Mobile Technology and Health Literacy Regarding Medication Information

by

Huda Wali

A thesis

presented to the University of Waterloo

in fulfillment of the

thesis requirement for the degree of

Master of Science

in

Pharmacy

Waterloo, Ontario, Canada, 2015

Author's Declaration

I hereby declare that I am the sole author of this thesis. This true copy of the thesis, including any required final revisions, as accepted by my examiners.

I understand that my thesis may be made electronically available to the public.

Abstract

Low health literacy is one of the main barriers to medication adherence. People with low literacy often have difficulty understanding health information and making appropriate health decisions. Currently, medication information is presented to populations with low health literacy in a way that is difficult to understand. On average, individuals with low health literacy can read at a fifth-grade level, while medication information tends to be presented in a manner targeted for individuals who can read at a tenth grade level. With current medication information too difficult to understand, low health literate populations are at a higher risk of misinterpreting prescription label instructions, dosage, duration, frequency, warning labels, written information and verbal pharmacist counseling. Therefore, pharmacists need to provide medication information that can be understood by individuals with low health literacy and is also adopted into a busy pharmacy practice. The objectives of this thesis included the following: 1) To systematically review the evidence on interventions for improving medication knowledge and adherence for low health literate populations, 2) To explore the major challenges low health literate adults face when trying to understand their medication therapy. 3) To design an innovative medication counseling tool that improves the medication knowledge of patients with low health literacy.

Acknowledgement

First and foremost, I would like to thank my supervisor, Dr. Kelly Grindrod, for her continual guidance and support. The accomplishments that I have achieved over the past two years serve as a testament of her mentorship. I would like to thank my advisory committee members, Bruce Baskerville and Eric Schneider, for their feedback and input throughout my masters. I would also like to thank my family for their unconditional love and support through the entire process. I am truly blessed to have you all.

"You are not a drop in the ocean, you are the entire ocean in a drop.

~Rumi

Table of Contents

List of Figures

List of Tables

List of Abbreviations

AHRQ	Agency for Healthcare Research and Quality
COREQ	Consolidated criteria for reporting qualitative research
CPHA	Canadian Public Health Association
ED	Emergency department
HON	Health On the Net
IPA	International Pharmaceutical Abstract
mAMS	Medication Adherence Measurement System
mHealth	Mobile health
NFC	Near-field communication
NRCT	Non-randomized controlled trial
NVT	Newest Vital Sign
PIAT-R	Peabody Individual Achievement Test
RCT	Randomized controlled trial
STOFHLA	Short Test of Functional Health Literacy in Adults
TOFHLA	Test of Functional Health Literacy in Adults
UCT	Uncontrolled trial
WHO	World Health Organization

Chapter 1.0: Health literacy introduction

Health literacy, a patient's ability to obtain, read and understand medication information to make appropriate health decisions, should be a major consideration for pharmacists. As the role of the pharmacist evolves from filling prescriptions and counseling to delivering patient-centered care, pharmacists need to be able to ensure patients can understand and self-monitor medication. People make choices about their medication on a daily basis. Approximately half of North Americans use at least one prescription medication and a startling 53% of seniors living in institutions and 13% living in communities take five or more medications.[1,2] At home, the patient's understanding of medication information is essential to ensure accurate medication regimens are followed.[3] Therefore, good communication between pharmacists and patients is fundamental for the safe and effective use of medications.[1,2]

1.1. Health Literacy and Medication Information

On average, individuals with low health literacy can read at a fifth-grade level, while medication information tends to be presented in a manner targeted for individuals who can read at a tenth grade level.[4] With current medication information too difficult to understand, low health literate populations are at a higher risk of misinterpreting prescription label instructions, dosage, duration, frequency, warning labels, written information and verbal pharmacist counseling.[5] Patients who struggle to understand medication information are more likely to be unable to self-manage their health and make appropriate health decisions.[6] There is a clear gap between the levels of skill required to understand current medication information and the actual level of understanding among low health literate populations.

Health literacy is essential for individuals to confidently understand, act and communicate personal medical needs and maintain good health.[1] Adequate health literacy allows people to self-manage their health and to apply health information on a daily basis.[6] Health literacy differs from general literacy because it involves the simultaneous ability to read, understand health instructions and to communicate medical information.[7]

1.2. Prevalence of Health Literacy

In recent years, there has been an increasing interest in health literacy due to the large number of individuals with low health literacy.[5-7] In Canada, 60% of adult Canadians do not have the ability to obtain, understand and act on health information.[8] In the United States, 35% of adults have difficulties understanding, interpreting and applying health information.[9] Similarly, one third of older adults in England have problems understanding and comprehending basic health information.[10] There is an increasing concern that low-income adults, ethnic/racial minorities and seniors in North American have the highest prevalence of low health literacy.[11]

1.3. Health literacy Associated Health Outcomes

Low health literacy is not only highly prevalent but also associated with poor health outcomes, higher hospitalization rates, higher risk of mortality, greater chance of medication errors and lower rates of treatment adherence.[5] Additionally, a systematic review found low health literacy to be responsible for an additional 3 to 5% of total annual health-care costs.[12] A study conducted by Schillinger et al. in 2002 explored the relationship between health literacy and health outcomes among patients with type 2 diabetes.[13] After controlling for socio-demographic characteristics, depressive symptoms, social support, treatment regimen and years with diabetes, lower health literacy scores

were independently correlated with poorer glycemic control, where people with low health literacy were twice as likely to have poor glycemic control (OR=2.33, p=0.02) compared to people with adequate health literacy scores.[13]

1.4. Improving Health Literacy

The World Health Organization (WHO) has identified health literacy as one of the main patient-related factors associated with non-adherence and argue that interventions targeted to improve adherence will positively affect the health of patients more than other interventions.[11, 14] For this reason, the safety of patients with low health literacy is a primary goal and there is an immediate need to develop effective solutions to improve medication information for this population.[11, 14]

1.5. Health Literacy Recommendations

The health literacy expert panel of the Canadian Public Health Association (CPHA) envisions all Canadians as having the capacity and support to obtain and accurately use health information for the self-management of health.[15,16] The expert panel recommended three goals for improving health literacy and attaining the health literacy vision: 1) to improve health literacy skills in Canada, 2) to reduce health inequalities found in seniors, ethnic/racial minorities, and low-income families by developing health literacy skills, and 3) to provide health information and services for people at all levels of health literacy.[16] Both the CPHA and WHO indicate the importance of health literacy and recommend developing health information that meet the needs of all population groups.[16, 17]

1.6. Thesis Objectives & Hypothesis

Given the need for improved medication information, there is a clear gap between the level of ability required to understand current medication information and the level of understanding that is present among the low health literate population. The objectives of this thesis included the following:

1) To systematically review the evidence on interventions for improving medication knowledge and adherence for low health literate populations;

2) To explore the major challenges low health literate adults face when trying to understand their medication therapy;

3) To design an innovative medication counseling tool that improves the medication knowledge of patients with low health literacy.

1.7. Conclusions

The notion of communicating information in a "one size fits all" approach does not consider individuals who have different learning needs, abilities and preferences, especially when that one size is meant for patients with adequate health literacy levels.[14] There is a need for novel methods for conveying medication information that is understandable and usable for all individuals.

1.6 References

1. Ramage-Morin PL. Medication use among senior Canadians. Healh reports Statistics Canada, 2009;20:37-44.

2. Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. J Am Pharm Assoc, 2001;Mar-Apr;41(2)192-9.

3. Marvanova M, Roumie CL, Eden SK, Cawthon C, Schnipper JL, Kripalani S. Health literacy and medication understanding among hospitalized adults. J Hosp Med. 2011;6:488-493. doi:10.1002/jhm.925.

4. Safeer RS, Keenan J. Health literacy: The gap between physicians and patients. Am Fam Physician. 2005;72:463-468.

5. Nielsen-Bohlman L, Panzer AM, Kindig D. Health Literacy: A Prescription to End Confusion. Heal San Fr. 2004:368.

6. Brown MT, Bussell JK. Medication adherence: WHO cares? Mayo Clin Proc. 2011;86:304-314. doi:10.4065/mcp.2010.0575.

7. Zarcadoolas C, Pleasant A, Greer DS. Understanding health literacy: An expanded model. Health Promot Int. 2005;20:195-203. doi:10.1093/heapro/dah609.

8. Canadian Council on Learning. Health Literacy in Canada. Rep Learn Canada. 2007;1-34.

9. Kirsch I. Adult Literacy in America: A First Look at the Results of the National Adult Literacy Survey.; 1993. doi:NCES 1993-275.

10. Bostock S, Steptoe A. Association between low functional health literacy and mortality in older adults: longitudinal cohort study. BMJ. 2012;344:e1602-e1602. doi:10.1136/bmj.e1602.

11. Kickbusch I, Pelikan J, Apfel F, Tsouros A. Health literacy: the solid facts. Copenhagen WHO Reg Office for Europe. 2013:7-8

12. Eichler K, Wieser S, Brügger U. The costs of limited health literacy: a systematic review. Int J Public Health. 2009;54:313-324. doi:10.1007/s00038-009-0058-2.

13. Schillinger D, Grumback K, Piette J, Wang F, Osmond D, Daher C et al. Association of health literacy with diabetes outcomes. - JAMA. 2002;31;288(4)475-82.

14. De Geest S, Sabaté E. Adherence to long-term therapies: Evidence for action. Eur J Cardiovasc Nurs. 2003;2:323. doi:10.1016/S1474-5151(03)00091-4.

15. Manzano AT, Raphael D. CPHA and the social determinants of health: An analysis of policy documents and statements and recommendations for future action. Can J Public Heal. 2010;101:399-404.

16 Rootman I, Gordon-El-Bihbety D. A Vision for a Health Literate Canada: Report of the Expert Panel on Health Literacy. Ottawa, Ontario: Canadian Public Health Association, 2008

17. Sabaté E, . Adherence to long-term therapies: Evidence for action. Geneva, Switzerland: World Health Organization. 2003

Chapter 2.0: A systematic review of interventions to improve medication information for low health literate populations

2.1. Introduction

Health literacy has gained considerable attention in recent years for improving medication infromation.[1-17] To our knowledge, there are no systematic reviews that have explored interventions targeted to improving medication information for low health literate populations. Previous systematic reviews on health literacy interventions have explored the positive association with health literacy and diabetes knowledge [18], the effectiveness of interventions to improve health literacy [19] and the association between low health literacy and poor health outcomes.[20] Therefore, the primary objective of this paper was to systematically review the evidence on interventions for improving medication knowledge and adherence for low health literate populations. Secondary objectives were to identify different categories of medication information intervention, to identify strategies used by effective interventions and to review the effect of interventions on clinical outcomes and user experience.

2.2. Material and Methods

In preparing this review, the methods outlined in the *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0,* and the 27-item Preferred Reporting Items for Systematic Reviews and Meta-Analyses checklist (PRISMA) was followed, to ensure transparent and complete reporting.[21, 22]

2.2.1. Criteria for considering studies for this review

2.2.1.1. Types of Intervention Studies

Interventions focused on using domains of health literacy to improve medication knowledge and/or adherence was included. Studies were included if they explicitly stated they included low health literate populations, included outcome measures for knowledge and/or adherence, focused on medication information, were written in English and were available in full text. When full text articles were not available, one author (HW) contacted the researcher and requested full text access. All study designs, including randomized controlled trials (RCT), non-randomized controlled trials (NRCT) and uncontrolled trials (UCT) were included. In order to define the health literacy of medication information for the inclusion criteria, four domains of health literacy were adapted, as described by the Institute of Medicine expert panel to medication information.[23] These included:

1) Cultural and conceptual knowledge: the understanding medication information
2) Oral literacy: the ability to listen to and communicate medication information
3) Print literacy: the ability to read and understand written medication information
4) Numeracy: the ability to understand numbers associated with the dosage, directions, quantity of medications and refills.

Full text papers were excluded if there was no clear mention of an intervention being studied, if the intervention had no focus on any of the domains of health literacy, if there was no measure of medication knowledge or adherence and if the authors did not specify the inclusion of patients with low health literacy.

2.2.1.2. Types of Participants

Currently, there is no gold standard for identifying patients with low health literacy. Studies were included if they identified at least one of the following measures of low health literacy: written assessments, verbal assessments and demographic characteristics was included. Written assessments of health literacy are the most common method of determining health literacy levels.[24] Written assessments consist of a set of questions for which an individual must provide a written answer within a specified time restriction. Examples include the Rapid Estimate of Adult Literacy in Medicine (REALM) [24], the Test of Functional Health Literacy in Adults (TOFHLA) [24], the Short-Test of Functional Health Literacy in Adults (STOFHLA) [24], Peabody Individual Achievement Test (PIAT) and the Newest Vital Sign (NVS).[25] Verbal assessments are a quick method of determining health literacy level and typically consist of oral questions that are answered using a 5-point Likert scale to identify a patient's self-assessed health literacy level.[26, 27] The demographic characteristics most associated with low health literacy include belonging to an ethnic/racial minority, older age, low household income and low education.[11]

2.2.2 Types of Outcome Measures

2.2.2.1. Primary Outcome Measure

The primary outcome measures were the improvement in medication knowledge and the improvement in medication adherence. Medication knowledge was determined through verbal or written questionnaires and surveys. Pill counts, prescription records, patient self-report and electronic devices such as smart pill vials were used to determine adherence.

2.2.2.2. Secondary Outcome Measures

The secondary outcome measures included clinical outcomes measures, user experience and preference. Clinical outcome measures were included to provide empirical evidence for effective interventions. Examples of clinical outcome measures include blood pressure, cholesterol, hemoglobin A1c, asthma control, weight loss, Body Mass Index (BMI), hospitalization and death. User experience and user preference provide information on what aspects of the intervention the user likes, wants and needs and include satisfaction, practicality, usage and acceptability of the intervention.

2.2.2.3. Search Methods For Identification of Studies

A health librarian assisted in identifying existing literature on health literacy and medication information for low health literacy populations. PubMed, Embase, International Pharmaceutical Abstracts (IPA), Web of Science, Cochrane Library, CINAHL, PsycINFO, and Scopus was searched from the start of each database to studies published before March 30, 2015. For the search strategy, the combination of the words "medication adherence," "health literacy," "medication information," including the corresponding MeSH terms. The reference lists of the literature found in the database search were hand searched for any remaining articles. To identify grey literature, the Google search engine was searched using the same methods and terms described above. An example of the search strategy includes the following:

(Medication adherence OR medication non adherence OR medication non-adherence OR medication compliance OR drug adherence OR drug non adherence OR drug non-adherence OR drug compliance OR patient adherence OR patient non adherence OR patient non-adherence OR patient compliance OR medication non compliance OR medication non adherence OR drug non compliance OR drug non-compliance OR patient non compliance) AND (Health literacy OR health literate OR medical literacy OR medication literacy OR low health literacy OR low health literate OR literacy OR illiterate OR functional literacy OR functional health literacy OR adult literacy OR patient literacy OR drug literacy OR patient understanding OR patient knowledge) AND

(medication information OR prescription information OR drug information OR verbal information OR oral information OR written information OR patient information OR health education OR health knowledge OR pharmacy counseling OR communication OR health information OR medical information OR pharmacy information OR pharmacy OR prescription OR medication OR drug OR pharmacist-patient OR pharmacist patient OR patient-pharmacist OR patient pharmacist)

2.2.3. Data Collection and Analysis

2.2.3.1. Selection of Studies

One author (HW) performed the search and combined all database titles into RefWorks 2.0 and removed all duplicates. All database titles were transferred into Mendeley, where three authors (HW, KG, ZH) reviewed 10 randomly selected titles as a group, to clarify any uncertainty with the inclusion/exclusion criteria. After all reviewers were certain with the inclusion/exclusion criteria, all three reviewers independently screened titles, abstracts and full text papers. The authors were not blind to any of the journal articles' information. Conflicts in evaluating articles for inclusion were resolved through a discussion between reviewers.

2.2.4. Data Extraction and Management

The following data were extracted from each included article: author, publication year, country, study design (type randomization, sample size), objective, subjects (gender, age, ethnicity/race, income, health literacy, education), health literacy assessment tool, intervention characteristics (type, passive or active, technology based) outcome measure, outcome effectiveness.

Using thematic analysis, all studies interventions were coded with NVivo 10 (QSR International Pty Ltd) by first identifying the intervention, comparing the types of

intervention and categorizing interventions into themes. A similar method was used to identify strategies used to create an effective intervention. To reduce the risk of bias, data extraction was confirmed by a second reviewer.

2.2.4.1. Assessment of Risk of Bias in Included Studies

Bias was assessed using the Cochrane Handbook for Systematic Reviews interventions.[28] In total, five strategies to reduce bias were assessed including random sequence generation/allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias) and selection reporting (reporting bias).[28] Review Manager (RevMan 5.2) was used to determine the risk of bias, where each study was assigned to be either low or high risk of bias based on the above characteristics.

2.3. Results

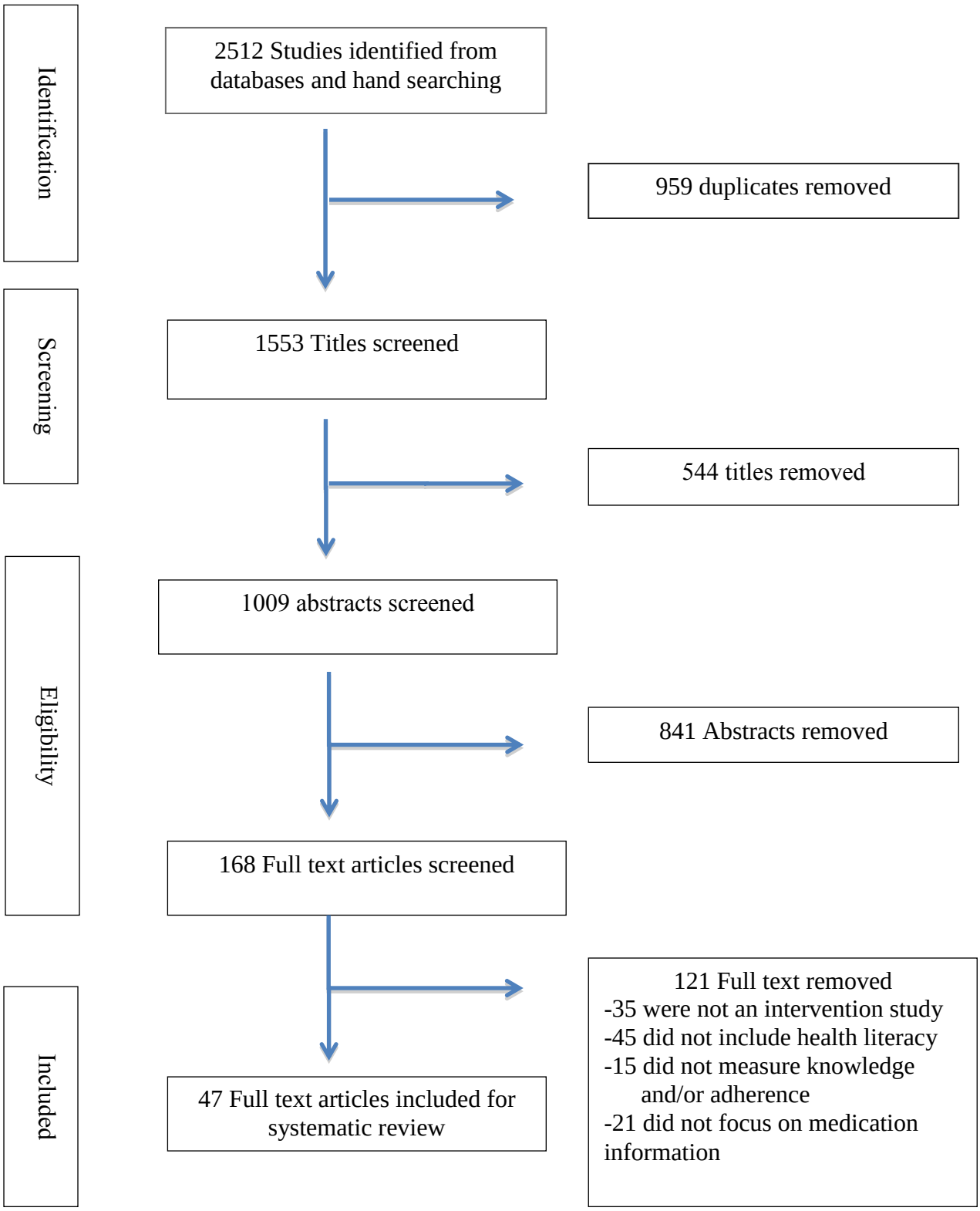
2.3.1. Characteristics of reviewed studies

The review identified 1553 titles, 1009 abstracts, 160 full text articles and included 47 full text articles for review (Figure 2.1). The inter-rater agreement for included abstracts was 97.2% and for included full text articles was 98.5%. The 47 intervention studies included 27 randomized controlled trials, 8 non-randomized controlled trials and 12 uncontrolled trials (Table 2.1). Of the 47 included studies, 70.2% (33/47) were published in the United States and 87.2% (41/47) were published between 2005 and 2014. A variety of different tools were used to assess health literacy. After assessing for risk of bias, 27/47 studies were at low risk, 8/47 studies were of moderate risk and 12/47 studies were at risk of bias.

2.3.1.1. Health literacy assessment and demographic characteristics

To measure health literacy, 51% (24/47) of studies used the REALM or STOFHLA/TOFHL. Other verbal assessments, which include the newest vital sign (NVS), readability assessments, Peabody Individual Achievement Test (PIAT-R) and three-item health literacy-screening test accounted for 12.7% (6/47) of studies. A total of 36.2% (17/47) of included studies relied on the four main demographic characteristics of low health literacy (older age, ethnic minority, lower income, lower education) to identify low health literacy. As outlined in Table 2.2, all studies used an objective measure of health literacy also included at least 2 of the higher risk populations. Twenty-eight studies reported on at least two of the four characteristics [29, 34, 37-39, 40, 41, 43-45, 47, 49, 50-53, 57, 58, 60-63, 65, 66, 68, 69, 71, 75], 9 reported on at three of the four characteristic. [34, 37- 40, 52, 61, 71, 75], and 3 reported on all four demographic characteristics [45, 47, 65]. Furthermore, 28 of the 30 studies did not provide detailed information and therefore may have been missing data in the results.

Figure 2.1: Systematic Review Flow Chart



2.3.2. Categories of interventions

Figure 2.2: Categories of medication information interventions

1. Written Information	Information expressed in writing	Patient information leaflet
2. Visual information	Information expressed with picture elements	Pictograms
3. Audible/verbal information	Information that expressed in spoken words	Counseling
4. Label information	Information expressed on medication bottle	Simplified medication instructions
5. Reminder systems	Serves to remind patients about important medication information	Automated telephone reminder
6. Educational programs/service	A plan or schedule of action for a specific period of time	Pharmacy based program

2.3.2.1. Effect of interventions

Overall, of the 47 studies included in the review, 37 interventions [29-32, 34, 35, 36-40, 42, 43, 45-48, 50-52, 54, 55, 56-60, 62, 63-69, 71, 73, 74] provided information on knowledge and 26 interventions provided information on adherence. [30, 31, 33, 34, 37, 40, 41, 43, 44, 45, 48, 49, 53, 54, 55, 57, 61, 63-65, 68, 70-73, 75] There was a significant improvement in knowledge in 27 studies, [30-32, 34, 35, 36-39, 43, 45, 48, 52, 55, 58, 59, 62-71, 73, 74.] and a significant improvement in adherence in 19 studies. [30, 33, 34, 41, 45, 48, 49, 54, 55, 57, 61, 63-65, 68, 70-73, 75]

Six different types of medication information interventions were identified. The most common type of intervention was written information, followed by visual, verbal, educational programs/services, reminder systems and medication label information. Interventions were able to fall into multiple categories because many include multidimensional strategies such as the combination of audible, visual and written

information. Including all categories applicable to the intervention provided a better description of the intervention.

2.3.2.2. Written information

The 41 intervention studies of written medication information included patient-centered prescription instructions, culturally tailored information, worksheets, brochures, leaflets, booklets, personalized feedback reports, illustrated medication schedules, pictograms, animated computerized text and graphics, educational board games, text messages, and information through videos, websites and software programs. Of the 31 studies that provided outcome data on patient knowledge [29-32, 34, 35, 37, 38, 39, 40, 42, 43, 45-48, 50-52, 54, 55, 56, 58, 59, 62, 64-67, 69, 71], 19 had a statistically significant improvement.[30-32, 34, 35, 38, 39, 43, 45, 48, 52, 55, 56, 58, 59, 62-67, 69, 71] Of the 22 studies that provided outcome data on adherence [30, 31, 33-35, 37, 40-42, 44, 45, 48, 49, 53, 54, 55, 61, 64, 65, 70-72, 75], 15 studies showed a statistically significant improvement on adherence.[30, 33, 34, 41, 45, 48, 49, 54, 55, 61, 64, 65, 71, 72, 75]

2.3.2.3 .Visual information

The 36 studies categorized as visual interventions included pictograms, color coded medication bottles, symbols label systems, illustrated medication schedules, culturally tailored visual aid, pamphlets, leaflets, animated audio booklets, educational videos, computerized programs and websites with graphics, animations and videos. Of the 27 studies that provided information on knowledge [31, 32, 34-36, 39, 40, 42, 43, 45, 47, 48, 50, 51, 52, 55, 58, 59, 62-66, 68, 71, 74], 21 had a statistically significant improvement. [31, 32, 34-36, 39, 43, 45, 48, 52, 55, 58, 59, 62-66, 68, 71, 74] Of the 22 studies provided information on adherence [31, 33, 34, 37, 40-42, 45, 48, 49, 53, 55, 57, 61, 63, 64, 65, 68, 70, 71, 72, 75], 16 had a statistically significant improvement.[33, 34, 41, 45, 48, 49, 55, 57, 61, 63, 64, 65, 68, 71, 72, 75]

2.3.2.4. Verbal information

The 36 studies of audible information included health coaching, outpatient consultation services, audio booklets, interactive voice response calls (IVR), culturally and patient-centered tailored videos, websites, multimedia educational programs and pharmacy counseling through standard counseling, medication reviews, phone counseling, personalized educational programs, and teach-back method. Of the 27 studies that provided information on knowledge improvement [29-32, 34, 35, 39, 42, 43, 45, 47, 48, 52, 54, 55, 56, 59, 60, 62-65, 67, 69, 71, 73, 74], 22 studies had a statistically significant improvement.[30-32, 34, 35, 39, 43, 45, 48, 52, 55, 56, 59, 62-65, 67, 69, 71, 73, 74] Of the 21 studies that provided data on adherence [30, 31, 34, 41, 42, 45, 48, 49, 52-55, 57, 61, 63-65, 70-73, 75], 17 studies had a significant improvement.[30, 34, 41, 45, 48, 49, 54, 55, 57, 61, 63, 64, 65, 71-73, 75]

2.3.2.5. Label/ medication bottle

The 6 studies categorized as prescription labels or medication bottles included medication bottle colors, label systems, prescription label instructions, pictograms, patient centered instructions and prescription label design. Of the 5 studies that assessed knowledge [36, 38,40, 56, 66], 4 studies had a statistically significant improvement.[36, 38, 56, 66] Of the 2 studies that provide data on adherence [40, 61], 1 study had a statistically significant improvement.[61]

2.3.2.6. Reminder systems

The 15 studies categorized as medication reminder systems included interactive voice response (IVR) calls, automated telephone reminder system, text messages, electronic blister pack, personalized medication schedule, medication adherence action plan, and medication technology. Of the 8 studies that assessed knowledge [37, 39, 45, 48, 51, 52, 56, 59], 6 studies had a statistically significant.[39, 45, 48, 52, 56, 59] Similarly, of the 10 studies that

provided information on adherence [33, 37, 44, 45, 48, 53, 57, 72, 75], 7 studies reported a statistically significant improvement.[33, 45, 48, 49, 57, 72, 75]

2.3.2.7. Educational programs/services

The 17 intervention studies classified as educational programs and services included, in person and Internet based self-management program, pharmacist initiated education intervention, personalized and multimedia educational programs, nurse delivered home visits and outpatient consultation services. Of the 17 studies, 11 provided data on knowledge [31, 39, 42, 48, 52, 54, 55, 62, 63, 71, 73], of which 9 had a statistically significant improvement.[31, 39, 48, 52, 55, 62, 63, 71, 73] Of the 14 studies that provided data on adherence [31, 33, 41, 48, 49, 54, 55, 57, 63, 70-74], 12 studies reported a statistically significant improvement.[33, 41, 48, 49, 54, 55, 57, 63, 71-74]

2.3.3. Other intervention characteristics

2.3.3.1. Active versus passive interventions

Active interventions were defined as strategies that attempt to change a behavior or thinking of an individual through patient involvement. Passive interventions were defined as strategies where a patient is not required to participate or respond to the intervention. An example of an active intervention is an educational program and an example of a passive intervention is a set of simplified medication instructions.

2.3.3.2. Active interventions

Of the 21 active interventions studies that reported data on knowledge [31, 32, 34, 35, 39, 42, 43, 45, 48, 52, 54, 55, 60, 62, 63, 64, 65, 67, 69, 71, 73], 17 had a statistically significant improvement.[31, 32, 34, 35, 39, 43, 45, 52, 54, 55, 62-65, 67, 69, 71, 73] Of the 21 studies that provided data on adherence [31, 33, 34,

[41, 42, 44, 45, 49, 53-55, 57, 61, 63-65, 70-73, 75], 16 studies had a statistically significant improvement.[33, 34, 41 45, 49, 54, 55, 57, 61, 63-65, 71-73, 75]

2.3.3.3. Passive interventions

Of the 15 passive intervention studies that included information on knowledge [29, 30, 36-38, 40, 46, 47, 50, 51, 56, 58, 59, 65, 74], 8 studies had a significant improvement.[30, 36, 38, 56, 58, 59, 65, 74] Of the 5 passive intervention studies that reported information on adherence [30, 37, 40, 65, 70], 2 studies had a significant improvement.[30, 65]

2.3.3.4. Language

Four studies provided bilingual information for individuals who speak English as a second language through a variety of interventions that included a website, audio booklet, health coach and bilingual health care professional.[41, 43, 60, 68] In all four studies information was translated into Spanish [41, 43, 60, 68] and in one of these studies also included a second translation into Cantonese.[68] Of the three language studies that provided data on knowledge, two showed a significant improvement.[43, 68] Of the two studies that included adherence, all two studies demonstrated a statistically significant improvement.[41, 68]

2.3.3.5. Innovative technology

Of the 47 studies in the review, 17 studies examined a digital technology in the intervention, which included telemonitoring devices, electronic blister packs with Near Field Communication (NFC) chip, handheld reminders, medication watch alarms and personalized medication schedule digital videos, multimedia education programs and audio booklets.[31, 33, 34, 41, 42, 43, 44, 49, 62, 65, 68, 69, 70, 72, 74, 75] Newer digital interventions focused on the portability and accessibility often seen with mobile technology.[33] For

example, one study examined the use of mobile technology with the combination of an NFC chip on a electronic blister pack, where patients were reminded to take their medication through a text message if the medication was not taken out of the blister pack.[33] Additionally, audio booklets and personal digital assistant videos were highly desired by patients because they believed audible and visual information made the content more clear and assisted in recalling medication information.[33, 34] Furthermore, a touch screen Personal Education Program found participants appreciated and were highly satisfied with animated and graphical information and found the program simple to use.[62,69]

2.3.4. Strategies of effective interventions

After thematic coding, 4 strategies were categorized as effective and patient-preferred interventions:

1) Additional aids to enforce written information;
2) Personalized information;
3) Ease of Navigation, and;
4) Accessibility.

2.3.4.1. Additional aid to enforce written information

Interventions that included additional sources of information, such as graphics, pictograms, icons, animations and verbal counseling in combination with written information were categorized as effective strategies for a health literacy intervention.[30, 39, 41, 48, 49, 52, 64-67, 74] A study conducted by Sahm et al. found the combination of written medication instructions with a graphical aid assisted in the accurate understanding of instructions.[66] Visual aids provide an illustrated representation of medication information

and help individuals gain interest in information. Among the low health literate populations, written information with the combination of verbal communication or narration helped patient understanding.[43, 54, 55] Savas et al. found that the combination of written and verbal information was significantly more effective than either strategy alone ($p<0.0001$).[67] The participants strongly believed that the combination of engaging information and pictograms improved their knowledge of their medications.[34, 50, 52]

2.3.4.2.. Personalized information

Individually tailored information is also an effective strategy.[39, 42, 48, 52, 54] Tailored information ensures the needs of an individual are met, and that all material given is applicable. Lefante et al. found that medication reviews are an effective intervention provided they last an average of 30-minutes, are delivered through a one-on-one patient-to-pharmacist interaction and are focused on helping patients understand their medications.[54]

2.3.4.2. Ease of Navigation

The ability to easily navigate through information was categorized as a strategy for successful interventions. Formats that improve navigation include bullets, subheadings, icons, bolding, underlining, larger font size and shorter words.[29, 43, 53, 58, 62, 65, 66] Aker et al. developed an improved format of written patient information with the use of icons, subheadings, bolding, underlining and larger font size and found the navigation time decreased from 59 seconds with the standard material to 22-23 seconds for the improved material.[29] Additionally, the Personal Education Program was an excellent example of simple navigation.[62] The program provided users with an interactive touch-screen computer program and allowed users to have full control over what information they

would like to access by simply touching clearly labeled information.[62] The Personal Education Program was used to teach older adults from senior programs about drug interactions with over-the-counter medications and significantly improved knowledge and participant satisfaction.[62]

2.3.4.3. Accessibility

Interventions that provided participants with information that they can have access to when needed was categorized as a strategy for an effective intervention.[32, 36, 51, 55, 72] For example, Kripalani et al. developed illustrated medication schedule called a "pill card" that participants were given to take home and refer to when needed.[51] Participants would carry the information in their purse or wallet and post it on the refrigerator.[51] Additionally, having access to information at home also improved patient knowledge scores ($p<0.001$) better than information only received through counseling and visual aids.[32] Automated telephone reminder systems were also effective and beneficial to help patients remember to refill their medications and provided patients with the option of refilling medication in advance to avoid long wait times in the pharmacy.[52,72]

2.3.5. Clinical outcome measure

Clinical outcome measures were provided by 9 out of 47 intervention studies and included blood pressure, cholesterol, hemoglobin A1c, asthma control, body mass index (BMI), hospitalization and death.[33, 39, 41, 42, 60, 61, 62, 72, 75] Of the nine studies, six reported an improvement in clinical outcomes.[33, 39, 42, 60, 61, 75] Brath et al. found that an electronic blister pack improved blood pressure and total cholesterol ($p<0.02$).[33] Neafsey et al. found that a four-visit personal education program improved blood pressure for 82% of participants.[62] A health coaching intervention had a 0.9% decrease in HbA1c% [60], while a

videotape education program increased weight loss without a significant change in hemoglobin A1c.[59] Goeman et al found that a face-to-face education intervention for asthma improved asthma control ($p<0.02$) in a 2-month period and had a higher level of improvement over a 12-month period ($p<0.001$).[42] In a 12-month randomized control trial of a primary care based self-management heart failure program, there were 42 fewer hospitalizations and one less death compared to usual care.[39] Similarly, another 12-month randomized control trial of a pharmacy-based program for patients with heart failure found a 19.5% reduction in emergency visits in the treatment group compared to usual care.[61]

2.4. Discussion

The present review was designed to determine the evidence on interventions for improving medication knowledge and adherence in low health literate populations. Overall, of the 47 studies included, 37 studies assessed knowledge and 26 assessed adherence. In total, 27 of the 37 studies assessing knowledge and 19 of the 26 studies assessing adherence found that the interventions had a statistically significant effect. This review demonstrates that interventions targeting low health literate population improve medication knowledge and adherence. Furthermore, the reviewed studies also show that interventions targeting low health literate populations benefit populations with moderate and adequate health literacy.

After thematic analysis, the interventions fell into six categories of medication information: written information, verbal information, label information, reminder systems, and educational program/services. There are variety of different types of initiatives focused on improving patient knowledge and adherence**.** Written information

was the most commonly used intervention and may be explained by the fact that current pharmacy practice legally requires pharmacies to provide patients with written medication information.

The results of this study also identified four strategies that were both effective and strongly preferred by patients, including additional aids to enforce written information, personalized information, ease of navigation and accessibility. People with low health literacy face challenges with interpreting, accessing and exchanging health information in consultation with healthcare providers.[1] The most effective interventions are tailored interventions that tackle barriers to health literacy. Individuals with low health literacy often feel social stigma because of their difficulties understanding medication information due to possible barriers such as language, culture, accessibility and disability. Low health literate individuals may also feel like a burden to the health system and may be too ashamed to seek clarification from the pharmacist. Therefore creating information that addresses the barriers low health literate patient face may support individual self-efficacy in these populations.

In the review four studies translated medication information to remove any language barriers for patient.[41, 43, 60, 68] However, translating medication information is not always practical or feasible. Challenges to translating information include finding equivalent terms in the translated language, translating information to a similar reading level, accounting for the numerous dialects and regional differences, and accounting for changes with label spacing and formatting.[5]

Medication adherence is a complex issue and education alone is not sufficient for positive long-term effects.[7] One of the main challenges is that physicians and pharmacists have difficulty identifying people who have low literacy.[12] While patients with low literacy are more likely to have difficulty reading medication bottles, and an estimated 50% of patients feel ashamed, do not seek assistance and often will not even inform their own family.[45, 46] It is an alarming notion that many people face challenges with their health information in secret and that this secrecy can negatively impact their health.

To improve the negative effects low health literacy imposes on medication adherence, a "shame free" and "blame free" environment must be established, where standard guidelines for obtaining information is provided to all individuals equally.[47] Patient counseling alone is not sufficient for improving medication adherence because patients recall only half of what was discussed.[46] Additional tools other than the traditional information provided by the pharmacist should be provided to patients to further aid their understanding of their medications. Given that 60% of the US population speaks English as a second language, an urgent intervention to improve medication information is needed to obtain the desired change in medication adherence.[12] Formal and intensive education programs, such as diabetes self-management education have been shown to improve medication adherence, but unfortunately program space and accessibility are a barrier to many patients.[47]

2.4.2. Limitations

One of the main challenges of a review of this nature is that the interventions are heterogeneous. The interventions included had a variety of different methods used to determine knowledge and adherence, which added to the heterogeneity of the review.

Currently, there is no gold standards for determining health literacy levels. Also, while the scope of the review was on health literacy interventions for adherence and knowledge, other outcomes such as medication errors were outside the scope of this review. Furthermore, 12 of the 47 studies identified were found to be at high risk of bias because the studies lacked the presence of a control group or follow-up. Additionally, there is no current standardized assessment for health literacy, but in this review the inclusion of a variety of different health literacy assessments was included to account for the variability.

2.5. Conclusions

Interventions designed to support low health literate populations can improve patients' medication knowledge and adherence. The most common interventions are written interventions but other effective strategies include visual information, verbal information, specialized labels, reminder systems and education programs. The most effective interventions include additional aids that enforce written information, information that is personalized, information that is easy to navigate and tools that can be accessed when needed.

Table 2.1: List of studies included in systematic review

Author	Year	Country	Study design	Setting	Sample size	Objective
Aker et al. [29]	2013	USA	NRCT	Research setting	105	To obtain consumer preferences to develop patient-friendly medication information.
Al-Saffar et al. [30]	2005	Kuwait	RCT	Hospital	278	To assess the acceptability and effectiveness of two educational initiatives on patterns of antidepressant medication use in Kuwait.
Boyne et al. [31]	2014	UK	RCT	Outpatient clinic	382	The aim of this prospective randomized multicentre telemonitoring study is to analyze the effects of telemonitoring on disease specific knowledge, self-efficacy, self-care and adherence.
Braich et al. [32]	2011	Canada	RCT	Across India	225	To examine the effectiveness of pictograms in educating low literacy patients to improve adherence to postoperative cataract regimens.
Brath et al. [33]	2013	Europe	RCT	N/A	53	To evaluate a mobile health (mHealth) based remote medication adherence measurement system (mAMS) in elderly patients with increased cardiovascular risk treated for diabetes, high cholesterol and hypertension.
Brock and Smith [34]	2007	UK	UCT	Outpatient clinic	51	To evaluate the effects of using an audiovisual animation displayed on a personal digital assistant (PDA) for patient education in a clinical setting.
Burghardt,et al. [35]	2013	USA	NRCT	Urban community pharmacy	185	To determine if the use of educational board games could impact community pharmacy patron intentions to seek pharmacist advice in an urban, minority, and economically- disadvantaged population.
Cardarelli et al. [36]	2011	USA	NRCT	Primary care clinics	100	To evaluate and refine an color-specific symbols system added to medication bottles and to evaluate the effectiveness with patients 65 years of age or older in identifying their medication.
Cordasco et al. [37]	2009	USA	RCT	Hospital discharge	210	To developed and evaluate a low-literacy medication education tool.
Davis et al. [38]	2008	USA	UCT	Hospital clinic	359	To describe dose and frequency of use for prescribed drugs could improve comprehension, especially among patients with limited literacy.
Dewalt et al. [39]	2006	USA	RCT	Hospital	123	To compare the effectiveness of a self-management program designed for patients with low literacy versus usual care in reducing hospitalizations and improve heart failure-related quality of life.
Dowse and Ehlers [40]	2005	South Africa	NRCT	Hospital discharge	87	To determine the influence of medicine labels incorporating pictograms on the understanding of instructions and on adherence.
Glasgow et al. [41]	2011	USA	RCT	Primary care clinic	270	The objective was to report on the use of the My Path/Mi Camino diabetes self-management website among a heterogeneous sample of adults with type 2 diabetes.
Goeman et al. [42]	2013	Australia	RCT	Home or hospital	123	To improve the asthma control and adherence to medication of older people using the Patient Asthma Concerns Tool (PACT) to identify and address unmet needs and patient concerns.

Gossey et al. [43]	2011	USA	RCT	Community health center	116	To determine the feasibility of the use of an audio booklet in a community health clinical setting with patients from a low health literate population.
Heinric and Kuiper [44]	2012	USA	UCT	Primary care	35	To examine adherence related to the use of handheld devices that delivered electronic medication reminders in a sample of adults experiencing a chronic illness.
Hussey [45]	1994	USA	UCT	Geriatric outpatient clinic	80	To evaluate the effectiveness of verbal teaching and of color-coded chart that had been designed to tailor medication regimen to elderly persons daily schedule
Jolly et al. [46]	1995	USA	NRCT	Inner-city university hospital	440	To determine whether improvements in comprehension can be achieved by simplification of available materials.
Joshi and Kothiyal [47]	2011	USA	UCT	Outpatient hospital	200	To determine whether these pictograms can be effectively understood by illiterate `patients, who otherwise cannot read the instructions given on their prescription order
Kalichman et al. [48]	2005	USA	UCT	HIV clinic	30	To develop and pilot-test a nurse-delivered counseling intervention designed to improve HIV treatment adherence among lower literacy adults receiving antiretroviral therapies
Kalichman et al. [49]	2013	USA	RCT	Aids services	446	To test the efficacy of a pictograph-guided adherence skills-building counseling intervention for limited literacy adults living with HIV.
King [50]	2012	USA	NRCT	Non-pharmacy education	161	The objective of this investigation was to assess whether short-term recall of pharmacy-generated prescription medication information could be enhanced in a low health literate sample through the use of symbols.
Kripalani et al. [51]	2007	USA	RCT	Inner city Primary care center	209	To describes the development, implementation, and preliminary evaluation of an illustrated medication schedule (a ‘‘pill card’’) that depicts a patient’s daily medication regimen using pill images and icons.
Kripalani et al. [52]	2012	USA	RCT	Tertiary care academic hospitals.	862	To determine the effect of a tailored intervention on the occurrence of clinically important medication errors after hospital discharge.
Kripalani et al. [53]	2012	USA	RCT	Primary care clinic	440	To test the effect of two low-literacy interventions (Illustrated medication schedule and refill reminder post card) on medication adherence
Lefante et al. [54]	2005	USA	UCT	N/A	844	To assess the impact of medication reviews on patient understanding, compliance, drug-drug and drug-disease interactions, and adverse events.
Magadza et al. [55]	2009	South Africa	UCT	Rhodes University	45	To investigated the effect of an educational intervention on selected hypertensive participants’ levels of knowledge about hypertension, their beliefs about medicines, and adherence to antihypertensive therapy.
Mansoor and Dowse [56]	2003	South Africa	RCT	Primary health care clinic	60	To design, develop, and evaluate a simple, understandable medicine label and patient information leaflet (PIL) for nystatin suspension, and to assess the effect of incorporating pictograms on understanding in low-literate participants.
McCarthy et al. [57]	2013	USA	RCT	Emergency department	3,984	To determine whether prescription information or services improve the medication adherence of emergency department (ED) patients.

Morrow et al. [58]	2005	USA	NRCT	Clinical setting	32	To investigated whether patient-centered instructions for chronic heart failure medications increase comprehension and memory for medication information in older adults diagnosed with chronic heart failure.
Morrow et al. [59]	2008	USA	RCT	Community setting	64	Whether an external aid (medtable) supports collaborative planning in the context of a simulated patient/provider task in which pairs of older adults worked together to create medication schedules.
Moskowitz et al. [60]	2013	USA	RCT	Clinic	299	To examine whether the effect of peer health coaching on hemoglobin A1c (A1c) is modified by characteristics that are known to be associated with diabetes control.
Murray et al. [61]	2007	USA	RCT	University-affiliated, inner-city, ambulatory care practice	314	To determine whether a pharmacist intervention improves medication adherence and health outcomes compared with usual care for low-income patients with heart failure.
Neafsey et al. [62]	2002	USA	RCT	N/A		To describe the effectiveness of a interactive multi- media software program called ‘‘Preventing Medicine Conflicts’’ to increase older adults’ knowledge of potential drug interactions arising from self-medication, increase their self-efficacy (confidence) in how to avoid such interactions, and decrease reported adverse self-medication behaviors.
Negarandeh et al. [63]	2013	Iran	RCT	Diabetes clinic	127	To explore the impact of pictorial image and teach back educational strategies on knowledge, adherence to medication and diet among patients with type 2 diabetes and low health literacy in Saqqez, Iran.
Ngoh and Shepherd [64]	1997	USA	RCT	Health centers	78	To examine the use of Western Medications in three communities in Mezam division in the North-West province of Cameroon.
Poureslami et al. [65]	2012	Canada	RCT	University-based pulmonary medicine clinic.	85	To explore the effectiveness of different formats of culturally relevant information and its impact on asthma patients’ self-management within the Punjabi, Mandarin, and Cantonese communities.
Sahm et al. [66]	2012	USA	RCT	Outpatient clinic	94	To assess the efficacy of patient-centered label (PCL) instructions on the knowledge and comprehension of prescription drug use compared to standard instructions.
Savas and Evcik [67]	2001	Turkey	RCT	Outpatient clinic	91	The aim of our study is to evaluate the effect of written information in improving the knowledge of the undereducated nonsteroidal anti-inflammatory drug (NSAID) users about the side effects of NSAIDs and to investigate the compliance of patients with the written information materials.
Schillinger et al. [68]	2005	USA	UCT	Hospital clinic	220	To explore whether concordance rates vary when patients report their regimen verbally or identify their regimen by use of a visual aid
Tait et al. [69]	2012	USA	UCT	Health care	200	To evaluate and compare subjects’ understanding and perceptions of risks and benefits presented using animated computerized text and graphics.
Unk and Brasington [70]	2014	USA	RCT	Rheumatology clinic	98	To use a multimedia modality to improve medication adherence of patients with rheumatoid arthritis.
Van Servelle et al. [71]	2005	USA	RCT	Community based clinic	85	The effects of a treatment adherence enhancement program on health literacy, patient-provider relationships, and adherence to highly active antiretrovirus therapy (HAART) in a population of low income Spanish-speaking Latinos receiving antiretroviral therapy in com- munity-based clinics.

Wang et al. [72]	2010	USA	RCT	HIV/AIDS treatment sites, including	116	To examine the effects of nurse-delivered home visits combined with telephone intervention on medication adherence, and quality of life in HIV-infected heroin users.
Watanabe et al. [73]	2012	Japan	NRCT	Outpatient from hospital	38	To examine the effectiveness of the Donepezil Outpatient Consultation Service .
Wong [74]	2006	USA	UCT	Hospital	34	To examine if culturally sensitive audiovisual patient education program would be of substantial and measurable benefit in increasing patient understanding of the concepts of antiretroviral medication resistance risk and medication-taking skills.
Zullig et al. [75]	2014	USA	UCT	Hospital-based primary care clinics	23	To determine whether antihypertensive medication adherence could improve using a Meducation1 technology health literacy intervention.

*Note sample size is population that completed the study
*RCT=Randomized control trials, NRCT=Non-randomized control trials, UCT= Uncontrolled-trials

Table 2.2: Health literacy assessment tool inclusion of low health literate demographic characteristics

Author	Low Health Literacy Risk Factors				Health literacy assessment tool	Health literacy prevalence	Number of demographic included in low health literacy population
	50+ in Age	Ethnic minority	Low Income	Low Education			
Aker et al. [29]	✔	✔	N/A		REALM	14.3% low literacy	2
Brock and Smith [34]	✔	✔	✔	N/A	REALM	55%	3
Cordasco et al. [37]	✔	✔	✔	N/A	TOFHLA	47.1%	3
Davis et al. [38]	✔	✔	N/A	✔	REALM	15% low literacy 30% marginal literacy	3
Dewalt et al. [39]	✔	✔	✔	N/A	STOFHLA	41% Inadequate health literacy	3

Dowse and Ehlers [40]	✔	✔	✔	✔	Short readability literacy test	35%	3
Glasgow et al. [41]	✔	✔		N/A	STOFHLA	Average score: 4.8= inadequate health literacy	2
Gossey et al. [43]	✔	✔	N/A	N/A	STOFHLA	31% inadequate health literacy	2
Heinric and Kuiper [44]	✔	✔		N/A	The Newest Vital Sign (NVS)	28.6% limited health literacy	2
Hussey [45]	✔	✔	✔	✔	Reading skills assessment	N/A	4
Jolly et al. [46]	N/A	N/A	N/A	N/A	PIAT-R test	31% below 9th grade reading level	1
Joshi and Kothiyal [47]	✔	✔	✔	✔	Reading and writing assessment	All illiterate	4
Kalichman et al. [48]		✔	N/A	N/A	TOFHLA	66% average core – marginal health literacy	1

Kalichman et al. [49]		✔	✔	N/A	TOFHLA	50% <85% score	2
King [50]		✔	✔	N/A	REALM	Mean score 24.48 score – low health literate	2
Kripalani et al. [51]	✔	✔	N/A	N/A	REALM	78.5% read at less than the 9th grade level based on their REALM scores	2
Kripalani et al. [52]	✔	✔	✔	N/A	STOFHLA	10% inadequate health literacy	3
Kripalani et al. [53]	✔	✔	N/A	✔	REALM	45.1% <6th grade level	2
McCarthy et al. [57]	✔	✔	✔	N/A	REALM	38% Reading level grade <8	2
Morrow et al. [58]	✔	✔	N/A	N/A	STOFHLA	34% marginal or inadequate health literacy	2
Moskowitz et al. [60]	✔	✔	N/A	N/A	REALM	Mean score 3.6 = low literacy	2

Murray et al. [61]	✔	✔	✔	N/A	STOFHLA	71.3%	3
Neafsey et al. [62]	✔	✔	N/A	N/A	REALM	N/A	2
Negarandeh et al. [63]	✔	✔	N/A	✔	TOFHLA	Average score of 34= low health literate	2
Poureslami et al. [65]	✔	✔	✔	✔	5-point Likert scale health literacy test	N/A	4
Sahm et al. [66]	✔		N/A	✔	REALM	30.9%	2
Schillinger et al. [68]	✔	✔	N/A	N/A	STOFHLA	48% inadequate health literacy	2
Tait et al. [69]	✔	✔	N/A	N/A	REALM	N/A	2
Van Servelle et al. [71]	✔	✔	✔	N/A	REALM	N/A	3

Zullig et al. [75]	✔	✔	✔	N/A	REALM	40% low health literacy	3

N/A= Not Available information about levels below high school or education in general was not mentioned

Table 2.3: Classification of medication information interventions

Author	Written information	Visual information	Verbal information	Medication label/bottle	Reminder systems	Educational Programs/ services	Intervention	Passive	Active	Use of technology	Significant knowledge	Significant adherence
Aker et al. [29]	✔		✔				Simplified written drug information	✔				**N/A**
Al-Saffar et al. [30]	✔		✔				Patient information leaflet (PIL)	✔			•	•
Boyne et al. [31]	✔	✔	✔			✔	Telemonitoring device		✔	✔	•	
Braich et al. [32]	✔	✔	✔				Pictogram		✔		•	**N/A**
Brath et al. [33]	✔	✔			✔	✔	Electronic blister pack		✔	✔	**N/A**	•
Brock and Smith [34]	✔	✔	✔				Digital video		✔	✔	•	•
Burghardt,et al. [35]	✔	✔	✔				Educational board game		✔		•	**N/A**
Cardarelli et al. [36]		✔		✔			Medication bottle color and symbol label system	✔			•	**N/A**
Cordasco et al. [37]	✔	✔			✔		Low-literacy medication education tool	✔		✔		
Davis et al. [38]	✔			✔			Prescription label instructions	✔			•	**N/A**
Dewalt et al. [39]	✔	✔	✔		✔	✔	Primary care based heart failure self-management program		✔		•	**N/A**
Dowse and Ehlers [40]	✔	✔		✔			Pictograms	✔				
Glasgow et al. [41]	✔	✔	✔			✔	Internet based multimedia diabetes self-management education		✔	✔	**N/A**	•
Goeman et al. [42]	✔	✔	✔			✔	Patient asthma concern tool		✔	✔		
Gossey et al. [43]	✔	✔	✔				Audio booklet		✔	✔	•	**N/A**
Heinric and Kuiper [44]	✔				✔		Handheld device reminder		✔	✔	**N/A**	
Hussey [45]	✔	✔	✔		✔		Picture schedule		✔		•	•
Jolly et al. [46]	✔						Simplified written instructions	✔				**N/A**
Joshi and Kothiyal [47]	✔	✔	✔				Pictograms	✔				**N/A**
Kalichman et al. [48]	✔	✔	✔		✔	✔	Personalized feedback report and medication adherence action plan		✔		•	•
Kalichman et al. [49]	✔	✔	✔		✔	✔	Pictograph-guided adherence skills building counseling intervention		✔	✔	**N/A**	•

King [50]	✔	✔					Medication information leaflet	✔				**N/A**
Kripalani et al. [51]	✔	✔			✔		Pill card	✔				**N/A**
Kripalani et al. [52]	✔	✔	✔		✔	✔	Pharmacist Intervention for Low Literacy in Cardiovascular Disease (PILL-CVD)		✔		•	**N/A**
Kripalani et al. [53]	✔	✔	✔		✔		Illustrated medication schedule and refill reminder postcard		✔		**N/A**	
Lefante et al. [54]	✔		✔			✔	Medication reviews		✔		**N/A**	•
Magadza et al. [55]	✔	✔	✔			✔	Pharmacist initiated education		✔		•	•
Mansoor and Dowse [56]	✔		✔	✔	✔		Medicine label and patient information leaflet	✔			•	**N/A**
McCarthy et al. [57]	✔	✔	✔		✔	✔	Prescription information and service		✔		**N/A**	•
Morrow et al. [58]	✔	✔					Patient centered instructions	✔			•	**N/A**
Morrow et al. [59]	✔	✔	✔		✔		Medication schedule	✔			•	**N/A**
Moskowitz et al. [60]			✔				Health coach		✔			**N/A**
Murray et al. [61]	✔	✔	✔	✔			Pharmacist based intervention		✔		**N/A**	•
Neafsey et al. [62]	✔	✔	✔			✔	Patient education program		✔	✔	•	**N/A**
Negarandeh et al. [63]		✔	✔			✔	Teach back and Pictorial image		✔		•	•
Ngoh and Shepherd [64]	✔	✔	✔				Culturally tailored visual aid		✔		•	•
Poureslami et al. [65]	✔	✔	✔				Educational video and pictorial pamphlet		✔	✔	•	•
Sahm et al. [66]	✔	✔		✔			Patient centered instructions	✔			•	**N/A**
Savas and Evcik [67]	✔		✔				Written and verbal information		✔		•	**N/A**
Schillinger et al. [68]		✔					Digital tablets	✔		✔	•	•
Tait et al. [69]	✔		✔				Animated computer-generated text and graphics		✔	✔	•	**N/A**
Unk and Brasington [70]	✔	✔	✔			✔	Multi-dimensional education program		✔	✔	**N/A**	
Van Servelle et al. [71]	✔	✔	✔			✔	Treatment adherence enhancement program				•	•

Wang et al. [72]	✔	✔	✔		✔	✔	Nurse delivered home visit + telephone calls		✔	✔	**N/A**	•
Watanabe et al. [73]			✔			✔	Outpatient consultation service		✔		•	•
Wong [74]		✔	✔				Culturally sensitive educational videotape	✔		✔	•	**N/A**
Zullig et al. [75]	✔	✔	✔		✔		Medication technology		✔	✔	**N/A**	•

Table 2.4: Primary outcome measure of knowledge and adherence

Author	Subjects					Health literacy assessment tool	Health literacy prevalence	Intervention	Outcome measure		Effectiveness
	Gender	Age	Ethnic	Income	Education				Type	Outcome measure tool	
Aker et al. [29]	50.5% woman	61% 45- 64,	20% African American	N/A	28% high school or less education	REALM	14.3% low literacy	Simplified written drug information	Knowledge	Questionnaire	Improvement
Al-Saffar et al. [30]	33 females 67 males	17(6%)	Kuwaiti	165 (59%)	14% no education	Demographic characteristic: age, ethnicity, income (Population demographics)	N/A	Patient information leaflet (PIL)	Adherence Knowledge	Self report and pill count Questionnaire	Significant improvement Statistically significant improvement
Boyne et al. [31]	59.1% male	Mean age 71 years old	Netherlands	N/A	33.6% primary school	Socio-demographics	N/A	Telemonitoring device	Knowledge Adherence	Questionnaire Heart Failure Compliance	Statistically significant improvement Improvement

										Scale	
Braich et al. [32]	141 Female 84 males	N/A	Indian	N/A	150 receiving no education	Education and geographical location (Population demographics)	Majority	Pictograms	Knowledge	Oral exam	Statistically significant improvement
Brath et al. [33]	57% female	Mean age 69.4 years old	European	N/A	N/A	Socio-demographic characteristic	N/A	Electronic blister pack	Adherence	Electronic blister pack	Statistically significant improvement
Brock and Smith [34]	Male (51%)	42.1 years average (25-70 range)	77% African American English speaking	65% low income	60% completed high school	REALM	55%	Digital video on PDA	Knowledge Adherence	Questionnaire Self-report	Statistically significant improvement Statistically significant improvement
Burghardt et al. [35]	121 females 64 males	83 (44.4% - 45-64 20 (107%) - 65+	95.6% African American	43.7% in poverty	25.4% no high school diploma	Population demographics	50%	Educational games	Knowledge	Verbal questionnaire	Statistically significant improvement
Cardarelli et al. [36]	44 female 56 males	Mean age 73.4	82% Caucasian 17%- African American and Hispanic	N/A	8% less than high school	Population demographics	N/A	Medication bottle color symbol label system	Knowledge	Pre and post medication identification test	Statistically significant improvement

Cordasco et al. [37]	38.9% female	Mean age 55.8	75% Hispanic 13.3% African American (73.5% foreign born)	30.4- Medicaid	60.1% less than high school (go back and look at details and add if u can)	TOFHLA	47.1%	Low-Literacy Medication Education Tool for	Knowledge Adherence	Verbal questionnaire Self reported pill count	Improvement Improvement
Davis et al. [38]	72% female	Mean age 48.4 years	61% African American	N/A	60% high or less education	REALM	15% low literacy 30% marginal literacy	Prescription label instructions	Knowledge	Verbal questionnaire	Statistically significant improvement
Dewalt et al. [39]	49% males	Mean age 62	55% African American	68% less than <$15,000 income	Average 9 years of education	STOFHLA	41% Inadequate health literacy	Primary care-based heart failure self-management program	Knowledge	4 point Likert scale questionnaire	Statistically significant improvement
Dowse and Ehlers [40]	93% females	33% between 41-65+	84% Xhosa ethnic group (African)	Most low income	75% less than 4 years of education	Short literacy test	35%	Pictograms	Knowledge Adherence	Questionnaire Self reported pill count	Improvement Improvement
Glasgow et al. [41]	130 (48.1%) female	57.8 average age	4.2% American Indian 1.5% Asian 18.1% African American 22.3% Latino =46.1%	44.8% <$49,999	20.4% high school or less	STOFHLA	Average score: 4.8= inadequate health literacy	Internet-based multimedia diabetes self-management education	Adherence	Hill-Bone Compliance Scale	Statistically significant improvement

Goeman et al. [42]	89 (72.3%) female	68 average age	79.6% born in Australia or New Zealand	27.6% <$24000	43.9% high school or less	Demographic characteristic: age * (mentioned	Majority	Patient Asthma Concerns Tool (PACT)	Adherence Knowledge	Tracking device Questionnaire	Improvement Improvement
Gossey et al. [43]	79 (68.1%) females	55-58 average age	60 (51.7%) African American 56 (48.3%) Hispanic	N/A	52.6% less than high school	STOFHLA	31% inadequate health literacy	Audio booklet	Knowledge	Questionnaire	Statistically significant improvement
Heinric and Kuiper [44]	83.8% females 16.2% males	58.6 average age	70.3% white 27% black 2.7% Native American		42.9% high school or less	The Newest Vital Sign (NVS)	28.6% limited health literacy	Handheld device technology	Adherence	On Time Rx on handheld device	Improvement
Hussey [45]	30% male	Average age 80	62% African American	100% less than $10, 552 income a year	Average of 8 years of education	Reading skills grade 3-4	N/A	Colour-coded daily schedule chart (Picture schedule)	Knowledge Adherence	Medication knowledge and compliance scale (MKCS) MKCS	Statistically significant improvement Statistically significant improvement
Jolly et al. [46]	N/A	N/A	N/A	N/A	35.5% high school or less	PIAT-R test	31% below 9th grade reading level	Simplified written instruction	Knowledge	Knowledge test	No improvement
Joshi and Kothiyal [47]	116 (58%) females 84 (42%) males	29.5% 50+	Indian	98% <$10,000 Rs	N/A	Literacy assessment not mentioned	All illiterate	Pictograms	Knowledge	Label interpretation test	Improvement

Kalichman et al. [48]	33% female	Mean age 44.8 years old	90% African American	N/A	10.4 mean years of education	TOFHLA	66% average core – marginal health literacy	Personalized Feedback Report and Medication Adherence Action Plan	Knowledge Adherence	Questionnaire Self -reported pill count	Statistically significant improvement Statistically significant improvement
Kalichman et al. [49]	136 (30.5% females) 310 (69.5%) males	47 average age	421 (94.4%) African American	317 (71%) <$10,000	Average less than 12 years	TOFHLA	50% <85% score	Pictograph-guided adherence skills-building counseling intervention	Adherence	Telephone-based pill count	Statistically significant improvement
King [50]	85 (52.8% females 76 (47.2%) males	Average age 33.8	African American 85%	N/A	75.8% less than high school education	REALM	Mean score 24.48 score – low health literate	Medication Information Leaflet	Knowledge	Questionnaire	No improvement
Kripalani et al. [52]	363 (42.1) females 499 males (57.9%)	Average age 59-61	Black (17.2%)	4% <$10,000 income	N/A	STOFHLA	10% inadequate health literacy	PILL-CVD (Pharmacist Intervention for Low Literacy in Cardiovascular Disease)	Knowledge	Medication Understanding Questionnaire	Statistically significant improvement
Kripalani et al. [53]	242 females (55.6%)	Average age 63.7	African American (91%)	N/A	Average 10.9 years of education	REALM	45.1% <6th grade	Illustrated medication schedule and refill reminder post card	Adherence	4-item Morisky Medication Adherence Scale (MMAS)	Improvement
Lefante et al. [54]	74.9% female	Mean age 66.2	African American 33.8%	N/A	Average 9.9 years of education	Demographics characteristics	N/A	Medication reviews	Knowledge Adherence	Verbal questionnaire Verbal questionnaire	Improvement Statistically significant improvement
Magadza et al. [55]	34 (76%) females 11 (24%) males	46% between 51-60 years old	91% black (South African)	N/A	96% less than grade 12 level	Socio-demographic characteristic-language	N/A	Pharmacist initiated education intervention	Patient knowledge Adherence	Verbal questionnaire Self-reported	Statistically significant improvement Statistically

										verbal questionnaire	significant improvement
Mansoor and Dowse [56]	65% female	16.7% over 40	84% Xhosa (South African)	N/A	100% grade 7 or less	Socio-demographic characteristic	N/A	Medicine label and patient information leaflet	Knowledge	Questionnaire	Statistically significant improvement
McCarthy et al. [57]	N/A	17.6% over the age of 55	44% black 3386	N/A	62.7% grade 12 or less education	REALM	Reading level grade 8 or less	Prescription information and services	Adherence	Self-reported medication adherence	Statistically significant improvement
Morrow et al. [58]	24 females (75%) 8 males (25%)	Average age 63.9	62.5% black	N/A	Average of 11.5 years of education	STOFHLA	34% marginal or inadequate health literacy	Patient centered instructions	Knowledge	Questionnaire	Statistically significant improvement
Morrow et al. [59]	52% female	Average age 69	N/A		Average 14.9 years of education	Demographic characteristic	N/A	Medication schedule	Knowledge	Medication problem test	Statistically significant improvement
Murray et al. [61]	66.9% females	Mean age 62	49.4% black	34% with Medicare insurance (low income)	Average 11 years of education	STOFHLA	71.3%	Pharmacy based program	Adherence	Medication Event Monitoring System (MEMS)	Statistically significant improvement
Neafsey et al. [62]	73% female	Mean age 73.8	Largely Caucasian	N/A	Mean years of education 12.6	REALM	Inclusion criteria must be above grade 6 level	Personal education program	Knowledge	Knowledge test	Statistically significant improvement

Negarandeh et al. [63]	58 (45.7%) females	Mean age 50.13 years old	Iranian	N/A	79.5% primary education	TOFHLA	Average score of 34 (low health literate)	Pictorial image and teach back	Knowledge Adherence	Self-structured questionnaire Self-reported	Statistically significant improvement Statistically significant improvement
Ngoh and Shepherd [64]	100% females	17% over 39 years old	Cameroon - West Africa	N/A	87% less than 7 years of education	Demographic characteristics	N/A	Culturally tailored visual aid	Adherence Knowledge	Pill count Questionnaire	Statistically significant improvement Statistically significant improvement
Poureslami et al. [65]	50.6% females 49.4% males	Mean age 62.9 years old	49% Chinese 51% Punjabi	29.4% unemployed	42.4% completed elementary school	Questionnaire	N/A	Educational video and pictorial pamphlet	Knowledge Adherence	Questionnaire using 5-point Likert scale Self reported	Statistically significant improvement Statistically significant improvement
Sahm et al. [66]	31.9% males	54.2% over 46+ years old	Irish	N/A	33.7% Secondary or less education	REALM	30.9% below secondary education	Patient centered instructions	Knowledge	Interpretation questionaire	Statistically significant improvement
Savas and Evcik [67]	79.1% females	Average age 50 years old	Turkish	N/A	Nearly 50% n educated at the primary school level or less	Socio-demographics	Nearly 50%	Written and verbal information	Knowledge	Verbal questionnaire	Statistically significant improvement

Schillinger et al.[68]	50% male	Median age 59	39% Asian 14% Black 28% Latino	N/A	N/A	STOFHLA	48% inadequate health literacy	Verbal and visual aid	Knowledge Adherence	Questionnaire Adherence	Statistically significant improvement Statistically significant improvement
Unk and Brasington [70]	87.8% females	Mean age 50.3 years old	30.3% black	50.6% less than $25,000 income	37.6% high school or less education	Socio-demographics	N/A	Multidimensional education program	Adherence	Medication Self-Assessment Questionnaire (MAQ)	No improvement
Van Servelle et al.[71]	90.7% male	Mean age 40.7 years old	75.3% Spanish	50% reported income of $6000 a year	81% less than high school education n	REALM	N/A	Treatment adherence enhancement program	Knowledge Adherence	Survey Self reported	Statistically significant improvement Statistically significant improvement
Wang et al. [72]	83.6% male	Mean age 36.7	Chinese	Eighty-seven subjects (75%) low income	53.4% middle school or below education	Socio-demographics	N/A	Nurse-delivered home visits + telephone calls	Adherence	CPCRA Antiretroviral Medication Self-Report.	Statistically significant improvement
Watanabe et al. [73]	19 (52.8%) male	Average age 77.7 years old	Japan	N/A	N/A	Socio-demographics	N/A	Outpatient Consultation Service	Knowledge	Survey	Statistically significant improvement

									Adherence	In clinic check	Statistically significant improvement
Wong [74]	28 (82.3%) female	Mean age 31.2 years old	South African	N/A	Mean of 8.8 years of education	Social demographics	N/A	Culturally sensitive educational videotape	Knowledge	Questionnaire	Statistically significant improvement
Zullig et al. [75]	91% male	Mean age 66.6	61% African American	31% inadequate income	9% completed less than high school	REALM	40% low health literacy	Medication technology	Adherence	Self-reported and medication possession ratio [MPR] of <80%)	Statistically significant improvement

2.6. References

1. Ramage-Morin PL. Medication use among senior Canadians. Heal reports Statistics Canada, 2009;20:37-44.

2. Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. J Am Pharm Assoc, 2001;Mar-Apr;41(2)192-9.

3. Marvanova M, Roumie CL, Eden SK, Cawthon C, Schnipper JL, Kripalani S. Health literacy and medication understanding among hospitalized adults. J Hosp Med. 2011;6:488-493. doi:10.1002/jhm.925.

4. Safeer RS, Keenan J. Health literacy: The gap between physicians and patients. Am Fam Physician. 2005;72:463-468.

5. Bailey SC, Hasnain-Wynia R, Chen AH, et al. Developing Multilingual Prescription Instructions for Patients with Limited English Proficiency. *J Health Care Poor Underserved*. 2012;23(1):81-87. doi:10.1353/hpu.2012.0000

6. Brown MT, Bussell JK. Medication adherence: WHO cares? Mayo Clin Proc. 2011;86:304-314. doi:10.4065/mcp.2010.0575.

7. Zarcadoolas C, Pleasant A, Greer DS. Understanding health literacy: An expanded model. Health Promot Int. 2005;20:195-203. doi:10.1093/heapro/dah609.

8. Canadian Council on Learning. Health Literacy in Canada. Rep Learn Canada. 2007;1-34.

9. Kirsch I. Adult Literacy in America: A First Look at the Results of the National Adult Literacy Survey.; 1993. doi:NCES 1993-275.

10. Bostock S, Steptoe A. Association between low functional health literacy and mortality in older adults: longitudinal cohort study. BMJ. 2012;344:e1602-e1602. doi:10.1136/bmj.e1602.

11. Kickbusch I, Pelikan J, Apfel F, Tsouros A. Health literacy: the solid facts. Copenhagen WHO Reg Office for Europe. 2013:7-8

12. Eichler K, Wieser S, Brügger U. The costs of limited health literacy: a systematic review. Int J Public Health. 2009;54:313-324. doi:10.1007/s00038-009-0058-2.

13. Schillinger D, Grumback K, Piette J, Wang F, Osmond D, Daher C et al. Association of health literacy with diabetes outcomes. - JAMA. 2002;31;288(4)475-82.

14. De Geest S, Sabaté E. Adherence to long-term therapies: Evidence for action. Eur J Cardiovasc Nurs. 2003;2:323. doi:10.1016/S1474-5151(03)00091-4.

15. Manzano AT, Raphael D. CPHA and the social determinants of health: An analysis of policy documents and statements and recommendations for future action. Can J Public Heal. 2010;101:399-404.

16. Shoemaker SJ, Staub-DeLong L, Wasserman M, -Spranca M. Factors affecting adoption and implementation of AHRQ health literacy tools in pharmacies. Res Soc Adm Pharm. 2013;9:553-563. doi:10.1016/j.sapharm.2013.05.003.

17. Abraham C, Kelly MP, West R, Michie S. The UK National Institute for Health and Clinical Excellence public health guidance on behaviour change: a brief introduction. Psychol Health Med. 2009;14:1-8. doi:10.1080/13548500802537903.

18. Al Sayah F, Majumdar SR, Williams B, Robertson S, Johnson JA. Health Literacy and Health Outcomes in Diabetes: A Systematic Review. J Gen Intern Med. 2013;28:444-452. doi:10.1007/s11606-012-2241-z.

19. Taggart J, Williams A, Dennis S, et al. A systematic review of interventions in primary care to improve health literacy for chronic disease behavioral risk factors. BMC Fam Pract. 2012;13:49. doi:10.1186/1471-2296-13-49.

20. Easton P, Entwistle VA, Williams B. Health in the "hidden population" of people with low literacy. A systematic review of the literature. BMC Public Health. 2010;10:459. doi:10.1186/1471-2458-10-459.

21. Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: Explanation and elaboration. Ann Intern Med. 2009;151. doi:10.1371/journal.pmed.1000100.

22. The Cochrane Collaboration. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011].; 2011. doi:Available from www.cochrane-handbook.org.

23. Baker DW. The meaning and the measure of health literacy. J Gen Intern Med. 2006;21:878-883. doi:10.1111/j.1525-1497.2006.00540.x.

24. Baker DW, Williams M V., Parker RM, Gazmararian JA, Nurss J. Development of a brief test to measure functional health literacy. In: Patient Education and Counseling. Vol 38. ; 1999:33-42. doi:10.1016/S0738-3991(98)00116-5.

25. Weiss BD, Mays MZ, Martz W, et al. Quick assessment of literacy in primary care: The newest vital sign. Ann Fam Med. 2005;3:514-522. doi:10.1370/afm.405.

26. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. Fam Med. 2004;36:588-594.

27. Jeppesen KM, Pharm JDC, Miser WF. Screening questions to predict limited health literacy: A cross-sectional study of Patients with diabetes mellitus. Ann Fam Med. 2009;7:24-31. doi:10.1370/afm.919.

28. Green S, Higgins P., T. J, Alderson P, Clarke M, Mulrow D C, Oxman D A. Cochrane Handbook: Cochrane Reviews: Ch 8: Assessing risk of bias in included studies. In: Cochrane Handbook for: Systematic Reviews of Interventions. Vol 6. ; 2011:3-10.

29. Aker J, Beck M, Papay JI, et al. Consumers Better Understand and Prefer Simplified Written Drug Information: An Evaluation of 2 Novel Formats Versus the Current CMI . Ther Innov Regul Sci . 2013;47 (1):125-132. doi:10.1177/0092861512462371.

30. AlSaffar N, Deshmukh AA, Carter P, Adib SM. Effect of information leaflets and counselling on antidepressant adherence: open randomised controlled trial in a psychiatric hospital in Kuwait. Int J Pharm Pract. 2005;13(2):123-131.

31. Boyne JJJ, Vrijhoef HJM, Spreeuwenberg M, De Weerd G, Kragten J, Gorgels APM. Effects of tailored telemonitoring on heart failure patients' knowledge, self-care, self-efficacy and adherence: a randomized controlled trial. Eur J Cardiovasc Nurs. 2014;13:243-252. doi:10.1177/1474515113487464.

32. Braich PS, Almeida DR, Hollands S, Coleman MT. Effects of pictograms in educating 3 distinct low-literacy populations on the use of postoperative cataract medication. Can J Ophthalmol. 2011;46(3):276-281.

33. Brath H, Morak J, Kästenbauer T, et al. Mobile health (mHealth) based medication adherence measurement - a pilot trial using electronic blisters in diabetes patients. Br J Clin Pharmacol. 2013;76:47-55. doi:10.1111/bcp.12184.

34. Brock TP, Smith SR. Using digital videos displayed on personal digital assistants (PDAs) to enhance patient education in clinical settings. Int J Med Inform. 2007;76(11-12):829-835.

35. Burghardt KJ, Bowman MR, Hibino M, et al. Using educational games to promote the seeking of a pharmacist and to teach key medication use messages: Results from an inner city health party; 23411370. Res Soc Adm Pharm. 2013;9(5):542-552.

36. Cardarelli R, Mann C, Fulda KG, Balyakina E, Espinoza A, Lurie S. Improving accuracy of medication identification in an older population using a medication bottle color symbol label system. Bmc Fam Pract. 2011;12:142.

37. Cordasco KM, Asch SM, Bell DS, et al. A Low-Literacy Medication Education Tool for Safety-Net Hospital Patients. Am J Prev Med. 2009;37(6 SUPPL. 1):S209-S216..

38. Davis TC, Federman AD, Bass PF, et al. Improving patient understanding of prescription drug label instructions. J Gen Intern Med. 2009;24:57-62. doi:10.1007/s11606-008-0833-4.

39. DeWalt DA, Malone RM, Bryant ME, et al. A heart failure self-management program for patients of all literacy levels: a randomized, controlled trial. BMC Health Serv Res. 2006;6:30..

40. Dowse R, Ehlers M. Medicine labels incorporating pictograms: do they influence understanding and adherence? Patient Educ Couns. 2005;58(1):63-70.

41. Glasgow RE, Christiansen SM, Kurz D, et al. Engagement in a diabetes self-management website: usage patterns and generalizability of program use. J Med Internet Res. 2011;13(1):e9.

42. Goeman D, Jenkins C, Crane M, Paul E, Douglass J. Educational intervention for older people with asthma: A randomised controlled trial. Patient Educ Couns. 2013;93(3):586-595.

43. Gossey JT, Whitney SN, Crouch MA, Jibaja-Weiss ML, Zhang H, Volk RJ. Promoting knowledge of statins in patients with low health literacy using an audio booklet. Patient Prefer Adherence. 2011;5:397-403.

44. Heinrich C, Anne RK. Using Handheld Devices to Promote Medication Adherence in Chronic Illness. J Nurse Pract. 2012;8(4):288-293.

45. Hussey LC. Minimizing effects of low literacy on medication knowledge and compliance among the elderly. Clin Nurs Res. 1994;3(2):132-145.

46. Jolly BT, Scott JL, Sanford SM. Simplification of emergency department discharge instructions improves patient comprehension. Ann Emerg Med. 1995;26(4):443-446.

47. Joshi Y, Kothiyal P. A pilot study to evaluate pharmaceutical pictograms in a multispecialty hospital at Dehradun. J Young Pharm. 2011;3(2):163-166.

48. Kalichman SC, Cherry J, Cain D. Nurse-delivered antiretroviral treatment adherence intervention for people with low literacy skills and living with HIV/AIDS. J Assoc Nurses AIDS Care. 2005;16(5):3-15.

49. Kalichman SC, Cherry C, Kalichman MO, et al. Randomized clinical trial of HIV treatment adherence counseling interventions for people living with HIV and limited health literacy. J Acquir Immune Defic Syndr. 2013;63(1):42-50.

50. King SR, McCaffrey DJ, Bentley JP, Bouldin A, Hallam J, Wilkin NE. The influence of symbols on the short-term recall of pharmacy-generated prescription medication information in a low health literate sample; 23030576. J Health Commun. 2012;17:280-293.

51. Kripalani S, Robertson R, Love-Ghaffari MH, et al. Development of an illustrated medication schedule as a low-literacy patient education tool. Patient Educ Couns. 2007;66(3):368-377.

52. Kripalani S, Roumie CL, Dalal AK, et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: a randomized trial. Ann Intern Med. 2012;157(1):1-10.

53. Kripalani S, Schmotzer B, Jacobson TA. Improving Medication Adherence through Graphically Enhanced Interventions in Coronary Heart Disease (IMAGE-CHD): a randomized controlled trial. J Gen Intern Med. 2012;27(12):1609-1617..

54. Lefante J, J.J, Harmon GN, et al. The effect of medication reviews in a rural community pharmacy assistance program: The Cenla Medication Access Program. J Pharm Pract. 2005;18(6):486-492.

55. Magadza C, Radloff SE, Srinivas SC. The effect of an educational intervention on patients' knowledge about hypertension, beliefs about medicines, and adherence. Res Soc Adm Pharm. 2009;5(4):363-375.

56. Mansoor LE, Dowse R. Effect of pictograms on readability of patient information materials. Ann Pharmacother. 2003;37:1003-1009. doi:10.1345/aph.1C449.

57. McCarthy ML, Ding R, Roderer NK, et al. Does providing prescription information or services improve medication adherence among patients discharged from the emergency department? A randomized controlled trial; 23561463. Ann Emerg Med. 2013;62(3):212-223e1.

58. Morrow DG, Weiner M, Young J, Steinley D, Deer M, Murray MD. Improving medication knowledge among older adults with heart failure: A patient-centered approach to instruction design. Gerontologist. 2005;45(4):545-552.

59. Morrow D, Raquel L, Schriver A, Redenbo S, Rozovski D, Weiss G. External support for collaborative problem solving in a simulated provider/patient medication scheduling task. J Exp Psychol. 2008;14(3):288-297.

60. Moskowitz D, Thom DH, Hessler D, Ghorob A, Bodenheimer T. Peer Coaching to Improve Diabetes Self-Management: Which Patients Benefit Most? J Gen Intern Med. 2013;28(7):938-942.

61. Murray MD, Young J, Hoke S, et al. Pharmacist intervention to improve medication adherence in heart failure: A randomized trial. Ann Intern Med. 2007;146:714-725. doi:146/10/714 [pii].

62. Neafsey PJ, Strickler Z, Shellman J, Chartier V. An interactive technology approach to educate older adults about drug interactions arising from over-the-counter self-medication practices. Public Health Nurs. 2002;19:255-262. doi:10.1046/j.1525-1446.2002.19405.x.

63. Negarandeh R, Mahmoodi H, Noktehdan H, Heshmat R, Shakibazadeh E. Teach back and pictorial image educational strategies on knowledge about diabetes and medication/dietary adherence among low health literate patients with type 2 diabetes. Prim Care Diabetes. 2013;7(2):111-118.

64. Ngoh LN, Shepherd MD. Design, development, and evaluation of visual aids for communicating prescription drug instructions to nonliterate patients in rural Cameroon. Patient Educ Couns. 1997;30(3):257-270.

65. Poureslami I, Nimmon L, Doyle-Waters M, et al. Effectiveness of educational interventions on asthma self-management in Punjabi and Chinese asthma patients: A randomized controlled trial. J Asthma. 2012;49(5):542-551.

66. Sahm LJ, Wolf MS, Curtis LM, et al. What's in a label? An exploratory study of patient-centered drug instructions. Eur J Clin Pharmacol. 2012;68(5):777-782.

67. Savas S, Evcik D. Do undereducated patients read and understand written education materials? A pilot study in Isparta, Turkey. Scand J Rheumatol. 2001;30(2):99-102.

68. Schillinger D. Language, Literacy, and Communication Regarding Medication in an Anticoagulation Clinic: Are Pictures Better Than Words?; 2005.

69. Tait AR, Voepel-Lewis T, Brennan-Martinez C, McGonegal M, Levine R. Using animated computer-generated text and graphics to depict the risks and benefits of medical treatment. Am J Med. 2012;125:1103-1110. doi:10.1016/j.amjmed.2012.04.040.

70. Unk JA. Efficacy study of multimedia to educate rheumatoid arthritis patients. Arthritis Rheum. 2013;65:S420.

71. Van Servellen G, Nyamathi A, Carpio F, et al. Effects of a treatment adherence enhancement program on health literacy, patient-provider relationships, and

adherence to HAART among low-income HIV-positive Spanish-speaking Latinos. AIDS Patient Care STDS. 2005;19(11):745-759.

72. Wang H, Zhou J, Huang L, Li X, Fennie KP, Williams AB. Effects of nurse-delivered home visits combined with telephone calls on medication adherence and quality of life in HIV-infected heroin users in Hunan of China. J Clin Nurs. 2010;19(3-4):380-388.

73. Watanabe N, Yamamura K, Suzuki Y, et al. Pharmacist-based Donepezil Outpatient Consultation Service to improve medication persistence. Patient Prefer Adherence. 2012;6:605-611.

74. Wong IY, Lawrence N V, Struthers H, McIntyre J, Friedland GH. Development and assessment of an innovative culturally sensitive educational videotape to improve adherence to highly active antiretroviral therapy in Soweto, South Africa. J Acquir Immune Defic Syndr. 2006;43(SUPPL. 1):S142-S148.

75. L. LZ, McCant F, D. SM, Danus S, B. HB. A health literacy pilot intervention to improve medication adherence using Meducation((R)) technology. Patient Educ Couns. 2014;95(2):288-291.

Chapter 3: Don't assume the patient understands: Qualitative analysis of low health literate patient insight to challenges faced with medication information at the pharmacy

3.1. Introduction

Good communication between pharmacists and patients is fundamental for the safe and effective use of medications.[1] To ensure patients can take their medication as prescribed, they must have at minimum the basic understanding of how to take their medication, and be able to recognize the risks and benefits of their prescriptions.[2] Yet, an estimated 50% of individuals with chronic disease struggle to take their medication as prescribed.[3]

The World Health Organization (WHO) has identified low health literacy is a primary patient-related factor contributing to medication non-adherence.[11] Low health literacy populations have difficulty understanding health information and making appropriate health decisions.[4] Patients with low health literacy skills are 10 to 18 times less likely to correctly identify all their medication, in comparison to those with adequate health literacy skills ($p<0.05$).[5] Low health literacy is associated with higher hospitalization and emergency care use, lower use of diagnostic and screening tools, lower ability to interpret and understand medication instructions, poorer health status and higher mortality.[6] Additionally, low health literate individuals are more likely to have difficulty understanding medication information which includes medication labels, auxiliary labels, instructions and written and verbal information.[7, 8, 9] Yet, these pharmacy education tools are the primary means for educating patients about medication.

A conceptual model developed by Baker (2006) describes health literacy in the real-world as the result of the individual's capacity to understand health information that is provided by the health care system.[10] Baker's model underlines that the health care system has the responsibility to provide health-specific knowledge to ensure patients can self-manage their health.[10,11] Yet, current medication information is too complex and prevents low health literate populations from self-managing their health. This struggle highlights the need for health care systems to recognize and address the challenges patients face when trying to understand medication. Therefore, the objective of the study was to explore the major challenges low health literate adults face when trying to understand their medication therapy.

3.2. Material and methods

Ethics approval from the University of Waterloo Research Ethics Board (Approval #19364) was obtained prior to conducting research. The consolidated criteria for reporting qualitative research (COREQ) checklist was used to report the results (Appendix 1).[12]

One-on-one semi-structured interviews were used to gather data on the major challenges low health literate adults face regarding their medication. Each interview began with a verbal health literacy assessment, followed by open-ended questions focused on medication information. After each interview was complete, a written health literacy assessment was given, which was later used to compare self assessed health literacy to written health literacy scores. All interviews were audio-recorded, transcribed and analyzed using thematic analysis.

3.2.1. Population sample

Participants were recruited using a purposive intensity sampling approach.[13] The sample included adults over the age of 50 who speak English as an alternate language. The participants also included a range of adults who were healthy and who were living with impaired mobility, health and/or cognition. Intensity sampling was chosen to ensure that the data reflected a wide range of incomes, ethnic/racial minorities and older adults.[19]

3.2.2 .Recruitment

Participants were recruited from Northwood Neighbourhood Services seniors programs held at five different locations in the Greater Toronto area. Interviews were conducted at five locations and included a Latin American seniors program, a Vietnamese and Chinese seniors program, an Albanian seniors program and two multicultural seniors programs. At each program, a female researcher (HW) verbally introduced herself by reading the recruitment script, which invited participants to engage in a thirty-minute interview exploring the challenges they face with medications. No previous relationship was established prior to research. Each participant was given the option to have an accredited interpreter present during the interview. Participants wishing to leave the study were to be documented and their data were excluded and destroyed, but none withdrew. If a participant did not speak English, the interpreter helped explain the research objective and obtained informed consent, meaning the participant signed the consent form stating they understood the study and willingly consented with full understanding. The interpreter was also required to complete a contractual agreement not to breach the subject's privacy and confidentiality.

3.2.3. Interview

The one-on-one semi-structured interviews took place in a private area within the seniors program facilities, to ensure information was kept confidential and to obtain a clear audio recording. The interview began with subjects verbally self-assessing their health literacy levels through a series of brief screening questions focused on medication and health information.[14] Throughout the interview, research questions were open-ended to promote a conversation where the participant communicated for the majority of the interview, while the interviewer listened, encouraged storytelling and asked probing questions. At the end of the interview participants were asked a series of demographic questions that included age, gender, language, education, and computer or smartphone usage. Interviews were conducted until saturation was met and no new information or themes were being observed.[13]

3.2.4. Health Literacy Assessment

At the start of each of interview, participants were asked the following verbal assessment questions to gauge their health literacy using a 5-point Likert scale: 1) how often do you have someone help you read materials about your medications; 2) how confident are you filling out medical forms by yourself, and; 3) how often do you have problems learning about your medications because of difficulty understanding written information.[14] At the end of each interview, a Short Test of Functional Health Literacy Assessment (STOFHLA) was administered.[14] The STOFHLA provided a quick and efficient way of determining the participant's health literacy level.[14] In the STOFHLA, participants are given a 7-minute time limit to complete 36 multiple-choice questions using a modified

cloze procedure, where every fifth to seventh word is absent and participants must determine the correct word from a set of four multiple choice options.[14]

3.2.5. Analysis

After the interviews were completed, each interview was transcribed and interviews that included an interpreter were documented and transcribed in the English interpretations. Transcripts were uploaded and analyzed in NVivo (version 10.0.418.0 Melbourne, Australia, QSR International). Analysis included the following stages: 1) open coding where large number of initial data were focused and labeled into concepts, 2) category development coding where open coding results were re-examined and further concentrated, and 3) thematic coding where previous codes were placed into themes.[15] To minimize bias, two authors independently coded the first three transcripts and compared their codes to develop a code book. From that point, the remaining transcripts were coded by a single author and reviewed with a second author.

3.3. Results

3.3.1. Participant characteristics

We reached saturation after 20 interviews. The participant ages ranged from 52-80 years old and had a mean age of 67 years old. The sample was 60% female and 40% male, and 90% had been educated outside of North America. On average, 85% of the population had less than a high school level of education from their country of origin. The population consisted of a variety of ethnic/racial groups, including Chinese, Vietnamese, Spanish, Afghan, Armenian, Italian, Albanian, Indian, Iranian and Somali. Additionally, in regards to health literacy, 75% of the population was classified as low health literate

based on the STOFHLA. Additionally, participants in the study generally over estimated their health literacy levels on the verbal brief health literacy screen tests in comparison to the scores on the STOFHLA.

3.3.2. Qualitative analysis

After thematic analysis, a flow chart that describes the low health literate population's pharmacy experience with medication information was developed to explain the cause and effect of challenges faced with current pharmacy medication information (Figure 3.1). The flow chart consisted of 3 themes (factors, results, outcome) and 5 categories (challenges, barriers, seeking help, unknown, medication related outcomes), where each category fell into one of the three themes. Challenges and barriers were factors, seeking help and the unknown were results and medication related outcomes were the outcomes of current medication information. flow chart began with identifying all sources of medication information from the pharmacy. The flow chart demonstrates that current challenges the low health literate populations face with medication information from the pharmacy are caused by encountered barriers. When low health literate individuals face challenges with medication information they seek additional help from other sources and attempt to address their challenges. When challenges are still present, low health literate populations are left with unanswered questions or concerns, which lead to the perception of negative medication related outcomes.

Figure 3.1: Low health literate population's pharmacy experience with medication information

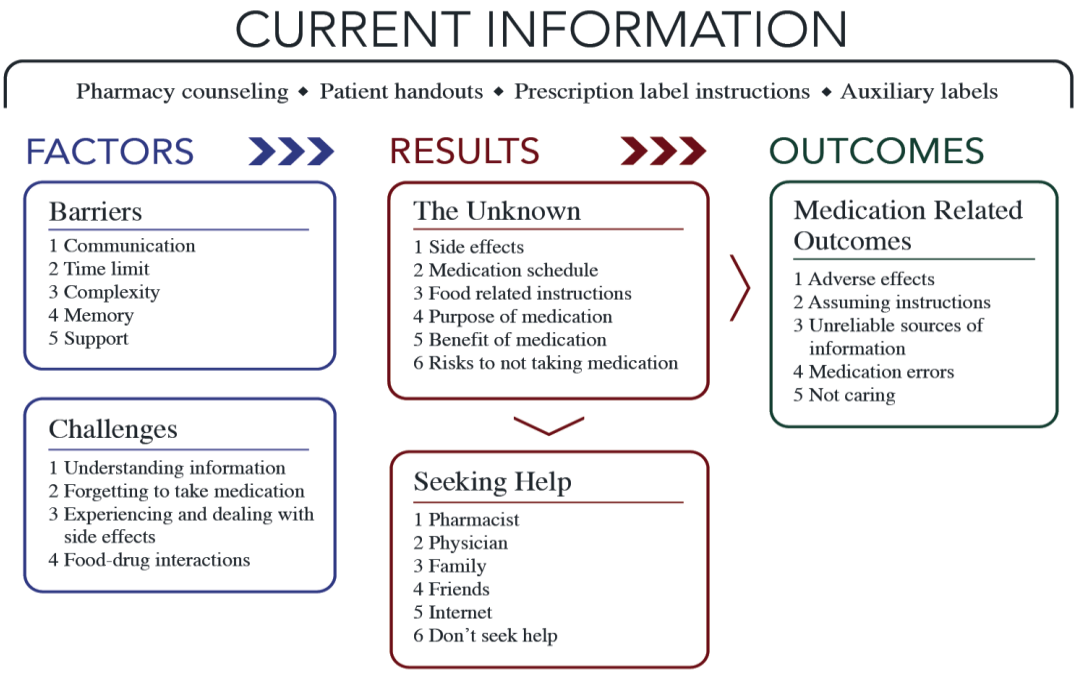


Figure 1: Low health literate population's pharmacy experience with medication information.

3.3.3 Current information from the pharmacy

Throughout the interviews participants reported that they currently receive a variety of different sources of information. This information was grouped into pharmacy counseling and information provided for reference at home. During pharmacy visits, participants indicated that they received pharmacy counseling generally when they had a new prescription. Medication information provided for reference at home included patient handouts, prescription label instructions and auxiliary labels. Most participants were unhappy with the current patient handout. Correspondingly, a 63-year-old male participant from India said,

"They put too much information there which may or may not be useful to you, I think because they want to save themselves from legal problems. Sometimes the information is overwhelming."

Participants highlighted their dependence on prescription label instructions as their major source of medication information. Specifically, most participants were grateful for auxiliary labels that indicate important instructions for the participant to follow. Participants paid close attention to auxiliary labels, as they would visually see the labels every time they took their medication. Further, because the pharmacist took the time to add the auxiliary label to the bottle, this signified the importance of the highlighted label. Several participants also indicated that they relied on the picture on the auxiliary label because of difficulty reading English and the small font size. A 72-year- old female participant from Armenia commented,

"Pictures it makes it very easy, there is no need for you to read it, just you see the picture and it explains everything, see drink with water, take with food."

3.3.4. Factors with current medication information

3.3.4.1. Challenges

A challenge is defined as a difficulty encountered by a patient. In response to the question "What challenges do you face with your medication," four types of challenges were identified, including understanding, forgetting, side effects and food instruction/interactions.

A common challenge amongst participants was the difficulty in understanding medication

information provided by the pharmacy, including counseling, prescription labels and patient handouts. Most participants attributed their difficulties to the time constraint of the pharmacist and the complex language in the patient handout. Current information received from the pharmacy is not sufficient for the patient to self-manage their own health. A 72-year-old male from India stated,

> **"How can I take care of myself, if I don't know what to do. When I take my medication I feel I take a chance because I don't know if I'm doing it right."**

In the low health literate population, a consistent challenge encountered was forgetting to take their medication, as well as forgetting medication information, such as when to take their medication, whether to take it on a full or empty stomach and what the medication is for. A 56-year-old male from Italy said,

> **"Oh I miss my medication so many times. I would be at home watching TV and I forget to take my medication. I would forget to take it with me when I'm working and sometimes I go somewhere and forget."**

Additionally, most participants highlighted their concern with side effects and food interactions. Most participants were concerned they were not given enough information to decide what foods and beverages to avoid while taking their medications, how many hours before and after they can consume certain food and beverages and whether their medication should be taken on a full or empty stomach. Several participants also indicated that they base the decisions about what foods to avoid on personal experience, and culture. Several participants shared many side effects and food restrictions not mentioned by the pharmacist, which they believed led to unwanted side effects. A 66-

year-old Italian male, was asked to share any experience faced with side effects and food and quoted,

> **"Yes grapefruit, I experienced myself because sometimes I had half grapefruit and then one day I could not walk and I say what happened. What happened to me than I mention to doctor and the pharmacist said no grapefruit! They no tell me, the pharmacist after this happened told me and put a sticker on my bottle."**

3.3.4.2. Barriers

A barrier is defined as a limitation or boundary that restrains the progress of a patient. Barriers encountered by the participants were time, communication, memory and support. A recurrent barrier identified throughout the interviews was the limited time and interaction available with the pharmacist. Pharmacists were described to be extremely busy and determined to finish counseling in the least amount of time possible. A 54 year-old woman from Vietnam commented,

> **"The pharmacist just want to finish their time and rush you through the door because no time and that makes the patient feel uncomfortable."**

Some participants expressed the belief that the pharmacist wants to help and give the patient their time, but because of the high demand for their assistance they are unable to provide sufficient time to every customer. However, some participants found the time constraint prevented them from asking questions or clarifying instructions. Communication was not limited to merely verbal communication but also written text. Most participants described verbal communication between patient and pharmacist to be

rushed due to time limitation and also found the patient handout to be complex and unappealing:

> **"There are so many technical, medical words they use I don't understand and sometimes it's not easy to follow the instructions I get when I go home on that paper."**

The participants in the study all spoke some English as a second language and found communication to be a barrier because they did not speak English as a primary language. Participants indicated they did not feel confident in asking the pharmacist questions or asking for clarification because of the feeling of the pharmacist not understanding them. Several participants commented on feeling embarrassed because of a heavy accent or not speaking English perfectly and felt hesitant to speak to the pharmacist.

Several participants believed that pharmacist "didn't care" about their medication needs because the pharmacist would only speak to the participant when they were picking up a new medication and would not ask any follow-up questions. A 66-year-old Spanish male commented,

> **"I don't even know my pharmacists name, he just gives me my medication and I leave. We barely talk at all."**

However, participants who received support from their pharmacist had fewer challenges with their medications and would take their medication regimens very seriously.

3.3.5. Results of current medication information

3.3.5.1. Seeking help

Other than medication information provided by the pharmacy, participants shared several other sources of information. Participants indicated that they seek help from pharmacists, physicians, family, friends, Internet or seek no help. Participants indicated seeking help from pharmacist and physicians during their next visit and through a phone call. Most participants preferred having a family member present or independently sending the family member to pick up their prescription medication. Participants highlighted the high dependence they have on their family members to disclose all information obtained from the pharmacy to them in their first language. A general concern was that information may be lost in translation and not provided by the pharmacist or family member. Although pharmacists provided counseling and prescription monographs, participants still felt the need to seek additional information from the Internet. A 72-year-old female participant from Chile quoted,

> **"We don't get the information from pharmacist because he doesn't tell us or understand, so my son find on the Internet. He writes it to me on a paper and I put it on the fridge."**

3.3.5.2. The unknown and risks

A primary concern was the unknown information. Participants did not know but were interested in understanding the side effects, medication schedule, foods to avoid, why they are taking their medication, the benefit of taking their medication and consequences related to not taking medication. A 56-year-old Afghan female commented,

"I know it's for thyroid. Now, you can ask me exactly what my thyroid does, exactly what it controls, why I take it, and how it works I have absolutely no idea...but why don't they tell me."

Participants frequently shared their frustration with the unknown medication information blaming their pharmacists and doctors for not disclosing all the necessary information to self-manage their medication.

3.3.6. Outcomes of current medication information

Participants attributed the unknown medication information to several negative outcomes including adverse events, their need to assume instructions, their need to refer to unreliable sources of information, errors and apathy towards their treatment

3.4. Discussion

The present study was designed to explore the major challenges low health literate populations face with medication information, specifically adults over the age of 50, who speak English as an alternate language. Overall, the results of this study found the major challenges to be time, understanding medication information, forgetting to take medication, side effects and food-drug interactions. To our understanding, this study was the first initiative to develop a flow chart demonstrating the low health literate populations associated factors, results and outcomes with current pharmacy medication information, based on qualitative interviews. The study demonstrates that a reasonable approach to tackle the challenges low health literate populations face with medication is for pharmacists to provide more time to patients to convey complex information simply,

to build a better relationship with the patient and to repeat medication instruction to the patient.

These results are in agreement with those of previous studies investigating challenges patients face with their medication. In the elderly population, research has shown that the primary challenges to medication use include side effects, taking too many medications, reading medication labels, understanding information and forgetting to take medications.[16] Another study with more focus on ethnic/racial minorities found the biggest challenge to be second language issues.[17] Lastly, in research on individuals with chronic conditions, the primary concerns have been found to be side effects, remembering and understanding medication regimens.[18]

According to the low health literate population in this study, current pharmacy medication information has not met their standard to ensure the proper self-management of medication. One interesting finding in the study was that participants overestimated their health literacy levels on the verbal brief health literacy self-assessment screening tests in comparison to the scores on the STOFHLA. A possible explanation is that participants felt embarrassed and feared being judged on not being able to read, write or understanding information. Pharmacists need to be mindful that it can be difficult to identify individuals with low health literacy.

3.4.1. Limitations

This study has several limitations that should be noted. Although we continued to conduct interviews until a saturation point was met, the sample size was small and also presented a population of low health literate adults limiting the generalization of the

results. Additionally, the use of purposive intensity sampling may impose selection bias because the sample was not representative of the entire population, and therefore may not be representative of the challenges all patients face with medication information. Further, the subjects in our study had their medication costs covered, as Ontarians over the age of 65 receive provincial drug coverage, which does not represent many international audiences who do not have their medications costs covered. Additionally, there is no current standardized assessment for health literacy, but of the available assessments, the STOFHLA is regarded as the most acceptable and commonly tool for determining health literacy.[21] Another major limitation to this study was that the two individuals who did not speak English and required an interpreter were unable to complete the STOFHLA and was classified as low health literate for English health literacy.

3.5. Conclusion

The goal of this study was to identify the challenges low health literate populations face at the pharmacy to help guide future development of patient-centered interventions. The major challenges patients with low health literacy face at the pharmacy are limited time with pharmacists, poor understanding of medication information, forgetting to take medications, side effects and food instruction/interactions. In future, effective tools should reflect patient preferences, needs, and values, and ensure that patient values guide clinical decisions.

3.5 References

1. De Geest S, Sabaté E. Adherence to long-term therapies: Evidence for action. *Eur J Cardiovasc Nurs*. 2003;2:323. doi:10.1016/S1474-5151(03)00091-4.

2. Shrank WH, Avorn J. Educating patients about their medications: The potential and limitations of written drug information. *Health Aff*. 2007;26(3):731-740. doi:10.1377/hlthaff.26.3.731.

3. Lee J, Grace K, Taylor A. pharmacy care program on medication adherence and persistence, blood pressure, and low-density lipoprotein cholesterol: a randomized controlled trial. *JAMA*. 2006;296(21):2563-2571. doi:10.1001/jama.296.21.joc60162.

4. Kickbusch I, Pelikan J, Apfel F, Tsouros A. Health literacy: the solid facts. Copenhagen WHO Reg Office of Europe. 2013:7-8.

5. Kripalani S, Henderson LE, Chiu EY, Robertson R, Kolm P, Jacobson TA. Predictors of medication self-management skill in a low-literacy population. *J Gen Intern Med*. 2006;21(8):852-856. doi:10.1111/j.1525-1497.2006.00536.x.

6. Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Crotty K. Low health literacy and health outcomes: An updated systematic review. *Ann Intern Med*. 2011;155(2):97-107. doi:10.7326/0003-4819-155-2-201107190-00005.

7. Raehl CL, Bond CA, Woods TJ, Patry RA, Sleeper RB. Screening tests for intended medication adherence among the elderly. *Ann Pharmacother*. 2006;40(5):888-893. doi:10.1345/aph.1G478.

8. Davis TC, Federman AD, Bass PF, et al. Improving patient understanding of prescription drug label instructions. *J Gen Intern Med*. 2009;24:57-62. doi:10.1007/s11606-008-0833-4.

9. Wolf MS, Davis TC, Shrank W, et al. To err is human: Patient misinterpretations of prescription drug label instructions. *Patient Educ Couns*. 2007;67(3 SPEC. ISS.):293-300. doi:10.1016/j.pec.2007.03.024.

10. Baker DW. The meaning and the measure of health literacy. *J Gen Intern Med*. 2006;21:878-883. doi:10.1111/j.1525-1497.2006.00540.x.

11. Babinec PM, Rock MJ, Lorenzetti DL, Johnson JA. Do researchers use pharmacists' communication as an outcome measure? A scoping review of pharmacist involvement in diabetes care. *Int J Pharm Pract*. 2010;18(4):183-193. doi:10.1111/j.2042-7174.2010.00038.x.

12. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups. *Int J Qual Heal Care*. 2007;19(6):349-357. doi:10.1093/intqhc/mzm042.

13. Patton M. *Qualitative Evaluation and Research Methods*.; 1990. doi:10.1002/nur.4770140111.

14. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. *Fam Med*. 2004;36:588-594.

15. Strauss A, Corbin J. *Basics of Qualitative Research: Techniques and Procedures for Developing Grounded Theory*. Vol 3. 2008. doi:10.4135/9781452230153.

16. Schaafsma ES, Raynor T, De Jong-van den Berg LTW. Accessing medication information by ethnic minorities: Barriers and possible solutions. *Pharm World Sci*. 2003;25(5):185-190. doi:10.1023/A:1025812716177.

17. Elliott R a. Problems with medication use in the elderly: an Australian perspective. *J Pharm Pract Res*. 2006;36(1):58-66.

18. Barber N, Parsons J, Clifford S, Darracott R, Horne R. Patients' problems with new medication for chronic conditions. *Qual Saf Health Care*. 2004;13(3):172-175. doi:10.1136/qshc.2003.005926.

Chapter 4: The future of pharmacy counseling: Feasibility study of providing low health literacy medication counseling through NFC-enabled AudibleRx

4.1. Introduction

In North America, pharmacists are typically required to provide patients with medication information through clear prescription labels, verbal counseling and patient handouts.[1] Yet, in the United States (US), an estimated one third of adults (35%) lack the required level of health literacy to necessary to identify what time of day a medication should be taken using the instructions on a medication label.[2] Similarly, in Canada, as many as 60% of adults do not have a high enough health literacy to read or act on prescription labels and patient handouts, to understand or act on pharmacist counseling or to convey their needs to the pharmacist.[3]

Low health literacy is associated with poorer health outcomes and higher hospitalization and mortality rates, as well as an increased risk of medication errors.[2] Low health literacy is also closely tied with social inequality and is more common for people who have a lower income, lower education, older age or who belong to an ethnic/racial minority group.[3] Health literacy also imposes an economic burden on the healthcare system, costing US healthcare payers an estimated $8 billion in healthcare costs.[1]

Two recent studies found that the main concerns patients with low health literacy have with pharmacy services is that current medication information is difficult to understand, and pharmacists have very little time to try to explain medication information in a way that is understood.[4,5] Furthermore, health professionals tend to overestimate a patient's

level of understanding because patients are reluctant to disclose their health literacy struggles for reasons such as language barriers, fear, shame, and heavy pharmacy workflow.[4] It should be unsurprising then that two strategies commonly used in pharmacies to support patients who appear to have difficulty managing medications include blister packaging and refill reminders--interventions that both focus on helping patients adhere, rather than understand. As of now, there is no widely accepted strategy that pharmacists have to help patients with low health literacy understand their medications.[5]

There are new and novel interventions being tested to improve health literacy in pharmacies, though none are widely adopted yet. For example, several studies have looked at the effect of illustrated medication schedules that show the patient what their medication looks like, what it is used for, and when to take it.[4, 5, 6, 7] While some versions appear to improve knowledge and adherence, one of the challenges with illustrated schedules is that any medication change requires that the schedule be revised and reprinted, increasing the workload of the pharmacy staff and increasing the risk of patient confusion.[5] Educational programs for topics such as hypertension and diabetes are also common and appear to improve medication knowledge and adherence, though such interventions require a substantial amount of time and resources.[8-13]

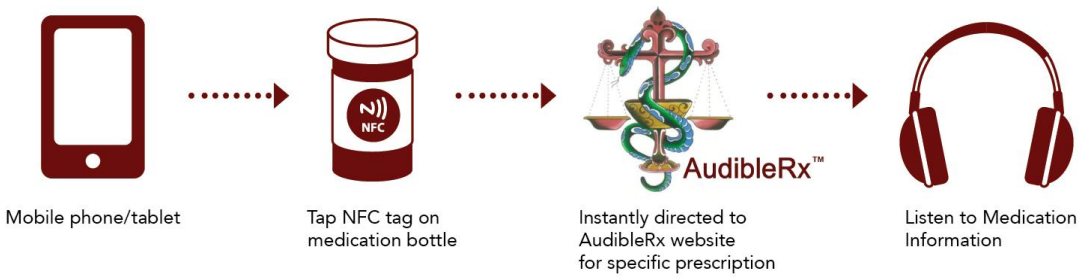
Pharmacists need interventions that can be easily incorporated into a busy pharmacy practice. Mobile information and communication technologies such as smartphones and tablet computers may be one of the best tools that have emerged in recent years for

patient education.[14] Mobile devices have already been used to deliver dietary programs [15], to send text messages for smoking cessation and medication adherence [16,17,18], and to provide monitoring for patient symptoms, health status and quality of life.[19] In developing countries, mobile health is quickly becoming the main source of communication in primacy healthcare.[20] Further, in the US, 91% of adults are already using a mobile device and 67% are using it to access the Internet.[20] The advantage of mobile technologies is that they allow patients to access health information anywhere and anytime at their own convenience.

Podcasting has emerged as an innovative approach to convey medication information using mobile devices. AudibleRx™ is a pharmacist-managed website that aims to provide consumers with web and mobile medication information in an audible format, particularly individuals who are challenged with low literacy, visual impairment, or who learn better by listening. AudibleRx™ was designed for patients who are picking up a new prescription and who may require additional counseling after speaking with the pharmacist. The goal of the podcasts is to give patients and caregivers a clearer idea of what the prescribed drugs does. AudibleRx™ is not affiliated with or influenced by any drug manufacturer or institution, thus maintaining an objective and unbiased approach to patient education. Each counseling session is prepared following a specific template, which meets the FDA guidelines on Useful Written Consumer Medication Information and is written at a grade 10 level.[21] The AudibleRx™ website has been certified through the Health On the Net (HON) code process and is also a member of the National Council on Patient Information and education.

One of the challenges with a technology such as AudibleRx™ is that it can be difficult to send patients to the correct website. However, this process can be automated. Near-field communication (NFC) technology uses short-range wireless technology to allow users to receive or exchange data by tapping their device to a small NFC tag.[22] In pharmacies, NFC technology could help patients receive digital information through a very simple and accessible method. For example, if a pharmacist wants to refer a patient to a website containing the patient handout, the pharmacist could program the website into a sticker containing an NFC chip and adhere the sticker to the pill vial. When the patient's pill vial and mobile device are close together, the mobile device would receive the information and automatically load the website.[23] The advantage of this approach is that it automates the transfer of information between the busy pharmacist and the patient who has a lower level of health literacy. Further, the patient can easily access the information at their own convenience and share the information with relevant friends or family members (Figure 4.1). Therefore, the objective of this study was to test the feasibility of using an NFC-enabled medication counseling podcast with patients who have mixed health literacy.

Figure 4.1: Pharmacy prescription bottle with NFC-enabled AudibleRx™ Podcast



4.2. Material and methodology

A randomized-controlled study design was used to assess the feasibility of comparing a medication counseling podcasts with standard pharmacy care. Ethics approval from the University of Waterloo Research Ethics Board (certificate #20525) was obtained prior to conducting research.

4.2.1. Development of the Intervention

The first step in developing the intervention was to identify a standard podcast for testing. The research team selected the medication warfarin, as it has a narrow therapeutic index and is a common source of serious drug interactions and adverse events.[24] The research team, identified that the original AudibleRx™ warfarin podcast was comprehensive but contained complex terminology and medical jargon such as "anticoagulation" and "atrial fibrillation". The research team developed a health literacy guideline for audible medication information (Table 4.1), and used the guidelines to rewrite the AudibleRx™ script for individuals with lower health literacy. A professional voice actor from the website Voices.com was hired and asked to read the script while applying the health literacy guidelines for audio recording, which included adding introductory music, transition sounds and voice inflection to provide a better listening experience.

Finally, after the podcast recording was complete, one NFC chip was programmed with the web address of the original podcast and a second NFC chip was programmed with the web address of the health literacy podcast. Each NFC chip was affixed to a standard warfarin medication vial. A Quick Response (QR) code was also affixed to the medication vial label as an alternative method for accessing podcasts.

Table 4.1: Health literacy guidelines for audible medication information

Guidelines for audible information script	How to	Guidelines for audio recording	Importance
1. Map script	- create a relationship with listener - organize ideas - list the topics being covered	1. Personality	How the speaker comes across as a person
2. Lower readability level of information	Use short sentences with commonly used words: - Rule 1: Use less than 25 words in one sentence - Rule 2: If it takes more than one breath to go through one sentence, break into two sentences - avoid polysyllabic - do not use acronyms	2. Energy	Makes listener feel they are in the same room with you
3. Be clear and concise	- use plain English - use familiar terminology - don't use jargon - convey one idea per sentence - change passive language into active language - avoid abbreviations	3. Tone of voice	Reflects confidence, strength and assurance of information
4. Write the way you would say it, not read it	- speak directly to listener - use punctuation to use to ensure script is easy to read	4. Voice inflection	Emphasis with inflections changes the meaning of sentences
5. Repeat new concepts and summarize main points	- aids the absorption of info	5. Timing of speech	Aids in understanding

4.2.2.Population sample

The population sample used in the feasibility study included adults over age 40 and who had used at least one prescription medication for a chronic disease within the last three months. Participants were excluded if they did not speak any English or if they had used warfarin in the past. Participants were recruited using purposive sampling to ensure that the sample population contained individuals likely to experience lower health literacy, including seniors, ethnic/racial minorities, and people with low income and with low education. Health literacy levels were determined using the Short-Test of Functional Health literacy (STOFHLA).[25]

4.2.3. Recruitment

Participants were recruited from the Kitchener-Waterloo area and the Greater Toronto region through seniors programs, English as a Second Language (ESL) programs, libraries and retirement homes. Participants were recruited using a study poster and verbal script, which invited participants take part in a 50-minute study comparing current pharmacy information to new audible medication information technology. Participants were given a $10 (CAD) for their involvement in the study.

4.2.4. Standard pharmacy care

After preliminary data was collected, all participants were provided with standard pharmacy care that consisted of pharmacy counseling and a patient handout on warfarin. The intention was to mimic standard pharmacy care provided to individuals with a new warfarin prescription. To develop the standard counseling statement, three pharmacists at different locations were randomly identified and asked to share the information they would disclose to a patient with a new warfarin prescription. The five statements were

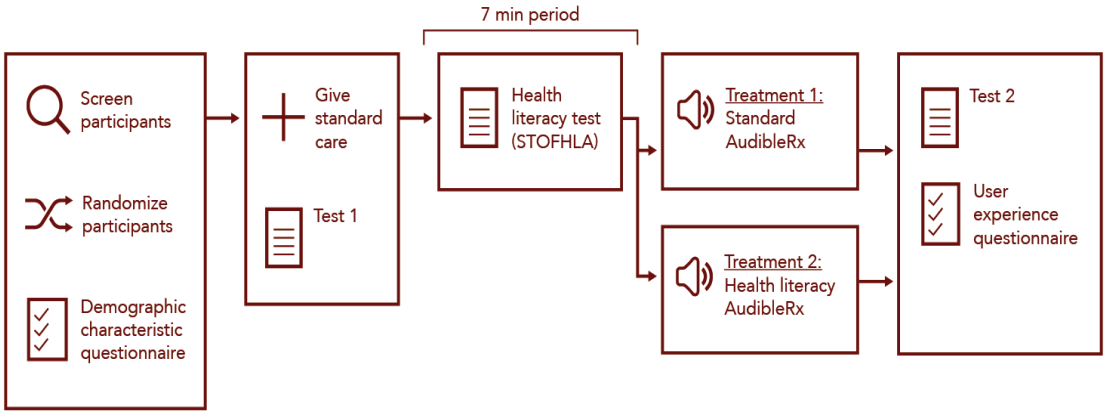
collated and used to prepare a standard statement that could be read to all patients. The final statement was reviewed by two additional community pharmacists. None of the pharmacists had a previous relationship with the research team. To simulate new use, participants were told,

> *"Picture yourself as a patient newly diagnosed with an irregular heartbeat by your physician. Imagine you have just come from the physician's office and now are headed toward the pharmacy to fill your prescription. The physician has prescribed a new medication called warfarin to prevent a stroke. You hand your prescription to the pharmacist who responds: "The medication prescribed by your doctor is called warfarin, a blood thinner that you use once a day. You will need regular blood work to make sure your blood isn't too thin and you will also need to monitor for any signs of bleeding. Please warn your doctor if you see any signs of bleeding. For more information, there is a medication information sheet inside your prescription bag. Have a great day."*

4.2.5. Testing of the Intervention

Figure 4.2 outlines the study flow. The study took place in a private area within each site, to ensure information was kept confidential. The study began with each participant completing a demographic characteristics questionnaire, which included sex, education, age, ethnicity and income.

Figure 4.2: Study design flow chart



The interviewer read the standard pharmacy care counseling statement to the participant and then provided the patient handout for warfarin. Participants were asked to use the patient handout as they would at home. When participants indicated they were done with the patient handout, a medication knowledge test was given to determine the knowledge they obtained from standard pharmacy care. To create a washout period before intervention, participants were given the 7-minute STOFHLA to assess health literacy levels.

The sample population was randomized using an online randomization website (https://www.randomizer.org/). Participants were randomized into two different intervention groups: 1) standard AudibleRx™ podcast, and 2) low health literacy AudibleRx™ podcast. Participants were asked to imagine they were back at the pharmacy where the pharmacist has just finished counseling them on their new prescription for warfarin. This time, the pharmacist has ended the counseling session by stating the following:

"For more information, there is reliable and simple information that you can

accessibly listen to on demand by simply tapping over your medication bottle to your phone or tablet. There is also a medication information sheet inside your prescription bag. Have a great day."

Participants were then provided with a smartphone that they could tap to the medication bottle to hear either podcast #1 or #2. Following the intervention, the medication knowledge test was re-administered with the questions in a different order to assess the participant's medication knowledge. Finally, participants were given a user experience questionnaire on their experience with the NFC-chip enabled podcast.

4.2.6. Outcome measures

The primary outcome measure was the number of correct answers the participants scored on the knowledge assessment with standard care, standard AudibleRx™ podcast and low health literacy AudibleRx™ podcast. A secondary outcome measure was the change in correct answers on the knowledge assessment at pre-intervention to post-intervention in the control and intervention groups. Another secondary measure was the participant's stated user experience.

4.2.7. Data analysis

Data were analyzed using the statistical analysis program, SPSS 22 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.) . Additionally, demographic characteristics, which included STOFHLA score, were compared using Pearson Chi square tests in both intervention groups. Interventions and standard pharmacy care were compared using standard one-sided and paired t-tests. A one way ANOVA was also used to find any significant difference between health literacy

levels and test scores in both standard and treatment groups. All results were considered statistically significant if the p-value was less than 0.05.

4.3. Results

4.3.1. Demographic characteristics

There were 30 participants who had a mean age of 59 years old and ranged in age from 40 to 70 years old (Table 4.2). The sample consisted of 66.7% female and 33.3% male participants, where 93.4% had an education below high school and 36.7% had an education below grade eight. Participant backgrounds included South Asian (33.3%), European (23.3%), East Asian (13.3%), East African (10%), Middle Eastern (10%), Latin American (3%) and Canadian (3%). Additionally, 40% of participants reported an income of less than $10,000 (CAD) per year. According to the STOFHLA, 56.7% of participants had low health literacy, 23.3% had moderate health literacy and 20% had adequate health literacy. Income and education was significantly associated with low health literacy but age, gender and ethnicity were not (Table 4.2). There was no significant difference between the demographics of participants in intervention 1 and intervention 2.

4.3.2. Medication Knowledge Test Scores

After all 30 participants were given standard pharmacy care, the overall mean score for the first knowledge test was 6.10/16 (38%) (Table 4.3). After the intervention, the overall mean score on the knowledge test for the standard and health literacy podcasts were 12.03/16 (75%) and 12.80/16 (80%), respectively (Table 4.3). Both intervention podcasts performed significantly better than standard pharmacy care ($p<0.001$). However, the

mean improvement from test score 1 to test score 2 was 4.93/16 for the standard podcast and 7.73/16 for the health literacy podcast. Hence, results indicate that the health literacy podcast improved test scores more than the standard podcast ($p < 0.001$).

4.3.3. Health Literacy and Knowledge Test Scores

After standard care, there significant difference between the test scores of different health literacy levels ($p<0.001$). Further analysis demonstrated that participants with low health literacy had a significantly lower test score than participants with marginal health literacy ($p=0.005$) and adequate health literacy ($p=0.01$). Specifically, participants with low health literacy scored 2.56 points less than participants with marginal health literacy, and 3.11 points less than participants with high health literacy. However, there was no significant difference in test score in the health literacy groups after both intervention podcasts meaning the difference in test scores that were apparent with standard care no longer existed after a podcast (Table 4.4).

4.3.4. AudibleRx Experience

Participants from both of the AudibleRx™ podcast versions described the intervention as a useful and effective method for understanding medication information. Participants also highlighted how the podcasts provided information that was not covered in pharmacist counseling and patient handouts, such as what do to when a dose is missed and the risks and benefits of not taking their medication. Additionally, for both versions of the AudibleRx™ podcast, participants reported that they enjoyed listening to the information and 20/30 (66.7%) participants preferred the podcasts to patient handouts because of challenges with reading, such as reading slow and mispronouncing words. Participants shared how they understand verbal information more than written information and found

listening to information to be less time consuming and simpler.

Participants given the standard AudibleRx™ podcast disliked the use of scientific jargon, the length, and found the information to be overwhelming. Participants reported that they would like to hear breaks in between podcast segments and for the speaker to be more engaging. By comparison, participants noted that the low health literacy AudibleRx™ podcast made them feel they were listening to their own pharmacist. Additionally, participants liked the introductory overview of the medication at the start of the podcast because it helped them prepare for what they were about to hear. Participants also highlighted that the transition sounds between segments and that the repetition of important information helped them stay alert, pay attention and listen with more clarity.

4.3.5. NFC and QR Code Preference

After the intervention, participants were asked to try accessing the podcast through both the NFC tag and the QR code. All participants favored the NFC tag because it did not require an additional software download, it was fast and it was very simple to understand. On the other hand, participants had difficulties scanning the QR code and believed the QR code was slow compared to the NFC tag. Finally, 28/30 (93%) participants stated they would use NFC enabled AudibleRx™ podcasts in the future and 25/30 (83%) participants stated they would use the QR code enabled AudibleRx™ podcasts in the future.

4.4. Discussion

This feasibility study demonstrated that patients from all health literacy levels can benefit from an NFC-enabled AudibleRx™ podcast. To our understanding, there has been no

study that explores the use of audio podcasting as an additional method of pharmacy counseling. The results of this study were also consistent with other research showing that lower income and education levels are closely tied to lower health literacy levels.[3] In regards to medication knowledge, the AudibleRx™ podcasts were successful in significantly improving the medication knowledge test scores of participants from all health literacy levels compared to standard pharmacy care. Although both AudibleRx™ podcasts improved test scores, the low health literacy AudibleRx™ podcast version had an additional significant improvement compared to the standard AudibleRx™ podcast. The low health literacy AudibleRx™ podcast in which we modified the content by mapping the script, simplifying the language, and repeating and summarizing information, was seen by participants as desirable, engaging and enjoyable.

One interesting finding was that there was a significant difference between health literacy levels and standard care test scores, where participants with lower health literacy had significantly lower test scores than participants with marginal and adequate health literacy. The differences between standard care test scores are a good reminder that pharmacy patients with low health literacy struggle more than patients with higher health literacy.

In this study, after participants were given the AudibleRx™ podcast interventions, there was no difference between health literacy levels and test scores, which demonstrates that AudibleRx™ podcasts may have tackled barriers and challenges individuals with low health literacy face. As described in chapter 3, people with low health literacy report that they have a variety of challenges with current medication information such as difficulty reading, understanding, and remembering medication information. Therefore, we cannot

overestimate the importance of low health literacy interventions for pharmacy patients such as the AudibleRx™ podcasts.

Previous novel interventions similar to AudibleRx™ such as the audio booklet for statin therapy [26] and electronic blister packs.[27] The audio booklet combined audio medication information with pictographs that covered basic information about cholesterol and how statin medications work.[26] Although the audio booklet improved patient knowledge, the format meant that patients could only access the audio booklet at the physician visit.[26] By comparison, the electronic blister pack aimed to improve medication adherence by detecting medication non-adherence through radio-frequency identification (RFID) technology and sending a text message reminder to participants when a medication was not taken. [27] However, the electronic blister packs only improved medication adherence for an average of one out of the four medications.[27]

4.1.1. Future studies

Although NFC tags were desired more than QR codes, future research with more focus on QR codes should be conducted. Implementing QR codes into pharmacy practice is simpler because QR codes can be printed on a medication label. AudibleRx™ podcasts could also be easily shared through email, social media, and on pharmacy websites. Future studies should also apply health literacy guidelines for medication information developed in this study as a method to develop information that will benefit all individuals, rather than focusing on higher literacy patients.

Pharmacy stakeholders and policy makers should consider implementing podcast interventions such as AudibleRx™ into pharmacy standard care to improve medication

knowledge across all patients, regardless of health literacy levels. Therefore, this feasibility study demonstrates that a full-scale pragmatic randomized control trial study in the pharmacy can be conducted. Future studies on interventions such as this would include testing more than one drug, including participants who were newly prescribed a medication and measuring long-term medication adherence and health outcomes. Future studies could also include a usual care group that continues to receive the standard care throughout the study, demonstrating the effect of general pharmacy information over the longterm. A full-scale study would provide further evidence of the effect of implementing NFC- or QR-code enabled AudibleRx^{TM} podcasts as an additional tool for pharmacy counseling.

4.1.2. Limitations

There are four main limitations in this study. The first is that the study targeted older adults, many of whom spoke English as an alternate language, which may limit the generalizability of the study results to populations who have low health literacy primarily due to education or economic variables other than ethnicity/race. The second limitation is that there is no current standardized assessment for health literacy, but of the available assessments, the STOFHLA is regarded as the most acceptable and commonly used tool for determining health literacy. The third limitation is that there was the risk of instrumentation bias as we used the same knowledge test both before and after. Though we did include a seven minute washout period using the STOFHLA, we recognize that it may not have been enough time to completely address this bias. Finally, the fourth limitation is that we recruited theoretical patients who were to imagine they had been

newly prescribed warfarin, which means they may not have been as motivated to learn as actual warfarin patients.

4.5. Conclusions

The NFC-enabled AudibleRx™ podcasts significantly improved medication knowledge in participants with low, marginal and adequate health literacy, especially when written for a low health literacy population. If patients are given reliable, comprehensive, and simple information about a medication through an intervention such as AudibleRx™, which they can accessibly listen to on demand, the patient should have sufficient understanding of their medication to properly follow instructions and self-manage their medications. Interventions such as AudibleRx™ are an important step towards supporting low health literacy patients in becoming more confident and taking steps toward understand their medication, adhering to their medication and feeling comfortable discussing their medication with health professionals.

Table 4.2: Demographic characteristics of sample (N=30)

Variables	Intervention 1 (n=15)	Intervention 2 (n=15)	Difference between groups
Age			
40-49	1	3	0.728
50-59	6	7	
60-64	3	1	
65+	5	4	
Gender			
Male	4	5	0.475
Female	11	10	
Ethnicity			
European	4	3	0.075
South Asian	4	6	
East Asian	2	2	
East Africa	1	2	
Middle Eastern	1	2	
Latin American	2	0	
Canadian	1	0	
Income			
<$10,000	6	6	0.794
$15,000-24,000	1	3	
$25,000-34,000	5	4	
$35,000-49,000	3	0	
>$50,000	0	2	
Education			0.781
<Grade 8	6	5	
Grade 9-11	3	3	
Completed high school	4	4	
College/University	2	3	
Health literacy score			0.606
Low	7	10	
Moderate	4	3	
Adequate	4	2	

N/A= not applicable

Table 4.3: Test score differences between intervention 1 and intervention 2 (N=30)

		Mean score	N	Mean difference	SD	CI(95%)	p-value
Intervention 1 (n=15)	Standard care test score	6.40/16	15	-4.86	2.03	-5.99,-3.72	.001
	Treatment test score	11.27/16					
Intervention 2 (n=15)	Standard care test score	5.80/16	15	-7.00	2.36	-8.30,-5`.69	.001
	Treatment test score	12.8/16					

Table 4.4: Test score differences between health literacy levels

ANOVA					Bonferroni Post Hoc Test				
		Df	F	p-value	Health literacy level		Mean difference	Std. Error	p-value
Standard care test score	Between groups	2	11.18	0.000	low	moderate	-2.56	0.731	0.005
					low	adequate	-3.11	0.773	0.01
	Within groups	27			moderate	adequate	-.571	0.905	1.00
	Total	29							
Intervention test score	Between groups	2	0.685	0.513	low	moderate	-1.04	1.22	1.00
					low	adequate	-1.30	1.29	0.969
	Within groups	27			moderate	adequate	-.262	1.51	1.00
	Total	29							

4.6. References

1. Nicole P, Rouse MJ. Scope of contemporary pharmacy practice: Roles, responsibilities, and functions of pharmacists and pharmacy technicians Executive summary. Am J Heal Pharm. 2010;67(12):1030-1031. doi:10.2146/ajhp100057.

2. Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Crotty K. Low health literacy and health outcomes: An updated systematic review. Ann Intern Med. 2011;155(2):97-107. doi:10.7326/0003-4819-155-2-201107190-00005.

3. Canadian Council on Learning.Health Literacy in Canada report. 2007:1-34.

4. Wali, H., Grindrod, K. (2015). Don't assume the patient understands: Low health literate patient insight to challenges faced with medication information at the pharmacy. Unpublished Master's thesis, University of Waterloo, School of Pharmacy

5. Wali, H., Hudani, Z., Wali, S., Grindrod, K. (2015). Don't assume the patient understands: A systematic review of interventions to improve medication information for low health literate populations. Unpublished Master's thesis, University of Waterloo, School of Pharmacy

6. Hussey LC. Minimizing effects of low literacy on medication knowledge and compliance among the elderly. Clin Nurs Res. 1994;3(2):132-145.

7. Kripalani S, Robertson R, Love-Ghaffari MH, et al. Development of an illustrated medication schedule as a low-literacy patient education tool. Patient Educ Couns. 2007;66(3):368-377.

8. DeWalt DA, Malone RM, Bryant ME, et al. A heart failure self-management program for patients of all literacy levels: a randomized, controlled trial. BMC Health Serv Res. 2006;6:30.

9. Glasgow RE, Christiansen SM, Kurz D, et al. Engagement in a diabetes self-management website: usage patterns and generalizability of program use. J Med Internet Res. 2011;13(1):

10. Kripalani S, Roumie CL, Dalal AK, et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: a randomized trial. Ann Intern Med. 2012;157(1):1-10.

11. McCarthy ML, Ding R, Roderer NK, et al. Does providing prescription information or services improve medication adherence among patients discharged from the emergency department? A randomized controlled trial; 23561463. Ann Emerg Med. 2013;62(3):212-223e1.

12. Unk JA. Efficacy study of multimedia to educate rheumatoid arthritis patients. Arthritis Rheum. 2013;65:S420.

13. Rogers EM. Diffusion of Innovations. Vol 27. 2003. doi:10.1287/opre.51.6.866.24918.

14. Free C, Phillips G, Watson L, et al. The Effectiveness of Mobile-Health Technologies to Improve Health Care Service Delivery Processes: A Systematic Review and Meta-Analysis. PLoS Med. 2013;10(1). doi:10.1371/journal.pmed.1001363.

15. Kubota A, Fujita M, Hatano Y. [Development and effects of a health promotion program utilizing the mail function of mobile phones]. Nippon Koshu Eisei Zasshi. 2004;51(10):862-873.

16. Free C, Knight R, Robertson S, et al. Smoking cessation support delivered via mobile phone text messaging (txt2stop): A single-blind, randomised trial. Lancet. 2011;378(9785):49-55. doi:10.1016/S0140-6736(11)60701-0.

17. Rodgers A, Corbett T, Bramley D, et al. Do U Smoke after Txt? Results of a Randomised Trial of Smoking Cessation Using Mobile Phone Text Messaging. Vol 14. 2005. doi:10.1136/tc.2005.011577.

18. Whittaker R, Borland R, Bullen C, Lin RB, McRobbie H, Rodgers A. Mobile phone-based interventions for smoking cessation. Sao Paulo Med J. 2010;128(2):106-107. doi:10.1002/14651858.CD006611.pub2.

19. Blake H. Innovation in practice: mobile phone technology in patient care. Br J Community Nurs. 2008;13(4):160, 162-165. doi:10.12968/bjcn.2008.13.4.29024.

20. Vital Wave Consulting. mHealth for Development: The Opportunity of Mobile Technology for Healthcare in the Developing World. Vol 46. 2009. doi:10.1145/602421.602423.

21. Wolf MS, Davis TC, Shrank WH, Neuberger M, Parker RM. A critical review of FDA-approved Medication Guides. Patient Educ Couns. 2006;62(3):316-322. doi:10.1016/j.pec.2006.06.010.

22. Innovision Research & Technology. Near Field Communication in the real world - Turning the NFC promise into profitable , everyday applications Innovision Research & Technology plc. White Pap. 2007.

23. Haselsteiner E, Breitfuß K. Security in Near Field Communication (NFC) Strengths and Weaknesses. Semiconductors. 2006;11(71):71

24. Somogyi A. Warfarin pharmacogenetics. Aust Prescr. 2009;32(5):119. doi:10.2165/00019053-200725110-00001.

25. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. Fam Med. 2004;36:588-594.

Chapter 5: Overall Discussion and Conclusions

Half of North American adults use at least one prescription medication. Yet, many North American adults do not have the capacity to obtain, process and understand basic medication information, meaning they struggle to self-manage their health and make appropriate health decisions. In today's busy pharmacies, medication information is presented at a tenth grade level, while huge swaths of the population can only read at a fifth-grade level. As described in the introductory chapter of this thesis, current medication information too difficult to understand, low health literate populations are at a higher risk of misinterpreting prescription label instructions, dosages, duration of therapy, frequency of dosing, warning labels, written information and verbal pharmacist counseling

In the first section, I completed a systematic review to investigate the evidence on interventions that improve medication knowledge and adherence for low health literate populations. I found that interventions that targeted low health literate populations were a positive approach to improving patient's medication knowledge and adherence. Effective interventions varied from providing patients with written information, verbal information, label information to reminder systems to educational program/services. The interventions targeted to low health literate populations that were effective generally aimed to remove specific barriers and challenges faced by low health literacy populations, by either giving more information that is simpler to understand, personalizing information or making information easier to use and more accessible. For example, interventions that involved translating medication information on a prescription label removed the challenge of reading and the barrier of language.

In second section, I outlined the low health literate population's pharmacy experience with medication information and found four main challenges: not understanding medication information, forgetting to take medication, experiencing and dealing with side effects and managing food-drug instructions and interactions. I found that these challenges were faced due to certain barriers such as time, communication, memory and support from the pharmacy. When these challenges and barriers were experienced, the low health literate participants reported that they would seek help from pharmacists, physicians, family, and friends in their attempts to address their challenges. However when challenges were still present, low health literate populations are left with unanswered questions or concerns, which lead to their perception of negative medication related outcomes including adverse events, their need to assume instructions, their need to refer to unreliable sources of information, errors and apathy towards their treatment. There is a clear gap between the levels of skill required to understand current medication information and the actual level of understanding among low health literate population.

Although there are a variety of interventions being tested to improve heath literacy in practice, none have been widely implemented. It may be possible health literacy interventions for medication information like PictureRx have not been implemented into pharmacy practice because it requires an increased workload for the pharmacy staff and requires a substantial amount of time and resources. One of the main challenges faced for pharmacists is the difficulty they face in identifying patients with low health literacy. Low health literacy becomes a more difficult problem when patients overestimate their health literacy levels because of the fear of being judged on not being able to read, write or understanding information and feeling ashamed

to seek clarification from the pharmacist. Therefore, interventions that provide a shame-free and blame-free environment and require minimal time and cost can be implemented into pharmacy practice.

Therefore, in section three I developed and tested a low health literacy intervention with patients of mixed heath literacy. Mobile information and communication technologies have been emerging as a tool for patient education and may be a solution for providing interventions that can be easily adopted into a pharmacy practice. AudibleRx^{TM} is a pharmacist-managed website that aims to provide consumers with web and mobile medication information through audio podcasting. We tested an existing AudibleRx^{TM} podcast and a podcast that was modified using communication strategies for low literacy populations. Both versions of the podcast were successful in significantly improving the medication knowledge test scores of participants from all health literacy levels compared to current standard pharmacy care. However, the low health literacy AudibleRx^{TM} podcast version provided an additional significant improvement over the standard AudibleRx^{TM} and was also perceived as a more desirable, engaging and enjoyable, which suggests the benefit of applying health literacy guidelines. The most important finding in the feasibility study was the significant difference between health literacy levels in standard care test scores, which demonstrated that low health literate participants scored poorer and were at a disadvantage with the current standard pharmacy care. Conversely, after the AudibleRx^{TM} podcast intervention, there was no difference between the health literacy levels and test scores, which demonstrates that AudibleRx^{TM} podcasts may have tackled barriers and challenges individuals with low health literacy face.

In conclusion, this thesis was an exploration of interventions to improve the experience of pharmacy patients who have low health literacy. The work herein highlights the importance of developing easy to implement tools that help low health literacy populations use, understand and explore medication therapy. This is an important step towards improving patient outcomes by reducing medication non-adherence and adverse event.

References

1. Ramage-Morin PL. Medication use among senior Canadians. Heal reports Statistics Canada, 2009;20:37-44.

2. Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. J Am Pharm Assoc, 2001;Mar-Apr;41(2)192-9.

3. Marvanova M, Roumie CL, Eden SK, Cawthon C, Schnipper JL, Kripalani S. Health literacy and medication understanding among hospitalized adults. J Hosp Med. 2011;6:488-493. doi:10.1002/jhm.925.

4. Safeer RS, Keenan J. Health literacy: The gap between physicians and patients. Am Fam Physician. 2005;72:463-468.

5. Bailey SC, Hasnain-Wynia R, Chen AH, et al. Developing Multilingual Prescription Instructions for Patients with Limited English Proficiency. *J Health Care Poor Underserved*. 2012;23(1):81-87. doi:10.1353/hpu.2012.0000

6. Brown MT, Bussell JK. Medication adherence: WHO cares? Mayo Clin Proc. 2011;86:304-314. doi:10.4065/mcp.2010.0575.

7. Zarcadoolas C, Pleasant A, Greer DS. Understanding health literacy: An expanded model. Health Promot Int. 2005;20:195-203. doi:10.1093/heapro/dah609.

8. Canadian Council on Learning. Health Literacy in Canada. Rep Learn Canada. 2007;1-34.

9. Kirsch I. Adult Literacy in America: A First Look at the Results of the National Adult Literacy Survey.; 1993. doi:NCES 1993-275.

10. Bostock S, Steptoe A. Association between low functional health literacy and mortality in older adults: longitudinal cohort study. BMJ. 2012;344:e1602-e1602. doi:10.1136/bmj.e1602.

11. Kickbusch I, Pelikan J, Apfel F, Tsouros A. Health literacy: the solid facts. Copenhagen WHO Reg Office for Europe. 2013:7-8

12. Eichler K, Wieser S, Brügger U. The costs of limited health literacy: a systematic review. Int J Public Health. 2009;54:313-324. doi:10.1007/s00038-009-0058-2.

13. Schillinger D, Grumback K, Piette J, Wang F, Osmond D, Daher C et al. Association of health literacy with diabetes outcomes. - JAMA. 2002;31;288(4)475-82.

14. De Geest S, Sabaté E. Adherence to long-term therapies: Evidence for action. Eur J Cardiovasc Nurs. 2003;2:323. doi:10.1016/S1474-5151(03)00091-4.

15. Manzano AT, Raphael D. CPHA and the social determinants of health: An analysis of policy documents and statements and recommendations for future action. Can J Public Heal. 2010;101:399-404.

16. Shoemaker SJ, Staub-DeLong L, Wasserman M, -Spranca M. Factors affecting adoption and implementation of AHRQ health literacy tools in pharmacies. Res Soc Adm Pharm. 2013;9:553-563. doi:10.1016/j.sapharm.2013.05.003.

17. Abraham C, Kelly MP, West R, Michie S. The UK National Institute for Health and Clinical Excellence public health guidance on behaviour change: a brief introduction. Psychol Health Med. 2009;14:1-8. doi:10.1080/13548500802537903.

18. Al Sayah F, Majumdar SR, Williams B, Robertson S, Johnson JA. Health Literacy and Health Outcomes in Diabetes: A Systematic Review. J Gen Intern Med. 2013;28:444-452. doi:10.1007/s11606-012-2241-z.

19. Taggart J, Williams A, Dennis S, et al. A systematic review of interventions in primary care to improve health literacy for chronic disease behavioral risk factors. BMC Fam Pract. 2012;13:49. doi:10.1186/1471-2296-13-49.

20. Easton P, Entwistle VA, Williams B. Health in the "hidden population" of people with low literacy. A systematic review of the literature. BMC Public Health. 2010;10:459. doi:10.1186/1471-2458-10-459.

21. Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: Explanation and elaboration. Ann Intern Med. 2009;151. doi:10.1371/journal.pmed.1000100.

22. The Cochrane Collaboration. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011].; 2011. doi:Available from www.cochrane-handbook.org.

23. Baker DW. The meaning and the measure of health literacy. J Gen Intern Med. 2006;21:878-883. doi:10.1111/j.1525-1497.2006.00540.x.

24. Baker DW, Williams M V., Parker RM, Gazmararian JA, Nurss J. Development of a brief test to measure functional health literacy. In: Patient Education and Counseling. Vol 38. ; 1999:33-42. doi:10.1016/S0738-3991(98)00116-5.

25. Weiss BD, Mays MZ, Martz W, et al. Quick assessment of literacy in primary care: The newest vital sign. Ann Fam Med. 2005;3:514-522. doi:10.1370/afm.405.

26. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. Fam Med. 2004;36:588-594.

27. Jeppesen KM, Pharm JDC, Miser WF. Screening questions to predict limited health literacy: A cross-sectional study of Patients with diabetes mellitus. Ann Fam Med. 2009;7:24-31. doi:10.1370/afm.919.

28. Green S, Higgins P., T. J, Alderson P, Clarke M, Mulrow D C, Oxman D A. Cochrane Handbook: Cochrane Reviews: Ch 8: Assessing risk of bias in included studies. In: Cochrane Handbook for: Systematic Reviews of Interventions. Vol 6. ; 2011:3-10.

29. Aker J, Beck M, Papay JI, et al. Consumers Better Understand and Prefer Simplified Written Drug Information: An Evaluation of 2 Novel Formats Versus the Current CMI . Ther Innov Regul Sci . 2013;47 (1):125-132. doi:10.1177/0092861512462371.

30. AlSaffar N, Deshmukh AA, Carter P, Adib SM. Effect of information leaflets and counselling on antidepressant adherence: open randomised controlled trial in a psychiatric hospital in Kuwait. Int J Pharm Pract. 2005;13(2):123-131.

31. Boyne JJJ, Vrijhoef HJM, Spreeuwenberg M, De Weerd G, Kragten J, Gorgels APM. Effects of tailored telemonitoring on heart failure patients' knowledge, self-care, self-efficacy and adherence: a randomized controlled trial. Eur J Cardiovasc Nurs. 2014;13:243-252. doi:10.1177/1474515113487464.

32. Braich PS, Almeida DR, Hollands S, Coleman MT. Effects of pictograms in educating 3 distinct low-literacy populations on the use of postoperative cataract medication. Can J Ophthalmol. 2011;46(3):276-281.

33. Brath H, Morak J, Kästenbauer T, et al. Mobile health (mHealth) based medication adherence measurement - a pilot trial using electronic blisters in diabetes patients. Br J Clin Pharmacol. 2013;76:47-55. doi:10.1111/bcp.12184.

34. Brock TP, Smith SR. Using digital videos displayed on personal digital assistants (PDAs) to enhance patient education in clinical settings. Int J Med Inform. 2007;76(11-12):829-835.

35. Burghardt KJ, Bowman MR, Hibino M, et al. Using educational games to promote the seeking of a pharmacist and to teach key medication use messages: Results from an inner city health party; 23411370. Res Soc Adm Pharm. 2013;9(5):542-552.

36. Cardarelli R, Mann C, Fulda KG, Balyakina E, Espinoza A, Lurie S. Improving accuracy of medication identification in an older population using a medication bottle color symbol label system. Bmc Fam Pract. 2011;12:142.

37. Cordasco KM, Asch SM, Bell DS, et al. A Low-Literacy Medication Education Tool for Safety-Net Hospital Patients. Am J Prev Med. 2009;37(6 SUPPL. 1):S209-S216..

38. Davis TC, Federman AD, Bass PF, et al. Improving patient understanding of prescription drug label instructions. J Gen Intern Med. 2009;24:57-62. doi:10.1007/s11606-008-0833-4.

39. DeWalt DA, Malone RM, Bryant ME, et al. A heart failure self-management program for patients of all literacy levels: a randomized, controlled trial. BMC Health Serv Res. 2006;6:30..

40. Dowse R, Ehlers M. Medicine labels incorporating pictograms: do they influence understanding and adherence? Patient Educ Couns. 2005;58(1):63-70.

41. Glasgow RE, Christiansen SM, Kurz D, et al. Engagement in a diabetes self-management website: usage patterns and generalizability of program use. J Med Internet Res. 2011;13(1):e9.

42. Goeman D, Jenkins C, Crane M, Paul E, Douglass J. Educational intervention for older people with asthma: A randomised controlled trial. Patient Educ Couns. 2013;93(3):586-595.

43. Gossey JT, Whitney SN, Crouch MA, Jibaja-Weiss ML, Zhang H, Volk RJ. Promoting knowledge of statins in patients with low health literacy using an audio booklet. Patient Prefer Adherence. 2011;5:397-403.

44. Heinrich C, Anne RK. Using Handheld Devices to Promote Medication Adherence in Chronic Illness. J Nurse Pract. 2012;8(4):288-293.

45. Hussey LC. Minimizing effects of low literacy on medication knowledge and compliance among the elderly. Clin Nurs Res. 1994;3(2):132-145.

46. Jolly BT, Scott JL, Sanford SM. Simplification of emergency department discharge instructions improves patient comprehension. Ann Emerg Med. 1995;26(4):443-446.

47. Joshi Y, Kothiyal P. A pilot study to evaluate pharmaceutical pictograms in a multispecialty hospital at Dehradun. J Young Pharm. 2011;3(2):163-166.

48. Kalichman SC, Cherry J, Cain D. Nurse-delivered antiretroviral treatment adherence intervention for people with low literacy skills and living with HIV/AIDS. J Assoc Nurses AIDS Care. 2005;16(5):3-15.

49. Kalichman SC, Cherry C, Kalichman MO, et al. Randomized clinical trial of HIV treatment adherence counseling interventions for people living with HIV and limited health literacy. J Acquir Immune Defic Syndr. 2013;63(1):42-50.

50. King SR, McCaffrey DJ, Bentley JP, Bouldin A, Hallam J, Wilkin NE. The influence of symbols on the short-term recall of pharmacy-generated prescription medication

information in a low health literate sample; 23030576. J Health Commun. 2012;17:280-293.

51. Kripalani S, Robertson R, Love-Ghaffari MH, et al. Development of an illustrated medication schedule as a low-literacy patient education tool. Patient Educ Couns. 2007;66(3):368-377.

52. Kripalani S, Roumie CL, Dalal AK, et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: a randomized trial. Ann Intern Med. 2012;157(1):1-10.

53. Kripalani S, Schmotzer B, Jacobson TA. Improving Medication Adherence through Graphically Enhanced Interventions in Coronary Heart Disease (IMAGE-CHD): a randomized controlled trial. J Gen Intern Med. 2012;27(12):1609-1617..

54. Lefante J, J.J, Harmon GN, et al. The effect of medication reviews in a rural community pharmacy assistance program: The Cenla Medication Access Program. J Pharm Pract. 2005;18(6):486-492.

55. Magadza C, Radloff SE, Srinivas SC. The effect of an educational intervention on patients' knowledge about hypertension, beliefs about medicines, and adherence. Res Soc Adm Pharm. 2009;5(4):363-375.

56. Mansoor LE, Dowse R. Effect of pictograms on readability of patient information materials. Ann Pharmacother. 2003;37:1003-1009. doi:10.1345/aph.1C449.

57. McCarthy ML, Ding R, Roderer NK, et al. Does providing prescription information or services improve medication adherence among patients discharged from the emergency department? A randomized controlled trial; 23561463. Ann Emerg Med. 2013;62(3):212-223e1.

58. Morrow DG, Weiner M, Young J, Steinley D, Deer M, Murray MD. Improving medication knowledge among older adults with heart failure: A patient-centered approach to instruction design. Gerontologist. 2005;45(4):545-552.

59. Morrow D, Raquel L, Schriver A, Redenbo S, Rozovski D, Weiss G. External support for collaborative problem solving in a simulated provider/patient medication scheduling task. J Exp Psychol. 2008;14(3):288-297.

60. Moskowitz D, Thom DH, Hessler D, Ghorob A, Bodenheimer T. Peer Coaching to Improve Diabetes Self-Management: Which Patients Benefit Most? J Gen Intern Med. 2013;28(7):938-942.

61. Murray MD, Young J, Hoke S, et al. Pharmacist intervention to improve medication adherence in heart failure: A randomized trial. Ann Intern Med. 2007;146:714-725. doi:146/10/714 [pii].

62. Neafsey PJ, Strickler Z, Shellman J, Chartier V. An interactive technology approach to educate older adults about drug interactions arising from over-the-counter self-medication practices. Public Health Nurs. 2002;19:255-262. doi:10.1046/j.1525-1446.2002.19405.x.

63. Negarandeh R, Mahmoodi H, Noktehdan H, Heshmat R, Shakibazadeh E. Teach back and pictorial image educational strategies on knowledge about diabetes and medication/dietary adherence among low health literate patients with type 2 diabetes. Prim Care Diabetes. 2013;7(2):111-118.

64. Ngoh LN, Shepherd MD. Design, development, and evaluation of visual aids for communicating prescription drug instructions to nonliterate patients in rural Cameroon. Patient Educ Couns. 1997;30(3):257-270.

65. Poureslami I, Nimmon L, Doyle-Waters M, et al. Effectiveness of educational interventions on asthma self-management in Punjabi and Chinese asthma patients: A randomized controlled trial. J Asthma. 2012;49(5):542-551.

66. Sahm LJ, Wolf MS, Curtis LM, et al. What's in a label? An exploratory study of patient-centered drug instructions. Eur J Clin Pharmacol. 2012;68(5):777-782.

67. Savas S, Evcik D. Do undereducated patients read and understand written education materials? A pilot study in Isparta, Turkey. Scand J Rheumatol. 2001;30(2):99-102.

68. Schillinger D. Language, Literacy, and Communication Regarding Medication in an Anticoagulation Clinic: Are Pictures Better Than Words?; 2005.

69. Tait AR, Voepel-Lewis T, Brennan-Martinez C, McGonegal M, Levine R. Using animated computer-generated text and graphics to depict the risks and benefits of medical treatment. Am J Med. 2012;125:1103-1110. doi:10.1016/j.amjmed.2012.04.040.

70. Unk JA. Efficacy study of multimedia to educate rheumatoid arthritis patients. Arthritis Rheum. 2013;65:S420.

71. Van Servellen G, Nyamathi A, Carpio F, et al. Effects of a treatment adherence enhancement program on health literacy, patient-provider relationships, and adherence to HAART among low-income HIV-positive Spanish-speaking Latinos. AIDS Patient Care STDS. 2005;19(11):745-759.

72. Wang H, Zhou J, Huang L, Li X, Fennie KP, Williams AB. Effects of nurse-delivered home visits combined with telephone calls on medication adherence and quality of life in HIV-infected heroin users in Hunan of China. J Clin Nurs. 2010;19(3-4):380-388.

73. Watanabe N, Yamamura K, Suzuki Y, et al. Pharmacist-based Donepezil Outpatient Consultation Service to improve medication persistence. Patient Prefer Adherence. 2012;6:605-611.

74. Wong IY, Lawrence N V, Struthers H, McIntyre J, Friedland GH. Development and assessment of an innovative culturally sensitive educational videotape to improve adherence to highly active antiretroviral therapy in Soweto, South Africa. J Acquir Immune Defic Syndr. 2006;43(SUPPL. 1):S142-S148.

75. L. LZ, McCant F, D. SM, Danus S, B. HB. A health literacy pilot intervention to improve medication adherence using Meducation((R)) technology. Patient Educ Couns. 2014;95(2):288-291.

76. Shrank WH, Avorn J. Educating patients about their medications: The potential and limitations of written drug information. *Health Aff*. 2007;26(3):731-740. doi:10.1377/hlthaff.26.3.731.

77. Lee J, Grace K, Taylor A. pharmacy care program on medication adherence and persistence, blood pressure, and low-density lipoprotein cholesterol: a randomized controlled trial. *JAMA*. 2006;296(21):2563-2571. doi:10.1001/jama.296.21.joc60162.

78. Raehl CL, Bond CA, Woods TJ, Patry RA, Sleeper RB. Screening tests for intended medication adherence among the elderly. *Ann Pharmacother*. 2006;40(5):888-893. doi:10.1345/aph.1G478.

79. Davis TC, Federman AD, Bass PF, et al. Improving patient understanding of prescription drug label instructions. *J Gen Intern Med*. 2009;24:57-62. doi:10.1007/s11606-008-0833-4.

80. Wolf MS, Davis TC, Shrank W, et al. To err is human: Patient misinterpretations of prescription drug label instructions. *Patient Educ Couns*. 2007;67(3 SPEC. ISS.):293-300. doi:10.1016/j.pec.2007.03.024.

81. Babinec PM, Rock MJ, Lorenzetti DL, Johnson JA. Do researchers use pharmacists' communication as an outcome measure? A scoping review of pharmacist involvement in diabetes care. *Int J Pharm Pract*. 2010;18(4):183-193. doi:10.1111/j.2042-7174.2010.00038.x.

82. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups. *Int J Qual Heal Care*. 2007;19(6):349-357. doi:10.1093/intqhc/mzm042.

83. Patton M. *Qualitative Evaluation and Research Methods*.; 1990. doi:10.1002/nur.4770140111.

84. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. *Fam Med*. 2004;36:588-594.

85. Strauss A, Corbin J. *Basics of Qualitative Research: Techniques and Procedures for Developing Grounded Theory*. Vol 3. 2008. doi:10.4135/9781452230153.

86. Schaafsma ES, Raynor T, De Jong-van den Berg LTW. Accessing medication information by ethnic minorities: Barriers and possible solutions. *Pharm World Sci*. 2003;25(5):185-190. doi:10.1023/A:1025812716177.

87. Elliott R a. Problems with medication use in the elderly: an Australian perspective. *J Pharm Pract Res*. 2006;36(1):58-66.

88. Barber N, Parsons J, Clifford S, Darracott R, Horne R. Patients' problems with new medication for chronic conditions. *Qual Saf Health Care*. 2004;13(3):172-175. doi:10.1136/qshc.2003.005926.

89. Nicole P, Rouse MJ. Scope of contemporary pharmacy practice: Roles, responsibilities, and functions of pharmacists and pharmacy technicians Executive summary. Am J Heal Pharm. 2010;67(12):1030-1031. doi:10.2146/ajhp100057.

90. Wali, H., Grindrod, K. (2015). Don't assume the patient understands: Low health literate patient insight to challenges faced with medication information at the pharmacy. Unpublished Master's thesis, University of Waterloo, School of Pharmacy

91. Wali, H., Hudani, Z., Wali, S., Grindrod, K. (2015). Don't assume the patient understands: A systematic review of interventions to improve medication information for low health literate populations. Unpublished Master's thesis, University of Waterloo, School of Pharmacy

92. Unk JA. Efficacy study of multimedia to educate rheumatoid arthritis patients. Arthritis Rheum. 2013;65:S420.

93. Rogers EM. Diffusion of Innovations. Vol 27. 2003. doi:10.1287/opre.51.6.866.24918.

94. Free C, Phillips G, Watson L, et al. The Effectiveness of Mobile-Health Technologies to Improve Health Care Service Delivery Processes: A Systematic Review and Meta-Analysis. PLoS Med. 2013;10(1). doi:10.1371/journal.pmed.1001363.

95. Kubota A, Fujita M, Hatano Y. [Development and effects of a health promotion program utilizing the mail function of mobile phones]. Nippon Koshu Eisei Zasshi. 2004;51(10):862-873.

96. Free C, Knight R, Robertson S, et al. Smoking cessation support delivered via mobile phone text messaging (txt2stop): A single-blind, randomised trial. Lancet. 2011;378(9785):49-55. doi:10.1016/S0140-6736(11)60701-0.

97. Rodgers A, Corbett T, Bramley D, et al. Do U Smoke after Txt? Results of a Randomised Trial of Smoking Cessation Using Mobile Phone Text Messaging. Vol 14. 2005. doi:10.1136/tc.2005.011577.

98. Whittaker R, Borland R, Bullen C, Lin RB, McRobbie H, Rodgers A. Mobile phone-based interventions for smoking cessation. Sao Paulo Med J. 2010;128(2):106-107. doi:10.1002/14651858.CD006611.pub2.

99. Blake H. Innovation in practice: mobile phone technology in patient care. Br J Community Nurs. 2008;13(4):160, 162-165. doi:10.12968/bjcn.2008.13.4.29024.

100. Vital Wave Consulting. mHealth for Development: The Opportunity of Mobile Technology for Healthcare in the Developing World. Vol 46. 2009. doi:10.1145/602421.602423.

102. Wolf MS, Davis TC, Shrank WH, Neuberger M, Parker RM. A critical review of FDA-approved Medication Guides. Patient Educ Couns. 2006;62(3):316-322. doi:10.1016/j.pec.2006.06.010.

103. Innovision Research & Technology. Near Field Communication in the real world - Turning the NFC promise into profitable , everyday applications Innovision Research & Technology plc. White Pap. 2007.

104. Haselsteiner E, Breitfuß K. Security in Near Field Communication (NFC) Strengths and Weaknesses. Semiconductors. 2006;11(71):71

105. Somogyi A. Warfarin pharmacogenetics. Aust Prescr. 2009;32(5):119. doi:10.2165/00019053-200725110-00001.

106. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. Fam Med. 2004;36:588-594.

Appendix

Appendix 1.0 Don't assume the patient understands: Low health literate patient insight to challenges faced with medication information at the pharmacy

1.1- ORE approval

Title: Don't assume the patient understands: Low health literate patient insight to challenges faced with medication information at the pharmacy
ORE #: 19364
Faculty Supervisor: Kelly Grindrod (kgrindrod@uwaterloo.ca)
Student Investigator: Huda Wali (hwali@uwaterloo.ca)

have been reviewed and are considered acceptable. As a result, your application now has received full ethics clearance.

A signed copy of the Notification of Full Ethics Clearance will be sent to the Principal Investigator or Faculty Supervisor in the case of student research.

Maureen Nummelin, Ph.D.
Director, Office of Research Ethics
519.888.4567 x 36005
maureen.nummelin@uwaterloo.ca

Appendix 1.2.- Information letter

Project: Exploring patient perceptions of drug-food interactions with adults over age 50.
Organizers: Huda Wali (Student), Kelly Grindrod (Supervisor)

INFORMATION LETTER & CONSENT
2 January 2014

Dear Potential Participant:

This letter is an invitation to participate in a study being led by Ms. Huda Wali at the School of Pharmacy at the University of Waterloo to fulfill my academic requirements. We are asking you to participate in a twenty-minute interview where we will explore your thoughts on drug-food interactions.

Study objectives

Certain foods can interact with drug and affect how safe and effective the drugs are. Many people take a prescription drugs and may not know the risks or benefits some foods can pose. The effects depend on the type of drug and the type of food or drink being consumed. In one example, many drugs that are taken orally travel from the stomach to the liver, where specific enzymes break them down. Introducing a new substance before or even after you take a drug may affect how the drug is broken down by making the enzymes work faster or slowing them down. Other food-drug interactions are related to vitamins and minerals being consumed such as Vitamin K, calcium and iron.

Current research has focused on investigating what foods or nutrients have interactions to certain drugs. Little research has been done to explore how we can assist an individuals understanding of food-drug interactions with their prescriptions. The purpose of this study is to explore the perceptions of food-drug interactions among people over age 50, particularly in individuals who speak English as an alternate language.

Our goal is to gather information to develop a targeted intervention designed to educate medication users about drug-food interactions by improving health literacy.

Study overview

If you agree to participate, you will be asked to join in a 30-minute interview at Northwood Neighborhood seniors program in Toronto, between January and March 2013. We will begin by asking you to share a little bit about yourself and any experiences in life you wish to share. We will then ask you to answer general questions about drugs such as your experience using prescription drugs, getting information from the pharmacy and any problems you have had or had to overcome with your prescriptions. Shortened Test of Functional Health Literacy Assessment (STOFHLA) will be used as a validated measure of health literacy (Ref. **Baker DW, Williams MV, Parker RM, Gazmararian JA, Nurss J. Development of a brief test to measure functional health literacy. Patient Educ Couns. 1999;38:33-42.).**This will assess

your level of understanding of health-related information. A language interpreter will be present should you require translating assistance.

Your participation is voluntary

Participation in this study is voluntary. You may decline to answer any of the questions we ask if you so wish. Further, you may decide to withdraw from this study at any time without any negative consequences by advising the researcher.

Risks

We do not anticipate any risks to you due to participating in this study.

Eligibility Requirements for Participation

All participants must be adults aged 50 or over. Participants are not required to speak and read English; a interpreter will be present for assistance. Participants are welcome to join the research study regardless of their health care services.

Confidentiality and Data Retention

All information you provide will be considered confidential and de-identified, which will not be anonymous. Your responses will be grouped with other participants and collected using paper forms and via audio recording of the interview discussions. A unique study identifier (e.g., ABC-123) will be used in the place of your name on data collection forms

Although the interview discussion will be audio recorded, nothing that you or anyone else says during the interview will ever be associated with your name in any report or publication. Only participants who agree to be audio-recorded will be eligible to participate in the study. All of your comments will remain confidential and, if you need an interpreter, we will ask the interpreter to keep what you say during the interview in strict confidence. . If you choose to withdraw from the study at any point, your information will be destroyed.

Even though the results may be used in reports or publications, only the research team will have access to your data from the evaluations. Data such as interview audio and written information will be stored in an encrypted and password protected file on an encrypted laptop kept in a locked office at the School of Pharmacy in Kitchener, Ontario for 25 years.

Remuneration

We will not be providing any payment to you for participating in this study but you will be served a hot meal on behalf of Northwood Neighborhood.

Questions and Contact

If you have any questions about participation, or would like additional information to assist you in reaching a decision about participation, please contact me: Huda Wali (647) 883-8304 or via email at hwali@uwaterloo.ca.

Ethics Review and Clearance

I would like to assure you that this study has been reviewed by, and received ethics clearance through, the Office of Research Ethics at the University of Waterloo. However, the final decision about participation is yours. In the event you have any comments or concerns resulting from your participation in this study, please contact Dr. Maureen Nummelin, the Director, Office of Research Ethics, at 1-519-888-4567, Ext. 36005 or maureen.nummelin@uwaterloo.ca.

We hope that the results of our study will be of benefit to those organizations directly involved in the study, other voluntary recreation organizations not directly involved in the study, as well as to the broader research community.

Yours sincerely,

Huda Wali, BSc
Graduate Student
School of Pharmacy
University of Waterloo
(647) 883- 8304
hwali@uwaterloo.ca

Kelly Grindrod, BScPharm, PharmD, MSc
Assistant Professor
School of Pharmacy
University of Waterloo
(519) 888-4567 x 21358
kgrindrod@uwaterloo.ca

Appendix 1.3 Consent form

CONSENT FORM – AGREEMENT TO PARTICIPATE

By signing this consent form, you are not waiving your legal rights or releasing the investigator(s) or involved institution from their legal and professional responsibilities.

I have read the information presented in the information letter about a study being conducted by Huda Wali of the School of Pharmacy at the University of Waterloo. I have had the opportunity to ask any questions related to this study, to receive satisfactory answers to my questions, and any additional details I wanted.

I am aware that I have the option of allowing the interview to be audio recorded to ensure an accurate recording of my responses. Audio recording will not begin until participants have consented. If I do not wish to be audio recorded I will not be able to participate in study.

I am aware a Shortened Test of Functional Health Literacy Assessment (STOFHLA) will be used as a validated measure of health literacy.

I am also aware that excerpts from the interviews may be included in any reports and/or publications to come from this research, with the understanding that the quotations will be de-identified.

I am aware that interpreter s are chosen by Northwood Neighborhood from an accredited list and will also be asked to sign a confidentiality form.

I was informed that I may withdraw my consent at any time without penalty by advising the researcher and all data and audio recording will be properly erased.

This project has been reviewed by, and received ethics clearance through, the Office of Research Ethics at the University of Waterloo. I was informed that if I have any comments or concerns resulting from my participation in this study, I may contact Dr. Maureen Nummelin, the Director, Office of Research Ethics, at 1-519-888-4567, Ext. 36005 or maureen.nummelin@uwaterloo.ca.

With full knowledge of all foregoing, I agree, of my own free will, to participate in this study.

☐YES ☐NO

I agree to the audio recording of the focus group discussion.

☐YES ☐NO

I agree to the use of anonymous quotations in any report and/or publication that comes of this research.

☐YES ☐NO

Participant Name: _____(Please print)

Participant Signature: _____

Date: _____

Appendix 1.4- Adult interview script

ADULT INTERVIEW SCRIPT

When participants arrive at senior program

If there's an interpreter present, research or interpreter to introduce both parties and remind potential participants that the interpreter is available if needed.

Researcher/Investigator: Thank you for agreeing to participate in this interview where we hope to get information to help us create a tool to educate people about drug-food interactions. Please take a seat and feel free to read about the project and fill out the consent forms if you decide you would like to participate.

Researcher/Investigator [Introduce self and study investigators]: Before we get started, I would like to go over guidelines for the interview. During the interview, I will ask answers. The purpose of these interviews is to generate as many different ideas and opinions as possible.

Turn on voice recorder

Questions:

Background questions

Measuring Health Literacy
On a scale from 1 to 5 how often do you have someone help you read materials about your medications? (1 rarely--> 5 very often)
On a scale from 1 to 5 how confident are you filling out medical forms by yourself? (not confident--> confident)
On a scale from 1 to 5 how often do you have problems learning about your medications because of difficulty understanding written information? (rarely-->very often)

Research study questions

Thinking of how you take your medication, can you take me through a typical day?

What happens when you get a new prescription?

Thinking of your medications, what challenges or troubles do you have taking your medication?

Can you list the medications including the dose, directions you are currently on?

What are you taking each one for?
Can you show me your pill packs or bottles?
If there are any labels on prescription bottle:

-Can you tell me what this label means?
If there are any auxillary/warning labels:
Can you tell me what this label means?
Are these labels useful?

7. Do you know if any of your medications are taken on an empty or full stomach . Or if the doctor or pharmacist gave you some special food instructions?

8. When thinking of medication do they include any over the counter medication, vitamins or natural products?

9. What challenges do you face with these medications?

10. Can you tell me a general description of the foods and drinks you eat, specifically if taking:
Alcohol (each day/week/month)
Fruits and veggies (generally what/how often)
Green leafy veggies such as kale, cabbage, brussel sprouts, spinach
Potassium containing fruits such as bananas
Grapefruit or grapefruit juice
Dairy products including milk, cheese, yogurt, ice cream, calcium-fortified orange juice/soy milk etc

11. Has a pharmacist ever told you to wait to consume or avoid a certain food or drink when taking a medication?

12. Do you think you had enough information to decide what to eat or when to eat it?

13. When you eat or drink something, anything, how often do you think about its effects on your medication? Why?

14. Is there anything else you would like to share with me?

15. If we build a tool in the future, would you be interested in trying it out for us?

General information

What is your age?
What is your gender?
What is your language you speak most often?
What is your highest level of education?
When did you begin speaking English?
Do you use a computer, tablet, smartphone
Where?

Researcher/Investigator: Provide a summary of the findings generated via the interview.

Turn off voice recorder

Researcher/Investigator: Thank you all again for participating. Your input is vital to our understanding of the usability of mobile medical apps for adults.

Appendix 1.5- Feedback letter

Organizer: Huda Wali
FEEDBACK LETTER

Dear Participants,

I would like to thank you for your participation in the study entitled "Exploring patient perceptions of drug-food interactions with adults over age 50." As a reminder, the purpose of this project is to gather information to develop a tool to educate people about drug-food interactions.

Please remember that information from the interview will be kept confidential. Once all of the data are collected and analyzed for this project, we plan on sharing this information with the research community through seminars, conference presentations and journal articles. If you are interested in receiving more information regarding the results of this research, or would like a summary of the results, please provide your e-mail address to the researchers. When the study is completed, anticipated by September 2015, we will send you the information.

In the meantime, if you have any questions about the study, please do not hesitate to contact Huda Wali by e-mail or telephone, as noted below. As with all University of Waterloo projects involving human participants, this project was reviewed by, and received ethics clearance through, the Office of Research Ethics at the University of Waterloo. Should you have any comments or concerns resulting from your participation in this study, please contact Dr. Maureen Nummelin, the Director, Office of Research Ethics, at 1-519-888-4567, Ext 36005 or maureen.nummelin@uwaterloo.ca.

Yours sincerely,

Huda Wali, BSc
Graduate Student
School of Pharmacy
University of Waterloo
(647) 883- 8304
hwali@uwaterloo.ca

Kelly Grindrod, BScPharm, PharmD, MSc
Assistant Professor
School of Pharmacy
University of Waterloo
(519) 888-4567 x 21358
kgrindrod@uwaterloo.ca

Appendix 2.0- The future of pharmacy counseling: AudibleRx and the application of health literacy guidelines

Title: Health literacy guidelines to improving audible information
ORE #: 20525
Faculty Supervisor: Kelly Grindrod (kelly.grindrod@uwaterloo.ca)
Student Investigator: Huda Wali (hwali@uwaterloo.ca)

have been reviewed and are considered acceptable. As a result, your application now has received full ethics clearance.

A signed copy of the Notification of Full Ethics Clearance will be sent to the Principal Investigator or Faculty Supervisor in the case of student research.

Maureen Nummelin, Ph.D.
Director, Office of Research Ethics
519.888.4567 x 36005
maureen.nummelin@uwaterloo.ca

2.1. Participant recruitment script

Researcher:
Hello, my name is Huda Wali. I'm a graduate student at the University of Waterloo School of Pharmacy and I am currently working on a study to improve medication information, specifically focusing on audile medication information. Currently medication information is written in a complex manner that may increase the risk of misinterpreting prescription label instructions, dosage, duration, frequency, warning labels, written information and verbal pharmacist counseling.

Health literacy is barrier to accurately understanding medication information because of the complex language required to understand current medication information. Low health literacy is defined as having an inadequate ability to obtain, read, understand and use health information to make appropriate health decisions and to follow proper instructions for treatment

The purpose of this study is to provide participants with a new innovative technology called AudibleRx that provides reliable, comprehensive and simple information about a medication so that they can accessibly listen to on demand. This will allow patients to have sufficient understanding of their medication to properly follow instructions and self-manage their health. Our goal is to gather information on the improvement in knowledge and user experience with the AudbileRx, to determine the effectiveness and usability

Participants attending senior program: Yes/No

Researcher
[If participants attending senior program]: Great, you will be asked to join in a fifty-minute interview at your retirement home/ senior program, between March and May 2015. We will begin with a screening assessment to determine if you are eligible to participate in this study by asking you to complete a Shortened Test of Functional Health Literacy Assessment (STOFHLA) to assess your level of understanding of health-related information and the Montreal Cognitive Assessment (MoCA) to assess cognitive levels. You will then by given a touch-screen tablet device where you will listen to the AudibleRx podcast. After listening to the audible podcast information, we will then ask you to complete a knowledge test about the medication and also your user experience with the AudibleRx podcast.

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee.
However, the final decision about participation is yours. Does this interest you at all?

[If yes, researcher to provide a copy of the information/consent form to read and sign before the researcher may advertise in the institution]

OR

[If participants attending senior program does not agree]: Okay, I understand
Researcher:
Thank you for your time.

2.2. Information letter & consent form

Dear Potential Participant:
This letter is an invitation to participate in a study being led by Ms. Huda Wali at the School of Pharmacy at the University of Waterloo to fulfill Huda Wali's Master thesis. We are asking you to participate in a fifty-minute interview where we will explore your thoughts on medication information you can listen to.

Study objectives
Health literacy is barrier to accurately understanding medication information because of the complex language required to understand current medication information. Low health literacy is defined as having an inadequate ability to obtain, read, understand and use health information to make appropriate health decisions and to follow proper instructions for treatment. Unfortunately, current medication information is written in a complex manner that may increase the risk of misinterpreting prescription label instructions, dosage, duration, frequency, warning labels, written information and verbal pharmacist counseling.

The purpose of this study is to provide participants with a new innovative technology for called AudibleRx that provides reliable, comprehensive and simple information about a medication so that they can accessibly listen to on demand. This will allow patients to have sufficient understanding of their medication to properly follow instructions and self-manage their health. Our goal is to gather information on the improvement in knowledge and user experience with the AudbileRx to determine the effectiveness and usability.

Study overview
If you agree to participate, you will be asked to participate in a 50-minute audio-recorded interview. Before you enter the study, participants will need to able to speak English and read English to some degree and will also be required to complete a series of screening tests to assess if you qualified for the study. The screening tests will include a Shortened Test of Functional Health Literacy Assessment (STOFHLA) to assess your level of understanding of health-related information and the Montreal Cognitive Assessment (MoCA) to assess memory levels. You will then by given a touch-screen tablet device where you will listen to the AudibleRx podcast. After listening to the audible podcast information, we will then ask you to complete a knowledge test about the medication and also your user experience with the AudibleRx podcast.

Your participation is voluntary
Participation in this study is voluntary. You may decline to answer any of the questions we ask if you so wish. Further, you may decide to withdraw from this study at any time without any negative consequences by advising the researcher.

Risks
We do not anticipate any risks to you due to participating in this study.

Eligibility Requirements for Participation

All participants must be adults aged 50 or over, who have used at least 1 prescription medication for a chronic disease within the last 3 months and who have not been on Warfarin.

Confidentiality and Data Retention

All information you provide will be considered confidential and de-identified. Your responses will be grouped with other participants and collected using paper forms and via audio recording of the interview discussions. A unique study identifier (e.g., ABC-123) will be used in the place of your name on data collection forms

Although the interview discussion will be audio recorded, nothing that you or anyone else says during the interview will ever be associated with your name in any report or publication. Only participants who agree to be audio-recorded will be eligible to participate in the study. The interviews will be recorded to gather patient experience that will be used for research data. All of your comments will remain confidential. If you choose to withdraw from the study at any point, your information will be destroyed.

Even though the results may be used in reports or publications, only the research team will have access to your data. Data such as interview audio and written information will be stored in an encrypted and password protected file on an encrypted laptop kept in a locked office at the School of Pharmacy in Kitchener, Ontario for 7 years.

Questions and Contact

If you have any questions about participation, or would like additional information to assist you in reaching a decision about participation, please contact me: Huda Wali (647) 883-8304 or via email at hwali@uwaterloo.ca.

Ethics Review and Clearance

I would like to assure you that this study has been reviewed by, and received ethics clearance through a University of Waterloo Research Ethics Committee.

. However, the final decision about participation is yours. In the event you have any comments or concerns resulting from your participation in this study, please contact Dr. Maureen Nummelin, the Director, Office of Research Ethics, at 1-519-888-4567, Ext. 36005 or maureen.nummelin@uwaterloo.ca.

We hope that the results of our study will be of benefit to organizations involved in the developing medication information, as well as individuals who take medication.

Yours sincerely,

Huda Wali, BSc
Graduate Student
School of Pharmacy
University of Waterloo
(647) 883- 8304
hwali@uwaterloo.ca

Kelly Grindrod, BScPharm, PharmD, MSc
Assistant Professor
School of Pharmacy
University of Waterloo
(519) 888-4567 x 21358
kgrindrod@uwaterloo.ca

By signing this consent form, you are not waiving your legal rights or releasing the investigator(s) or involved institution from their legal and professional responsibilities.

I have read the information presented in the information letter about a study being conducted by Huda Wali of the School of Pharmacy at the University of Waterloo. I have had the opportunity to ask any questions related to this study, to receive satisfactory answers to my questions, and any additional details I wanted.

I am aware that I have the option of allowing the interview to be audio recorded to ensure an accurate recording of my responses. Audio recording will not begin until participants have consented. If I do not wish to be audio recorded I will not be able to participate in study.

I am also aware that excerpts from the interviews may be included in any reports and/or publications to come from this research, with the understanding that the quotations will be de-identified. With your permission quotations may be used from the interview, however your name will not appear in any thesis or report resulting from this study.

I was informed that I may withdraw my consent at any time without penalty by advising the researcher and all data and audio recording will be confidentially erased.
This project has been reviewed by, and received ethics clearance through a University of Waterloo Research Ethics Committee was informed that if I have any comments or concerns resulting from my participation in this study, I may contact Dr. Maureen Nummelin, the Director, Office of Research Ethics, at 1-519-888-4567, Ext. 36005 or maureen.nummelin@uwaterloo.ca.

With full knowledge of all foregoing, I agree, of my own free will, to participate in this study.
☐YES ☐NO
I agree to the audio recording of the interview.
☐YES ☐NO
I agree to the use of anonymous quotations in any report and/or publication that comes of this research.
☐YES ☐NO
Participant Name: _____(Please print)
Participant Signature: _____
Date: _____

2.3. Feedback letter

Dear Participants,

I would like to thank you for your participation in the study entitled "Health literacy guidelines to improving audible information." As a reminder, the purpose of this project is to gather information to determine the effectiveness and preference for the AudibleRx intervention, a tool to educate people about prescription medications.

Please remember that information from the interview will be kept confidential. Once all of the data are collected and analyzed for this project, we plan on sharing this information with the research community through seminars, conference presentations and journal articles. If you are interested in receiving more information regarding the results of this research, or would like a summary of the results, please provide your e-mail address to the researchers. When the study is completed, anticipated by September 2015, we will send you the information.

In the meantime, if you have any questions about the study, please do not hesitate to contact Huda Wali by e-mail or telephone, as noted below. As with all University of Waterloo projects involving human participants, this project was reviewed by, and received ethics clearance through, the Office of Research Ethics at the University of Waterloo. Should you have any comments or concerns resulting from your participation in this study, please contact Dr. Maureen Nummelin, the Director, Office of Research Ethics, at 1-519-888-4567, Ext 36005 or maureen.nummelin@uwaterloo.ca.

Yours sincerely,

Huda Wali, BSc
Graduate Student
School of Pharmacy
University of Waterloo
(647) 883- 8304
hwali@uwaterloo.ca

Kelly Grindrod, BScPharm, PharmD, MSc
Assistant Professor
School of Pharmacy
University of Waterloo
(519) 888-4567 x 21358
kgrindrod@uwaterloo.ca

2.4.Standard AudibleRx podcast script

Warfarin (Coumadin)
Warfarin is an anticoagulant medication that is used to treat blood clots and prevent new clots from forming in your circulatory system. Warfarin works by limiting the specific event that produces functional vitamin K in the liver. Vitamin K is necessary for the formation of clotting factors. By limiting Vitamin K production and therefore decreasing the formation of clotting factors, warfarin is able to treat and prevent the formation of blood clots.

Specific conditions pose an increased risk for developing a blood clot, such as irregular heart rhythm, a recent heart attack, heart valve replacement, and certain surgeries such as hip or knee replacement. Blood clots form when there has been damage to the blood vessel, either the artery or the vein, and also when blood stops moving and becomes stagnant.

An artery blood clot may occur when someone has developed plaque along the inside of the blood vessel from increased cholesterol, called atherosclerosis. The plaque increase and limits the space the blood has to flow. If the plaque ruptures then a blood clot may form and lead to a stroke or a heart attack.

A blood clot in the vein may occur when a person is immobilized for some reason and their muscles are not contracting to push the blood back to their heart. Small clots begin to form in the stagnant blood along the walls of the vein. These clots increase and eventually limit the amount of blood that returns to the heart.

A blood clot may form in the heart when the heart is not beating in an organized fashion. When the heart has irregular rhythm, blood tends to pool or stagnate in certain sections. When the blood stagnates, little clots may form on inside wall of the heart. These clots may then be pumped out into the circulatory system and lead to a stroke or a heart attack.

Warfarin has a Black Box Warning. Warfarin can cause major and even fatal bleeding. This is more likely to happen during the starting/titration period, or when you have other ongoing disease states, or when warfarin is taken with other medications. Your doctor will monitor your INR (bleeding time) very closely, especially during the startup period. ...done with BBW and on with the session.

Warfarin is usually taken once daily, with or without food. It is important to take warfarin at the same time each day. Your dosage of warfarin is based on your specific medical condition, your response to therapy and your INR results (your bleeding time results). If you miss a dose of this medication, please take it as soon as you remember. If it is near the time of your next dose than just skip it and continue with your normal dose time. Please do not take a double dose to make up the missed dose.

Warfarin is available from 2 or 3 different generic manufacturers. The FDA has approved generic warfarin and it is an acceptable product. Once your are stable on your dose of warfarin, it is a good idea to continue with the same generic brand so there are not any changes in the absorption characteristics of the medication. Please, ask your pharmacist if they always maintain

the same brand of warfarin on their shelf, and definitely talk with your pharmacist before taking your warfarin if the pills look different than they looked last time.

Your doctor may refer you to the local Anticoagulation Clinic for follow-up monitoring. If your doctor does not bring this up, ask them about it. An Anticoagulation Clinic is usually staffed by a Pharmacist or a Nurse. They will have a protocol in place so that they may check your INR (your bleeding time) with just a finger stick and then adjust your warfarin dose if necessary. The goal of the anticoagulation clinic is to educate you about your anticoagulation medication, monitor your bleeding time and help prevent you from having an adverse event that leads you to the emergency room.

If you are not involved in an anticoagulation clinic, than your doctor will have you go to a lab where they draw blood from your vein. They will then check the INR in their lab and send the information to your doctor. Your doctor will then call you and adjust your dose as necessary.

Make sure you let your pharmacist or doctor know of all your medication allergies so they may determine if warfarin is safe for you to take.

2.5 Low health literate AudibleRx podcast medication script

Welcome to AudibleRx.
AudibleRx is here to provide you with simple, reliable information about your medication that you can listen to on demand. We hope to help educate you about your medication so you can confidently mange it.
My name is Steve and I am a licensed pharmacist here to share information on your medication, Warfarin, also known as Coumadin.
The purpose of this podcast is to help you understand:
-What warfarin is
-How to take warfarin safely
- And why it is important to take warfarin.
We also want you to understand:
- How to monitor the effect of warfarin
- The consequences of not taking Warfarin
-And review some of its side effects.
Lets begin learning about Warfarin.

What is Warfarin and how does it work?
Warfarin is an anticoagulant medication, which means it reduces the formation of blood clots. Warfarin is used to prevent heart attacks, strokes and to treat blood clots in the veins and arteries. Warfarin works by limiting blood clots forming by blocking vitamin K. Vitamin K is needed to form blood-clotting factors. By blocking vitamin K, we can stop and limit the blood clots from forming. Warfarin can also prevent existing clots from getting bigger.

The **key point** here is, warfarin limits vitamin K clotting factors and decreases the body's ability to form blood clots.
Blood clots form when there has been damage to the blood vessel, either the artery or the vein, and also when blood stops moving in the body.
You may be at a higher risk of developing blood clots if you have any of the following four conditions:

1) Irregular heart rhythm
2) A recent heart attack
3) Heart valve replacement
4) Certain surgeries such as hip or knee replacement

The **key** point is, if you do not take your medication, you are at a higher risk of forming blood clots. If you do not take warfarin, blood clots can form and cause a stroke or heart attack.

How to take Warfarin?
Warfarin is usually taken once daily, with or without food. It is important to take warfarin at the same time each day. Your dosage of warfarin is based on your specific medical condition and your response to warfarin. Your response to warfarin is determined by what is called your "international normalized ratio" (INR for short), which is your bleeding time result. If you miss a dose of this medication, please take it as soon as you remember. If it is near the time of your

next dose then do not double up your dose, skip the dose you missed and wait for your normal time of dosing to then take your normal dose.

How do I know if the medication is working?
Your doctor will check your international normalized ratio (the INR), to help ensure your dose is right for you and to prevent any negative effect of the drug. For this purpose, your doctor may refer you to the local Anticoagulant Clinic to monitor the effect of the drug on your body. At the anticoagulant clinic, they will check your INR, the bleeding time, and will help educate you on your medication.
In case you are not involved in an anticoagulation clinic, your doctor will have you go to a lab, where they will take your blood and check the INR in their lab. The lab report will then be sent to the doctor to change your dose as needed.

What are the side effects?
Warfarin has a Black Box Warning. A Black Box warning is an alert to warn patients of any potentially severe side effect. Warfarin's Black Box side effect is that it can cause major and even life-threatening bleeding. Major Bleeding is more likely to happen during the starting period of medication or if you have other current diseases. To reduce your risk, your doctor will monitor your bleeding time very closely, especially as you start taking Warfarin.
Be sure to let your pharmacist or doctor know about all the medications you are taking, including over the counter supplements, even if you only take them sometimes. Your pharmacist will be happy to check to see if what you are taking is safe to take with warfarin.
You may experience some minor side effects when taking warfarin. You may experience nausea, loss of appetite and may have a tendency to bleed easily. If you notice any unusual bleeding, such as bleeding from the gums while brushing your teeth, a constant nosebleed, or long bleeding from a cut, you should report this to your doctor.

The key point to remember is everyone who takes warfarin will experience side effects; however, if you notice any concerning side effects, talk to your doctor or pharmacist.
Warfarin is not recommended for use during pregnancy because of the potential for serious harm to the unborn baby. If you are of childbearing age, discuss with your doctor the best option for you to keep from becoming pregnant while you take warfarin. Likewise, consult your doctor before breast-feeding while you take warfarin.

What is a generic medication?
Sometimes your pharmacy will give you the generic brand name of your medication, if you have concerns about the differences, talk to your pharmacist.
A generic medication is drug product that is comparable to the brand name drug. The Food and Drug Administration, the FDA, has approved generic warfarin, which is the same drug but a different brand. Warfarin is available from 2 or 3 different generic manufacturers. Once you are consistent with your dose of warfarin, it is a good idea to continue with the same generic brand. Please, ask your pharmacist if they always maintain the same brand of warfarin on their shelf, and talk with your pharmacist before taking your warfarin if the pills look different than they looked last time you filled your prescription.

Here are some everyday tips when taking warfarin.

Tip number 1- Check your diet
Remember when we talked earlier about how warfarin works, by blocking vitamin K to stop blood clots from forming? Well, many foods have high levels of vitamin K in them, so, along with all the other monitoring, you also need to pay attention to what you eat. Green leafy vegetables such as kale, spinach, and cabbage, along with broccoli, cauliflower, brussel sprouts and green tea are all high in vitamin K. Having large amounts of vitamin K-filled foods will affect how the warfarin is working in your body. If you normally have some of these foods in your diet, it is alright to go ahead and continue to do so. But, be **aware** if you do not eat these types of foods on a regular basis, do not eat a large serving. If you want to start eating more of these foods, talk to your doctor about how to do so. It is important to try to have a balanced diet and be sure to talk about food intake with your health care provider.

Tip number 2:
Please be cautious and limit or avoid the use of alcohol while taking warfarin. Drinking alcohol while taking warfarin significantly increases your risk for stomach bleeding and can also change how warfarin affects your bleeding time.

Tip number 3
Our final tip is to please use extra caution while performing activities with sharp objects that may lead to bleeding, such as shaving and nail trimming. Use an electric razor when shaving and be sure you use a soft toothbrush when brushing your teeth. If you fall or injure yourself, check in with your doctor immediately to make sure you do not have any internal bleeding.
This concludes our podcast on Warfarin. Thanks for listening to AudibleRx, here to provide you with simple, reliable information about your medication that you can listen to on demand. If you have any questions, please contact your pharmacist or doctor. Remember, this recording is not meant to replace your counseling session with your own pharmacist. We hope to help educate you about your medication so you can confidently mange your medication.

2.6 Demographic Characteristic Questionnaire

Sex
Male ☐
Female ☐

Age
18-24 ☐
25-34 ☐
35-44 ☐
45-54 ☐
55-64 ☐
65+ ☐

Income
Less than $10,000 ☐
$10,000-$14,999 ☐
$15,000-$24,999 ☐
$25,000-$34,000 ☐
$35,000-$49,000 ☐
$50,000 + ☐

Education
Less than grade 8 ☐
Grade 9-11 ☐
High school ☐
College or higher ☐

Ethnicity
Caucasian ☐
Black ☐
Asian ☐
South Asian ☐
Aboriginal ☐
Other : ☐ _____

How often do you have someone help you read material about your medication?
1☐ 2☐ 3☐ 4☐ 5☐
Rarely ---------- > Always

How confident are you filling out medical forms by yourself?
1☐ 2☐ 3☐ 4☐ 5☐
Confident----------> Not confident

How often do you have problems learning about your medication because of difficulties understanding written information?
1☐ 2☐ 3☐ 4☐ 5☐
Confident----------> Not confident