@monash.edu **Mr Gregory Duncan** Eastern Health Clinical School Faculty of Medicine, Nursing and Health Services Monash University 5 Arnold St Box Hill VIC 3128 Tel: +61412040320 Email: gregory.duncan@monash.edu	**Executive Officer** **Monash University Human Research Ethics Committee (MUHREC)** **Building 3e Room 111** **Research Office** **Monash University VIC 3800** **Tel: +61 3 9905 2052 Fax: +61 3 9905 3831** **Email: muhrec@monash.edu**

Appendix 21: Explanatory statement - A controlled trial of a health literacy education program in community pharmacies (Pharmacy owner/manager and pharmacy staff members)(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 telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

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 Tel: 08 9266 2535 | Fax: 08 9266 2769 Email: E.Elhebir@curtin.edu.au	**Associate Professor Lynne Emmerton** Director of Research Training | School of Pharmacy Faculty of Health Science | Curtin University Tel: 08 9266 7352 | Fax: 08 9266 2769 Email: Lynne.Emmerton@curtin.edu.au
Professor Jeff Hughes Head | School of Pharmacy Faculty of Health Science | Curtin University Email: J.D.Hughes@curtin.edu.au	**Dr Kreshnik Hoti** Lecturer | School of Pharmacy Faculty of Health Science | Curtin University Email: Kreshnik.Hoti@curtin.edu.au
Professor Moyez Jiwa Chair Health Innovation – Chronic Disease Curtin Health Innovation Research Institute (CHIRI) Email: M.Jiwa@curtin.edu.au	

Appendix 22: Explanatory statement – A controlled trial of a health literacy education program in community pharmacies (Pharmacists and pharmacy staff members) (The University of Sydney)

Dr Betty Chaar
Room S303-Bldg A15
Faculty of Pharmacy
University of Sydney
NSW 2006
Australia
Telephone: +61 2 90367101
Email: betty.chaar@sydney.edu.au

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 (+61 2 90367101), Gregory Duncan (+61 412040320), Glen Swinburne (+61 9903 9025) or Kim Bellamy (+61 451610529)*

(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 (02) 8627 8176 (Telephone); (02) 8627 7177 (Facsimile) or human.ethics@usyd.edu.au (Email)

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 23: Consent form – A health literacy survey of attitudes of pharmacy staff and the pharmacy environment (Employee pharmacist/pharmacy staff member) (Monash University)

MONASH University
Pharmacy and Pharmaceutical Sciences

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.

☐ 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 24: Consent form – A health literacy survey of attitudes of pharmacy staff and the pharmacy environment (Pharmacist regularly and usually in-charge) (Monash University)

MONASH University
Pharmacy and Pharmaceutical Sciences

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 25: Consent form - A controlled trial of a health literacy education program in community pharmacies (Pharmacy owner/manager) (Monash University)

MONASH University
Pharmacy and Pharmaceutical Sciences

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 26: Consent form – A health literacy survey of attitudes of pharmacy staff and the pharmacy environment (Employee pharmacist/pharmacy staff member) (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 27: Pharmacist regularly and usually in-charge consent form – A health literacy survey of attitudes of pharmacy staff and the pharmacy environment (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 28: Consent form – A controlled trial of a health literacy education program in community pharmacies (pharmacy owner/manager) (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 29: Consent form – A controlled trial of a health literacy education program in community pharmacies (employee pharmacists/pharmacy assistants) (Curtin University)

Curtin University

Curtin University
CURTIN HEALTH INNOVATION RESEARCH INSTITUTE

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 30: Consent form – A health literacy survey of attitudes of pharmacy staff and the pharmacy environment (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
Telephone: +61 2 90367101
Email: betty.chaar@sydney.edu.au

Miss Kim Bellamy

Faculty of Pharmacy
Room N508-Building A15
University of Sydney NSW 2006
AUSTRALIA
Telephone: +61 451610529
Email: 1905kim@gmail.com

PARTICIPANT CONSENT FORM

I, ...[PRINT NAME], give consent to my participation in the research project

1. 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 31: Consent form – A controlled trial of a health literacy education program in community pharmacies (Pharmacist manager/trainer) (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
Telephone: +61 2 90367101
Email: betty.chaar@sydney.edu.au

Miss Kim Bellamy

Faculty of Pharmacy
Room S303-Building A15
University of Sydney NSW 2006
AUSTRALIA
Telephone: +61 451610529
Email: kim.bellamy@sydney.edu.au

PARTICIPANT (PHARMACIST MANAGER/TRAINER) CONSENT FORM

I, ...[PRINT NAME], give consent to my participation in the research project

2. 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 32: Consent form – A controlled trial of a health literacy education program in community pharmacies (Employee pharmacists and pharmacy staff) (The University of Sydney)

Dr Betty Chaar
Lecturer in Pharmacy Practice
ABN 15 211 513 464

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Miss Kim Bellamy

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University of Sydney NSW 2006
AUSTRALIA
Telephone: +61 451610529
Email: 1905kim@gmail.com

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 33: Permission letter – A health literacy survey of attitudes of pharmacy staff and the pharmacy environment (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 34: Permission letter – A health literacy survey of attitudes of pharmacy staff and the pharmacy environment (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
Tel: 08 9266 7726 | Fax: 08 9266 2769
Email: E.Elhebir@curtin.edu.au

Associate Professor Lynne Emmerton
Director of Research Training | School of Pharmacy
Faculty of Health Science | Curtin University
Tel: 08 9266 7352 | Fax: 08 9266 2769
Email: Lynne.Emmerton@curtin.edu.au

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>

Appendix 35: Permission letter – A health literacy survey of attitudes of pharmacy staff and the pharmacy environment (The University of Sydney)

Permission Letter for project: A health literacy survey of attitudes of pharmacy staff and the pharmacy environment

Date:

Dr Betty Chaar
Faculty of Pharmacy
Room N508-Building A15
University of Sydney NSW 2006
Telephone: +61 2 90367101
Email: betty.chaar@sydney.edu.au

Kim Bellamy
Faculty of Pharmacy
Room N508-Building A15
University of Sydney NSW 2006
Telephone: +61 451610529
Email: xxx

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 and participant information statement 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 36: Permission letter - A controlled trial of a health literacy education program in community pharmacies (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 37: Permission letter – A controlled trial of a health literacy education program in community pharmacies (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
Tel: 08 9266 2535 | Fax: 08 9266 2769
Email: E.Elhebir@curtin.edu.au

Associate Professor Lynne Emmerton
Director of Research Training | School of Pharmacy
Faculty of Health Science | Curtin University
Tel: 08 9266 7352 | Fax: 08 9266 2769
Email: Lynne.Emmerton@curtin.edu.au

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 38: Permission letter – A controlled trial of a health literacy education program in community pharmacies (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
Telephone: +61 451610529
Email: 1905kim@gmail.com

Dr Betty Chaar
Faculty of Pharmacy
Room N508-Building A15
University of Sydney NSW 2006
Telephone: +61 2 90367101
Email: betty.chaar@sydney.edu.au

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 39: Attributes of a Health Literacy Friendly Pharmacy questionnaire

MONASH University
Medicine, Nursing and Health Sciences

THE UNIVERSITY OF SYDNEY

Curtin University

Health Literacy in Pharmacy study

Attributes of a Health Literacy Friendly Pharmacy

The aim of this survey is to assess the health literacy of the pharmacy environment. It's been shown that a navigable and 'health literacy friendly' pharmacy can improve consumers' use of services within the pharmacy, and improve their understanding of information provided to them.

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.[1]

The term 'pharmacy staff' refers to all pharmacists, pharmacy interns, dispensary technicians and assistants.

Investigator use only
Code:

Promotion of Services

Health Literacy Attribute	A: This is something the pharmacy does not appear to be doing	B: The pharmacy is doing this but could make some improvements	C: The pharmacy is doing this well	D: Not sure/can't make a judgement	E: Not applicable to this pharmacy
1. When pharmacy staff give verbal or written directions for finding the pharmacy, they refer to familiar landmarks (e.g. tram stops, train stations, bus stops).	☐	☐	☐	☐	☐
3. The phone number is easy for everyone to find on all promotional or informational materials.	☐	☐	☐	☐	☐
5. The difference between check in/prescription drop-off areas and prescription pick-up areas is clear to consumers when they enter the service area of the pharmacy.	☐	☐	☐	☐	☐

1. Kanj M, Mitic W. Health literacy and health promotion. 7th Global Conference on Health Promotion; Nairobi, Kenya: World Health Organization; 2009. P. 1-46

Health Literacy Attribute	A: This is something the pharmacy does not appear to be doing	B: The pharmacy is doing this but could make some improvements	C: The pharmacy is doing this well	D: Not sure/can't make a judgement	E: Not applicable to this pharmacy
7. It's easy for consumers to pick out the important information on the walls and bulletin boards.	☐	☐	☐	☐	☐
8. The pharmacy displays pamphlets and educational brochures (e.g. PSA Self-Care Cards) in a way that allows people to find information.	☐	☐	☐	☐	☐
9. The pharmacy uses a variety of ways to inform consumers about its services once in-store: video and/or printed materials.	☐	☐	☐	☐	☐

Printed materials

When answering this question, consider both written information the pharmacy may develop itself if this occurs, as well as pre-prepared written information that is used within the pharmacy for consumers.

Health Literacy Attribute	A: This is something the pharmacy does not appear to be doing	B: The pharmacy is doing this but could make some improvements	C: The pharmacy is doing this well	D: Not sure/can't make a judgement	E: Not applicable to this pharmacy
10. The following print materials are **written in simple and clear language**, avoiding the use of technical jargon and medical terms.					
i) Prescription information leaflets that the pharmacist prints out	☐	☐	☐	☐	☐
ii) Consumer education brochures that the consumer takes home	☐	☐	☐	☐	☐
iii) Information posters and signs on the pharmacy walls and shelves	☐	☐	☐	☐	☐

Health Literacy Attribute	A: This is something the pharmacy does not appear to be doing	B: The pharmacy is doing this but could make some improvements	C: The pharmacy is doing this well	D: Not sure/can't make a judgement	E: Not applicable to this pharmacy
iv) Medication labels	☐	☐	☐	☐	☐
v) Warning labels	☐	☐	☐	☐	☐
vi) Signage	☐	☐	☐	☐	☐
11. The following print materials used within the pharmacy have **sufficient clear space** to provide relief from the print:					
i) Prescription information leaflets that the pharmacist prints out	☐	☐	☐	☐	☐
ii) Consumer education brochures that the consumer takes home	☐	☐	☐	☐	☐
iii) Information posters and signs on the pharmacy walls and shelves	☐	☐	☐	☐	☐
iv) Medication labels	☐	☐	☐	☐	☐
v) Warning labels	☐	☐	☐	☐	☐
vi) Signage	☐	☐	☐	☐	☐

Health Literacy Attribute	A: This is something the pharmacy does not appear to be doing	B: The pharmacy is doing this but could make some improvements	C: The pharmacy is doing this well	D: Not sure/can't make a judgement	E: Not applicable to this pharmacy
12. The pharmacy uses the following print materials that contain **simple visual graphics or illustrations** that convey the meaning of the text and decrease dependence on the text for comprehension:					
i) Prescription information leaflets that the pharmacist prints out	☐	☐	☐	☐	☐
ii) Consumer education brochures that the consumer takes home	☐	☐	☐	☐	☐
iii) Information posters and signs on the pharmacy walls and shelves	☐	☐	☐	☐	☐
iv) Medication labels	☐	☐	☐	☐	☐
v) Warning labels	☐	☐	☐	☐	☐
vi) Signage	☐	☐	☐	☐	☐
13. The pharmacy uses the following written materials that are typed in **12-point font size or larger**					
i) Prescription information leaflets that the pharmacist prints out	☐	☐	☐	☐	☐
ii) Consumer education brochures that the consumer takes home	☐	☐	☐	☐	☐
iii) Information posters and signs on the pharmacy walls and shelves	☐	☐	☐	☐	☐
iv) Medication labels	☐	☐	☐	☐	☐

Health Literacy Attribute	A: This is something the pharmacy does not appear to be doing	B: The pharmacy is doing this but could make some improvements	C: The pharmacy is doing this well	D: Not sure/can't make a judgement	E: Not applicable to this pharmacy
v) Warning labels	☐	☐	☐	☐	☐
14. If appropriate, these print materials are available in languages other than English:					
i) Prescription information leaflets that the pharmacist prints out	☐	☐	☐	☐	☐
ii) Consumer education brochures that the consumer takes home	☐	☐	☐	☐	☐
iii) Information posters and signs on the pharmacy walls and shelves	☐	☐	☐	☐	☐
iv) Medication labels	☐	☐	☐	☐	☐
v) Warning labels	☐	☐	☐	☐	☐
vi) Signage	☐	☐	☐	☐	☐

15. Overall, these print materials are **easy for adults with limited literacy skills to understand:**					
i) Prescription information leaflets that the pharmacist prints out	☐	☐	☐	☐	☐
ii) Consumer education brochures that the consumer takes home	☐	☐	☐	☐	☐
iii) Information posters and signs on the pharmacy walls and shelves	☐	☐	☐	☐	☐
iv) Medication labels	☐	☐	☐	☐	☐
v) Warning labels	☐	☐	☐	☐	☐
vi) Signage	☐	☐	☐	☐	☐

Comments:

Health Literacy Attribute	A: This is something the pharmacy does not appear to be doing	B: The pharmacy is doing this but could make some improvements	C: The pharmacy is doing this well	D: Not sure/can't make a judgement	E: Not applicable to this pharmacy
16. Has the pharmacy developed policies and/or standards associated with recognising health literacy as an important aspect of consumer care?	☐	☐	☐	☐	☐
17. Has the pharmacy implemented policies and/or standards associated with recognising health literacy as an important aspect of consumer care?	☐	☐	☐	☐	☐
18. Do staff at all levels receive health literacy training?	☐	☐	☐	☐	☐
19. The pharmacy staff seek feedback from consumers regarding the health information and services provided by the pharmacy.	☐	☐	☐	☐	☐
20. The pharmacy staff secure language assistance, or knows how to access these services, for speakers of languages other than English.	☐	☐	☐	☐	☐
21. The pharmacy staff provide easy to understand descriptions of health care related schemes and processes (e.g. PBS, concession cards, Safety Net, Medicare).	☐	☐	☐	☐	☐
22. A private space is available for counselling.	☐	☐	☐	☐	☐
23. The pharmacy leadership promotes commitment to health literacy and clear consumer communication.	☐	☐	☐	☐	☐

Please seal the completed survey in the provided envelope. Thank you for your participation.

Appendix 40: Consumer data collection form (pre-consultation)

MONASH University Medicine, Nursing and Health Sciences | THE UNIVERSITY OF SYDNEY | Curtin University

Investigator use only
Code:

HEALTH LITERACY IN PHARMACY PROJECT
CONSUMER DATA COLLECTION FORM (PRE-CONSULTATION)

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:

Appendix 41: Consumer data collection form (pre-consultation)

MONASH University Pharmacy and Pharmaceutical Sciences | THE UNIVERSITY OF SYDNEY | Curtin University

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? *(Note to data collector – if not exactly this, check if it was an open question; otherwise answer 'No')*		☐ 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 42: Perceptions and Activities Survey – Employee (Pre-train-the-trainer)

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.

Investigator use only
Code:

1. In which state is your pharmacy located?

Victoria ☐ New South Wales ☐ Western Australia ☐

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 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 43: Perceptions and Activities Survey – Employee (Pre-in-house training)

MONASH University Medicine, Nursing and Health Sciences | THE UNIVERSITY OF SYDNEY | Curtin University

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.

Investigator use only
Code:

1. In which state is your pharmacy located?

Victoria ☐ New South Wales ☐ Western Australia ☐

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.	☐	☐	☐	☐	☐	☐	☐
If you are the manager, skip this question. 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 44: Perceptions and Activities Survey – Employee (Post-train-the-trainer)

MONASH University Medicine, Nursing and Health Sciences | THE UNIVERSITY OF SYDNEY | Curtin University

Health Literacy in Pharmacy Study

Perceptions and Activities survey – Employee (Post-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.

Investigator use only
Code:

1. In which state is your pharmacy located?

Victoria ☐ New South Wales ☐ Western Australia ☐

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. Following this training, 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.	☐	☐	☐	☐	☐	☐	☐
8. I believe that implementing a health literacy training program for pharmacy staff in my pharmacy is important.	☐	☐	☐	☐	☐	☐	☐
9. I expect my pharmacy to achieve a high standard of service delivery in this pharmacy relating to health literacy.	☐	☐	☐	☐	☐	☐	☐
10. Many of the consumers in my pharmacy have low levels of health literacy.	☐	☐	☐	☐	☐	☐	☐
11. Those consumers in my pharmacy with low levels of health literacy are likely to experience worse health outcomes than other consumers.	☐	☐	☐	☐	☐	☐	☐
12. By providing appropriate counselling, pharmacy staff can help consumers to avoid many problems associated with low levels of health literacy.	☐	☐	☐	☐	☐	☐	☐
13. A consumer should never be considered to have adequate health literacy without clear evidence.	☐	☐	☐	☐	☐	☐	☐
14. I have the right to assume that a consumer understands my advice, unless he/she indicates otherwise.	☐	☐	☐	☐	☐	☐	☐
15. It is the consumer'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
16. If I counsel all consumers in the manner recommended during health literacy training, there are clear health benefits for consumers.	☐	☐	☐	☐	☐	☐	☐
17. It is essential to counsel all consumers in a manner that assumes they have limited health literacy, unless proven otherwise.	☐	☐	☐	☐	☐	☐	☐
18. Suggestions provided for implementing health literacy training in the pharmacy are likely to be very helpful.	☐	☐	☐	☐	☐	☐	☐
19. Most of the people working in my pharmacy will encourage my efforts to apply health literacy principles to my consumer counselling.	☐	☐	☐	☐	☐	☐	☐
20. Addressing the challenges of health literacy with my consumers will be personally rewarding.	☐	☐	☐	☐	☐	☐	☐
21. My consumers have strong expectations of me to counsel in a way that addresses their health literacy needs.	☐	☐	☐	☐	☐	☐	☐
22. Pharmacy management will be 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.	☐	☐	☐	☐	☐	☐	☐

Statement	1 Strongly disagree	2	3	4 Not sure	5	6	7 Strongly agree
25. It would be easy for me to apply the counselling principles outlined in the 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 in my personal ability to counsel in a way that ensures universal precautions.	☐	☐	☐	☐	☐	☐	☐
29. I am confident I have the skills to run a health literacy training program for my staff.	☐	☐	☐	☐	☐	☐	☐
30. The ability for me to run the health literacy training session for the pharmacy staff is beyond my control.	☐	☐	☐	☐	☐	☐	☐
31. My managers will now expect me to counsel consumers in a way that addresses their health literacy needs.	☐	☐	☐	☐	☐	☐	☐
32. Whether I can run the health literacy training session for the pharmacy staff is not entirely up to me.	☐	☐	☐	☐	☐	☐	☐
33. Whether or not I can achieve a high level of service delivery relating to health literacy in this pharmacy is beyond my control.	☐	☐	☐	☐	☐	☐	☐
34. 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.	☐	☐	☐	☐	☐	☐	☐
35. I have a clear vision of how to implement health literacy counselling into all counselling in the pharmacy	☐	☐	☐	☐	☐	☐	☐

Statement	1 Strongly disagree	2	3	4 Not sure	5	6	7 Strongly agree
36. Implementing health literacy counselling in the pharmacy seems like a complicated process	☐	☐	☐	☐	☐	☐	☐
37. I anticipate that my pharmacy would provide sufficient practical support for the implementation of a health literacy program	☐	☐	☐	☐	☐	☐	☐
38. In the past, my pharmacy has provided reasonable support to implement professional programs.	☐	☐	☐	☐	☐	☐	☐
39. I intend to understand the concepts and skills required to implement health literacy counselling.	☐	☐	☐	☐	☐	☐	☐
40. I intend to apply the principles of healthy literacy counselling to how I communicate with all of my consumers.	☐	☐	☐	☐	☐	☐	☐
41. I have already successfully incorporated and sustained changes to the way I counsel consumers in everyday practice.	☐	☐	☐	☐	☐	☐	☐
42. I will implement health literacy training sessions for pharmacy staff in my pharmacy.	☐	☐	☐	☐	☐	☐	☐
43. 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 45: Perceptions and Activities Survey – Employee (Post-in-house training)

Health Literacy in Pharmacy Study

Perceptions and Activities Survey – Employee (Post-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.

Investigator use only
Code:

1. In which state is your pharmacy located?

Victoria ☐ New South Wales ☐ Western Australia ☐

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. Following this training, 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.	☐	☐	☐	☐	☐	☐	☐
8. Most other pharmacy staff would require additional training to fully meet the health literacy needs of their consumers.	☐	☐	☐	☐	☐	☐	☐
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 consumer'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. If I counsel consumers in the manner recommended during health literacy training, there are clear health benefits for consumers.	☐	☐	☐	☐	☐	☐	☐
16. It is essential to counsel all consumers in a manner that assumes they have limited health literacy, unless proven otherwise.	☐	☐	☐	☐	☐	☐	☐
If you are the manager, skip this question. 17. My managers will now expect me to counsel consumers in a way that addresses their health literacy needs.	☐	☐	☐	☐	☐	☐	☐
18. Most of the people working in my pharmacy will encourage my efforts to apply health literacy principles to my consumer counselling.	☐	☐	☐	☐	☐	☐	☐
19. Addressing the challenges of health literacy with my consumers will be personally rewarding.	☐	☐	☐	☐	☐	☐	☐
20. My consumers have strong expectations of me to counsel in a way that addresses their health literacy needs.	☐	☐	☐	☐	☐	☐	☐
21. Pharmacy management will be keen to see health literacy principles applied consistently by all employees.	☐	☐	☐	☐	☐	☐	☐

Statement	1 Strongly disagree	2	3	4 Not sure	5	6	7 Strongly agree
22. The employees in my pharmacy will be very keen to see that health literacy principles are applied consistently to all consumer counselling.	☐	☐	☐	☐	☐	☐	☐
23. 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.	☐	☐	☐	☐	☐	☐	☐
24. It would be easy for me to apply the counselling principles outlined in the health literacy training program for all consumers when providing health information.	☐	☐	☐	☐	☐	☐	☐
25. I am confident that I could use effective communication techniques for all consumers when providing health information.	☐	☐	☐	☐	☐	☐	☐
26. I am confident in my personal ability to counsel in a way that ensures universal precautions.	☐	☐	☐	☐	☐	☐	☐
27. Whether or not I can achieve a high level of service delivery relating to health literacy in this pharmacy is beyond my control.	☐	☐	☐	☐	☐	☐	☐
28. 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.	☐	☐	☐	☐	☐	☐	☐
29. The concepts described in health literacy training are logical and reasonable.	☐	☐	☐	☐	☐	☐	☐

Statement	1 Strongly disagree	2	3	4 Not sure	5	6	7 Strongly agree
30. I have a clear vision of how to implement health literacy counselling into all counselling in the pharmacy.	☐	☐	☐	☐	☐	☐	☐
31. Implementing health literacy counselling in the pharmacy seems like a complicated process.	☐	☐	☐	☐	☐	☐	☐
32. I anticipate that my pharmacy would provide sufficient practical support for the implementation of a health literacy program.	☐	☐	☐	☐	☐	☐	☐
33. In the past, my pharmacy has provided reasonable support to implement professional programs.	☐	☐	☐	☐	☐	☐	☐
34. I intend to understand the concepts and skills required to implement health literacy counselling.	☐	☐	☐	☐	☐	☐	☐
35. I intend to apply the principles of healthy literacy counselling to how I communicate with all of my patients.	☐	☐	☐	☐	☐	☐	☐
36. I expect my pharmacy to achieve a high standard of service delivery in this pharmacy relating to health literacy.	☐	☐	☐	☐	☐	☐	☐
37. I have already successfully incorporated and sustained changes to the way I counsel patients in everyday practice.	☐	☐	☐	☐	☐	☐	☐
38. 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.

Appendix 46: Mystery shopper data collection form

MONASH University Pharmacy and Pharmaceutical Sciences · THE UNIVERSITY OF SYDNEY · Curtin University

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 ☐		

ENGAGMENT 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 47: 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 48: Focus groups questions for focus groups regarding usability of health literacy education package

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 as "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?

Appendix 49: Monash University Human Ethics Approval for a health literacy survey of attitudes of pharmacy staff and the pharmacy environment.

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 50: Monash University Human Ethics Approval for a controlled trial of a health literacy education program in community pharmacies

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 51: Curtin University Human Ethics Approval for a health literacy survey of attitudes of pharmacy staff and the pharmacy environment

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
TELEPHONE 9266 7418
FACSIMILE 9266 3793
EMAIL A.J.Smith@curtin.edu.au

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,

Alison Smith
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 52: Curtin University Human Ethics Approval for a controlled trial of a health literacy education program in community pharmacies.

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,

Alison Smith
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 53: Mean scores of face-to-face, electronic and control group pharmacies at baseline in relation to the health literacy of the pharmacy environment.

Variable	Face-to-face (mean)	Electronic (mean)	Control (mean)
Promotion of services			
1. When pharmacy staff give verbal or written directions for finding the pharmacy, they refer to familiar landmarks (e.g. tram stops, train stations, bus stops)	2.89	2.77	2.80
2. The phone number is easy for everyone to find on all promotional or informations materials.	2.83	2.79	2.70
3. The difference between check in/prescription drop-off areas and prescription pick-up areas is clear to consumers when they enter the pharmacy.	1.87	2.30	2.38
4. It's easy for consumers to pick out the important information on the walls and bulletin boards.	2.25	2.33	2.00
5. The pharmacy displays pamphlets and educational brochures (e.g. PSA Self-Care Cards) in a way that allows people to find information.	1.95	2.14	2.20
6. The pharmacy uses a variety of ways to inform consumers about its services once in-store: video and/or printed materials.	2.11	1.93	2.22

Variable	Face-to-face (mean)	Electronic (mean)	Control (mean)
Printed materials			
7. The following print materials are written in simple and clear language, avoiding the use of technical jargon and medical terms.			
i) Prescription information leaflets that the pharmacist prints out	2.63	2.64	2.40
ii) Consumer education brochures that the consumer takes home	2.19	2.29	2.40
iii) Information posters and signs on the pharmacy walls and shelves	2.47	2.29	2.40
iv) Medication labels	2.95	2.77	2.50
v) Warning labels	2.79	2.71	2.40
vi) Signage	2.71	2.54	2.33
8. The following print materials used with the pharmacy have sufficient clear space to provide relief from the print.			
i) Prescription information leaflets that the pharmacist prints out	2.56	2.58	2.44
ii) Consumer education brochures that the consumer takes home	2.41	2.43	2.40
iii) Information posters and signs on the pharmacy walls and shelves	2.33	2.21	2.10
iv) Medication labels	2.61	2.62	2.60
v) Warning labels	2.43	2.50	2.50

vi) Signage	2.38	2.50	2.20
9. The pharmacy uses the following print materials that contain visual graphics or illustrations that convey the meaning of the text and decrease dependence on the text for comprehension.			
i) Prescription information leaflets that the pharmacist prints out	1.53	2.17	2.00
ii) Consumer education brochures that the consumer takes home	1.89	2.50	2.10
iii) Information posters and signs on the pharmacy walls and shelves	2.00	2.08	1.90
iv) Medication labels	1.56	2.17	2.00
v) Warning labels	1.78	2.33	2.00
vi) Signage	2.06	2.33	2.20
10. The pharmacy uses the following written materials that are typed in 12-point font size or larger.			
i) Prescription information leaflets that the pharmacist prints out	2.40	2.91	2.38
ii) Consumer education brochures that the consumer takes home	2.20	2.36	2.25
iii) Information posters and signs on the pharmacy walls and shelves	2.69	2.67	2.38
iv) Medication labels	2.14	2.36	2.00
v) Warning labels	1.47	2.40	1.75
11. If appropriate, these print materials are available in languages other than			

English.			
i) Prescription information leaflets that the pharmacist prints out	1.23	1.75	1.11
ii) Consumer education brochures that the consumer takes home	1.33	1.58	1.22
iii) Information posters and signs on the pharmacy walls and shelves	1.00	1.67	1.11
iv) Medication labels	1.23	1.50	1.22
v) Warning labels	1.00	1.50	1.11
vi) Signage	1.08	1.42	1.00
12. Overall, these print materials are easy for adults with limited literacy skills to understand.			
i) Prescription information leaflets that the pharmacist prints out	1.76	2.54	1.78
ii) Consumer education brochures that the consumer takes home	1.76	2.46	1.89
iii) Information posters and signs on the pharmacy walls and shelves	1.94	2.46	1.63
iv) Medication labels	2.12	2.38	1.56
v) Warning labels	2.06	2.38	1.56
vi) Signage	1.94	2.38	1.70

Variable	Face-to-face (mean)	Electronic (mean)	Control (mean)
Health literacy policies			
13. Has the pharmacy developed policies and/or standards associated with recognising health literacy as an important aspect of consumer care?	1.36	2.17	1.40
14. Has the pharmacy implemented policies and/or standards associated with recognising health literacy as an important aspect of consumer care?	1.33	2.17	1.30
15. Do staff at all levels receive health literacy training?	1.31	1.83	1.30
16. The pharmacy staff seek feedback from consumers regarding the health information and services provided by the pharmacy.	1.78	1.93	1.40
Clear verbal communication			
17. The pharmacy staff secure language assistance, or knows how to access these services, for speakers of languages other than English.	1.82	2.00	1.56
18. The pharmacy staff provide easy to understand descriptions of health care related schemes and processes (e.g. PBS, concession cards, Safety Net, Medicare).	2.17	2.50	2.40
19. A private space is available for counselling.	2.26	2.54	2.60
20. The pharmacy leadership promotes commitment to health literacy and clear communication.	2.11	2.62	2.40

Appendix 54: Mean scores of face-to-face, electronic and control group pharmacies at post-intervention in relation to the health literacy of the pharmacy environment.

Variable	Face-to-face (mean)	Electronic (mean)	Control (mean)
Promotion of services			
1. When pharmacy staff give verbal or written directions for finding the pharmacy, they refer to familiar landmarks (e.g. tram stops, train stations, bus stops)	3.00	2.60	2.50
2. The phone number is easy for everyone to find on all promotional or informations materials.	2.89	3.00	2.50
3. The difference between check in/prescription drop-off areas and prescription pick-up areas is clear to consumers when they enter the pharmacy.	2.13	2.80	2.20
4. It's easy for consumers to pick out the important information on the walls and bulletin boards.	2.63	2.80	2.33
5. The pharmacy displays pamphlets and educational brochures (e.g. PSA Self-Care Cards) in a way that allows people to find information.	2.50	2.50	2.17
6. The pharmacy uses a variety of ways to inform consumers about its services once in-store: video and/or printed materials.	1.70	2.67	1.83

Variable	Face-to-face (mean)	Electronic (mean)	Control (mean)
Printed materials			
7. The following print materials are written in simple and clear language, avoiding the use of technical jargon and medical terms.			
i) Prescription information leaflets that the pharmacist prints out	2.90	3.00	2.67
ii) Consumer education brochures that the consumer takes home	2.89	2.50	2.50
iii) Information posters and signs on the pharmacy walls and shelves	2.75	3.00	2.67
iv) Medication labels	3.00	3.00	3.00
v) Warning labels	2.89	2.80	3.00
vi) Signage	2.90	3.00	2.60
8. The following print materials used with the pharmacy have sufficient clear space to provide relief from the print.			
i) Prescription information leaflets that the pharmacist prints out	2.70	2.83	2.67
ii) Consumer education brochures that the consumer takes home	2.81	2.80	2.67
iii) Information posters and signs on the pharmacy walls and shelves	3.00	3.00	2.83
iv) Medication labels	2.91	3.00	2.83
v) Warning labels	2.82	3.00	2.83

vi) Signage	2.91	3.00	2.67
9. The pharmacy uses the following print materials that contain visual graphics or illustrations that convey the meaning of the text and decrease dependence on the text for comprehension.			
i) Prescription information leaflets that the pharmacist prints out	2.18	2.20	2.00
ii) Consumer education brochures that the consumer takes home	2.20	2.50	2.00
iii) Information posters and signs on the pharmacy walls and shelves	2.44	2.50	2.40
iv) Medication labels	2.13	3.00	2.20
v) Warning labels	2.00	3.00	2.20
vi) Signage	2.25	3.00	2.40
10. The pharmacy uses the following written materials that are typed in 12-point font size or larger.			
i) Prescription information leaflets that the pharmacist prints out	2.70	2.67	2.67
ii) Consumer education brochures that the consumer takes home	2.78	2.83	2.67
iii) Information posters and signs on the pharmacy walls and shelves	3.00	2.83	2.60
iv) Medication labels	2.67	2.33	2.20
v) Warning labels	2.44	2.40	2.00

11. If appropriate, these print materials are available in languages other than English.			
i) Prescription information leaflets that the pharmacist prints out	1.80	2.17	1.67
ii) Consumer education brochures that the consumer takes home	1.91	2.17	1.00
iii) Information posters and signs on the pharmacy walls and shelves	1.73	2.20	1.00
iv) Medication labels	1.80	2.20	1.00
v) Warning labels	1.50	2.20	1.00
vi) Signage	1.70	2.20	1.00
12. Overall, these print materials are easy for adults with limited literacy skills to understand.			
i) Prescription information leaflets that the pharmacist prints out	2.45	2.75	2.17
ii) Consumer education brochures that the consumer takes home	2.50	2.40	2.00
iii) Information posters and signs on the pharmacy walls and shelves	2.67	2.80	2.17
iv) Medication labels	2.70	2.60	2.00
v) Warning labels	2.60	2.60	2.00
vi) Signage	2.75	2.60	2.17

Variable	Face-to-face (mean)	Electronic (mean)	Control (mean)
Health literacy policies			
13. Has the pharmacy developed policies and/or standards associated with recognising health literacy as an important aspect of consumer care?	2.33	2.17	1.50
14. Has the pharmacy implemented policies and/or standards associated with recognising health literacy as an important aspect of consumer care?	2.75	2.33	1.67
15. Do staff at all levels receive health literacy training?	2.22	2.33	1.50
16. The pharmacy staff seek feedback from consumers regarding the health information and services provided by the pharmacy.	2.00	2.17	1.67
Clear verbal communication			
17. The pharmacy staff secure language assistance, or knows how to access these services, for speakers of languages other than English.	2.80	2.50	2.00
18. The pharmacy staff provide easy to understand descriptions of health care related schemes and processes (e.g. PBS, concession cards, Safety Net, Medicare).	2.82	2.83	2.67
19. A private space is available for counselling.	2.22	2.80	3.00
20. The pharmacy leadership promotes commitment to health literacy and clear communication.	2.75	2.83	2.40

Appendix 55: Explanatory statement – A controlled trial of a health literacy education program in community pharmacies (consumers) (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 9266 2784 or by emailing hrec@curtin.edu.au.

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 Tel: 08 9266 2535 | Fax: 08 9266 2769 Email: E.Elhebir@curtin.edu.au	**Associate Professor Lynne Emmerton** Director of Research Training | School of Pharmacy Faculty of Health Science | Curtin University Tel: 08 9266 7352 | Fax: 08 9266 2769 Email: Lynne.Emmerton@curtin.edu.au
Professor Jeff Hughes Head | School of Pharmacy Faculty of Health Science | Curtin University Email: J.D.Hughes@curtin.edu.au	**Dr Kreshnik Hoti** Lecturer | School of Pharmacy Faculty of Health Science | Curtin University Email: Kreshnik.Hoti@curtin.edu.au
Professor Moyez Jiwa Chair Health Innovation – Chronic Disease Curtin Health Innovation Research Institute (CHIRI) Email: M.Jiwa@curtin.edu.au	

Appendix 56: Explanatory statement – A controlled trial of a health literacy education program in community pharmacies (Consumers) (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 (02) 8627 8176 (Telephone); (02) 8627 7177 (Facsimile) or human.ethics@usyd.edu.au (Email)

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 57: Explanatory statement – a controlled trial of a health literacy education program in community pharmacies

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	If you have a complaint concerning the manner in which this research **<insert your**

the Supervisor:	**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 Tel: +61 3 9903 9025 Email: glen.swinburne@monash.edu **Dr Safeera Hussainy** Centre for Medicine Use and Safety Monash University 381 Royal Pde Parkville, VIC 3052 Australia Tel: +61 3 9903 9176 Email: safeera.hussainy@monash.edu **Mr Gregory Duncan** Eastern Health Clinical School Faculty of Medicine, Nursing and Health Services Monash University 5 Arnold St Box Hill VIC 3128 Tel: +61412040320 Email: gregory.duncan@monash.edu	**Executive Officer** **Monash University Human Research Ethics Committee (MUHREC)** **Building 3e Room 111** **Research Office** **Monash University VIC 3800** **Tel: +61 3 9905 2052 Fax: +61 3 9905 3831 Email: muhrec@monash.edu**

Appendix 58: Consent form – A controlled trial of a health literacy education program in community pharmacies (consumers) (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 59: Consent form – A controlled trial of a health literacy education program in community pharmacies (Consumers) (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
Telephone: +61 2 90367101
Email: betty.chaar@sydney.edu.au

Miss Kim Bellamy

Faculty of Pharmacy
Room N508-Building A15
University of Sydney NSW 2006
AUSTRALIA
Telephone: +61 451610529
Email: 1905kim@gmail.com

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 6o: Consent form - A controlled trial of a health literacy education program in community pharmacies (Consumers) (Monash University)

MONASH University
Pharmacy and Pharmaceutical Sciences

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 61: Explanatory statement - The usability of a health literacy education package – views of pharmacists and pharmacy assistants (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
Tel: 08 9266 2535 | Fax: 08 9266 2769
Email: E.Elhebir@curtin.edu.au

Associate Professor Lynne Emmerton
Director of Research Training | School of Pharmacy
Faculty of Health Science | Curtin University
Tel: 08 9266 7352 | Fax: 08 9266 2769
Email: Lynne.Emmerton@curtin.edu.au

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 Tel: 08 9266 2535 | Fax: 08 9266 2769 Email: E.Elhebir@curtin.edu.au	Associate Professor Lynne Emmerton Director of Research Training | School of Pharmacy Faculty of Health Science | Curtin University Tel: 08 9266 7352 | Fax: 08 9266 2769 Email: Lynne.Emmerton@curtin.edu.au
Professor Jeff Hughes Head | School of Pharmacy Faculty of Health Science | Curtin University Email: J.D.Hughes@curtin.edu.au	Dr Kreshnik Hoti Lecturer | School of Pharmacy Faculty of Health Science | Curtin University Email: Kreshnik.Hoti@curtin.edu.au
Professor Moyez Jiwa Chair Health Innovation – Chronic Disease	

Curtin Health Innovation Research Institute (CHIRI)
Email: M.Jiwa@curtin.edu.au

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 9266 2784 or by emailing hrec@curtin.edu.au.

Thank you,

Dr Sam Elhebir

Appendix 62: Explanatory statement - The usability of a health literacy education package – views of pharmacists and pharmacy assistants (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
Centre for Medicine Use and Safety
Phone: +61 3 99099176
email: safeera.hussainy@monash.edu

Mr. Glen Swinburne
Phone : +61 432505360
email: glen.swinburne@monash.edu

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.

21.1.1.1.1.1.1.1 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.

21.1.1.1.1.1.1.2 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.

21.1.1.1.1.1.1.3 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.

21.1.1.1.1.1.1.4 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 on 0432 505 360 or via email glen.swinburne@monash.edu. 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

Tel: +61 3 9905 2052 Email: muhrec@monash.edu Fax: +61 3 9905 3831

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
Telephone: 9903 9176/ Fax: 99039629
Email: safeera.hussainy@monash.edu

Glen Swinburne B.Pharm(Hons) GCPharmPrac
(Student researcher)
PhD candidate
Centre for Medicine Use and Safety,
Monash University.
Telephone: 0432505360
Email:glen.swinburne@monash.edu

Appendix 63: Consent form - The usability of a health literacy education package – views of pharmacists and pharmacy assistants (Curtin University)

Curtin University

CONSENT FORM

Curtin University
CURTIN HEALTH INNOVATION RESEARCH INSTITUTE

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 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 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. Tel: 08 9266 2535 | Fax: 08 9266 2769 or Email: E.Elhebir@curtin.edu.au

Thank you for your participation

Appendix 64: Consent form - The usability of a health literacy education package – views of pharmacists and pharmacy assistants (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

or email to glen.swinburne@monash.edu

Thank you for your participation

Appendix 65: Human Research Ethics approval - The usability of a health literacy education package – views of pharmacists and pharmacy assistants (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 66: Human Research Ethics approval - The usability of a health literacy education package – views of pharmacists and pharmacy assistants (Curtin University)

Curtin University

Memorandum

Faculty of Health Sciences

School of Pharmacy

TELEPHONE 9266 7418
FACSIMILE 9266 3793
EMAIL A.J.Smith@curtin.edu.au

To	Lynne Emmerton
From	Alison Smith, Form C Coordinator
Subject	Protocol Approval PH-26-13
Date	14th January 2014
Copy	Elsamaul Elhebir, Jeff Hughes, Moyez Jiwa, Kreshnik Hoti

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,

Alison Smith
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.

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