

Consumer Medication Information:  
Memory, Perceptions, Preferences, and Information Needs

by

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Bachelor of Science, Carleton University, 2008  
Master of Arts, Carleton University, 2010

A Dissertation Submitted in Partial Fulfillment  
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University of Victoria

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## Abstract

**INTRODUCTION:** Electronic health resources are becoming prevalent. However, consumer health information is still predominantly text based. Relying on text alone to deliver health information may not be the most effective way to promote learning or sufficient to meet consumer needs.

**OBJECTIVES:** This study assessed a) whether adding images to text and/or replacing text with narration influenced memory for Consumer Medication Information (CMI), b) if participants perceived CMI formats differently in terms of comprehensibility, utility, or design quality, and if they preferred one format overall c) what participants' information needs were with respect to CMI.

**METHODS:** Participants' ( $N = 36$ ) remembered CMI presented in three formats: 1) Text, 2) Text + Images, and 3) Narration + Images. Additionally, participants rated the three CMI formats in terms of comprehensibility, utility, design quality and overall preference. Semi-structured interviews were used to investigate participants' opinions and preferences regarding the CMI formats, as well as their experiences with CMI and information needs.

**RESULTS:** No significant differences in memory were observed,  $F(2, 70) = 0.1, p = 0.901$ . Thus, this study did not find evidence that Mayer's (2001) multimedia or modality principles apply to CMI. Despite the absence of effects on memory, CMI format impacted perceptions of the material. Participants rated the Text + Images format highest in terms of comprehensibility,  $\chi^2(2) = 26.5, p < .001$  and design quality,  $\chi^2(2) = 35.69, p < .001$ . However, after correcting for multiple comparisons, no significant differences in utility ratings between the three formats were observed,  $\chi^2(2) = 8.21, p <$

.016. Further, overall preferences revealed that the most participants' chose the Text + Images format as their favourite ( $n = 27$ , 75%) and Text as their least favourite ( $n = 23$ , 63.8%). Directed and conventional content analysis were used to explore participants' CMI preferences and information needs. Various aspects related to provision, comprehensibility, utility, and design quality all appeared to affect perceptions of CMI and whether or not participants used or would use it. Results of this analysis, paired with evidence from other studies, were used to develop a model proposing factors that influence CMI use.

**CONCLUSION:** This study investigated the potential impact of design and distribution changes on perceptions of CMI. Despite the lack of differences in memory, participants' perceptions of the formats differed. Findings from this study could be used to inform future research on how CMI could be designed to better suit the needs of consumers and potentially increase the likelihood it is used.

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## Glossary

*Note: Some definitions are specific to the context of this study. Thus, other definitions or terminology may be more appropriate in other contexts.*

**Adherence** (or compliance) is the extent to which prescription directions are followed (e.g., how much to take, how often to take it, how long to take it, what to avoid while taking it).

**Cognitive Theory of Multimedia Learning (CTML)** is a theoretical model developed by Mayer (2001) describing how people process visual and verbal information and how factors facilitate or impede learning.

**Comprehension** is the ability to understand or when the audience accurately perceives the intended meaning of the content. Transfer tests are used to test comprehension. Transfer tests require application of knowledge learned to novel problems.

**Comprehensibility**, refers to consumer assessments of the extent of perceived difficulty to read, understand, remember, and locate important Consumer Medication Information (CMI). Keeping CMI for future reference rated as a subtheme of comprehensibility the adapted Consumer Information Rating Form (CIRF; Koo, Krass, & Aslani, 2007). Comprehensibility is one of three items, as well as design quality and utility, measured by the adapted CIRF (Koo et al., 2007). However, keeping CMI for future reference was reassigned to the provision theme based on qualitative interviews with participants.

**Consumer Medication Information (CMI)**, is the printed-paper information sheet(s) typically given to consumers at Canadian pharmacies when they fill a prescription for the first time. In Canada, CMI is referred to as patient medication information leaflets. However, CMI may also be referred to with other terms including Patient Information Leaflet (PIL), Prescription drug Information Leaflet (PIL), product information leaflet, Patient Medication Information (PMI). CMI outlines important aspects about prescription medications (e.g., indications, side effects, storage). CMI is developed by organizations (e.g., pharmacies) not manufacturers and purchased or distributed by pharmacies. CMI is not reviewed or approved by Health Canada. CMI provides information to help facilitate the safe and effective use of a medication. CMI describes important aspects of a prescription medication typically including:

- Information about the dispensing pharmacy (e.g., name, address, phone number)
- The consumer's name
- The prescriber's name
- The date
- The brand and chemical (or generic) names of the medication
- The Drug Identification Number (DIN)
- What the medication is usually used to treat
- How it typically administered
- Potential side effects
- Important information about the medication

- How to store the medication
- General information

**Consumer Medication Information (CMI) Use**, encompasses both consumers' actual CMI use and their intention to use CMI. As an index of intentions to use CMI, consumers report how likely they are to read, use, and keep CMI in the adapted Consumer Information Rating Form (CIRF; Koo et al., 2007). Additionally, evidence from this study suggests that providing multimedia CMI may increase the likelihood that consumers' use CMI.

**Design Quality** refers to consumer assessments of different aspects of the design of consumer medication information (CMI) including organization, attractiveness, print size, tone, helpfulness, and spacing. Design quality is one of three items, as well as comprehensibility and utility, measured by the adapted Consumer Information Rating Form (CIRF; Koo et al., 2007).

**eHealth Literacy** is the use of electronic tools to acquire the knowledge and skills to make informed and appropriate health decisions.

**The eHealth Literacy Scale (eHEALS)** is an 8-item self-report measure of eHealth literacy skills developed by Norman and Skinner (2006b).

**Food and Drug Administration (FDA)** is an American federal agency of the United States Department of Health and Human Services. Amongst various other responsibilities, the FDA provides guidance for Consumer Medication Information (CMI) and regulates other types of medication information for consumers (i.e., paper package inserts, medication guides) and healthcare providers.

**Health Information System (HIS)** is an electronic tool used to capture, store, access and manage health information.

**Health Literacy** is the use of traditional materials (e.g., pamphlets), other than electronic tools, to acquire the knowledge and skills to make informed and appropriate health decisions.

**Learning** is the acquisition of knowledge or skills. People can learn through practice, experience, study, or by being taught.

**Memory** is the ability to remember information. There are two types of memory tests: recognition (i.e., choosing the target item from lures) or recall (i.e., generating the responses without any cues).

**Multimedia Learning Principles** are a set of evidence-based design principles aimed at optimizing the efficacy of learning from multimedia presentations.

**The Multimedia Principle** is a multimedia learning principle based on evidence that people learn better from words and images than words alone (Mayer 2001).

**The Modality Principle** is a multimedia learning principle based on evidence that people learn better from narration and images than written words and images (Mayer, 2001).

**Newest Vital Sign (NVS)** is an assessment of health literacy developed by Weiss and colleagues (2005) containing 6-items which require participants to interpret and ice cream label.

**Patient Medication Information Monograph** is part of the product monograph is a description of a medication developed by the manufacturer and approved by Health Canada. Health Canada provides federal guidance and templates for these documents. Patient medication information monographs are developed in an attempt to promote safe and effective use of medications. Product Monographs are divided into three parts: Part I: Health Professional Information, Part II: Scientific Information and Part III: Patient Medication Information. Monographs for consumers in the United States are referred to as medication guides and regulated by the Federal Drug Administration.

**Provision**, for the purposes of this study, refers to factors related to obtaining, accessing, and keeping CMI, or having CMI available to use. Initially, keeping CMI was a subtheme of comprehensibility (see Koo, Krass, & Aslani, 2007) but was reallocated to the provision theme after qualitative analysis of the participant interviews.

**Utility** refers to consumers' assessments of appropriateness of quantity and usefulness of the consumer medication information. Utility is one of three items, as well as design quality and comprehensibility, measured by the adapted Consumer Information Rating Form (CIRF; Koo et al., 2007).

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## Chapter 1: Introduction

Many people take medications. In fact, approximately, four in ten Canadians (40.5%) between the ages of six and 79 are taking at least one prescription medication (Rotermann, Sanmartin, Hennessy, & Arthur, 2014). Unsurprisingly, the probability of taking at least one prescription increases with age. That is, on average 11.7 % of 6 to 14-year old's take at least one prescription with proportions steadily increasing up to approximately 82.7% of adults aged 65-79 (Rotermann et al., 2014). Given their widespread use, there is a variety of information consumers should understand and remember about medication(s) they take. Consumers' comprehension and memory of medication information has important implications for adherence and administration, as well as how to recognize and what to do in the event of an adverse (or side) effect due to medication use, an allergic reaction, or a drug interaction.

Adherence (or compliance) is used to describe the extent to which people use medications as prescribed (Aronson, 2007). Medication adherence is important because it is associated with better health outcomes, fewer hospital admissions, lower associated healthcare costs (Osterberg & Blaschke, 2005), and lower mortality (Simpson et al., 2006). People with acute conditions are more likely to adhere than people with chronic conditions (Osterberg, & Blaschke, 2005). Moreover, the World Health Organization (2003) estimated that only about half of people with long-term therapies were adherent. Aronson (2007) argued that an array of factors can create barriers to medication adherence (e.g., number of prescriptions or medication regimen complexity, costs of medications, lack of understanding the importance of adherence). Brown and Bussell (2011) suggested that barriers to adherence could be subsumed into

three general categories: patient-related factors, physician-related factors, and health system/team building related factors. Limited health literacy, mental health issues, patient participation, financial issues and access to care are examples of patient-related factors that have the potential to impede medication adherence (Brown & Bussell, 2011). Physician-related factors that may create barriers to adherence include failure to recognize poor adherence, prescribing complex medication regimens, failure to communicate risks and benefits of medications, lack of communication amongst providers, and not recognizing that the medication may be cost prohibitive for the patient (Brown & Bussell, 2011). Health system/team building related factors and potential adherence inhibitors include medication costs, fragmented healthcare information and provision, as well as time limitations for patient-provider encounters (Brown & Bussell, 2011).

A model of effective communication in medical practice was proposed by Ley (1988), which emphasized the importance of memory (i.e., recalling or recognizing information), comprehension (i.e., understanding of information), and satisfaction with the treatment as factors affecting therapy adherence. Importantly, Ley's model is from the perspective of communicating health information to consumers. Thus, this model does not address challenges and facilitators of remembering *when* to engage in therapy (e.g., taking a tablet before breakfast). Indeed, memory of medication information has also been found to be a predictor of medication adherence (Linn, van Dijk, Smit, Jansen, & van Weert, 2013). However, reports of memory for verbal information provided by healthcare providers has shown to be highly variable and generally poor: consumers only remember 20-60% of information healthcare professionals provide

immediately after the interaction (Anderson, Dodman, Kopelman, & Fleming, 1979; Ley, 1985; Rice, Meyer, & Miller, 1989). Therefore, it is important to explore complementary and supplementary ways of delivering information to consumers to improve comprehension, memory, and ultimately adherence. Providing consumers with comprehensive information that is easy to understand and remember may not only positively impact adherence but administration technique as well.

For some medications, an important factor in medication use is administration technique. Some medications have multiple steps for administration and there can be consequences if they are not administered correctly. For example, evidence consistently suggests that many people use inhalers incorrectly, which reduces therapeutic benefits (Lee, Boo, Lim, Kim, & Kim, 2013; Melani et al., 2011). New initiatives have been developed to try to improve inhaler technique (e.g., Halpin, Holmes, Calvert, & McInerney, 2015). Both adherence and inhaler technique were shown to be important for controlling asthma (Baddar, Jayakrishnan, & Al-Rawas, 2014). Other medications such as eye drops, nasal sprays, creams, and injections may pose similar administration challenges and have respective consequences associated with poor technique.

Remembering medication information can be important due to adverse drug reactions, adverse (or side) effects, and drug allergies. Medications do not affect everyone the same way. In some cases, a medication may not be suitable for a consumer and consequences ensue. An adverse *drug reaction* is:

“an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future

administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product” (Edwards & Aronson, 2000, p. 1255)

In contrast, adverse *events* are when patient harm occurs but is not necessarily linked to the use of a medication (Edwards & Aronson, 2000). An adverse *effect* is “an adverse outcome that can be attributed to some action of a drug” (Edwards & Aronson, 2000, p. 1256). Similarly, a side effect is “any unintended effect of a pharmaceutical product occurring at normal dosage which is related to the pharmacological properties of the drug” (World Health Organization, 2011, p. 5). Many side effects of medications are mild to moderate (e.g., headaches, local irritation, nausea, weight gain). In these circumstances, users may need to evaluate if the benefits of taking the medication outweigh the inconvenience of the side effects. Moreover, people may fail to associate physiological symptoms as being side effects of a medication. Thus, it is important that consumers are aware of the potential consequences of medications and how best to deal with them. People can also have allergic reactions (e.g., hives, wheezing, fainting, abdominal pain, vomiting) to medications. Given that some medications may cause severe and potentially even fatal adverse effects, it can be critical for consumers to recognize these as being caused from the medication and how to deal with them.

Yet another factor of the importance of medication information is the notion of drug interactions. The United States Food and Drug Administration (FDA) describes a drug-drug interaction as an unexpected side effect resulting from two or more drugs reacting with each other (FDA, 2013). Similarly, some medications react with food or beverages referred to as drug-food/beverage interactions (FDA, 2013). Further, consumers have

specific health conditions (e.g., high blood pressure) taking certain medications can have potentially harmful effects (FDA, 2013). Additionally, medications can also interact with over-the-counter (OTC) medications (FDA, 2013). Thus, because of the risks, medication information should make consumers aware of the potential interactions that may be relevant to them.

In summary, medications can affect people differently and, in some circumstances, create discomfort or even harm people. Thus, due to the potential consequences of taking medications, it is imperative that users are informed about how medications may affect them and what to do if these situations occur.

### **1.1 Consumer Medication Information (CMI)**

Given the high volume of consumers prescribed at least one medication, paired with potential effects of non-adherence, poor administration technique, adverse reactions, and drug interactions, equipping consumers with information about their medications is imperative. Hopkins, Wade, and Weir (2000, p. 103) posited that consumers want their providers to give them answers to the following questions about a medication they take:

- What is the medicine for?
- What are the likely effects?
- What are the adverse effects and what do I do if I experience them?
- Will it interact with the other medicines I take, including over-the-counter and complementary medicines?
- What about the long-term effects?

- What are the instructions for taking the medicine, how do I take it, how much do I take and when do I take it?

Further, Hopkins and colleagues noted that consumers often appreciate written information to take home with them and read later.

Consumer Medication Information (CMI) attempts to address this need for medication information. CMI, for the purposes of this study, is the term used for the printed-paper information sheet(s) typically given to consumers at Canadian pharmacies when a prescription is filled for the first time. Although verbal patient counselling for all prescriptions (including refills) is a legislated practice requirement for pharmacists in British Columbia (College of Pharmacists of British Columbia, 2015), dispensing CMI is not a legislated practice. CMI is not usually offered to consumers when subsequent refills are dispensed. CMI outlines important aspects about prescription medications (e.g., indications, side effects, storage). Importantly, CMI is not regulated by Health Canada and is developed by organizations other than the manufacturer and therefore often varies between pharmacies (e.g., Monkman & Kushniruk, 2017b). CMI may also be referred to as patient information leaflets (PILs), pharmacy medication information leaflets, written medication information (WMI), and drug factsheets. However, these terms are not always used consistently internationally. CMI typically conveys a variety of general information about the medication including:

- Information about the dispensing pharmacy (e.g., name, address, phone number)
- The consumer's name
- The prescriber's name
- The date

- The brand and chemical (or generic) names of the medication
- The Drug Identification Number (DIN)
- What the medication is usually used to treat
- How it typically administered
- Potential side effects
- Important information about the medication
- How to store the medication
- General information

Currently, in Canada, CMI is provided by community pharmacies strictly as text on paper when a new prescription is filled. CMI are developed independently by community pharmacies or purchased from outside organizations. Therefore, dispensed information often varies between different pharmacy chains. Further, some medications have more comprehensive CMI such as outlining the steps for using medications whereas other CMI relies on referring consumers to paper package inserts. CMI provides general medication information (e.g., typically this medication is taken twice a day), whereas prescription labels offer details specific dosage instructions. Both CMI and prescription labels play an important role in medication management by providing information about the use, precautions, and potential hazards of medications.

Evidence from three studies (Nair et al., 2002; Pollock, Grime, Baker, & Mantala, 2004; Raynor, Savage, Knapp, & Henley, 2004) on medication information needs were synthesized in a systematic review by Grime, Blenkinsopp, Raynor, Pollock, and Knapp (2007). Based on evidence from the aforementioned studies, Grime and colleagues

reported that consumers want information about the following medication information topics:

- “Diagnosis. Is this the right treatment for me?”
- Other forms of treatment for the condition – both drug and non-drug.
- Name of medicine.
- When and how to take the medicine. Dosage.
- Purpose of medicine/intended therapeutic effect.
- Consequences of not taking the medicine.
- What it feels like to take the drug.
- How long the drug was likely to be prescribed.
- Interactions with other medicines.
- All side-effects with a likelihood of their occurrence.
- What to do about side-effects.
- Long-term effects and risk of damage” (p. 291)

Thus, it is apparent that what information about medications consumers want does not necessarily align with what is currently offered.

Despite the importance of CMI, currently it has two important shortcomings. First, in contrast to prescription labels affixed to the medication container, CMI is separate from the medication itself and typically provided in hardcopy on paper. This may result in occasions when CMI is not available when consumers need it (e.g., are taking the medication, experiencing a side effect) and therefore limit its value. Second, CMI is strictly text-based. CMI content may exceed consumers’ levels of health literacy and

therefore risk being not understood, misunderstood, as well as readily forgotten.

Therefore, CMI in their current form may offer limited value to users.

Consumers seeking out medication information, aside from what is dispensed by their prescriber or pharmacist, may turn to the Internet as a resource. The availability of online health information for consumers (i.e., laymen or citizens) is unprecedented. Currently, a high overall proportion of Canadians (70%) and American (72%) adult Internet users seek health information online (Fox & Duggan, 2013; Statistics Canada, 2010). Approximately one in five (18%) American Internet users consulted online reviews for specific drugs or medical treatments (Fox & Duggan, 2013). However, information resources on the Internet are highly variable on factors such as quality, comprehensiveness, and demands they place on health literacy. Further, issues and limitations identified in paper-based materials (e.g., limited to text, high demands on health literacy) are likely to transcend into electronic health information, but could also be compounded with other issues due to the medium. Thus, it is especially important to develop electronic health information, such as medication information, that is easy for consumers to access, use, understand, and remember.

Delivering CMI electronically (e.g., by email or stored in an application) either alone or in addition to a paper copy is a strategy to combat the first challenge identified: not having medication information available when users need it. In the United States, more than half (62%) of smartphone owners have used their devices to search for information about a health condition in the past year (Pew Research Center, 2015). Thus, consumers may want to receive medication information electronically, as it could then be accessible and used or reprinted as necessary. This method of dissemination

would also overcome the issues of quality and credibility of Internet medication information resources. Further, electronic CMI could also leverage the potential benefits of this format by incorporating such features as narration and videos. Complementing text with images (i.e., using multimedia presentations) for CMI is a strategy that may prove useful for mitigating the second identified shortcoming of these documents: that the information may not be understood, misunderstood, and readily forgotten.

## **1.2 Multimedia**

Multimedia is an approach to information design that has yet to be systematically applied and investigated for its potential benefits in disseminating health information to consumers (Monkman & Kushniruk, 2015). Multimedia research is motivated by evidence that combining multiple methods of communication to convey information is more successful than relying on a single method. Thus, the definition of *multimedia* is “presenting words (such as printed text or spoken text) and pictures (such as illustrations, photos, animation, or video)” (Mayer, 2005a, p. 2). However, Lányi’s (2006) definition of multimedia emphasized a technological component arguing that *multimedia* is “a means of communication that combines text with graphics, sound, animation, full-motion video, etc. - usually in a highly interactive way, and it also includes the use of the Internet” (p. 38). Domains such as education, entertainment, advertising and more recently healthcare have embraced the benefits of multimedia (Lányi, 2006). Additionally, investigations of the potential benefits of multimedia for communication of health information to consumers have begun (e.g., Houts, Doak, Doak, & Loscalzo, 2006; Katz, Kripalani, & Weiss, 2006). However, this work has overlooked the body of

research done in multimedia learning and therefore the materials developed may not be as effective as possible (Monkman & Kushniruk, 2015).

Although multimedia has demonstrated benefits, simply adding images to text does not necessarily result in enhanced learning and some combinations of communication methods are more beneficial than others (Mousavi, Low, & Sweller, 1995). Mayer (2001) developed the Cognitive Theory of Multimedia Learning (CTML) to integrate evidence and depict how people process multimedia presentations. Effects consistently observed and reported in multimedia learning studies have been organized into a set of multimedia principles that are used to both a) describe why particular cognitive phenomena occur and b) guide multimedia design to ensure it is designed most effectively. Thus, it is important to leverage existing evidence-based multimedia principles for the design of new multimedia health information to optimize its efficacy (Monkman & Kushniruk, 2015).

Given its demonstrated benefits in other domains, multimedia is a promising method of enhancing understanding and memory for medication information. All of the multimedia principles have potential implications for the impact of multimedia medication information and multimedia consumer health information more generally. However, in the proposed study only the multimedia and modality principles will be used to explicitly explore medication information. The multimedia principle asserts that people learn better from pictures and words, whereas the modality principle suggests people learn better when words are presented as narration instead of text (Mayer, 2001). Thus, these two principles will be applied to CMI in an attempt to improve CMI.

### 1.3 Current Study

This study explores the design and delivery of CMI by examining a) whether consumers' memory of CMI is affected by format (i.e., Text vs. Text + Images vs. Narration + Images), b) what consumers' perceptions of CMI format(s) are in terms of comprehensibility, utility, and design quality, and whether consumers' prefer a particular type of CMI format and c) the information needs of consumers' around CMI (e.g., what information they want, when they want the information, how they want to receive the information). Specifically, this study seeks to answer the following eight research questions divided by category:

#### Memory

1. Is there evidence of a multimedia effect for CMI on memory?
2. Is there evidence of a modality effect for CMI on memory?

#### Perceptions

3. Do participants perceive one CMI format as more comprehensible?
4. Do participants perceive one CMI format as having more utility?
5. Do participants perceive one CMI as superior in terms of design quality?

#### Preferences

6. Do participants prefer one CMI format overall?

#### Information Needs

7. When do consumers want to receive CMI?
8. How do consumers want to receive CMI?

Many have asserted that the benefits of CMI, as currently available, are limited (e.g., Krass, Svarstad, & Bultman, 2002; Patel et al., 2018). Some of the suggested limitations to the current materials are related to both content and design. For example,

from the content perspective, Pander Maat and Lentz (2010) asserted CMI presents challenges for consumer understanding in terms of the length of these materials, language ambiguity, lack of emphasis on important information and organization. Other researchers have argued that medication information is often not readable or suitable for consumers, especially those with limited health literacy (Wolf, Davis, Shrank, Neuberger, & Parker, 2006; Wolf et al., 2012). Additionally, others have argued that it is difficult for consumers to locate specific information to answer specific medication related questions using CMI (Pander Maat & Lentz, 2010). Finally, some researchers have identified physical characteristics of the design of CMI and related medication information, such as visual formatting (e.g., Pander Maat & Lentz, 2010, Wolf et al., 2014) and small font size (e.g., Hanson, 1995) that limit the utility of this information.

Studies are emerging attempting to improve CMI by addressing the identified shortcomings in currently distributed CMI. However, three primary factors motivate the current study that, to the investigator's best knowledge, have not been addressed in other research. First, most previous studies that explore potential opportunities to improve different types of medication information have manipulated multiple aspects of design and content simultaneously. For example, Wolf et al. (2014) modified the content and the layout to explore differences in comprehension of medication guides, which are very similar to CMI. Similarly, other researchers complemented text with pictures, made the content more readable, and reorganized the content (e.g., Morrow et al., 2005). Though studies such as these are valuable, their methods prevent attribution of performance (e.g., comprehension, memory) gains to individual factors. In contrast, this study used the same content for all three formats to determine if format affected

memory, perceptions, and preferences. That is, the exact same words and sequence of words were used to describe a medication, regardless of whether its presentation format (i.e., Text, Text + Images, or Narration + Images). This control allowed for the potential effect of multimedia to be isolated. Second, although multimedia (e.g., adding pictures to complement text, using narration instead of text) has gained popularity and evidentiary support as a potential method of enhancing CMI and other types of consumer health information, the domain of literature on multimedia learning has yet to be incorporated into these initiatives. Further, studies have generally limited the use of images to complement text to a single component of medication information such as dosing schedules (e.g., Kripalani et al., 2007; Morrow et al., 2005) or an image of the medication (e.g., Patel, Bapat, Bhansali, & Sansgiry, 2018). Thus, to address this shortcoming in the existing literature around use of multimedia medication information, this study used images throughout the entire medication description. Third, no studies were identified that have explored the use of narration for medication information specifically. In response, the proposed study created a format of CMI using narration to convey information in lieu of text with complementary images.

A mixed methods approach was used to investigate participant's memory, perceptions, preferences and information needs regarding CMI. To determine whether multimedia improves memory for medication information, the multimedia principles were applied to compare participants' memory of traditional text CMI with multimedia formats. Specifically, CMI currently dispensed at a community pharmacy (i.e., hardcopy plain text) was converted into two additional types of multimedia presentations to test Mayer's (2001) multimedia principle and modality principle. The multimedia principle proposes

that people learn better from words and images than words alone (Mayer 2001). In contrast, the modality principle proposes that people learn better from narration and images than written words and images (Mayer 2001). To test whether there are effects due to multimedia or modality on the amount of knowledge that can be remembered during learning, participants were asked to recall information about the medications in three different formats, as an index of memory. The Text format was printed in hardcopy and served as the control arm. To test the multimedia principle, images were added to complement the text for the Text + Images format. In contrast, to test the modality principle, images were used but the text was delivered as narration, for the Narration + Images format. Participants were asked questions about each medication in their respective formats to assess what they remembered. Participants were randomly assigned to different sequences counterbalanced for both format and medication. Formats were counterbalanced to compensate for potential learning and fatigue effects and medications were counterbalanced to minimize potential differences in the memorability of the medication material itself.

To determine participants' perceptions of the three format(s) in terms of comprehensibility, utility, and design quality, participants rated each of the formats on (i.e., Text, Text + Images, Narration + Images) on each dimension after they have seen them all. Further, participants ranked the three formats overall from favourite to least favourite. Semi-structured interviews were conducted to generate insight on consumers' previous experiences with CMI and how these materials might be more effectively delivered in terms of factors such as content, medium, format, and timing.

## **Chapter 2: Guidelines and Strategies for Consumer Medication Information**

Health information and more specifically medication information is important for consumers to understand and remember. Medication information is available in a variety of forms (e.g., prescription labels, package inserts, pharmacy handouts). Different strategies have been implemented to improve consumer comprehension of different types of medication information (e.g., regulated monographs, drug facts boxes, standardized prescription labels) and others are currently being explored (e.g., adding images to text).

Consumer health information is increasingly ubiquitous. However, the majority of consumer health information distributed and available remains strictly limited to text. Given the potential shortcomings of plain text for effective communication with consumers, especially those with challenges (e.g., limited health literacy, limited proficiency in the language, visual impairments) several different strategies have been explored to improve the effectiveness of consumer health information.

This section begins with a discussion about the importance of effective communication and memory of consumer health information. Next, examples of strategies that have been recently implemented in an attempt to improve different types of medication information are outlined. A discussion of current regulatory approaches to different types of patient medication information in Canada and internationally will follow. Subsequently, research on medication guides, CMI, user-centered medication information, and the provision of online medication information are presented.

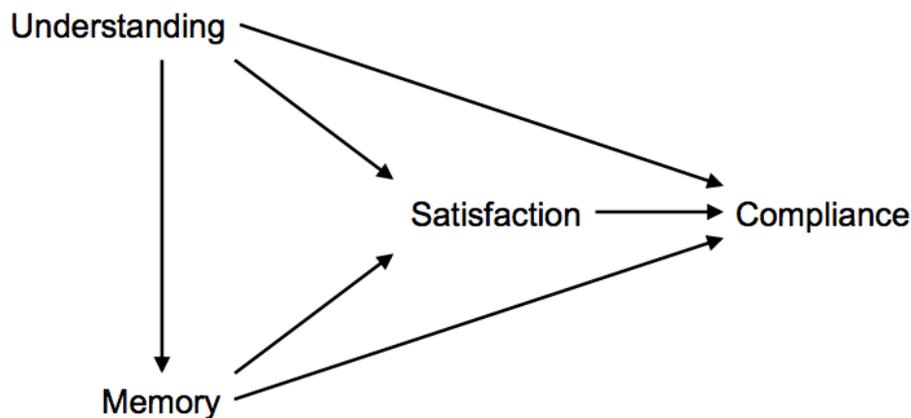
There is evidence that medication information, as currently provided to consumers, is of limited utility (Krass, Svarstad, & Bultman, 2002; Pander Maat & Lentz, 2010; Wolf

et al., 2006; Wolf et al., 2012). Furthermore, changing the layout and modifying the content of CMI can result in knowledge gains (Patel et al., 2018). However, the majority of research on existing medication information materials has limited their exploration to modifying the text to improve comprehension. One technique gaining traction is using multimedia to augment consumer health information. Adding images to medication information to facilitate comprehension has been used as a strategy aimed specifically for consumers with limited health literacy and/or older consumers. Some studies have explored the effects of adding images as a component of a broader improvement strategy called patient-centred medication information, whereas some studies have looked at the effect of adding images in isolation.

Despite evidence of its benefits to understanding and memory, as well as researchers' endorsement of this strategy (Monkman & Kushniruk, 2015; Pusic, Ching, Yin, & Kessler 2014), multimedia remains underutilized in consumer health information and medication information especially. Thus, given the potential benefits, it is important to explore whether multimedia presentations of CMI facilitates memory and potentially understanding. Although the evidence is mounting in support of using multimedia (i.e., images and words facilitate learning more than words alone) in studies of medication information, other phenomena warrant investigation as potential strategies to enhance consumer learning of health information. Additionally, studies have typically explored hardcopy, paper-based medication information, a format with inherent limitations. Thus, there is an opportunity to explore the potential capabilities of electronic medication information (e.g., using narration in lieu of text, disseminating CMI through email).

## **2.1 The Importance of Effective Communication, Comprehension, and Memory for Consumer Health Information**

Ley (1988) developed a model inferring the interactions between consumer understanding, memory, satisfaction, and ultimately adherence as an outcome of effective communication in medicine (see Figure 1). Ley developed the cognitive model relationships reported between these factors in the literature. Ley warned that some studies did not find evidence of these correlations and further, most of the pairings were weakly or moderately correlated. Ley (1988) only found evidence of a strong relationship between understanding and satisfaction (mean correlation = 0.58). However, Linn, and colleagues (2013) found that delayed recall of medication information from consultations was a significant predictor of self-reported adherence. Additionally, Ley posited “understanding will have direct effects on memory, satisfaction and compliance, and through its effect on satisfaction, and additional indirect effect on compliance” (p. 72). Ley also noted that there are additional anticipated benefits of enhanced consumer health communication (oral and/or written) beyond those included in his model. For example, Ley suggested that recovery from illness and surgical procedures would be more expedient and less stressful provided there was .



*Figure 1.* The Hypothesised Relationships Between Understanding, Memory, Satisfaction, and Compliance (Ley, 1988, p. 73)

Ley (1988) reviewed a variety of interventions aimed at improving consumer memory and identified few robust methods of enhancing memory for keeping appointments and taking medications on time. However, Ley noted that with respect to oral communication, there was evidence that primacy (i.e., information presented first) and emphasis (i.e., stressing the importance of some content) improved memory. Additionally, Ley noted that more information was remembered if it was simplified, categorized, repeated, and specific. Moreover, Ley noted that healthcare providers frequently failed to communicate important information (e.g., drug interactions, how medications should be used, appropriate antibiotic therapy) to consumers. Ley outlined the following four advantages to supplementing oral communication with written materials:

1. It can be constructed to facilitate understanding and memory
2. Coverage of all the important aspects can be ensured
3. It provides a permanent record that can be referred to if necessary
4. Consumers appreciate it

Ley (1988) argued that the efficacy of written information hinges on it being “noticed, read, understood, believed, and remembered” (p. 111). Ley reported that over 11 studies, most (47-95%) participants reportedly read the written information provided to them.

Minimally, providing consumers with health information can be used to complement and supplement communication with healthcare professionals. Consumers forget a great deal (40-80%) of information immediately after interacting with healthcare professionals (Anderson, Dodman, Kopelman, & Fleming, 1979; Ley, 1985; Rice, Meyer, & Miller, 1989).

Compared with other studies of memory for health information, a study by Tarn and Flocke (2011) investigating memory for prescription medication information yielded surprisingly high rates of recall. Specifically, Tarn and Flocke (2011) analyzed physician-patient encounters ( $N = 117$ ) to determine which of the following topics were discussed: medication purpose, medication directions (i.e., how often, how much, how long to take it), when it should be taken, and the possible side effects. Participants were asked to recall topics that their physicians covered with them (Tarn & Flocke, 2011). Tarn and Flocke asked participants “to provide specific pieces of information about their new prescription” (p. 3) right after each consultation and found that patients remembered 86% of new prescription information on average. Further, 64% of participants remembered all of the medication information provided to them (Tarn & Flocke, 2011). Interestingly, Tarn and Flocke found no relationship between complete recall of medication information and the amount of information provided, education, race, or length of relationship with provider. Of the participants who forgot some of the

prescription information, the most common topics forgotten were the dosage details (47%), potential side effects (42%), and the directions (24%).

Consumers can also misconstrue the health information that they remember. In one study, participants misconstrued 48% of information (Anderson, Dodman, Kopelman, & Fleming, 1979). Intuitively, the more information presented by healthcare professionals, the less likely it is to be remembered (Anderson, Dodman, Kopelman, & Fleming, 1979; McGuire, 1996). Therefore, it is critical to provide materials that can scaffold and/or trigger consumer memory. Additionally, consumers are increasingly responsible for adhering to different therapies with limited supervision by healthcare professionals. Thus, providing consumers with materials that successfully inform and guide them through their therapy is imperative.

A variety of factors can potentially affect memory for medication information. For example, Kessels (2003) outlined the following factors that have the potential to impact memory for medical information: age-related memory decline, anxiety and distress, perceived importance of the information, and the mode of information delivery (i.e., spoken, written, or non-verbal). Thus, the influence of different factors that may influence whether consumers remember medication information or not are important considerations in the design and delivery of CMI.

## **2.2 Implemented Strategies for Improving Various Types of Medication Information**

Medication information is provided to consumers in a variety of ways (e.g., package labeling, package inserts, prescription labels, medication monographs). In response to recognized shortcomings of medication information, different strategies have been developed and implemented, in an attempt to improve these materials. This

section discusses standardized prescription labeling and drug facts boxes as two approaches successfully implemented in the domain of medication information.

### **2.2.1 Standardized Prescription Labels**

Consumers turn to prescription labels for instructions on how to take their medications. However, prescription label instructions are not always straightforward and easy to understand, and as a result are often misunderstood by consumers. The AHRQ (2014) claimed that only 12% of Americans are able to correctly interpret prescription labels. At least one in 10 common prescription labels were misinterpreted by 79% of participants (Davis et al., 2009). Further, the most challenging medication was only correctly understood by about half of the participants (53%; Davis et al., 2009). Davis and colleagues (2009) noted that explicit language improves consumers' comprehension; however, people with limited health literacy may still have difficulty understanding materials even if they are written with precise wording.

In another study, Davis and colleagues (2006) found that prescription medication warning labels were especially difficult for people with limited health literacy to understand. Prescription medication warning labels, or auxiliary labels, are additional instructions about taking the medication (e.g., "do not drink alcoholic beverages when taking this medication", "for external use only"). Icons are often used in conjunction with written prescription medication warning labels. Their results led Davis and colleagues (2006) to endorse a user-centered design approach for the development of prescription drug warning labels "to ensure comprehension of short, concise messages created with familiar words and recognizable icons" (p. 847).

A series of cognitive interviews including a literacy assessment were conducted with 395 patients in an attempt to identify how and why common dosage instructions were misunderstood on prescription medication container labels (Wolf, et al., 2007). Labels were misunderstood an average of 8-33% of the time depending on the medication stimulus. Analysis of their data allowed Wolf and colleagues to attribute misunderstanding of prescription to the following six causal themes: label language, complexity of instructions, implicit versus explicit dosage intervals, presence of distractors, label familiarity, and attentiveness to label instructions. The authors warned that dosage instructions are frequently misunderstood. Further, although limited health literacy is a contributing factor, the complexity and ambiguity of the instructions themselves needs to be addressed (Wolf et al., 2007). Thus, Wolf and colleagues asserted that prescription labels should use “explicit dosing intervals, clear and simple language, within a patient-friendly label format” and the designers of these materials should be guided by evidence from health literacy and cognitive human factors research.

You and colleagues (2011) tested comprehension of three different pregnancy icon labels: standard labels, simplified text-only labels, and simplified text with icons. The majority of the sample ( $N = 132$ ) had low (18.2%) or marginal (39.4%) health literacy. Comprehension was significantly higher for warnings with simplified text and icons (94%) than the simplified text-only (79%) and standard labels (76%). Thus, it appears simplified text and icons in conjunction are a more effective way to communicate warnings on prescription labels. In summary, typical prescription labels

and warning labels have proven difficult for consumers to understand, especially consumers with limited health literacy.

One approach to mitigate the challenges associated with prescription labels and warnings is standardization. The Institute of Medicine's Roundtable on Health Literacy published *Standardizing Medication Labels: Confusing Patients Less* in 2008, arguing for the benefits of standardization. Further, the U.S. Department of Veterans Affairs (VA) recently redesigned and standardized the format of their prescription labels in an attempt to reduce medication safety incidents due to prescription label misunderstanding by making the labels patient-centered (Trettin, 2015). Pharmacists ( $n = 697$ ) and veteran consumers ( $n = 446$ ) were consulted (Trettin, 2015). Petersen (2015) reported that the following prescription label changes resulted from pharmacist and consumer feedback:

- The consumer's name is located at the top
- Directions for how to take the medication are larger and in bold
- The date the prescription can no longer be refilled is included

The VA filled over 143 million prescriptions in 2014 (Petersen, 2015). The VA hopes that standardized prescription labels will reduce medication safety incidents (Petersen, 2015). However, Wolf and colleagues (2016) reported that standardized prescription labels in a non-veteran sample ( $N = 845$ ) did not improve adherence overall. However, standardized prescription labels' benefitted participants with limited literacy and more complex regimens (Wolf et al., 2016).

### 2.2.2 Drug Facts Boxes

The United States Food and Drug Administration (FDA) endorsed “Drug Facts Boxes” as guidance for over the counter (OTC), non-prescription medications (FDA, 2008) and issued specific regulations on how this information is displayed to ensure a standardized experience (FDA, 2014). Based on practices in the United States, Health Canada (2014c) has adopted a similar approach for non-prescription medications. The FDA (2008) noted “the Drug Facts labeling for OTC drug products is intended to make it easier for consumers to read and understand OTC drug product labeling and use OTC drug products safely and effectively” (p. 1). All OTC drug products must include the following headings in the order listed (FDA, 2008, p. 2):

1. Title (Drug Facts or Drug Facts (continued))
2. Active ingredient(s)
3. Purpose(s)
4. Use(s)
5. Warning(s)
6. Directions
7. Other information
8. Inactive ingredients
9. Questions? or Questions or comments? (optional)

Although implemented for OTC medications, this approach has not yet been adopted for prescription medications. However, prescription medications were used for the majority of the development and testing of the utility of drug facts boxes (FDA, 2008).

Drug facts boxes are a prime example of how design has been used to lower demands on health literacy and a series of studies have documented their development and demonstrated their utility. Woloshin, Schwartz, Tremmel, and Welch (2001) found that prescription drugs advertisements were likely to describe benefits in “vague, qualitative terms (58, 87%) than with data (9, 13%)” (p. 1141). These authors argue that both providers and consumers would be better served if complete, succinct and understandable information about the medications was available. The findings from this study motivated Woloshin and colleagues (2001) to develop a standardized method for conveying information about the efficacy of prescription drugs to consumers.

A drug facts box was described as “a table quantifying outcomes with and without the drug” (p. 516, Schwartz, Woloshin, & Welch, 2009). The example drug facts boxes provided the following information (Schwartz et al., 2009, p. 520):

- What is this drug for?
- Who might consider taking it?
- Who should NOT take it?
- Recommended testing
- Other things to consider doing

In addition, the drug facts box example provided a summary of the study results about the efficacy of the medication (i.e., risk of experiencing a heart attack, risk of dying from a heart attack, general risk of dying), both life threatening side effects and less severe side effects, and when the medication was approved by the United States Food and Drug Administration (Schwartz et al., 2009).

First, Woloshin, Schwartz, and Welch (2007) set out to establish that people could understand the information in a drug facts box. Woloshin and colleagues (2007) found participants' ( $N = 224$ ) answered 4 out of 5 questions correctly using the drug facts box. However, there was evidence that people who had not completed high school understood less (Woloshin et al., 2007). To advance these findings, Schwartz and colleagues (2009) compared comprehension between drug facts boxes and traditional medication materials. Specifically, Schwartz and colleagues (2009) sought to determine whether drug facts boxes would improve participants' knowledge about the drugs over traditional materials and decision-making amongst alternatives. Schwartz and colleagues (2009) found that consumers ( $N = 231$ ) provided with drug facts boxes were more likely to accurately comprehend the risks of a health condition and the potential benefits and side effects of medications. Moreover, participants with drug facts boxes were more likely to select the more efficacious medication from a pair of alternatives (Schwartz et al., 2009). Thus, re-designing health information can improve consumers' comprehension and decision-making capabilities.

Canada is in the process of adopting drug facts boxes (or drug facts tables) for all non-prescription medications to help Canadians easily locate important information (Government of Canada, 2017). New non-prescription medications had to include a drug facts table beginning June 13, 2017 and all non-prescription medications must include a drug facts table by June 30, 2021 (Government of Canada, 2017).

### **2.3 Medication Information for Consumers**

For the purposes of this study the nomenclature developed by the FDA (no date) will be adopted. Patient information is the overarching term for three distinct types of

medication information provided to consumers: CMI, medication guide, patient package insert (see Table 1 for comparison).

Table 1

*Comparison of Patient Information (FDA, n.d.)*

	<b>Consumer Medication Information (CMI)</b>	<b>Medication Guide</b>	<b>Patient Package Insert (PPI)</b>
<b>What kind of information is in it?</b>	Specific information on the safe and effective use of a medicine	Specific information on the safe and effective use of a medicine	Specific information on the safe and effective use of a medicine
<b>Which medicines have it?</b>	All prescription medicines filled for the first time	Certain prescription medicines with serious and significant public health concerns as decided by the FDA	Oral contraceptives (birth control pills) and medicines with estrogen, and some other prescription medicines as decided by the FDA or the drug company
<b>Is the pharmacist required to give it?</b>	Provided voluntarily by pharmacies to meet goals established by Congress; It is usually stapled to the outside of or put in the pharmacy bag with the patient's prescription	Yes, for all new and refilled prescriptions that are required by FDA to have a Medication Guide	No, except for oral contraceptives (birth control pills) and medicines with estrogen where the information is usually part of a unit-of-use package
<b>Who writes it?</b>	Pharmacy or outside company	Drug company	Drug company
<b>Is it reviewed and approved by FDA?</b>	No	Yes	Yes

In Canada, CMI is the patient medication information (PMI, formerly consumer information) part of the product monograph. Other terms for similar written medication information target at consumers are also used. For example, Patient Information Leaflets (PIL) and Package Leaflets (PL) are used in the European Union, whereas

Consumer *Medicines* Information is used in Australia (Yuan, Raynor, & Aslani, 2018). Unlike the United States of America, both the European Union and Australia offer only a single type of medication information targeted towards consumers. Thus, CMI will be compared with PILs, PLs, and Consumer *Medicines* Information as they appear to be the most similar. In addition to having different names for their information, different countries and regions have different guidance as well. The following section will summarize the guidance on different types of medication information for consumers most closely resembling CMI in Canada and discuss some of the guidance for patient information materials from other countries around the world. Subsequently, research on patient medication information will be presented.

#### 2.3.1.1 Canadian Guidance on Patient (i.e., Consumer) Medication Information Monographs

Health Canada (2016) defines a product monograph as

“A product monograph is a factual, scientific document on a drug product that, devoid of promotional material, describes the properties, claims, indications, and conditions of use for the drug, and that contains any other information that may be required for optimal, safe, and effective use of the drug.” (p. 1)

Patient medication information, referred to in this study as CMI, is just one of three parts of what are referred to as product monographs. Specifically, the three parts of Health Canada’s product monographs are Part I: Health Professional Information, Part II: Scientific Information and Part III: Patient Medication Information (Health Canada, 2016). In 2014, Health Canada released plain language revisions to Part III: Patient

Medication Information and its associated template, which were fully implemented by 2017. These changes included (Health Canada, 2014, p.1):

- a more descriptive title;
- eliminating columns and streamlining the use of headings;
- providing some information in a Question and Answer format;
- using simpler language and shorter sentences;
- requiring font types and sizes which enhance legibility; and
- using Grades 6-8 level vocabulary where appropriate to enhance comprehension

CMI is intended to be a plain language translation of Parts I and II, where plain language is defined as “using the simplest, most common words possible, so that information is clear, concise and easy to understand for the intended audience” (Health Canada, 2016, p. 40). Health Canada encouraged monograph developers to leverage plain language resources (e.g., Canadian Public Health Association, 2002; Good Medicine for Seniors Guidelines of Plain Language and Good Design in Prescription Medication). Health Canada (2016) also endorsed testing patient medication information with users, but it is not mandatory, nor do they elaborate on what types of users and testing methods are most appropriate.

The potential challenges of communicating effectively with people with limited health literacy is identified in the documentation. Specifically, Health Canada (2016) argued:

“Health literacy levels in Canada vary significantly among regions and demographically. For this reason, language should be adjusted for lower literacy

levels. Assume that the reader has no prior knowledge of the medication or how to use it. Use the simplest, shortest words possible” (p. C-9)

Health Canada also made several recommendations regarding readability and usability. Specifically, a 6<sup>th</sup> to 8<sup>th</sup> grade reading level is ideal (Health Canada, 2016). Further, Health Canada argued that CMI should be “simple, clear and easy to understand so that patients are able to find, understand and act upon the information” (p. 42).

With respect to illustrations, Health Canada (2014a) suggests:

“Illustrations that help demonstrate the proper use of a self-administered product (e.g., inhaler, injectable product) are encouraged. Pictures or graphics can often be misleading as to the use, merit, and character of a drug product and should be avoided. Pictograms should not be used” (p. 35)

Health Canada’s (2016) general template for CMI suggests that patient medication information should include all of the following:

- General Information
- Opening Disclaimer
- About the Medication
- Warnings and Precautions
- Interactions
- Proper Use
- Side Effects
- Reporting Side Effects
- Storage

- More Information
- Date

Health Canada (2016) also has a style guide section in its guidance on monographs, which provides minimal advice on headers, margins, page justification, headings, font, and the use of italics and uppercase.

### **2.3.2 International Guidance on Consumer Medication Information**

A recent article by Yuan and colleagues (2018) compared the international regulations for medicine information written for consumers between the United States of America, Australia, and the European Union. Yuan and colleagues found of the three, the European Union had the strongest legislation for written information for consumers. Specifically, the Quality Review of Documents (QRD) guidance is comprehensive and PILs are evaluated by both the European Medicines Agency (EMA) and the Committees for Medicinal Products (CMPH; Yuan et al., 2018). Similar to Canada, although guidance is provided by the FDA, CMI is developed by organizations and not evaluated by any federal agency. Although Australia's CMI is written by "the regulatory affairs, medical, and marketing personnel within the pharmaceutical company" (p. 7) it is not evaluated either (Yuan et al., 2018). Further, although Australia has recommendations for CMI, there is no legislated guidance (Yuan et al., 2018).

In the United States, it is law that consumers receive "useful written information" to accompany prescriptions filled for the first time (Trettin, 2015). Useful CMI must be (Trettin, 2015, p.3):

- scientifically accurate,
- non-promotional in tone and content,

- sufficiently specific and comprehensive as to adequately inform
- consumers about the use of the product
- understandable, legible format that is readily comprehensible”

Similar to Health Canada’s (2014a) guidance, the FDA (2006) recommended a set of eight criteria with an emphasis on promoting the usefulness of written information (see Table 2).

Table 2

*Action Plan Criteria for Defining Useful Information (FDA, 2006)*

<b>Criterion</b>	<b>Description</b>
1	Drug names, indications for use, and how to monitor for improvement
2	Contraindications and what to do if they apply
3	Specific directions about how to use and store the medicine, and overdose information
4	Specific precautions and warnings about the medicine
5	Symptoms of serious or frequent possible adverse reactions and what to do
6	Certain general information, including encouraging patients to communicate with healthcare professionals, and disclaimer statements
7	Information that is scientifically accurate, unbiased in tone and content, and up-to-date
8	Information in an understandable and legible format that is readily comprehensible to consumers

The Institute of Medicine’s (IOM; 2006) report entitled *Preventing Medication Errors* argued that improving medication labeling and information for both consumers and providers could positively affect the quality and safety of medication use. The IOM (2006) argued that the government agencies should identify and adopt strategies to enhance CMI. Specifically, the IOM endorsed adopting standardization of pharmacy prescription information in “a format designed for readability, comprehensibility, and

usefulness to consumers” (p. 12) as well as tailoring the leaflets according to consumers’ individual needs (e.g., limited health literacy, language, visual acuity).

In recent years, the concerns voiced by the IOM paired with a petition by stakeholders and other initiatives, have motivated the FDA to begin developing a framework for providing consumers with current, high quality, prescription medication information to facilitate safe use and emphasize consumer comprehension (Pearsall, Araojo, & Hinton, 2014). As previously discussed, currently, the FDA (no date) differentiates between three types of patient medication information: patient package inserts, medication guides, and CMI. However, the FDA is going to replace these three distinct types of patient medication information with a single online repository of patient medication information to be dispensed with the prescription and available to the public free of charge (Pearsall et al., 2014). Pearsall and colleagues describe the importance of developing content and formatting standards for patient medication information. Currently, the FDA is weighing different methods for ensuring the accessibility of patient medication information (e.g., consumer-friendly vocabularies, readability tests, consumer testing), but it appears likely that a multi-pronged approach will be adopted that will include testing materials with consumers (Pearsall et al., 2014). Pearsall and colleagues (2014) also noted that “pilot studies have been administered to test content and format standards, pharmacy workflow impact, and potential alternate distribution techniques” (p. 163) but the results had not yet been analyzed.

Recognizing the shortcomings and variability of written medication information dispensed from pharmacies, Australia standardized their consumer medicines information in 1993 (Koo, Krass, & Aslani, 2007). Further, Sless and Shrensky (2006)

wrote the third edition of a set of guidelines to inform the development of consumer medicine information in Australia and endorsed testing the materials with users. Sless and Shrensky (2006) argued that consumer medicine information should reach the following performance thresholds:

1. At least 90% of literate consumers should be able to find information on the CMI quickly and easily
2. At least 90% of those who find the information should be able to act appropriately on the information
3. Thus at least 81% of literate consumers should be able to use the CMI appropriately (p. 7)

The European Commission (2001) acted as a pioneering group by issuing a directive mandating user testing in consumer medicine information development in which was implemented in 2005 (Pander Maat & Lentz, 2010). As previously mentioned, Health Canada (2016) advocated testing medication information with consumers, but no guidance on methods was provided, nor was it a mandated practice.

Other agencies have developed style guides for patient information similar to that of Health Canada. For example, the European Medicines Agency (2015) requires manufacturers to abide by the guidance template for medication information referred to as the Quality Review of Documents (QRD) template. Additionally, the Committee on Safety of Medicines (2005), since renamed the Commission on Human Medicines, in the United Kingdom, provides similar guidance to that of Health Canada, but arguably more offers more detailed guidance, in a more succinct manner. Specifically, the

Committee on Safety of Medicines (2005) provided the following guidance on factors they deemed influential to the clarity and legibility of monographs:

- **Writing style:** advice is given on choice of words, punctuation and sentence length, short paragraphs and use of bullets to make the text easier to understand.
- **The typeface:** including easy-to-read serif-type fonts, restricting the use of capitals, and avoiding italics and underlining to make word recognition easier. A key change is an increase in the recommended text size to ensure more patients are able to read the information provided.
- **Design and layout:** is key to aiding the reader to navigate around the sections of the leaflet. Principles identified include the need for clear spacing, attention to paragraph length and choice of uncoated paper. Use of column formats was found to be helpful and advice is given on separation of columns and sections and on ensuring that key information is kept together.
- **Headings:** these are important for navigation and should be presented consistently throughout the document. Use of colour or bold text can help to make headers stand out.
- **Use of colour:** judicious use of colour can aid navigation, but attention to contrast is important for readability. Advice is also provided on use of reverse type to highlight key information.
- **Use of symbols and pictograms:** it is essential that the meaning of any symbol is clear and this should always be user tested. It cannot substitute for verbal advice.

Interestingly, Health Canada (2016) argued against the repetition of content in the patient medication information whereas the Committee on Safety of Medicines (2005) in the United Kingdom, argued that repetition was beneficial if it was a concise summary. Specifically, the Committee on Safety of Medicines (2005) posited that the lengthiness of monographs could deter users from reading them in full, as well as create challenges for locating the most important information. Therefore, the Committee on Safety of Medicines (2005) endorsed the use of “headlines” whereby the most important information in a monograph pertaining to safe and effective use should be summarized and presented prominently at the monograph onset (for example, see Figure 2). The Committee on Safety of Medicines (2005) also noted that for most products the following headlines are appropriate to summarize the key aspects of monographs before providing more detail:

- Why the patient should take the product
- The maximum doses or duration of treatment
- Potential side effects/withdrawal reactions (symptoms to look out for, especially for common or serious side effects)
- Contraindications
- Important drug interactions
- Circumstances in which the drug should be stopped
- What to do if the medicine doesn't work; or
- Where to find further information (p. 40-41)

### Carbamazepine 200mg Tablets

#### Important things that you need to know:

- Carbamazepine tablets are prescribed for different illnesses including epilepsy, manic-depression and neuralgia.
- **Take carbamazepine regularly to get the maximum benefit.** You should not stop taking the medicine without talking to your doctor. Sometimes stopping the medicine can cause problems.
- Carbamazepine can cause side effects, although most people do not have serious problems – see page 2 for details. If you have fever, sore throat, skin rashes or skin yellowing, mouth ulcers, bruising or bleeding, see your doctor immediately.
- Some side effects may occur early in treatment. These often disappear after a few days as your body gets used to the drug (for example dizziness, drowsiness or clumsiness).
- Taking other medicines, including other anti-epilepsy drugs, may sometimes cause problems. Check with your doctor or pharmacist before taking any other medicines.
- If you are (or might become) pregnant while taking carbamazepine, it is important to talk to your doctor about this.

**Now read the rest of this leaflet.** It includes other important information on the safe and effective use of this medicine that might be especially important for you. **This leaflet was last updated on xx/xx/xx**

*Figure 2. An Example of the Use of Headlines Which Would Precede the Full CMI (the Committee on Safety of Medicines, 2005, p. 42)*

In summary, the guidance around medication information for consumers in terms of what should topics should be included as well as how it should be designed, written, and tested vary between countries and regions. Despite the good intentions motivating medication information for consumers, countries world-wide have recognized as currently designed, CMI often fails to meet consumer needs. In response, countries are exploring and adopting multiple approaches CMI to make it easier to access and increase its usefulness. Such improvement strategies include:

- standardizing CMI (e.g., Koo et al., 2007)
- including a CMI summary (e.g., Committee on Safety of Medicines, 2005)

- making CMI available digitally (e.g., Pearsall et al., 2014)

Unfortunately, other countries appear to be more committed to pursuing opportunities to improve CMI than Canada.

### **Chapter 3: Research on Medication Information for Consumers**

Different types of health information may have unique priority topics. With respect to safe and effective medication taking, Hermann, Herxheimer, and Lionel (1978) outlined the minimum necessary knowledge consumers must have (see Table 3). Specifically, Hermann and colleagues argued that at minimum consumers should know how to take a medication, how to store it, how it is expected to help, and finally recognize and deal with any problems that may arise from taking it. This work clearly overlaps with what governments mandate manufacturers to include in the information they include with medications.

Many recognize the importance, as well as potential value and benefits of providing consumers with information about medications they are prescribed. However, the actual benefits observed are often suboptimal as a result of shortcomings in the dispensed information. There is a dearth of research on CMI specifically and terminology used is variable. Therefore, this section will outline research on CMI as well as other types of medication information developed for consumers (e.g., standard drug monographs, medication guides, patient information leaflets, patient medication information).

Table 3

*Guide to minimum information needed to enable patients to make treatment with a prescribed drug effective and safe (Hermann et al., 1978, p. 1133)*

1. To know how to take the drug:	1.1 To take a specific dose	{ 1.1.1 Amount of drug per tablet or other dosage form 1.1.2 Average dose and dose range, adult 1.1.3 Average dose and dose range, child
	1.2 To take a dose in a specific manner	1.2.1 Manner directed by dosage form or drug
	1.3 To take a dose at specific times	{ 1.3.1 Clock time 1.3.2 Time since last dose 1.3.3 Time since or until food intake 1.3.4 Duration of treatment
2. To know how to store the drug:	2.1 To store it properly	2.1.1 Storage conditions
	2.2 To recognise the time at which the medicine becomes subpotent	{ 2.2.2 Expiry date 2.2.3 Event showing deterioration
3. To know how the drug is expected to help:	3.1 To recall the basic facts about the complaint	{ 3.1.1 Disease or symptoms to be affected 3.1.2 Potential consequence of compliance 3.1.3 Potential consequence of non-compliance
	3.2 To recognise the desired effect and act upon its absence	{ 3.2.1 Events showing effect 3.2.2 Time at which to expect effect 3.2.3 Direction for follow-up if there is no effect
4. To know how to recognise problems caused by the drug:	4.1 To recognise unwanted effects and act if they occur	{ 4.1.1 Events showing unwanted effect 4.1.2 Direction for follow-up of events
	4.2 To recall that certain unwanted effects can only be detected by clinical examination or tests	{ 4.2.1 Unwanted effects that the patient cannot observe 4.2.2 Direction for detection of such effects
	4.3 To recall circumstances indicating need for change of treatment, and act if they occur	{ 4.3.1 Change in the patient's state 4.3.2 Direction for follow-up of change 4.3.3 Other drug added to therapy 4.3.4 Direction for follow-up of drug addition
	4.4 To verify components of medicine	{ 4.4.1 Name of drug and "active" excipient 4.4.2 Direction for follow-up of "action"
	4.5 To act if overdosage occurs	4.5.1 Direction for follow-up of occurrence

### 3.1 Early Research on CMI

Distributing CMI has not always been common practice. It appears that CMI distribution became more prevalent during the late 1980's and early 1990's. For example, early work exploring the benefits of CMI in the United States was conducted by Gibbs, Waters, and George (1989a, 1989b) and Australia began its distribution of CMI in 1993 (Winter, Harlow, Abarno, & Alderman, 2013). It is unclear when CMI distribution became common practice in Canada.

Before CMI distribution was common practice, Gibbs, Waters, and George (1989a, 1989b) compared giving consumers CMI with not giving them any medication information. Gibbs and colleagues explored the impact of distributing CMI for non-steroidal anti-inflammatory drugs (NSAIDs),  $\beta$ -adrenoceptor antagonists and inhaled bronchodilators (1989a) as well as penicillins, diuretics and benzodiazepines (1989b). Gibbs and colleagues (1989a, 1989b) found that people who received CMI were generally more knowledgeable about their medications (e.g., potential side effects, how to take the medications, storage and disposal) than those who had not received CMI. However, participants had equivalent knowledge of the names of medication(s) regardless of whether participants had received CMI or not (Gibbs et al., 1989a). Participants who received CMI for NSAIDs and  $\beta$ -adrenoceptor antagonists were surveyed one year later and had improved knowledge over those who had not received CMI, but not as pronounced as originally observed (Gibbs et al., 1989a). Further, participants who received CMI, except for penicillins (Gibbs et al., 1989b), reported higher levels of satisfaction than those who had not received CMI (Gibbs et al., 1989a, 1989b). Thus, initial exploration into CMI distribution suggests that there were subjective

and objective benefits which warranted this practice. Since CMI distribution has become common practice, subsequent have studies explored the extent to which consumers actually use CMI, expert assessments of CMI, consumers' perceptions of CMI, and finally consumers' objective CMI performance (e.g., memory, comprehension, application of information). The following sections discuss address these topics.

### **3.2 CMI Use**

Providing medication information to consumers does not ensure that they will read or use it. Ley (1988) noted that written health information might not be noticed, not be read, not understood, and not remembered. However, studies have shown that many people generally read written medication information (47-95% range over 11 studies; Ley, 1988). In one study, participants were more likely to have read the medication materials if they were taking the medication for the first time or older, but education did not predict the likelihood of reading written information (Kanouse et al., 1981).

In a study by Koo, Krass, and Aslani (2005a) 90 (64%) reported having read CMI of the 184 participants reported having received CMI in the past. Further, most of the participants (61%) who reporting having read CMI reportedly read it in its entirety, whereas some participants either read selective sections from the CMI (17%) or scanned it (22%; Koo et al., 2005a). Participants reportedly read CMI to "gain knowledge about the medication and concerns about side effects" (Koo et al., 2005a, p. 95). The primarily explanation for not reading CMI was that participants had taken the medication in the past (Koo et al., 2005a). Of those that read it, consumers felt that reading CMI informed them about the medication (76%), increased their confidence in taking the medication (58%) and increased their awareness of the importance of taking

the medication as directed (38%; Koo et al., 2005a). Many participants (38%) did not feel that reading CMI affected how they took their medication; however, others stopped taking their medications because of possible side effects (12%) or drug interactions (9.5%) discussed in the CMI (Koo et al., 2005a). Reading CMI stimulated questions or concerns in some of the participants (21%) which often led to consulting a healthcare professional (Koo et al., 2005a). Koo and colleagues (2005a) found that more than half of the variance in attitudes towards CMI was explained by the perception of disease/condition, role of carer, health locus of control, as well as readability and presentation.

Concerning findings about medication guides have also been reported. Specifically, fewer than one quarter (23%) of the 251 participants in Wolf and colleagues' (2006) study, even looked at the medication guides. Participants were less likely to have consulted the medication information if they had limited health literacy and/or were male (Wolf et al., 2006).

An investigation of the CMI use in the United States found that participants ( $N = 307$ ) reported reading CMI that accompanied new prescriptions always (49.2%), often (21.2%), seldom (16.0%), or never (13.7%; Nathan, Zerilli, Cicero, & Rosenberg, 2007). Further, the usage was reversed in those who received CMI with a refilled prescription ( $n = 296$ ; Nathan et al., 2007), Specifically, participants reported reading CMI with refilled prescriptions always (21.6%), often (13.9%), seldom (26.4%) or never (38%). This corroborates the Koo and colleagues' (2005a) finding that patients who had previously taken the medication were not likely to read CMI. However, in Canada it is atypical for consumers to receive CMI with prescription refills. Of those who reported

reading CMI at least seldom and responded to the questions, the majority of participants reported that CMI was very easy (56.2%) or somewhat easy (34.5%) to understand and very (63.8%) or somewhat (35.0%) useful (Nathan et al., 2007).

Leemans, Heylen, Quanten, and Deferme (2011) explored the use of patient information leaflets (PILs) and factors affecting their use in Belgium. Again, it is assumed that PILs and CMI are similar enough for a valid comparison. Leemans and colleagues (2011) found that few participants actually searched the internet for patient information leaflets, despite high reports of using the internet for health information more generally. Belgium's Federal Agency Medicines and Health Products (FAMHP) provides its CMI online in French, Dutch, and German, but few participants were aware of the website (Leemans et al., 2011). Leemans and colleagues suggested that it would be prudent to increase the awareness of the FAMHP website.

Although 58.5% of Belgian participants ( $N = 800$ ) reportedly read the patient information leaflets, only 26.3% of the sample read them in their entirety (Leemans et al., 2011). Not reading patient information leaflets was more common in older people and males (Leemans et al., 2011). Participants who did not read patient information leaflets rationalized that they received enough information from their healthcare providers about medications, therefore reading the patient information leaflets was not necessary (Leeman et al., 2011). Participants most frequently reported reading the patient information leaflets sections on dosage and side effects (Leeman et al., 2011). Leemans and colleagues (2011) argued that strategies to increase the appeal of patient information leaflets (e.g., increasing patient friendliness, aligning patient information leaflets with consumers' needs) should be implemented to bolster reading rates.

In a Swedish study ( $N = 406$ ) participants ranged in their reports of always (37%), occasionally (52%), or never (11%) reading PILs (Hammar, Nilsson, Hovstadius, 2016). Again, for the purposes of this comparison, patient information leaflets were assumed to be equivalent to CMI. Patient information leaflets are typically included in the package. Females were significantly more likely to report reading patient information leaflets than males (Hammar et al., 2016). However, there was no evidence of differences in the likelihood of reading patient information leaflets between older (56 years or older) or younger (55 years or younger) respondents.

More recently, Ramia, Zeenny, Hallit, and Salameh (2017) reported that 36% of their Lebanese sample ( $N = 921$ ) reported reading CMI very often or always, whereas 38% reported rarely or never reading it (Ramia, Zeenny, Hallit, & Salameh, 2017). Further, Ramia and colleagues found that the following predictors of reading CMI: age, gender, education, and adverse drug reaction awareness. That is, younger, highly educated females, whose physicians had counseled them about potential adverse drug reactions were most likely to read CMI. Thus, both Ramia and colleagues and Hammar and colleagues (2016) reported females being significantly more likely to read medication information. However, unlike Hammar and colleagues (2016), Ramia and colleagues found differences in reading CMI reports associated with age.

Recently, a study by Patel, Bapat, Bhansali, and Sansgiry (2018) examined reading rates of CMI in their sample of university students ( $N = 306$ ; Mean age = 23.6 years old). The researchers found that a minority of participants (11%) reported always reading CMI and over a quarter (26%) read CMI often (Patel et al., 2018). Alarming, a

large portion of the participants reported rarely (21%) or never (11%) reading CMI (Patel et al., 2018). However, Patel and colleagues' study did not explore predictors affecting the likelihood of reading or not reading CMI.

A summary of key findings on CMI use presented chronologically can be found in Table 4. It appears as though CMI use has generally declined over time. For example, Gibbs and colleagues (1989a) reported a 97% CMI reading rate. Recently, Ramia and colleagues (2017b) reported only 17% of participants reported always reading CMI. Females were more likely than males to read CMI in three studies (i.e., Hammar et al., 2016, Leemans et al., 2011, and Ramia et al., 2017). The evidence as to whether age plays a factor in reading CMI was mixed. Ramia and colleagues reported being older was negatively correlated with reading CMI. Leemans and colleagues reported that older people were more likely to read CMI. Indeed, Hammar and colleagues found no reading differences between participants older and younger than 55. Intuitively, participants in two explained that they were less likely to read CMI if it was for a refill prescription or a medication they had taken in the past (Koo et al., 2005a; Nathan et al., 2011).

Consider this comparison of CMI use (see Table 4) with caution. The investigator included studies on patient information leaflets, considered equivalent to CMI, although it is difficult to ensure their equivalence with any certainty. However, even CMI within the same country has been shown to vary (Monkman & Kushniruk, 2017b), therefore some CMI may have been inherently more appealing to read than others. Differences in reported CMI use could also be attributable to several different factors such as the novelty of the intervention (novel vs. well established) or the location of the study

(United States vs. Lebanon). Additionally, people may be more motivated to read CMI given the specific circumstances of their condition or the medication (e.g., severity of potential side effects). Only Gibbs and colleagues (1989a) controlled for this by limited their sample to those taking specific medications. Further, there were methodological differences (e.g., when and how questions were posed) between the CMI use studies, which may account for some of the variability. For example, Gibbs and colleagues (1989a) interviewed patients one to two weeks after receiving CMI whereas Koo and colleagues (2005a) interviewed patients the day of or the day after receiving CMI. Less time between when participants received the CMI and when they were interviewed may have precluded some participants from reading it. Also, earlier studies reported CMI use using a binary (i.e., yes or no) response (Gibbs et al., 1989a; Koo et al., 2005a), whereas later studies used likert scales (Nathan et al., 2007; Leemans et al., 2011, Hammar et al., 2016; Ramia et al., 2017).

Table 4

*Comparison of Studies on Consumer Medication Information (CMI) and Patient Information Leaflet Use*

<b>Study (chronologically)</b>	<b>Country</b>	<b>Sample Size</b>	<b>Reported Reading</b>	<b>Reported Not Reading</b>	<b>Predictors or Motivators of Reading</b>	<b>Predictors or Explanations of Not Reading</b>
Gibbs et al. (1989a)	United States	419	97%			
Koo et al. (2005a)	Australia	153	64%		<ul style="list-style-type: none"> <li>To learn about the medication and side effects</li> </ul>	<ul style="list-style-type: none"> <li>Previously taken the medication</li> </ul>
Wolf et al. (2006)	United States	251	23% consulted			<ul style="list-style-type: none"> <li>Limited health literacy</li> <li>Gender (male)</li> </ul>
Nathan et al. (2007)	United States	307	49% always 21% often	16% seldom 14% never		<ul style="list-style-type: none"> <li>Previously taken the medication</li> </ul>
Leemans et al. (2011)	Belgium	800	58.5% always	23% never	<ul style="list-style-type: none"> <li>Gender (female)</li> <li>Age (older than 65)</li> </ul>	<ul style="list-style-type: none"> <li>Belief that sufficient information is provided by the doctor and pharmacist</li> </ul>
Hammar et al. (2016)	Sweden	406	37% always 52% occasionally	11% never	<ul style="list-style-type: none"> <li>Gender (female)</li> </ul>	
Ramia et al. (2017)	Lebanon	921	17% always 19% very often	17% rarely 2% never	<ul style="list-style-type: none"> <li>Gender (female)</li> <li>Education (highly educated)</li> <li>Counselled on adverse drug events</li> </ul>	<ul style="list-style-type: none"> <li>Age (older)</li> </ul>
Patel et al. (2018)	United States	360	11% always 26% often	21% rarely 9% never		

### 3.3 Provision and Quality of Existing Medication Information for Consumers

A few private vendors develop CMI content, whereas pharmacies or their software vendors are responsible for formatting this information (Winterstein, Linden, Lee, Fernandez, & Kimberlin, 2010). In 1995, the FDA established goals for the distribution and quality of CMI (Winterstein, Linden, Lee, Fernandez, & Kimberlin, 2010) and sought to assess performance of these unregulated materials in a series of studies.

The initial study by Svarstad and Bultman (2001) was conducted in collaboration with the National Association of Boards of Pharmacy (NABP) and a national panel of experts on medication information and communications. Svarstad and Bultman trained people to act as patients and use a standard scenario and script to fill three new prescriptions (ibuprofen, amoxicillin, and paroxetine) at randomly selected community pharmacies ( $N = 306$ ) across eight states. Experts evaluated these materials using the criteria, which varied according to the content important for each medication (Svarstad & Bultman, 2001). Svarstad and Bultman (2001) investigated the following four research questions:

1. "What percentage of patient-observers were given *any written prescription information* with the study drugs (in addition to the labels and stickers on their medication containers)?"
2. What were the panelists' *overall evaluations of written information* given with the study drugs?
3. What were the panelists' *evaluations of written information on the 10 general criteria* listed in the Patient Information Evaluation Forms?

4. What were the panelists' *evaluations of written information on the sub-criteria* listed in the Patient Information Evaluation Forms?" (n.p.)

Most (approximately 87%) new prescriptions were accompanied with printed information about the medication (Svarstad & Bultman, 2001). Svarstad and Bultman (2001) also found that most information sheets were of high quality (i.e., unbiased and accurate) and described the benefits of the medication, provided information about monitoring and identified adverse reactions, and they were legible and comprehensible to consumers (from an evaluator perspective). However, Svarstad and Bultman noted the following shortcomings of the CMI: identifying contraindications and how to respond to them; precautions, their significance and how they can be avoided; storage instructions and general information; currency and publication information. In summary, Svarstad and Bultman reported that the quality of written information was variable and there were opportunities to improve it. Svarstad and Bultman also asserted that consumers should be involved in the evaluation of medication information being provided to them.

Monkman and Kushniruk (2017b) developed a framework to compare the readability and content utility of CMI from three Canadian pharmacies. Readability measures were Simple Measure of Gobbledygook (SMOG; McLaughlin, 1969) scores, word count, and reading time. There were 11 content utility topics which were based on those from the adapted CIRF (Koo et al., 2007) but were complemented with missed dose, allergic reactions, drug interactions, and overdose (Monkman & Kushniruk, 2017b). The comparison between the CMI from the three pharmacies (two hardcopies and one online) identified potentially problematic differences because CMI is

unstandardized and often varies between pharmacies (Monkman & Kushniruk, 2017b). Monkman and Kushniruk (2017b) argued that online CMI failed to leverage the capabilities of the digital medium. All three pharmacies exceeded Health Canada's (2016) recommended sixth to eighth grade reading level guide. Alarmingly, one pharmacy reported just two possible side effects and no serious side effects, whereas another pharmacy listed 10 possible and five rare, but serious, side effects for the same medication (Monkman & Kushniruk, 2017b). It is unclear the extent to which consumers are aware of how much CMI varies between pharmacies or even that it varies at all.

In a second inspection study (2017a), the framework from Monkman and Kushniruk (2017b) was used to compare CMI for 10 medications from the same leading Canadian pharmacy. This investigation revealed potential shortcomings of CMI which could potentially impact medication safety and efficacy. Examples of potential problems with CMI included no information on three of the content utility topics (allergic reactions, overdoses, drug interactions) and no directions for use of inhalers. Additionally, information identified as important was not visibly different from the surrounding text and could easily be overlooked (Monkman & Kushniruk, 2017a).

The content utility criteria, but not the readability measures, from Monkman and Kushniruk (2017a, 2017b) were also used to compare Danish and Canadian CMI (Monkman, Nøhr, & Kushniruk, 2017). In contrast to the Canadian process of typically offering consumers hardcopies with a new prescription, Danish CMI is only offered to its citizens through its online resource (i.e., <http://min.medicin.dk/>; Monkman et al., 2017). Danish CMI was found to be more comprehensive (i.e., it satisfied all 11 of the content utility criteria) and even had several unique categories (e.g., blood donor, Image

identification, effect) not included in Canadian CMI (Monkman et al., 2017). Further, unlike the Canadian CMI, Danish CMI capitalized on the digital medium. For example, min.medicin.dk used collapsible categories to minimize the potential for overwhelming and deterring users and potentially facilitate finding information (Monkman et al., 2017). Additionally, Danish CMI included multimedia presentations (e.g., annotated slideshows, videos) to illustrate directions for using medications (Monkman et al., 2017). Min.medicin.dk also described potential side effects in more detail than Canadian CMI (Monkman et al., 2017). Specifically, Canadian CMI only used verbal labels (e.g., possible, rare) to describe side effect frequency, whereas Danish CMI used a tabular format with both verbal labels paired with proportions “(e.g., no more than 1 out of 100 people)” (Monkman et al., 2017, p.150). Interestingly, in their meta-analysis, Büchter, Fechtelpeter, Knelangen, Ehrlich, and Waltering (2014) found using numbers to convey the probabilities of side effects resulted in more accurate estimates than words which led to overestimations. Further, participants were more satisfied with the materials and were more likely to use medications when side effects reported using numbers rather than words (Büchter et al., 2014). Despite its potential value as a medication resource for Danish citizens, there is no published information about how many people are aware of and use min.medicin.dk.

In addition to studies of CMI, others have inspected medication guides for utility (e.g., readability and suitability). Wolf and various colleagues (i.e., Wolf, Davis, Shrank, Neuberger, & Parker, 2006; Wolf et al., 2012) investigated the utility of medication guides and compared strategies for improving these materials. Medication guides were considered to be of limited value because they were written at high reading levels and

were generally assessed as unsuitable health materials for consumers with limited health literacy. Further, Wolf and colleagues (2012) compared 32 medication guides assessed from their initial study (i.e., Wolf et al., 2006). Unfortunately, Wolf and colleagues (2012) reported no substantial gains in assessments of readability or suitability. Two medication guides were considered to have improved; however, seven medication guides were deemed to be worse than their initial evaluation for suitability (Wolf et al., 2012).

### **3.4 Consumers' Perceptions and Preferences for Existing Medication Information**

Provision, use, and expert evaluations medication information for consumers are valuable. However, it is also important to know how consumers, the target audience of CMI, perceive it. Moreover, consumer perceptions may contribute to criteria used in expert inspections. Thus, several studies have looked at consumer ratings of medication information either in conjunction with expert evaluations or in isolation.

Building on Svartstad and Bultman's (2001) preliminary study, the FDA commissioned two subsequent studies using consumer assessments of CMI in addition to expert inspections. A random sample of community pharmacies ( $N = 384$ ) in 44 states were selected from a national electronic list and professional shoppers were hired to pose as patients to fill prescriptions for four medications: atenolol, atorvastatin, glyburide, and nitroglycerin (Svartstad & Mount, 2001). Experts and consumers evaluated materials gathered in this study. Consumer evaluators assessed the legibility, comprehensibility, and usefulness of the information, whereas expert evaluators assessed the materials on the basis of how "specific, comprehensive, scientifically accurate, unbiased, up-to-date, and consistent with principles known to facilitate

legibility and comprehension of written materials” (Svarstad & Mount, 2001, p.3) it was. Additionally, the readability of the CMI was assessed. Svarstad and Mount (2001) sought to address the following three research questions:

1. “What percentage of patient-observers were given *any written patient information* with the four study drugs (atenolol, atorvastatin, glyburide, and nitroglycerin)?
2. What percentage of patient-observers were given *written patient information that adhered to various criteria used by expert panelists?*
3. What percentage of patient-observers were given *written information that adhered to various criteria used by consumer panelists?*” (p. 3)

Expert evaluation forms included the eight criteria for useful CMI based on general criteria from the aforementioned 1996 Action Plan for the Provision of Useful Prescription Medicine Information (refer back to Table 2). As in Svarstad and Bultman’s (2001) study, Svarstad and Mount (2001) generated sub-criteria specific to each of the medications to aid in their individual assessments. Svarstad and Mount (2001) also developed consumer evaluation forms consisting of criteria from the 1996 action plan as well as the Consumer Information Rating Form (Krass et al., 2002).

Svarstad and Mount (2001) reported that consumers received CMI with the majority of new prescriptions (over 88%). However, the information was generally deficient on criteria 2, 4, 5, 6, and 8 and especially criteria 2 (contraindications), 4 (precautions) and 6 (general information; Svarstad & Mount, 2001). Consumer ( $N = 154$ ) ratings of the materials ranged from 57.0% (glyburide) to 64.6% (nitroglycerin;

Svarstad & Mount, 2001). Consumers generally rated the CMI poorly on print size, quality, line spacing, and overall ease of reading (Svarstad & Mount, 2001).

In the follow-up study, Kimberlin and Winterstein (2008) essentially replicated Svarstad and Mount's (2001) study, but assessed different medications (i.e., metformin and lisinopril) and incorporated the FDA's (2006) Guidance for Useful Written CMI into their assessments. Kimberlin and Winterstein (2008) sought to answer the following four research questions:

1. "What percentage of shoppers getting prescriptions filled for lisinopril and metformin in community pharmacy settings was given any written Consumer Medication Information (CMI) beyond label directions?"
2. What percentage of shoppers was given written CMI that adhered to criteria as defined by the FDA Guidance document, developed for two specific study drugs, and applied by a panel of experts to evaluate the quality of CMI leaflets?"
3. What percentage of CMI leaflets adhered to criteria consumers were asked to use to evaluate quality of the leaflets?"
4. How did expert and consumer evaluations of the quality of CMI differ in the 2001 and 2008 studies?" (p. 2-3)

Professional shoppers, posing as patients, filled new prescriptions at 364 (lisinopril) and 365 (metformin) randomly selected pharmacies in 41 states. The majority (94%) of new prescriptions were accompanied with printed CMI (Kimberlin & Winterstein, 2008). Kimberlin and Winterstein (2008) reported the average quality scores were 62% for lisinopril and 59% of metformin compared with the range of means

from 51% - 55% in the initial study (Svarstad & Mount, 2001). Thus, generally gains were observed in the quality of information compared between the two studies. However, Kimberlin and Winterstein (2008) noted declines on criterion 3 (directions for use, monitoring, maximizing benefits) and criterion 8 (comprehensibility and legibility). Using the same consumer evaluation form as Svarstad and Mount (2001), consumers ( $N = 212$ ) rated the CMI. Only 56% of the Svarstad and Mount's (2001) materials met the threshold of 60% performance points, whereas 71% of the materials assessed by consumers in the Kimberlin and Winterstein (2008) study met this threshold. Thus, consumers also considered the materials to have improved. However, deficits persisted from the 2001 study as consumers rated the 2008 materials poorly (with almost identical scores) in terms of their print size, line spacing, and readability (Kimberlin & Winterstein, 2008). Despite overall improvement and high levels of distribution, Kimberlin and Winterstein (2008) argued that CMI still suffered from a "lack of critical information about the management of medications, significant redundancy of information resulting in excessively long leaflets, poor formatting, and inadequate legibility and reading level" (p. 29-30). Further, Kimberlin and Winterstein (2008) noted that more research is necessary to determine the quantity, presentation, and format of CMI will ensure the highest levels of comprehension and maximize patient safety.

### **3.5 The Impact of Design on Medication Information for Consumers**

Recognizing these many shortcomings in existing materials, researchers have investigated how the design and format of medication information can improve it. Specifically, researchers have explored how different formats can affect consumers perceptions and preferences (i.e., subjective measures) as well as their performance

(i.e., objective measures) using the medication information. Studies strictly exploring consumer

### **3.5.1 Consumers' Perceptions of Redesigned Medication Information**

Krass, Svarstad, and Bultman (2002) found that their Medication Information Design Assessment Scale (MIDAS), an indirect method of evaluating medication information, was highly correlated with consumers' perceptions of comprehensibility, utility and design quality (i.e., the Consumer Information Rating Form). Moreover, the authors found that re-designed medication information abiding by the MIDAS guidelines was received more positively by consumers. These two tools will be discussed in more detail.

MIDAS is a thirteen-item scale for researchers to evaluate paper-based medication monographs by inspection (Krass et al., 2002). The MIDAS criteria are strictly graphic guidelines:

- Type size ( $\geq 10$  point)
- Serif style letters in text
- Sharp ink contrast
- Line spacing ( $\geq 2.2$  mm)
- Margins ( $\geq 0.5$  in. sides and bottom;  $\geq 0.25$  in. at the top)
- True heading (separate line)
- Upper and lower-case headings
- Upper and lower text
- Line length ( $\leq 40$  letters)

- Bullet points
- Bolding/box or summary to highlight important points
- No watermarks under the text
- Relevant pictures/illustrations

The Consumer Information Rating Form (CIRF) is a measure administered to consumers to evaluate users' subjective perceptions of comprehensibility, utility (both amount and usefulness of information), and overall design quality (Krass et al., 2002; see Table 5). The MIDAS was positively correlated with the CIRF; that is, the more design principles the medication pamphlets abided by (i.e., higher MIDAS score) the more positively they were received by consumers (i.e., higher CIRF score; Krass et al., 2002). The CIRF was adapted, validated using a larger sample ( $N = 282$ ), and deemed a robust index of consumer impressions of medication information (Koo, Krass, & Aslani, 2007).

Table 5

*The Consumer Information Rating Form (CIRF; adapted from Krass et al., 2002, p. 32)*

CIRF Scale	Scoring
<b>Comprehensibility</b> Read Understand Remember Locate information Keep for future reference	1: very hard, 5: very easy
<b>Utility</b> Benefits Contraindications Directions Precautions Side effects Storage	Composite scale: 1: not so useful, 3: very useful plus 1: right amount of information, 0: too little or too much information (i.e., score range 1-4)

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<b>Design Quality</b>	1: low quality, 5: high quality
Organization	
Attractiveness	
Print size	
Tone	
Helpfulness	
Spacing	

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In addition to studying how consumers perceive CMI, researcher have also examined consumers' preferences for different Patient Medication Information (PMI) formats. As Pearsall and colleagues described, the FDA is moving towards a single source of medication information for consumers referred to as PMI. Thus, some of the more recent work has started adopting this terminology. In an attempt to inform the design of PMI to make it more user-friendly, Kish-Doto and colleagues (2014) used interviews with health consumers ( $N = 90$ ; 30 with immune disorders, 30 with other chronic diseases, and 30 general public) to explore consumers' preferences between two different versions of PMI.

An interesting method was used to explore preferences. Specifically, two PMI handouts were presented simultaneously, with and preference decisions were made in sequence between alternatives (Kish-Doto et al., 2014). That is, consumers were first shown information for the same fictitious medication called Rheutopia in two different formats (over-the-counter vs. bubble), using the same fonts, order, and content (Kish-Doto et al., 2014). Similar to Wolf and colleagues (2014), the over-the-counter format was inspired by drug facts boxes (Kish-Doto et al., 2014). If the participant preferred the bubble format (dividing the content into sections enclosed by rounded rectangles), the next pairing would both be bubble format but would vary in terms of font (Times New Roman vs. Arial; Kish-Doto et al., 2014). If the participant preferred the Arial font, the next pairing would be bubble format with Arial font but would vary in terms of order (i.e.,

warnings first vs. directions for use first; Kish-Doto et al., 2014). Once the preferred format, font, and order had been selected from the alternatives, other questions were asked about the content (Kish-Doto et al., 2014). Participants in this study reported preferring both test formats to currently distributed PMI because the stimuli seemed to provide more information and it was better organized and concise (Kish-Doto et al., 2014).

There were no discernable differences in terms of ordering preferences (i.e., 51% directions for use first); however, participants preferred the bubble format (66%) and Arial font (68%; Kish-Doto et al., 2014). However, age, education, and health status influenced preferences, such as older people preferring Times New Roman font (Kish-Doto et al., 2014). Participants reported preferring the bubble format because it was easier to locate specific information and the Arial font because it seemed easier to read (Kish-Doto et al., 2014).

### **3.5.2 Consumers' Performance Using Redesigned Medication Information**

Although consumers' subjective perceptions of medication information are important, they may not necessarily be representative of objectively measured performance. Thus, some studies examined objective performance either in conjunction with consumer ratings or in isolation. Specifically, researchers have investigated how redesigning medication information for consumers can affect consumers' memory, comprehension, and ability to find and apply medication information.

Standard drug monographs (assumed to be comparable to medication guides) are often too complex and lengthy to provide value to consumers (Gossell-Williams et al., 2012). Unsurprisingly, a study in Jamaica by Gossell-Williams and colleagues (2012)

found that PILs developed for three medications (i.e., hydrochlorothiazide, nifedipine, and enalapril) were superior to standard medication monographs both subjectively in terms of preference and objectively to the standard drug monographs in terms of preference and some aspects of memory. Specifically, participants found the PILs easier to read and more attractive than the standard drug monographs (Gossell-Williams et al., 2012). Further, participants were more likely to recommend distributing PILs to other patients. Participants' recall of contraindications and when to contact a physician were better in the when exposed to PILs than in the standard drug monograph condition (Gossell-Williams et al., 2012). However, no differences between the conditions were observed with respect to memory of side effects (Gossell-Williams et al., 2012). Therefore, participants both preferred the PILs to the standard drug monographs and further participants remembered as much or more information using the PIL compared to the standard drug monograph (Gossell-Williams et al., 2012). Importantly, the PILs developed by Gossell-Williams and colleagues appear to be abridged versions of CMI commonly distributed in Canada.

The European Medicines Agency (2015) Quality Review of Documents (QRD) medication information template in Europe “regulates four aspects of package leaflets: (1) its content elements; (2) the order in which these topics should be discussed; (3) the headings for paragraphs and subparagraphs; (4) the wording of a number of specific passages” (Pander Maat & Lentz, 2010, p. 113). However, Pander Maat and Lentz (2010) argued that the QRD template may, paradoxically, impede the efficacy of package leaflets of Patient Information Leaflets (PILs). For example, Pander Maat and Lentz (2010) noted that: 1) the QRD template headings and text structure have not

been validated with users; 2) lengthy text may be required to satisfy the template requirements; 3) to ensure successful tests, manufacturers may use simple questions with a more educated sample of consumers. Thus, Pander Maat and Lentz (2010) sought to test Dutch CMI with consumers attempting to address the following two research questions: “(1) Do these leaflets enable patients to find, comprehend and apply relevant information? (2) Can the leaflets be improved while remaining within the European regulatory framework?” (p. 114).

Pander Maat and Lentz (2010) revised the texts based on the following seven design principles grounded in research:

1. Integrate information on the same topic. Where the QRD template prevents this, include cross-references.
2. Use headings
3. Use discriminable heading levels
4. Limit emphasis (e.g., underline, bold) in body text
5. Use bulleted lists
6. Present the most important information first
7. Align the information with the users' pre-existing schemas

Additionally, the revised texts used active and more simplified sentences than the originals (Pander Maat & Lentz, 2010). Thus, revisions affected the text structure and visual signaling while the paper and font size controlled. Moreover, the revisions were constrained by ensuring adherence to the European Union regulations of the QRD template. Consumers answered questions based on a scenario for each of the three original ( $n = 154$ ) and revised ( $n = 164$ ) CMI leaflets (oxazepam, bisoprolol,

rosuvastatin; Pander Maat & Lentz, 2010). For example, “participants were told to imagine that they were allergic for titiandioxid and then had to find out whether they would be allowed to take

Rosuvastatin” (Pander Maat & Lentz, 2010, p.115). Pander Maat and Lentz’s posed 15 questions to participants, assessing the following five areas, based on information provided in the scenario:

1. Did the medication correspond with their illness?
2. Could they safely take it?
3. How would they it?
4. What side effects might occur and what is the appropriate response?
5. Would using the medication affect common activities (e.g., alcohol consumption, breastfeeding, driving)?

Pander Maat and Lentz (2010) used four dependent measures: localization success, localization time, comprehension, and comprehensibility ratings (using the revised Consumer Information Rating Form; Koo, et al., 2007), and composite measure of task success (i.e., % localization success x % comprehensibility). Literacy was used as a control variable (Pander Maat & Lentz, 2010). Pander Maat and Lentz (2010) found that none of the original materials met the 80% success (average over all questions and users) scores (based on localization and comprehension) whereas two of the three revised materials did (Pander Maat & Lentz, 2010). However, neither the original nor revised materials met the more stringent European Guidelines of all participants scoring over 80% (Pander Maat & Lentz, 2010). Given these findings, Pander Maat and Lentz (2010) argued that existing materials should be subject to real performance tests.

Consumers rated all of the revised materials more positively than the originals (Pander Maat & Lentz, 2010). Additionally, a comparison between A4 (i.e., 8.5 x 11-inch paper) and package inserts also yielded similar gains due to revisions over the original text.

Pander Maat and Lentz (2010) identified the following four general limitations of CMI as prevalent in their study as well as others:

1. “The leaflet is quite long and its text structure is unclear; some of the obligatory headings are interpreted incorrectly;
2. The visual formatting of the text does not adequately reflect its structure;
3. Important information is ‘hidden’ in long text sections;
4. The information is often unclear about patient actions” (p. 118)

These limitations were consistent with inspections of Canadian CMI by Monkman and Kushniruk who described problematic examples of the length of CMI (2017a, 2017b) with important information that was buried (2017a), as well as ambiguous information (2017a). Further, Pander Maat and Lentz (2010) found that being constrained by the QRD template (e.g., adding optional subheadings, but not given the flexibility to add/modify main headings or sequence) may result in suboptimal materials. Thus, the authors argued that although gains can be achieved whilst abiding by the QRD template as demonstrated by the application of design principles, achieving optimal performance, which is arguably the goal of dispensing medication information, may require a new approach to CMI regulation (Pander Maat & Lentz, 2010).

Motivated by their previous inspection work that identified shortcomings of FDA regulated medication guides in the United States in terms of readability and suitability for people with limited health literacy, Wolf and colleagues (2012) compared

comprehension of three medication guides: 1) Ritalin (oral tablet), 2) Morphine Sulphate (oral solution), and 3) Aranesp (injectable). Participants ( $N = 449$ ) were asked questions in three categories: “1) decision making prior to use, 2) general use and storage, and 3) side effects” (Wolf et al., 2012, p. 1716) to assess their understanding of the medication guides. Participants had the medication guide for reference during questioning, responses were untimed, and participants were tested on all three medication guides (Wolf et al., 2012). Participants demonstrated poor understanding of the medication guides: 53% of the information was understood on average (Wolf et al., 2012). Further, people with limited health literacy were even less likely to understand the content of medication guides (Wolf et al., 2012). Wolf and colleagues expressed serious concern given that “med guides are frequently the only means that patients have for receiving critical information on how to safely use higher risk drugs” (p. 1718) and further that lack of comprehension was not expressly exhibited in people with limited health literacy, but people with adequate literacy skills as well. There is a mandate imposed, called the Plain Writing Act (2010), whereby federal agencies in the United States (e.g., the FDA) must ensure public communications are understandable, clear and jargon free. However, Wolf and colleagues argued that there is no clear framework to develop usable, comprehensible materials, nor is there an evaluation to determine if the goal has been achieved, but that the Agency for Healthcare Research and Quality (AHRQ) are working to develop standards. Both Wolf and colleagues (2006) and Wolf and colleagues (2012) endorsed including the purpose of medication guides and emphasizing essential medication information in a summary.

In an effort to address the findings of poor medication guide comprehension, Wolf and colleagues (2014) compared strategies for improving medication guides. Based on results from earlier work with consumer participants, Wolf and colleagues developed and tested three patient-centered formats of one-page medication guides were tested:

1. Resembled Drug Facts box adopted by the FDA (2008)
2. A simple two column format, with shorter line width
3. The health literacy format was tabular whereby the heading was in the left-hand column and the corresponding information was in the right column

Purposefully, Wolf and colleagues (2014) used the same stimuli medications (i.e., ritalin, morphine sulphate, and Aranesp) and questioning procedure from their previous study (i.e., from Wolf et al., 2012), to allow comparison between the with previous comprehension results. Participants' ( $N = 1003$ ) comprehension was better for all three redesigned medication guide prototypes than the standard medication guide in the between groups comparison (Wolf et al., 2014). Amongst a comparison of participants' comprehension of the three prototypes ( $n = 554$ ), the health literacy format was deemed to have the greatest benefits in helping consumers find and apply medication information (Wolf et al., 2014). Importantly, significant comprehension gains were observed for older people and people with limited health literacy as a result of using the prototypes (Wolf et al., 2014). However, Wolf and colleagues noted that there was still opportunity for improvement to ensure that all consumers are informed about their prescriptions, which may require more aggressive strategies (e.g., physician counselling, pharmacist counselling).

Similar to Wolf and colleagues (2014), Boudewyns and colleagues (2015) also investigated how design and formatting could affect comprehension. Building on the work of Kish-Doto and colleagues (2014), a study by Boudewyns and colleagues (2015) tested the potential impact of patient medication information design on comprehension and application (i.e., applying information to hypothetical situations) of the information contained in patient medication information using Rheutopia (i.e., the same fictitious medication Kish-Doto et al. used in their study). A large sample of participants ( $N = 1397$ ) was recruited who had either rheumatoid arthritis, ankylosing spondylitis, or plaque psoriasis, all of which the fictitious medication treated (Boudewyns et al., 2015). Participants saw one of three versions of the CMI: either the bubbles or over-the-counter (i.e., drug facts) formats used in Kish-Doto and colleagues (2014), or the standard Med Guides format (i.e., the control; Boudewyns et al., 2015). Notably, both the bubbles and over-the-counter formats were only one page in length whereas the Med Guides format was four pages long (Boudewyns et al., 2015). Participants had higher comprehension scores in both the bubbles and over-the-counter formats than the MedGuides format; however, no differences were observed between former two formats (Boudewyns et al., 2015). Further, no differences between the formats were observed in terms of application performance (Boudewyns et al., 2015).

Recently, Park, Jones, Pearsall, and Araojo (2017) discussed how the FDA improved the quality of medication guides by using research informed strategies. Park and colleagues described that newly developed medication guides were more likely to include plain language, sections ordered based on consumer feedback, streamlined layout, bulleted text, negative space, distinct headings, larger font sizes, and sans-serif

fonts. The FDA has adopted these improvements in an attempt to improve the usability of medication guides and enhance consumer comprehension of the content (Park et al., 2017).

Recently, Patel, Bapat, Bhansali, and Sansgiry (2018) compared three formats of PILs to determine the effects of cognitive effort and user involvement on comprehension. The first PIL format was redesigned to have the lowest cognitive load (i.e., low cognitive effort required) by using cognitive principles in its redesign. The redesigned PIL was inspired by drug facts boxes, limited to a single page (i.e., content was reduced), and icons and an image of the medication were added (Patel et al., 2018). The second format medium level of cognitive effort and was a simplified text-only, single page, colourless, icon free PIL developed in another quality improvement initiative seeking to provide clearer PIL (Wilson & Ramspacher, 2013). This medium level cognitive effort format was resembled the bubbles format in Boudewyns and colleagues' study (2015). This single-page text-only format was piloted for 3 medications with over 32,000 patients (Wilson & Ramspacher, 2013). The majority of questionnaire respondents ( $N = 3,255$ ), found this format very useful: 64% of 18 – 40 year old's, 69% of 41-64 year old's, and 64% of those 65 or older. The third format was traditional PIL, which was the shortest PIL available from one of four pharmacies in an effort for this condition to have the lowest possible cognitive load of the traditional PIL available (Patel et al., 2018).

In addition to cognitive effort, the researchers also manipulated the level of user involvement by providing one of two scenarios to the groups in an effort to make the Prescription drug Information Leaflet (PIL) more or less relevant and important to the

users. Participants in the high involvement condition were “asked to imagine that they had a life-threatening disease and that reading the leaflet was important because the medication had significant side effects” (Patel et al., 2018, p. 120). In contrast, participants in the low involvement condition were told “that the prescription they were picking was a refill for a medicine that they had used for a year and never experienced any problems. Further, they had to reach home quickly as they were hosting a party” (Patel et al., 2018, p. 120). Thus, Patel and colleagues (2018) conducted a 3(cognitive effort: low, medium, high) x 2(involvement: low, high) repeated measures study design to test the potential impact of these two factors on a) product knowledge, b) attitude towards PIL design, and c) intention to read the CMI with 360 participants, using three different medications.

As expected, the PIL format inspired by the drug facts box outperformed the other two formats with respect comprehension, attitude, and intention to read (Patel et al., 2018). Additionally, there was an interaction such that high involvement further improved product knowledge, attitude, and intention to read the PIL (Patel et al., 2018). Therefore, both how medication information materials are designed as well as consumers’ perceptions of the severity of their illness and how possibly harmful the medication is (i.e., the risk of serious side effects) can affect their motivation to read medication information, how much they like it, as well as how likely they are to understand it.

To summarize, several different methods of redesigning and testing have been used in an attempt to identify how redesigning medication information for consumers can improve how well consumers are able to use it. Consumers consistently showed

gains in performance (e.g., comprehension, information localization) with redesigned materials, at least to some extent (see Table 6 for summary).

Table 6

*Summary of the Effects of Format on Consumer Performance Using Medication Information*

<b>Study (chronologically)</b>	<b>Country</b>	<b>Sample Size</b>	<b>Formats</b>	<b>Measures</b>	<b>Main Findings Associated with Redesign</b>
Pander Maat & Lentz, 2010	The Netherlands	318	<b>2 Formats</b> 1. Standard patient information leaflet (PIL) 2. Redesigned text structure and visual signalling, but controlled font size	<b>Localization success:</b> if participants found the relevant information in less than 5 minutes  <b>Localization speed:</b> how quickly participants found the relevant information  <b>Comprehension</b> 15 free-response questions, 2 required inferences from the scenario  <b>Task Success</b> (Composite measure) = % Localization Success x % Comprehension	↑ localization success  ↑ localization speed  ↑ comprehension  ↑ task success for all 3 medications (but only 2 of the 3 medications met the 80% threshold)
Gossell-Williams et al., 2012	Jamaica	40	<b>2 Formats</b> 1. Standard Drug Monograph 2. PIL – similar to CMI	<b>Comprehension</b> Free-response or recall	= side effects = missed dose ↑ things to avoid ↑ when to contact a physician

Study (chronologically)	Country	Sample Size	Formats	Measures	Main Findings Associated with Redesign
Wolf et al. 2014	United States	1003	<b>4 Formats</b> <ol style="list-style-type: none"> <li>1. Standard Medication Guide (MG)</li> <li>2. Two columns – abbreviated</li> <li>3. Drug facts – abbreviated</li> <li>4. Health literacy – abbreviated, left column contained headings to facilitate localization</li> </ol>	<b>Comprehension</b> (Information Localization and Application) Free-response	All 3 Redesigns: ↑ comprehension  Overall, comprehension was best for the health literacy format (but not for all medication stimuli)
Boudewyns et al., 2015	United States	1397	<b>3 Formats</b> <ol style="list-style-type: none"> <li>1. Standard Medication Guide – 4 pages (control)</li> <li>2. Over-the-counter (drug facts) – 1 page</li> <li>3. Bubbles – two columns, sections separated by rectangles – 1 page</li> </ol>	<b>Comprehension</b> True / False Multiple Choice  <b>Application</b> (inference) Closed-ended items presenting different scenarios	Both redesigns ↑ comprehension of over standard, but over-the-counter = bubbles  = application

Study (chronologically)	Country	Sample Size	Formats	Measures	Main Findings Associated with Redesign
Patel et al., 2018	United States	360	<b>3 Formats</b> <ol style="list-style-type: none"> <li>1. High cognitive effort (standard) – shortest CMI from one of four community pharmacies</li> <li>2. Medium cognitive effort (bubbles) – 1 page</li> <li>3. Low cognitive effort, over-the-counter (drug facts) – 1 page, colour, symbols, image of medication</li> </ol>	<b>Comprehension</b> 11 questions using a 7-point likert scale	Low cognitive effort ↑ comprehension

### 3.5.3 Summary of Impact of Design on Medication Information for Consumers

In summary, researchers have used various different methods and indices in their assessments of CMI. Some studies used expert evaluators to compare CMI against evidence-based guidelines or other criteria (e.g., Svarstad & Mount, 2001; Monkman & Kushniruk 2017a, 2017b; Monkman et al., 2017). However, these inspections may not be a perfect proxy for consumers' impressions of CMI. Other studies have reported expert evaluations and consumers' ratings of CMI (e.g., Kimberlin & Winterstein, 2008; Svarstad & Mount, 2001) or compared user perceptions with CMI's level of adherence to design guidelines (Krass et al., 2002). Consistently, studies have found that various redesigns improved improves consumers' perceptions of medication information. Some studies have shown redesigns improve consumer ratings of comprehensibility (Pander Maat & Lentz, 2010), utility, and design quality, or all three (e.g., Krass et al., 2002). Other studies have shown consumers rate redesigned medication information more favourably in terms of attractiveness, readability (Gossell-Williams et al., 2012), attitude towards the materials, and intention to read it (e.g., Patel et al., 2018).

Although consumers' perceptions of medication information are important, perhaps the most valuable CMI data is objective data collected on different aspects consumer performance using CMI (for summary, see Table 7). Indeed, studies have consistently demonstrated that redesigning medication information can bolster different aspects of consumer performance such as locating information more quickly (Pander Maat & Lentz, 2017) and effectively (Pander Maat & Lentz, 2017; Wolf et al., 2014) as well as improving comprehension (Boudewyns et al., 2015; Gossell-Williams et al., 2012; Pander Maat & Lentz, 2017; Wolf et al., 2014; Patel et al., 2018). However, a major shortcoming

of these studies is that none appeared to control for length or content of the materials. That is, comparisons were often between lengthier and much more brief stimuli, which may be a confound in their results. For example, Boudewyns and colleagues (2015) compared a four-page medication guide with one-page redesigns. Thus, it is not necessarily surprising that consumers understood the shorter materials better, because there was less information that could potentially distract them or exceed their cognitive processing capabilities.

### **3.6 Emerging Approaches for the Provision and Design of Medication Information for Consumers**

Historically, medication information for consumers has been limited to printed text in hardcopy. However, consumer health information is becoming increasingly available online and medication information is no exception. Deploying information electronically provides a new set of affordances (e.g., narration, videos, progressive disclosure) not feasible for medication information in paper format. This section explores some early research on peoples' attitudes towards digital CMI, CMI currently available for consumers on the Internet, as well a resource that may help inform the design of new types of CMI being developed.

#### **3.6.1 Attitudes Towards Electronic CMI**

Naturally, researchers are beginning to explore the opportunities of providing CMI digitally. However, the investigator only found one study to date that studied peoples' attitudes towards receiving patient information leaflets (PILs, similar to CMI) electronically instead of the current paper practice. In a sample of 406 Swedes, only a minority (17%,  $n = 53$ ) would have preferred receiving PILs in electronic form (Hammar

et al., 2016). However, most participants (41%,  $n = 168$ ) responded positively about reading PILs on a computer, phone, or tablet, whereas nearly a third (32%,  $n = 131$ ) were hesitant or uncertain (Hammar et al., 2016). Unsurprisingly, younger respondents were more receptive to digital PILs than older respondents, but there was no difference between the genders (Hammar et al., 2016). Although the demand for desire for electronic PILs was limited, it is likely to become at least an alternative to the paper practice, if not a replacement, in the coming years.

### 3.6.2 Online CMI

Currently in Canada, CMI is typically dispensed at community pharmacies to complement a new prescription. However, the FDA is moving towards an online CMI model (Pearsall et al., 2014) and Denmark offers its CMI exclusively through its online resource (i.e., <http://min.medicin.dk>; Monkman, Nøhr, & Kushniruk, 2017). This movement towards offering CMI online aligns with the Committee on Safety of Medicines (2005) who asserted “options should be explored for improved access to PILs, including availability at or before the prescription or purchase of a medicine, and in other situations where a PIL is not currently available” (p. 5).

Rexall™ (<http://www.rexall.ca/articles/drugs>), Pharmasave® (<http://www.pharmasave.com/default/0/medications.aspx>) and Guardian™ (<https://www.guardian-pharmacy.ca/health-advisor/drug-database>) are Canadian pharmacy chains that offer CMI on the Internet. Users can search the name of a prescription medication and find CMI that covers the following topics:

- Brand name, common (generic) name
- Drug Identification Number (DIN)

- How does this medication work? What will it do for me?
- How should I use this medication?
- What form(s) does this medication come in?
- Who should NOT take this medication?
- What side effects are possible with this medication?
- Are there any other precautions or warnings for this medication?
- What other drugs could interact with this medication?

CMI from Rexall™, Pharmasave®, and Guardian® are produced from a company called MediResource Inc. In the United States, the National Library of Medicine offers MedlinePlus (<http://www.nlm.nih.gov/medlineplus/druginformation.html>), a similar compendium of CMI with information sourced from AFHS CMI. There are also specialized resources such as Cancer Care Ontario (<https://www.cancercare.on.ca/toolbox/patientdruginfo/>) and the BC Renal Agency (<http://www.bcrenalagency.ca/healthcare-professionals/pharmacy-formulary/medication-information-sheets>). All of the aforementioned websites and others, provide credible, high quality information to consumers and some even offer detailed information about non-prescription medicines. Despite the increasing amount of CMI available online, it is unclear whether consumers are aware of it, or the extent to which they use these resources. Moreover, consumers do not appear very receptive towards electronic medication information instead of a paper-based format (Hammar et al., 2016). However, even electronic CMI remains predominantly text-based. In addition to being text-based, other types of medication information presentations are emerging online.

### 3.6.3 Additional Information and Alternative Presentations of CMI Online

Some websites are beginning to collect and disseminate additional medication information in new ways. In addition to providing traditional medication information as is contained in CMI, WebMD ([www.webmd.com/drugs/](http://www.webmd.com/drugs/)) also includes images and descriptors (e.g., colour, shape, imprint) of medications. Additionally, WebMD also has a pill identification tool ([www.webmd.com/pill-identification/default.htm](http://www.webmd.com/pill-identification/default.htm)) that allows users to search for medications based on descriptors of what they look like. WebMD's mymedicine ([www.webmd.com/my-medicine/default.htm#how-to-use](http://www.webmd.com/my-medicine/default.htm#how-to-use)) feature allows users to save medications and functionality such as storing them on mobile devices, checking for interactions, and receiving FDA warnings, as well as creating different profiles for other family members. In a recent evaluation of the readability and comprehensiveness of online CMI, Kim, Metzger, Wigle, and Choe (2011) found that despite providing accurate information, the readability levels of Medline Plus, Yahoo Health, and WebMD far exceeded the recommended 6<sup>th</sup>-8<sup>th</sup> grade reading level.

Pharmaceutical companies have been scrutinized for excluding critical information on medication side effects to boost sales, but which have resulted in dire consequences for the people prescribed these medications (e.g., Bass, 2008). To this end, many are recognizing the need for independent evidence of medication side effects with the added benefits of increased sample size and identifying side effects that are may not have been observed in clinical trials. For example, [www.rxisk.org](http://www.rxisk.org) encourages users to report side effects and adverse events they experience from medications in an attempt to provide independent information on the potential consequences associated with taking different medications that often go unreported. RXisk also offers users medication information from the FDA and other sources. Additionally, RXisk presents

side effect data from the FDA and Health Canada using word clouds, the font is used to convey the frequency (size) and severity (colour) of the reported side effects for a given medication. Another recently launched website (still beta version), [www.iodine.com](http://www.iodine.com) offers a range of different information about a medication. For example, this site polls and displays user reports of whether a medication is deemed worth taking, how well it works, if it is a hassle, as well as comparing user reported side effects with those from clinical trials. Iodine also offers tips related to taking the medication from users who have taken the medication as well as pharmacists.

Other approaches have also been used to convey medication information. For example, *How to Use Inhalers: Interactive Guidance & Management* (<http://use-inhalers.com/>) is a site specifically developed to assist consumers with an often incorrectly used medication type: inhalers. *How to Use Inhalers* provides a variety of different communication materials and tools to improve inhaler administration including videos, multimedia handouts and flyers, quizzes, and interactive in depth-training using device cameras to portray the consumer alongside the demonstration as well as supervision from an expert.

#### **3.6.4 Potential Resources for Developing Alternative Presentations Consumer Health Information**

As health data proliferates and new ways of communicating health information are being deployed, it is imperative to determine effective ways of summarizing and communicating this information to consumers. *Visualizing Health* ([www.vizhealth.org](http://www.vizhealth.org)) is an evidence-based style guide for health data communication. *Visualizing Health* is a collaborative project between University of Michigan and the Robert Wood Johnson Foundation. This research group seeks to help users select the most effective way to

communicate health data (e.g., side effect risks, side effect severity, racial disparities in disease rates, contextualizing outbreaks) by testing different formats using Google Consumer Surveys, Survey Sampling International, and Amazon Mechanical Turk. Visualizing Health has a wizard to help users select the most appropriate visualization format depending on the goals of the project.

### **3.7 Research on Multimedia Medication Information for Consumers**

Although new methods of communication medication information are being developed and deployed, as with traditional text-based CMI, these materials are often launched without testing representative users. Multimedia has been explored from the broader perspective of consumer health information, frequently with an emphasis on how it may benefit users with limited health literacy and/or aging adults. These areas of research may be informative for medication information for consumers as well. Further, researchers have used multimedia (to a limited extent) as part of more comprehensive redesign efforts to make medication information more patient-centred. Therefore, this section will begin with a discussion of the research on multimedia consumer health information for people with limited literacy, followed by multimedia as a component of patient-centered medication information, and conclude with studies on multimedia medication information for consumers.

#### **3.7.1 Multimedia Health Information for Consumers with Limited Health Literacy**

Similar to other domains, the advantages of using pictures to complement text in health communications have been recognized and investigated (for review refer to Houts, Doak, Doak, & Loscalzo, 2006). Health information presented with pictures tended to attract more attention (e.g., actually reading wound instructions), improve

comprehension, improve memory, and adherence (Houts et al., 2006). For example, Delp and Jones (1996) found that patients given discharge wound care instructions with cartoons were significantly more likely to have read them, had better memory for them, and were more likely to adhere daily to the wound care instructions than those who received traditional text only instructions. Moreover, despite having the exact same written content, participants who received the cartoon instructions were significantly more satisfied with them as well as perceived them as more readable (Delp & Jones, 1996). Moreover, Houts and colleagues noted that the gains associated with adding images to text were frequently more substantial for those with limited health literacy.

In an updated systematic review for the Agency for Healthcare Research and Quality (AHRQ), Berkman and colleagues (2011) synthesized the findings of the 21 studies that employed a single specific strategy in an attempt to mitigate the effects of low health literacy (i.e., enhance comprehension). Berkman and colleagues grouped studies into the following intervention type categories: alternative document design (2 studies), alternative numerical presentation (3 studies), additive and alternative pictorial representation (8 studies), alternative media (4 studies), combination of alternative readability and document design (7 studies), and physician notification of patient literacy status (1 study).

Although Berkman and colleagues (2011) did not endorse any of the strategies based on the limited strength and/or inconsistent evidence supporting the specific interventions, they did make a number of specific evidence-based recommendations for the information design features to facilitate comprehension by low health literacy

consumers that still warrant further investigation. Specifically, (p.152) they identified the following features as likely beneficial for low health literacy users:

- Present only essential information (eliminating distracting information)
- Present essential information first (before less important information)
- Use higher numbers as indices of higher quality
- Use consistent denominators to present both baseline risk and treatment benefits
- Add pictographs (i.e., icon arrays) to depict numerical treatment benefits
- Add video to complement verbal narrative
- Use reduced reading level
- Use illustrated narratives

Incorporating pictographs (i.e., simple, descriptive, line drawings or symbols) into health information is becoming an increasingly popular strategy for people with limited health literacy. For example, older limited-literacy participants reported that hip replacement discharge instructions pictographs enhanced their understanding of the materials (Choi, 2013). In a pilot study, Choi (2012) found that immigrant women with limited literacy were receptive to having pictographs included on instructions for breast healthcare. Additionally, techniques are being developed and tested that can automatically generate pictographs from text. For example, written discharge instructions were parsed for content (e.g., call doctor, faint, dizziness) and matched with pictographs in a database to automatically generate illustrated discharge instructions (Zeng-Treitler et al., 2014). These illustrated discharge instructions were found to improve recall over their standard text-based counterparts (Zeng-Treitler et al.,

2014). Thus, it would seem that pictographs not only improve comprehension, but can also benefit memory for the instructions.

Using multimedia to communicate health information to consumers is an approach that is gaining traction. This strategy appears to be especially beneficial for people with limited health literacy. Research has also begun to explore the use of multimedia in conjunction with other design strategies to make the materials better align with the needs and preferences of consumers thereby improving comprehension. This approach is referred to as patient-centered consumer health information and the next section will outline research on how this strategy has been used for medication information specifically.

### **3.7.2 Multimedia as an Approach to Patient-Centered Medication Information**

Motivated by the goal of enhanced understanding, attempts have been made to reveal what type of factors and make content and design changes accordingly to improve consumer comprehension of medication information. Different strategies have been tested and recommendations made to create medication information that is more understandable and many of these included the use of multimedia. Further, the challenges and implications of understanding medication information may be exacerbated in older people because of age-related physiological and cognitive decline as well as polypharmacy.

Despite being developed for older consumers, effective strategies for enhancing comprehension are likely applicable for younger consumers as well. Morrow and Conner-Garcia (2013, p. 24) made the following three recommendations to improve patient education materials for older adults:

1. Use concrete language with precise meaning to help patients understand how to take their medications and motivate them to do so.
2. Organize medication information to match patient expectations.
3. Reinforce text with graphics that are relevant to the text.

The first recommendation made by Morrow and Connor-Garcia (2013) is based on evidence that older adults understood longer, more explicit instructions better than briefer but more vague instructions. For example, manipulating the language of prescription label information has been shown to affect how well it is understood. For example, Davis and colleagues (2009) found that more explicit timing language (i.e., morning, eight AM) was better understood than number of times per day or hourly intervals. However, there is a risk that key aspects of messages may be compromised through over simplification and consumers could feel patronized by overly simplistic health communications (Zarcadoolas, 2011).

Morrow and Conner-Garcia's (2013) second recommendation was based on previous work by Morrow, Leirer, Altieri, and Tanke (1991) who found that older adults remembered medication information better if it is was aligned with their schemas around medication. Subsequently, Morrow, Leirer, Andrassy, Tanke, and Stine-Morrow (1996) determined that older and younger people have similar medication taking schemas. Participants generally organized medication information into the following "three categories: (a) General information: Doctor Name, Medication Name, and Purpose; (b) How to take: Dose, Schedule, Duration, and Warnings; and (c) Possible outcomes: Mild Side-effects, Severe Side-effects, and Emergency information)" (Morrow et al., 1991, p. 380). Further, Morrow and colleagues' (1991, 1996) findings suggested that both

grouping *and* order of these categories should be compatible with peoples' schemas to optimize memory for medication information (i.e., doctor name, medicine name, purpose, dose, schedule, duration, warnings, mild-side effects, and severe side effects). Morrow and Conner-Garcia's (2013) third recommendation is aligned with Mayer's (2001) multimedia principle.

Many patient-centered medication information studies have incorporated multimedia into their test stimuli. In a pilot study ( $N = 32$ ), Morrow and colleagues (2005) tested patient-centered medication instructions for efficacy. The patient-centered instructions had a larger font, better readability scores, were briefer, and had an integrated timeline for how to take the medication: a visual depiction of dosage instructions (Morrow et al., 2005). These authors found that older adults understood more quickly and remembered patient-centered instructions better than standard pharmacy format of medication instructions (Morrow et al., 2005). However, memory accuracy of the instructions was better for familiar medications with standard instructions and unfamiliar medications with patient-centered instructions (Morrow et al., 2005). Similarly, Hanson (1995) did a feasibility study to determine if patient-centered pictorial medication instructions were effective for visually impaired and low literacy consumers. Participants ( $N = 258$ ) were tested for comprehension of the materials 7-10 days after exposure to them (Hanson, 1995). Gains in comprehension were reported for those with low literacy using the patient-centered instructions, but not for those with adequate literacy skills (Hanson, 1995). Participants generally preferred the larger print-size of the patient-centered instructions (Hanson, 1995).

In contrast, Morrell, Park, and Poon (1990) found that image-based medication regimen information (not in a timeline format) facilitated younger adults' ( $n = 32$ , mean age = 19.2) comprehension, but impaired older participants' comprehension ( $n = 32$ , mean age = 71.4), compared with text only information. The authors also reported that generally, younger adults' comprehension of prescription information was superior to that of older adults (Morrell et al., 1990). Moreover, Morrell and colleagues noted that the image-based prescriptions might have impeded comprehension for all participants (with respect to text information alone), regardless of age, perhaps due to the necessary interpretation and integration of the separate components (i.e., dose, frequency, and instructions) of the symbology.

In summary, evidence from Morrow and colleagues (1998a) suggest that information should be integrated rather than separated to support learning, especially for older adults. Further, Hanson's (1995) and Morrow and colleagues' (2005) studies provide evidence that patient-centered medication information can benefit health consumer comprehension. Although benefits of multimedia have been observed, the inclusion of multimedia has typically been limited (e.g., dosing schedules, images of the medication itself) in studies of patient-centred medication information. All of the studies that sought to make medication information more patient-centred modified multiple aspects of the medication information (e.g., content, formatting, addition of images) in their test stimuli. Thus, it is impossible to determine whether one of these changes had more impact than another or if the impacts are additive or interactive. However, there is a dearth of research investigating the isolated effect of multimedia on understanding and memory, which will be presented next.

### 3.7.3 Multimedia Medication Information for Consumers

Given its demonstrated value in other domains, multimedia presentation has been explored for its utility in conveying medication information specifically. In 1988, Ley (1988) cautioned that support for using illustrations to supplement written health information was not consistent and “the conditions under which graphical aids will be effective are not known with any certainty” (p. 127). Further, Ley warned that in some illustrations could actually be deleterious if: a) they distract consumers causing them to ignore the text; b) they interfere or are incongruent with images consumers spontaneously generate while reading the text; or c) the nature of the images themselves provokes anxiety. However, Ley (1988) also argued that procedures (e.g., inserting eye drops) might be better communicated through images than words. Further, Ley (1988) noted two potential objectives for including images in written health information: 1) to enhance comprehension and 2) to increase the likelihood that consumers will read the materials by making it more appealing. Dwyer (1972) found that participants who were shown simple line drawings of hearts or provided oral instructions understood heart structure and function better than if they were shown full colour photographs or shaded images. However, Lovius, Lovius, and Ley (1973) found that illustrations for oral hygiene had no effect on childrens’ knowledge over the use of plain text. Hardie, Gagnon, and Eckel (1979) found that symbols were not effective in replacing written words and resulted in poorer comprehension of directions. Moll et al., (1977) found no differences in memory regardless of whether cartoons were included in their materials or not.

Despite the initial lack of evidence supporting the use of images to complement text in health communications, work endured in this area and more recent studies and

reviews suggest that health information images may benefit consumers. In a review of the efficacy of pictorial aids in medication instructions, the evidence suggested that pictorial aids often facilitated memory, comprehension, and adherence (Katz et al., 2006). Additionally, Katz and colleagues noted that pictorial aids were particularly beneficial for depicting dose times, dose instructions, as well as communicating the importance of completing a course of therapy (e.g., antibiotics). However, these authors noted that some studies did not yield benefits from using images to convey medication instructions. Specifically, Katz and colleagues described that some icons (e.g., clock icons) did not enhance understanding because they were too complex. Thus, these authors endorsed a combined approach whereby images should be used in conjunction with written or oral medication instructions to mitigate image misinterpretation (Katz et al., 2006).

An example of a successful multimedia medication intervention is using icons (i.e., small graphic symbols) for medication schedules. Participants reported that pill cards using icons to depict what the medication is prescribed to treat (e.g., blood pressure, cholesterol, diabetes) and when the medication should be taken (i.e., morning/breakfast, noon/lunch, evening/dinner, night/bedtime) were helpful tools to scaffold memory in consumers with limited health literacy (Kripalani et al., 2007). Moreover, many community-based pharmacies (e.g., Shoppers Drug Mart) have adopted the use of pictographs on blister packs to reinforce the time of day medications (e.g., morning, lunch, dinner, bed time) should be taken.

Another example of multimedia medication information that has been investigated is using a timeline approach to describing medication schedules. Both younger ( $n = 36$ ,

mean age = 22.3) and older ( $n = 36$ , mean age = 72.4) participants reaped significant comprehension gains when a medication regimen (i.e., the number of pills and time when each dose should be administered) was depicted as an integrated timeline diagram rather than a strictly text explanation (Morrow, Hier, Menard, & Leirer, 1998a). In their second study, Morrow and colleagues tested the text-only and integrated timeline diagram again but added a third condition with a less integrated form of the medication timeline. In this experiment, the younger ( $n = 36$ , mean age = 18.6) and older ( $n = 45$ , mean age = 71.2) participants performed better in the integrated timeline condition than the text-only and non-integrated timeline conditions; however, no difference in comprehension between the latter two conditions was observed. Furthermore, in both studies comprehension was preserved despite the complexity of the instructions in the timeline condition, but negatively affected by complexity in the text-only condition and non-integrated timeline conditions (Morrow et al., 1998a). Morrow and colleagues found that older participants performance suffered in the non-integrated timeline condition and argued that non-integrated information may be particularly detrimental to older adults. Additionally, the authors found that older participants required more study time and time to make inferences than the younger participants. The majority of participants in both studies preferred the diagrammatical medication regime instructions (Morrow et al., 1998a). Thus, integrating time and dosage information on a timeline fostered comprehension of medication regimens and participants favoured this presentation format.

Other research has not identified a clear pattern on whether presenting information in different modes (e.g., verbal vs. written) affects memory for health information. In

Ley's (1988) review of the literature on providing health information in different modes (e.g., oral vs. written) there was no evidence of a superiority effect in memory between these modes. Thomson, Cunningham, and Hunt (2001) compared the difference in short term and long-term memory of information presented as verbal, written, and visual information in orthodontic patients and parents of the patients ( $N = 84$ , i.e., 3 groups of 14 patient, parent pairs). Written information was presented as a leaflet to participants to read at their leisure, but removed before administering the questionnaire to the parent and child individually (Thomson, et al., 2001). The visual information was presented as a 20-slide presentation with images and brief captions and the participants could move forward and backward through the presentation, but the projector was removed before the questionnaire was administered (Thomson, et al., 2001). The verbal format provided the same information as the other two formats just presented to the parent and patient orally. Both short-term memory and long-term memory were tested using the same questionnaire composed of open and closed questions. Short-term memory was tested 10-15 minutes after exposure to the information, whereas long-term retention was eight weeks later administered (Thomson, et al., 2001). With the exception of a few questions, recall was generally quite good even over time, and only four questions yielded any differences due to format administered (Thomson, et al., 2001). Memory for written information was significantly better than verbal information in two instances administered (Thomson, et al., 2001). Written and verbal presentations significantly outperformed visual information for one question, but this may have been attributable to an issue with the selected image (Thomson et al., 2001). Thomson and colleagues warned against relying solely on information delivered verbally, as it is ineffective when

patients fail to pay attention. However, this argument could be made about any type of information that is provided only once instead of being given to consumers to take with them. Further, Ellis, Hopkin, Leitch, and Crofton (1979) found that supplementing verbal discharge information with written information did improve memory over participants who were only provided the verbal information.

### 3.7.3.1 Multimedia Medication Information for Consumers with Limited Health Literacy

Multimedia has also been studied for its potential to improve medication information specifically for consumers with limited literacy, health literacy, or eHealth literacy. Van Buesekom, Gootens-Wigers, Bos, Guchelaar, and van den Boek (2016) supported incorporating images into written medication information to help users with limited literacy find information and improve comprehension. Further, Van Buesekom and colleagues (2016) also posited that the inclusion of images in written medication information could bolster patient empowerment.

Six types of interventions were identified in a systematic review of how medication information could be improved for people with limited health literacy: written information (e.g., CMI), visual information, audio and verbal information, label information, reminder systems, and educational programs and services (Wali, Hudani, Wali, Mercer, & Grindrod, 2016). Visual information was found to benefit medication knowledge in 21 out of 27 studies and adherence in 16 out of 22 studies. Verbal information included interventions such as “culturally and patient-centered tailored videos, websites, multimedia educational programs and pharmacy counseling through standard counseling, medication reviews, phone counseling, personalized educational programs, and teachback method” (Wali, et al., 2016, p. 844). Verbal interventions were found to

improve knowledge in 22 out of 27 studies and adherence in 17 out of 21 studies.

However, written information was found to benefit medication knowledge in 19 out of 31 studies and adherence in 15 out of 22 studies. Thus, of these three types of interventions, written information appeared to be the least effective in terms of enhancing medication knowledge in people with limited health literacy and no approach seemed especially effective in improving adherence.

Wali and colleagues (2016) described the four overarching strategies that appeared to be effective and preferred by patients with limited health literacy in their review. First, supported by evidence from 10 studies, using additional visual or verbal aids to complement written information was an effective strategy (Wali et al., 2016). Second, five studies supported the use using personalized medication information (e.g., pharmacist and patient medication reviews) were beneficial. Third, ease of navigation, described as using “bullets, subheadings, icons, bolding, underlining, larger font size and shorter words” (Wali et al., 2016, p. 856) was another effective strategy with evidence from seven studies supporting its use. Finally, accessibility, or ensuring participants had access to the medication information when necessary, was found to be a beneficial intervention in five studies.

Although evidence supporting the use of images in medication information for consumers with low health literacy appears to be mounting, some studies have only found limited benefits of using multimedia. For example, Advani, Lopez, Jones and Patel (2013) assessed whether adding United States Pharmacopeia standardized pictograms to medication information generated any benefits in participants' perceptions of “user-friendliness, long-term comprehension, likelihood of referring to the handout in

the future, and effectiveness” (p. 40). Advani and colleagues (2013) used measured user-friendliness, long-term comprehension, and effectiveness with one question each using a 5-point likert scale, whereas referring to the patient handout in the future was a yes or no question. Results of the combined sample ( $N = 84$ ) only yielded a significant difference whereby participants were more likely report that they would refer back to the materials in the pictogram condition. There was evidence that perceptions of the pictogram materials were favoured more highly in one data collection site than the other (Advani et al., 2013). The investigators inferred post hoc, that one site may have had higher levels of health literacy, which resulted in the participants’ higher ratings of the text-based materials (Advani et al., 2013). However, given that health literacy was not measured at either of the sites, it is difficult to determine whether this was the true cause of the differences in perceptions.

In addition to the limited effects of multimedia on consumers’ perceptions of materials, another study also found no effect of multimedia on memory for medication information (King et al., 2012). Participants ( $N = 161$ ) with limited health literacy saw one of three types of medication information: text alone, text with symbols, or symbols only (i.e., a between-groups study). As with Advani and colleagues (2013), King and colleagues (2012) also used the United States Pharmacopeia pictograms in their fictitious medication stimuli. Notably, King and only conveyed directives (i.e., instructions and warnings) in their stimuli, rather than CMI in its entirety. Each leaflet had eight directives (King et al., 2012). Participants had one minute to review the leaflet and then investigators posed eight questions to them, using free recall method, and the questions were scored as either correct or incorrect (King et al., 2012). King and

colleagues found that memory was similar between the three groups, suggesting that multimedia does not impact memory for medication directives in consumers with limited health literacy. Possible explanations of the lack of differences included that the written directives were simple (i.e., did not exceed participants' capabilities), the teach back method increased participants' involvement and in turn memory, and that differences may only be observable after some length of time has elapsed between the exposure and testing (King et al., 2012). King and colleagues conducted a systematic, theory driven, investigation of the potential impact of images on consumers' memory for medication information. However, the researchers only examined specific aspects of medication information (i.e., directives. Further, only eight items were used in the stimuli, therefore it is unlikely that working memory was taxed significantly and ceiling effects may have been observed.

### **3.8 Summary of Research on Medication Information for Consumers**

Medication information comes in a variety forms, formats, and methods of presentation. Given the importance of this information, some of it is government regulated. However, evidence suggests that much of the medication information currently dispensed has limited consumer value because it is difficult to understand and/or difficult to find answers to specific questions about the medication. In response to these recognized shortcomings, various strategies have been developed and tested in an effort to improve consumer comprehension and in some cases memory. Some of these strategies have been deployed and others are still in testing. The research exploring electronic delivery of medication information is developing and the FDA plans to disseminate their unified medication information online in the future.

Studies on various types of medication information for consumers (e.g., medications guides, CMI, PILs, and patient-centered medication), have primarily emphasized the importance of consumer comprehension of medication information. However, as Ley's (1988) model on the interactions between patient-related factors and therapy adherence (Figure 1) depicts, memory is another important factor affecting medication adherence. Arguably, there are several important aspects of memory for medication information, not limited to simply remembering to take a medication. For example, directions for how a medication should be taken, what should be avoided while taking the medication, what side effects are worrisome etc. are also important aspects of medication information that should be remembered. People may not always have medication information materials available to them when they are taking a medication (i.e., read the hardcopies before beginning treatment and then dispose of them).

Two strategies could be used to mitigate issues associated with limited memory for medication information. First, CMI could be made more memorable. Reviews have suggested that the incorporation of images improves memory for consumer health information (Houts, Doak, Doak, & Loscalzo, 2006) as well as medication information more specifically (Katz et al., 2006). Second, CMI could be made more readily available. Delivering consumer medication electronically, either in lieu of or in complement to hard copy, may facilitate consumers' accessing this information when they need it. Medication information is currently primarily limited to text. However, electronic delivery of medication information has affordances that paper materials do not. For example, videos and narratives could be used for electronic CMI. Although

these alternative formats are beginning to be deployed for medication information, no studies were found assessing their efficacy. It is possible that alternative presentation formats such as videos or narrated images may improve comprehension and memory of these materials.

Evidence supporting the use of multimedia (i.e., words and images) to improve medication information is mounting. Many of these studies were designed as interventions for consumers with limited health literacy in an attempt to reduce the cognitive demands of these materials and make them more easily understood. However, much of the research on improving different types of medication information manipulated both design and content (e.g., Morrow et al., 2005; Wolf et al., 2014), which makes it challenging to attribute any potential gains to specific changes. Although one study failed to find any impact of images on memory for medication directives (King et al., 2012), the lack of findings may have been due to the simplicity of the stimuli. Therefore, it is worthwhile to explore whether changes to CMI format, while controlling content, affects consumers' memory, perceptions, and preferences of these materials. Further, although verbal communication has been explored for communicating medication information in lieu of text (e.g., Thomson, et al., 2001), no studies were identified that investigated the potential impact of using narration and images to communicate CMI. Exploring whether there are benefits to conveying CMI as narration and images is beneficial for consumers is another worthwhile line of research. Given that many of the studies on medication information have emphasized the importance of health literacy and eHealth literacy, the next chapter will be used to discuss different topics related to eHealth literacy as they pertain to medication information.

## Chapter 4: eHealth Literacy Constructs and Measures

Literacy and illiteracy are not simply dichotomous, but rather exist on a continuum which offers lifelong opportunities for developing literacy skills. The Canadian Education Research Information System (1999) identified a variety of skills necessary for functioning in society: quantitative literacy, scientific literacy, technological literacy, cultural literacy, media literacy, and computer literacy. However, as it plays an important role in disease prevention and illness management, many argue that health literacy belongs on this list (e.g., Kickbush, 2001).

Although the concept of health literacy emerged nearly thirty years ago (Simonds, 1974), it became a prominent research topic around the turn of the 21<sup>st</sup> century. It was at this time researchers began to recognize the importance of health literacy within the context of health promotion and education and began to develop definitions and conceptual frameworks for health literacy (Rootman, Frankish, & Kaszap, 2007).

There are a number of health literacy definitions that are diverse in both scope and perspective. An example of a narrow definition of health literacy is the “ability to read and comprehend prescription bottles, appointment slips, and other health related materials” (Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, American Medical Association, 1999, p. 552). This definition reflects the classic concept of literacy as the ability to read, write and comprehend. However, many argue that health literacy extends beyond reading and writing and encompasses a variety of other skills (e.g., listening, speaking, arithmetic, problem-solving and decision-making), and may also be influenced by culture and society (Cutilli, 2005). As such, Kwan, Frankish and Rootman (2006) developed a more encompassing definition of health literacy.

Specifically, Kwan and colleagues defined health literacy as “the degree to which people are able to access, understand, appraise and communicate information to engage with the demands of different health contexts in order to promote and maintain good health across the life-course.” This definition considers health literacy from an information processing perspective as well as emphasizes several different facets of health literacy. Specifically, this definition suggests health literacy: 1) exceeds mere comprehension and involves a variety of cognitive processes; 2) may vary as a function of context; 3) plays a role in health promotion; and 4) is important throughout life (Rootman et al., 2007).

From a broader perspective, which will be adopted for this study, Ratzan and Parker (2000) define health literacy as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” (p. 7). This definition illustrates how health literacy can be considered a goal of health education and communication activities and how it plays an important role in health promotion and disease prevention (Nutbeam, 2000).

#### **4.1 The Prevalence, Predictors and Impact of Health Literacy Levels**

Approximately 60% of Canadians have low health literacy (Canadian Council on Learning, 2007). The strongest predictor (even stronger than education) of higher levels of health literacy, for younger and older Canadians, was daily reading (e.g., magazines, newspapers, websites, emails, books; Canadian Council on Learning, 2008).

Alternatively, the groups identified as being most vulnerable to having low levels of

health literacy were: seniors, immigrants, unemployed Canadians (Canadian Council on Learning, 2008).

Research has shown that low health literacy levels create barriers to patient education (Edmunds, 2005) and limit understanding of one's conditions (Williams, Baker, Parker, & Nurss, 1998). According to *Health Literacy in Canada: A Healthy Understanding* "without adequate health-literacy skills, ill-informed decisions may be taken, health conditions may go unchecked or worsen, questions may go unasked or remain unanswered, accidents may happen and people may get lost in the health-care system" (Canadian Council on Learning, 2008, p. 5-6). Thus, it is not surprising that Canadians with the lowest levels of health literacy are much more likely to report poor health statuses than those with high levels of health literacy (Canadian Council on Learning, 2008).

In contrast, higher health literacy levels are associated with increased health knowledge and better self-reported health status (Speros, 2005). Moreover, an inverse correlation between the prevalence of diabetes and health literacy levels was found and a similar, yet less strong, relationship was found for high blood pressure and health literacy levels (Canadian Council on Learning, 2008). That is, Canadians with higher levels of health literacy are less likely to have diabetes or high blood pressure than those with lower levels of health literacy. Additionally, higher health literacy levels are also associated with shorter hospitalizations and less frequent use of health care services, and as a result, financial savings for healthcare (Speros, 2005).

Higher health literacy may reduce the prevalence and improve the management of certain chronic conditions and illnesses (e.g., diabetes, high blood pressure) and

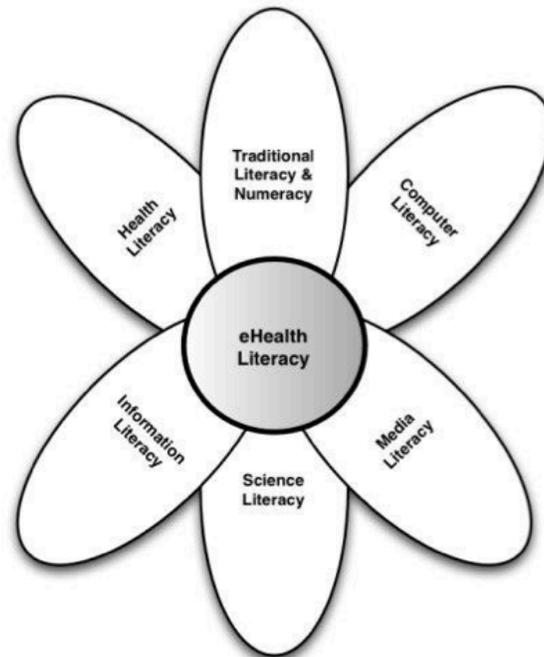
thereby reduce financial and human resource demands on the Canadian healthcare system (Canadian Council on Learning, 2008). Thus, an emerging area of research is devoted to exploring two approaches to mitigating the negative impact of low health literacy: 1) Increasing health literacy levels, and 2) Lowering health-system demands on health literacy (Canadian Council on Learning, 2008).

## **4.2 eHealth Literacy**

The concept of eHealth literacy has emerged due to increased use of computers, mobile devices, and the Internet for health information seeking and access. eHealth literacy elaborates on the concept of health literacy by combining it with eHealth. The term eHealth has been defined as “the use of emerging information and communication technology, especially the Internet, to improve or enable health and health care” (Eng, 2001, p. 2). Norman and Skinner (2006) expanded on this definition by integrating it with the concept of health literacy to generate the following definition of eHealth literacy: “the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem” (p. 3).

These authors also developed the Lily Model (see Figure 3) which serves as a visual metaphor for the six proposed competencies that contribute to eHealth literacy (Norman & Skinner, 2006). Moreover, Norman and Skinner posited that these six literacies could be grouped into two more general categories: analytic (traditional, media, information) and context-specific (computer, scientific, health). These authors argued that the analytic competencies are applicable in broad range of contexts, whereas context-specific competencies are relevant to clearly defined situations

(Norman & Skinner, 2006). Furthermore, deficiencies in any of these literacies may hinder eHealth literacy levels more generally (Norman & Skinner, 2006).



*Figure 3.* The Lily Model of eHealth Literacy (Norman & Skinner, 2006, p. 9)

A different approach to conceptualizing eHealth literacy was taken by Norgaard and colleagues (2015) who developed the eHealth Literacy Framework (eHLF) based on input from a variety of stakeholders. The eHLF was derived using concept mapping from a series of workshops with patients and professionals (e.g., health professionals, health informatics professionals, public health researchers, computer scientists) as well as stakeholder responses to a survey to identify topics. Findings from this work resulted in the eHLF which proposes the following seven domains of eHealth literacy (Norgaard et al., 2015, p. 523):

1. Ability to process information
2. Engagement in own health
3. Ability to engage actively with digital services

4. Feeling safe and in control
5. Motivation to engage with digital services
6. Having access to systems that work, and
7. Digital services that suit individual needs.

The eHLF was proposed as a framework for eHealth evaluation as well as a tool that could inform enhancement of existing services and development of new ones (Norgaard et al., 2015).

### **4.3 Consumers' eHealth Literacy Skills and System Demands on eHealth Literacy as Moderators of Adoption**

Monkman and Kushniruk (2015a) proposed a model to depict the hypothesized impact of consumers' eHealth literacy skills and the demands consumer Health Information Systems (HISs) place on eHealth literacy. Specifically, Monkman and Kushniruk hypothesized, based on evidence in the literature, that the aforementioned factors affect the strength of the relationship between usability and usefulness (i.e., predictors of use) and adoption, value, and successful use (i.e., measures of use; see Figure 4). That is, if consumer HIS demands on eHealth literacy exceed consumers' skills, these users are less likely to see the value in using these systems (i.e., negatively impact perceived usefulness) and/or be able to use them successfully (i.e., impede usability) and therefore unlikely to adopt them (Monkman & Kushniruk, 2015a).

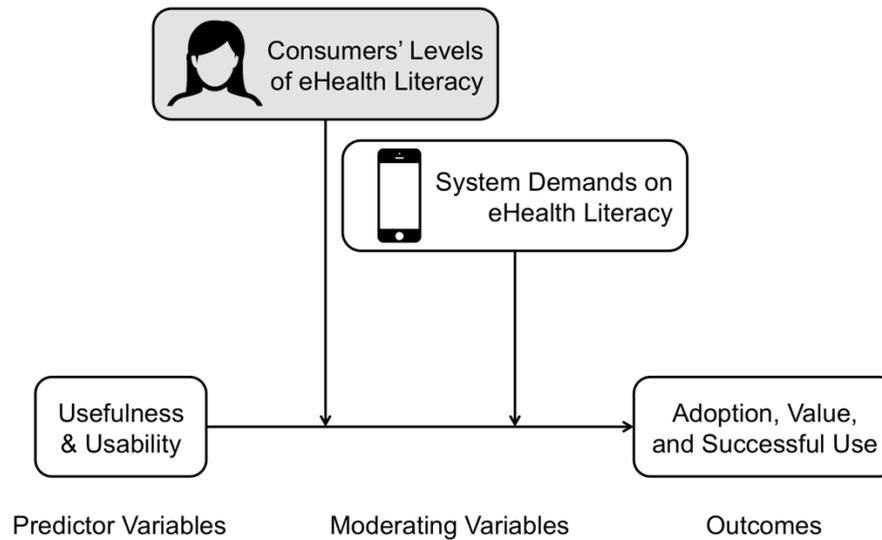


Figure 4. The Consumer Health Information System Adoption Model (Monkman & Kushniruk, 2015a, p. 28)

When demands on eHealth literacy exceed consumers' eHealth literacy levels, consumer HISs Monkman and Kushniruk (2015a) described two strategies to align these factors. First, interventions can be used to increase consumers' eHealth literacy levels. Second, changes can be made to the design of the system to lower its demands on eHealth literacy (e.g., simplify the content, use images to complement text). Given the potential impact of limited health literacy skills, measures are well established to assess these skills. However, given that eHealth is a newer construct, measures are still in their infancy. Further, tools for measuring demands on health literacy remain limited in number and scope and even fewer tools exist for assessing demands on eHealth literacy. The next section will outline tools for measuring consumers' levels of health and eHealth literacy, and a discussion of measures for assessing demands on health and eHealth literacy will follow.

#### 4.4 Health Literacy and eHealth Literacy Skills Assessments

Several assessment instruments have been developed and validated for assessing health literacy levels (see Altin, Finke, Kautz-Freimuth, & Stock, 2014 for review). These tools aim to assist clinicians and researchers in identifying health consumers who may have difficulty understanding health information which negatively affect compliance and preventative care (Murphy, Davis, Long, Jackson, & Decker, 1993) and who may benefit most from interventions.

In a recent systematic review, Collins and colleagues (2012) compared several potential eHealth literacy measures. However, in actuality their review offered limited value with respect eHealth literacy evaluation, as all, but one of the tools were paper-based health literacy measures and failed to assess skills related to interacting with information technology. As such, a limited review of paper-based health literacy evaluation tools will be discussed here. This discussion will begin with the two most popular paper-based health literacy measures: The Test of Functional Health Literacy in Adults (TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM).

The TOFHLA consists of 3 prose passages to assess reading comprehension and 17 items to assess numerical ability (Parker, Baker, Williams, & Nurss, 1995). The TOFHLA categorizes health literacy into three levels: inadequate, marginal and adequate; individuals with either inadequate or marginal health literacy are referred to as having “limited health literacy”. Although validated in its paper-based format, several issues arose (e.g., low completion rates) when researchers translated the TOFHLA and administered it in an interactive computer-based format (Yost et al., 2009); further, evidence from this study suggested that the Spanish translation of the tool had low sensitivity. The REALM does not attempt to measure comprehension; instead, it is a

word recognition test, where health consumers read a list of 66 words aloud and are given points for words pronounced correctly (Davis et al., 1993). The REALM was developed in an attempt to address the gap between the readability of the information being dispensed (e.g., educational brochures, written instructions, prescription labels, health questionnaires) and the reading ability of health consumers (Davis et al., 1993).

Researchers identified the TOFHLA and the REALM as the “gold standard” measures for assessing health literacy (Collins et al., 2012); however, these two instruments can be time consuming to administer. For example, the TOFHLA can require up to 22 min (Parker et al., 1995) and thus, may not always be feasible for administration. Given the time constraints often associated with clinical settings, abbreviated versions of the TOFHLA and the REALM were developed, namely the S-TOFHLA and REALM-R, respectively. The Shortened-Test of Functional Health Literacy (S-TOFHLA) was reduced to 36 comprehension and four numeracy questions, which reduced administration time to a maximum of 12 minutes (Baker, Williams, Parker, Gazmararian, & Nurss, 1999). The numeracy items were subsequently eliminated and reduced the administration further to only seven to eight minutes (Paasche-Orlow & Wolf, 2008). However, many of the questions on the TOFHLA and S-TOFHLA are specific to navigating the healthcare environment in the United States, where they were developed. These questions may not be applicable to other contexts (e.g., Canada) and omitting specific questions may affect the validity of the instrument. Therefore, researchers outside of the United States may opt for tools that are more appropriate for their local healthcare environment.

The Rapid Estimate of Adult Literacy in Medicine-Revised (REALM-R) was reduced to eight items to test pronunciation of words commonly encountered in a health setting and requires only two minutes to administer (Bass, Wilson, & Griffith, 2003). The REALM-R requires further validation, but appears to be an efficient measure for identifying consumers with low health literacy (Bass et al., 2003). However, both the REALM and REALM-R use pronunciation as a proxy of health literacy skills without assessing the capabilities of users to navigate within the healthcare system or make a health related decision, for example.

The Newest Vital Sign (NVS) was developed by Weiss and colleagues (2005) and funded by Pfizer Pharmaceuticals. The NVS evaluates health literacy levels by using a scenario based around an ice cream nutrition label to test numeracy and comprehension. There are six questions in the NVS and it requires approximately three minutes to administer (Weiss et al., 2005). Additionally, the NVS is available in both English and Spanish (Weiss et al., 2005). The NVS categorizes participants according to their likelihood of having limited health literacy as a function of how many questions they answer correctly (Weiss et al., 2005).

Other researchers have adopted a different approach to assessing health literacy and have developed tools to reflect this unique perspective. Specifically, Osborne, Batterham, Elsworth, Hawkins, and Buchbinde (2013) developed the Health Literacy Questionnaire (HLQ) using a different approach to identify and measure different consumer needs with respect to health literacy using self-report. Researchers have noted that with respect to the HLQ, “the self-report format is not intended to capture actual skills, but instead reflects what the individual experiences in relation to the health

literacy demands in their environment, given whatever level of skills they may have” (Bo et al., p. 11). Data collected during consultations (i.e., workshops and interviews) was used to generate different questionnaire items on the HLQ, which sought to “capture the full range of experiences of people currently engaged in healthcare through to people in the general population” (Osborne et al., 2013, p. 1). After a series of revisions and testing using a validity driven approach, the following nine scales (with 44 corresponding items excluded here for brevity) were selected for inclusion for the HLQ:

1. Feeling understood and supported by healthcare providers
2. Having sufficient information to manage my health
3. Actively managing my health
4. Social support for health
5. Appraisal of health information
6. Ability to actively engage with healthcare providers
7. Navigating the healthcare system
8. Ability to find good health information
9. Understanding health information well enough to know what to do (Osborne et al., 2013, p. 11)

The nine scales of the HLQ are used to determine whether consumers have high or low capabilities (for descriptions refer to p. 8) on each of the constructs (Osborne et al., 2013, p. 11). Therefore, based on the results of the HLQ, care providers and government agencies can identify and tailor approaches to target building skills in specific deficit areas. Moreover, the HLQ also identifies opportunities for organizations to improve the delivery of care provision. Osborne and colleagues (2013) argued that

unlike most other health literacy measures which emphasize only a subset of consumers' health reading competency, numeracy, comprehension, or decision-making skills as an index of health literacy, the HLQ is better aligned with current definitions of health literacy which emphasize using the healthcare system successfully to promote and maintain good health. Instead of strictly screening and categorizing consumers, the HLQ seeks to identify needs and opportunities for improvement.

Two of the dimensions of the HLQ (i.e., 6) Ability to actively engage with health care providers, and 9) Understanding health information well enough to know what to do) were assessed in the Danish capital region (Bo, Friis, Osborne, & Maindal, 2014). Between 8.8% and 20.2% respondents (N = 29,473) perceived that individual items assessed on these two scales were either difficult or very difficult. Respondents who reported difficulties were more likely to have low income, low education level, live alone, and be non-Danish. Two other socio-economic factors (i.e., gender and age) exhibited a more complex relationship with inconsistencies between the two scales. Moreover, these estimates of difficulty may be underestimating actual values in the population because Danes with limited health literacy may have been deterred from participating in the questionnaire (Bo et al., 2014). Thus, Bo and colleagues (2014) argued that despite that Denmark has a universal healthcare system and a patient-centered perspective, a significant portion of Danes have difficulty understanding health information and engaging with healthcare providers. Further, using a subset of the dimensions from HLQ demonstrated utility in garnering a better understanding of a country's perceived challenges with respect to its citizens and the healthcare environment (Bo et al., 2014). Particularly pertinent to the current study, the highest proportion of respondents in both

the initial validation of the HLQ (Osborne et al., 2013) in Australia and the Danish study (Bo et al., 2014) reported difficulty being able to “read and understand all the information on medication labels” (Bo et al., 2014, p. 3).

Other researchers have sought to expand on the HLQ by adapt it to make it suitable for the European Union. Specifically, Sørensen and colleagues (2015) designed and developed the European Health Literacy Survey Questionnaire (HLS-EU-Q). Sørensen and colleagues (2015) noted that their tool was developed “for measuring the health literacy of general populations and not of specific patient groups, it does not follow a narrow clinical or medical focus, but captures a broad public health perspective” (p. 7). Further, the HLS-EU-Q was developed using a concept validation approach and operationalized health literacy as a 12 cell matrix with 3 domains (healthcare, disease prevention, health promotion) and 4 goals of processing health information (accessing/obtaining, understanding, processing/appraising, and applying/using; Sørensen et al., 2015). After refinement, with input from focus groups, field test data, and domain experts, the HLS-EU-Q contained 47 self-report items with 3 to 5 items to address each of the 12 parts of the conceptual framework matrix (Sørensen et al., 2015). The HLS-EU-Q is available in Bulgarian, Dutch, English, German, Greek, Polish, and Spanish. As this tool is relatively new, it is as of yet unclear the impact it will have. However, Sørensen and colleagues (2015) noted that they seek to validate the HLS-EU-Q. This tool may even allow countries’ facing health literacy population level challenges to gain from successes reported other countries by examining and implementing their strategies. Therefore, more recent work has strayed from the conventional purpose of screening individuals for specific health related skills as a

measure of health literacy and not only adopted a more holistic perspective of health literacy assessment, but also moved towards assessing population level to identify shortcomings and opportunities for improvement. Information technology is another factor that is becoming increasingly used for accessing and disseminating health information to consumers and therefore warrants consideration with respect to health literacy.

The eHealth Literacy Scale (eHEALS), developed by Norman and Skinner (2006b), was the first tool developed specifically for assessing eHealth literacy (as opposed to health literacy). The eHEALS is an eight item self-report measure where participants respond on a five-point likert scale (from strongly agree to strongly disagree). The eHEALS measures “consumers’ combined knowledge, comfort, and perceived skills at finding, evaluating, and applying electronic health information to health problems” (n.p.) by posing the following eight questions:

1. I know how to find helpful health resources on the Internet
2. I know how to use the Internet to answer my health questions
3. I know what health resources are available on the Internet
4. I know where to find helpful health resources on the Internet
5. I know how to use the health information I find on the Internet to help me
6. I have the skills I need to evaluate the health resources I find on the Internet
7. I can tell high quality from low quality health resources on the Internet
8. I feel confident in using information from the Internet to make health decisions

One limitation of the eHEALS is that it measures *perceived* skills as opposed to providing an objective measure of eHealth literacy levels (Norman & Skinner, 2006b). Further, van der Vaart and colleagues (2011) failed to find a significant correlation between eHealth tasks completed and scores on eHEALS, which casts doubt on the validity of this measure as an index of eHealth literacy. Thus, this measure may be selected as a complementary tool in a battery of tests, but it would not be prudent to rely on it as a sole measure of eHealth literacy.

For over a decade, the eHEALS was the most popular tool for measuring eHealth literacy. However, the eHEALS has weaknesses and different investigators have sought to develop a better measure of eHealth literacy. Two such recently developed tools are the eHealth Literacy Questionnaire (Kayser et al., 2018) and the Digital Health Literacy Instrument (van der Vaart & Drossaert, 2017).

Researchers who developed the HLQ (Osborne et al., 2013) also created an eHealth Literacy Questionnaire (eHLQ; Kayser et al., 2018). The eHLQ is based on the seven dimensions of the previously discussed the eHealth Literacy Framework (eHLF; Norgaard et al., 2015). Items representing the eHLF were tested for potential inclusion in both Danish and English simultaneously to preclude any potential translation issues. The resultant eHLQ is a 35-item questionnaire comprised of seven scales which correspond with the dimensions of the eHLF (Kayser et al., 2018). Each item is rated on a four-point likert scale (strongly disagree to strongly agree) with no neutral value (Kayser et al., 2018). The eHLQ could prove to be a valuable tool to evaluate eHealth interventions, provide insights into the success or failure of eHealth services, and to assess and compare the self-reported capabilities of various populations (Kayser et al.,

2018). The eHLQ may prove to be a more valuable tool than the eHEALS in practice as its development was guided by a framework grounded in empirical evidence (i.e., the eHLF).

Arguably their findings that performance on the eHEALS did not correspond with performance on eHealth tasks (van der Vaart and colleagues, 2011) motivated two of these researchers from this group developed an alternative tool called the Digital Health Literacy Instrument (DHLI; van der Vaart & Drossaert, 2017). Van der Vaart and Drossaert (2017) argued that existing eHealth literacy measures emphasized Health 1.0 skills such as information gathering but ignored Health 2.0 skills related to interactivity on the Web (e.g., adding content, using Web portals). To overcome this, the DHLI developed based on findings from a previous qualitative study which identified and categorized eHealth literacy issues observed in a sample of participants with rheumatic diseases (Van der Vaart, R., Drossaert, de Heus, Taal, & van de Laar, 2013).

The DHLI measures “operational skills, navigation skills, information searching, evaluating reliability, determining relevance, adding self-generated content, and protecting privacy” (van der Vaart & Drossaert, 2017, p.1). The DHLI has 21 self-report items (i.e., three items per skill type) which are scored on four-point likert scales indicating either difficulty (very easy to very difficult) or frequency (never to often). In a Dutch sample ( $N = 200$ ), internal consistencies were all adequate and supported the seven subscales, with the exception of protecting privacy and the test-retest analysis was sufficient as well (van der Vaart & Drossaert, 2017). Further, as expected the DHLI was significantly correlated with demographic measures as well as a health and eHealth literacy measures (van der Vaart & Drossaert, 2017). Taken together, these findings

suggest that the DHLI could be used as a new measure for assessing eHealth literacy. In addition to the self-report scale, the DHLI also has a performance-based component.

Adopting a novel and complementary approach to self-report, each of the seven skills had one corresponding item that was performance-based (van der Vaart & Drossaert, 2017). Each performance-based item poses a multiple-choice question and provides screenshots to illustrate the hypothetical situation (van der Vaart & Drossaert, 2017). Examples of performance-based include “what button to press for a certain action, or what piece of information would be most valuable in a certain situation” (van der Vaart & Drossaert, 2017, p. 3). The performance-based items had low internal consistency (i.e., did not form a single scale) and should be examined independently (van der Vaart & Drossaert, 2017). Further, the authors van der Vaart and Drossaert (2017) noted that performance was very high on several of the performance-based items and more difficult assessments of skill may be more suitable. Unfortunately, neither DHLI nor the eHLQ were developed when the present study was conducted and thus could not be administered to participants in this study.

Both the eHLQ (Kayser et al., 2018) and eHEALS (Norman & Skinner, 2006b) are self-report measures and thus are inherently subjective. The DHLI employs a combination of self-report and performance-based assessment pursuing an important line of research in developing a more robust tool that objectively measures eHealth literacy skills. However, van der Vaart and Drossaert (2017) noted that the performance-based component of the DHLI required further adaptation and investigation. An objective assessment of eHealth literacy will likely be challenging to develop because it must evaluate users’ health literacy levels, how effectively they can

use health information technology to find relevant information and services, as well as how to act on and apply this information. Furthermore, given the variability in consumer HIS interfaces, users may experience more or fewer challenges finding the information they need depending on the health information system they are using. A reliable measure of eHealth literacy should generate a stable assessment for users' levels of eHealth literacy, independent of the specific application that is going to be used (e.g., the Internet vs. a specific website vs. a mobile application). Thus, continued research toward developing a valid and reliable measure of eHealth literacy is warranted. In addition to measuring users' skills, it is also worth exploring methods to evaluate develop content design systems to be less taxing on users' levels of health literacy.

In summary, there are many tools available to assess health literacy (see Altin et al., 2014 for review). In contrast, the eHEALS was the single dominant eHealth literacy measure for many years until the development of new tools such as eHLQ (Kayser et al., 2018) and the DHLI (Van der Vaart & Drossaert, 2017). These three eHealth literacy measures all have their respective strengths and weaknesses (see Table 7 for summary).

Table 7

*Comparison of eHealth Literacy Measures*

<b>Name</b>	<b>Study</b>	<b>Method</b>	<b>Strengths</b>	<b>Weaknesses</b>
eHealth Literacy Scale (eHEALS)	Norman & Skinner, 2006b	8 questions of self-reported capabilities	Brief	Subjective skills
eHealth Literacy Questionnaire (eHLQ)	Kayser et al., 2018	35 items on 7 scales	Based on an empirical framework of eHealth literacy	Subjective skills
Digital Health Literacy Instrument	Van der Vaart & Drossaert, 2017	21 self-report on 7 subscales	Based on an evidence of eHealth challenges,	Performance questions use Dutch screenshots

7 performance  
based multiple  
choice questions

includes  
objective skills

---

## **4.5 Assessments of Demands on Health Literacy and eHealth Literacy**

The primary goal achievable through design changes to print materials and consumer HISs is lowering the demands these systems place on consumers' health or eHealth literacy. Methods for both designing materials and systems such that they place low demands on users' health or eHealth literacy levels, as well as identifying how hardcopy materials and electronic systems can be modified to lower the demands on eHealth literacy will be examined.

Few measures have been identified for evaluating paper-based consumer health information, yet even fewer were identified for consumer HISs. Thus, given the dearth of parallel tools for consumer HISs these tools may be worth exploring for their utility or as a preliminary assessment for consumer HISs. It is hoped that new tools will be researched specifically to measure demands consumer HISs' place on user' eHealth literacy.

### **4.5.1 Readability**

As reading is a core component of health literacy, readability is a frequently used measure in determining the level of difficulty of written health information. Ley (1988) argued that more readable text is more likely to be read, is read faster, will be considered by consumers as easier to read, and is more likely to be understood. As such, several studies on medication information previously described here have assessed readability in their experiments (Kim et al., 2011; Kimberlin & Winterstein, 2008; Morrow et al., 2005; Svarstad & Mount, 2001; Wolf et al., 2006; Wolf et al., 2012).

However, Ley also described conditions where improving readability may not affect consumers' comprehension. Specifically, Ley (1988) noted that enhancing readability is less likely to benefit comprehension if consumers: a) have high reading ability, b) are highly motivated, c) are interested in the content, and d) have pre-existing knowledge on the topic. Similarly, the effects of multimedia may be limited by the similar factors.

Readability refers to how easily information can be understood and thus is an index of reading ease. Typically, these measures report the health information in terms of a grade level which facilitates comparison with literacy grade levels and identifying when the complexity of information exceeds a target grade level (e.g., grade 7; Walsh & Volsko, 2008). The Canadian Public Health Association (2008) recommends that information targeted for the general public should not exceed the 8<sup>th</sup> grade reading level. Two of the most common readability measures to assess health information on the Internet are the Simple Measure of Gobbledygook (SMOG; McLaughlin, 1969) and the Flesch-Kincaid grade level formula (Flesch, 1948). SMOG grade level varies as a function of the number of polysyllabic (i.e.,  $\geq 3$  syllables) words in an excerpt. In contrast, Flesch-Kincaid grade level is calculated using the average sentence length (in number of words) in addition to the average number of polysyllabic words. Both of these readability measures, and many others, are readily available for assessing health information. For example, the Flesch-Kincaid grade level can be calculated within MS Word. Further, there are many online tools that evaluate text copied on one (e.g., [www.harrymclaughlin.com/SMOG.htm](http://www.harrymclaughlin.com/SMOG.htm)), or multiple measures (e.g., [www.readability-score.com](http://www.readability-score.com)), or entire web pages (e.g., [www.read-able.com](http://www.read-able.com)). In a recent review, the SMOG was the most frequently cited measure for health information (Luk, & Aslani,

2011) and was referred to as the gold standard for measuring readability (Fitzsimmons, Michael, Hulley, & Scott, 2010).

#### **4.5.2 Plain Language and Clear Design Principles**

Given its potential to support, and in some cases, replace oral communication between providers and consumers, researchers have long been motivated to explore techniques for optimizing written health information in terms of how it is written and displayed. For example, Ley summarized the recommendations of Kanouse and Hayes-Roth (1980) for improving consumers' comprehension of medical text as follows:

1. Use active voice
2. Use specific content words rather than filler words
3. Use concrete not abstract language
4. Use consistent terminology
5. State things explicitly before referring to them implicitly
6. Repeat previous information and follow it with new information
7. Do not omit pronouns or clause markers
8. Use numbering and bullet points
9. Make time and cause and effect explicit
10. Keep sentences brief

With respect to the layout and design of the content, Ley (1988) endorsed the evidence-based recommendations made by Poulton, Warren, and Bond (1970) to facilitate reading ease and speed:

1. Lines should be unjustified
2. At least 10 point font should be used

3. Leading is unnecessary
4. The first line of paragraphs should be indented
5. All capitals should be avoided for both headings and body text
6. Italics should be avoided
7. Headings should be easily distinguishable
8. Roman numerals should be avoided

Much of this early work has evolved and been adopted to inform the content design of consumer health information in the form of plain language and clear design principles. Further, although readability may an efficient and easy method of assessing health information content, it is not prudent to examine readability without considering a more holistic view of health information, as argued by the concept of plain language principles (Wizowski, Harper, & Hutchings, 2008). As defined by Wizowski and colleagues “plain language is a way of writing information so that it is easy for people to read, understand, and use” (p. 41) and is “communications that engage and are accessible to an intended audience” (Stableford & Mettger, 2007, p. 75). Plain language engages patients and accurately describes medical concepts and how to apply this information, without making the information unnecessarily complicated and cognitively taxing (Wizowski et al., 2008). It does not imply a “dumbed down” version of the material that lacks meaning in favour of using short synonyms to enhance reading ease, because this does not ensure clarity, appeal or comprehension (Stableford & Mettger, 2007). That is, it is important that although the material is easy to read, simplified versions remain comprehensive and retain the same meaning as the original materials.

Instead, the preferred approach is testing the material with representative consumers (e.g., U.S. Department of Health and Human Services, 2007; Wizowski et al., 2008).

Stableford and Mettger (2007) argued that plain language is a strategic approach to the challenge of limited health literacy. “In health care, plain language can help all people understand health information, but it is most helpful for those who do not read” (Wizowski et al., 2008, p. 41). This argument emphasizes that using plain language is valuable for all users of health information, not just those with limited health literacy and that increasingly, health information can be delivered orally through online mediums. It is increasingly common that health web sites integrate functionality that reads content aloud for individuals who struggle with reading for either reasons of physical impairment or lack of skills. Plain language guidelines were developed to improve communication in patient education materials (e.g., pamphlets, brochures).

Plain language principles are often complemented by clear design principles to guide the development of the presentation of the paper-based material. The practice of clear design includes selecting design features “to make the information look attractive, simple and easy to read” (Wizowski et al., 2008, p. 50). The goal of clear design is to facilitate consumers finding, reading and retaining the health education information (Wizowski et al., 2008). Clear design principles focus on how the written and visual information are displayed. Thus, these principles include recommendations like “use bulleted lists” and “use simple line drawings” (Wizowski et al., 2008). Thus, plain language and clear design principles attempt to improve both the content and display of consumer health information. Importantly, many of these recommendations were observed as being incorporated into the medication information guidance.

### 4.5.3 Suitability and Comprehensibility of Materials

The evaluation of the success of plain language principles and clear design in printed materials is largely measured by assessing materials in terms of their suitability. As such, suitability has been measured in previously discussed studies (i.e., Wolf et al., 2006; Wolf et al., 2012). Doak, Doak, and Root (1996) developed the Suitability Assessment of Materials (SAM) to assess the presentation of health information. Thus, SAM consists of 22 criteria that are known to affect readability and comprehension. The scale categorizes information into three levels: superior, adequate and not suitable (Doak et al., 1996). The criteria are grouped into the following six topics: content, literacy demand, graphics, layout and typography, learning stimulation and motivation, and cultural appropriateness. In a recent review, the SAM was the most frequently cited measure for suitability of health information (Luk & Aslani, 2011). However, Wizowski and colleagues (2008) developed their own suitability checklist (see p. 104) that also assesses various aspects of the health information (i.e., content, writing style, design, illustrations, and process of development). Readability is a component of the SAM, however a common approach is to examine readability independently and in complement with the findings from a suitability instrument (e.g., Shieh & Hosei, 2008).

The SAM has been used extensively in its original format; however, one noted attempt was made to modify it. Specifically, Helitzer, Hollis, Cotner, and Oestreicher (2009) modified the SAM to emphasize comprehensibility and named their instrument the SAM + CAM. These authors developed the SAM + CAM to measure additional constructs (i.e., numeric literacy factors, persuasive techniques, behavioral theory, and communication assessment) and remove the cultural appropriateness construct. Helitzer and colleagues used the SAM + CAM to evaluate cervical cancer prevention

materials; however, this tool does not appear to have gained much traction in other studies.

#### **4.6 Evaluation of Medication Information**

Given the importance of medication information, tools have been developed specifically to assess these types of materials. However, these tools have primarily focused on printed medication information, as it is the historically dominant medium for delivering this type of information. The Medication Information Design Assessment Scale (MIDAS) is a thirteen-item scale meant for researchers to evaluate medication information for the United States Department of Health and Human Services goal of “evaluating and improving the usefulness of written medication information” (Krass, Svarstad, & Bultman, 2002, p. 1). The MIDAS criteria are strictly graphic guidelines (e.g., sharp ink contrast, line spacing  $\geq 2.2$  mm, bullet points). The Consumer Information Rating Form (CIRF) is a measure administered to consumers to evaluate comprehensibility, utility (including both quantity and usefulness) of information, and overall design quality (Krass et al., 2002). The MIDAS and the CIRF two measures were positively correlated; that is, the more design principles medication pamphlets abided by (i.e., higher MIDAS score) the more positively they were received by consumers (i.e., higher CIRF score; Krass et al., 2002). Small modifications were made and the adapted CIRF was considered a robust measurement tool when subsequently validated using a larger sample ( $n = 282$ ; Koo et al., 2007). Specifically, the principle components analysis yielded three factors and each one demonstrated good internal reliability as indexed by strong Cronbach’s  $\alpha$  values for comprehensibility (0.74), utility (0.92), and design quality (0.75; Koo, et al., 2007). These findings were supported by another study

yielding the same three factors through factor analysis and the construct validity of the CIRF with comprehensibility, utility, and design quality with Cronbach's  $\alpha$  values of 0.83, 0.69, and 0.82 respectively (Desplenter, Laekeman, Demyttenaere, VZA-Leaflet Research Group, & Simoens, 2009).

#### **4.6.1 Summary of eHealth Literacy Constructs and Measures**

This chapter provided an overview of the construct of eHealth literacy as an emergent construct of health literacy. An estimated three of five Canadians have low levels of health literacy, which may lead to making poor health decisions (e.g., delaying treatment, going to the hospital unnecessarily; Canadian Council on Learning, 2007). In contrast, people with higher health literacy are less likely to have some chronic illnesses (Canadian Council on Learning, 2008), use services less often, and have shorter hospital stays (Speros, 2005). Thus, given the potential implications of limited health literacy it has garnered researchers attention. Increasingly, digital health information is becoming available for consumers to access as use. However, this electronic delivery may create a new set of challenges for people with limited health literacy. As a result, many have shifted their attention towards eHealth literacy.

There are two important factors to consider with respect to eHealth literacy: 1) the consumers' skills, and 2) the demands of the system (Monkman & Kushniruk, 2015a). For consumer HISs to be effective, these factors must be aligned (Monkman & Kushniruk, 2015a). Therefore, research efforts have focused on measuring consumers' skills and also the demands of the materials and systems. For a long time, Norman and Skinner's (2006b) eHEALS was the only eHealth literacy measure available and many researchers continued to use health literacy measures. However, new tools are being

developed and show promise (e.g., eHLQ by Kayser et al., 2018). Moreover, one tool is even exploring complementing self-report with objective performance measures (i.e., the DHLI by Van der Vaart & Drossaert, 2017). Again, unfortunately these tools were not available at the time data was collected for this study. In contrast tools for assessing eHealth literacy demands of remain limited to tools developed for paper-based materials. This is likely a suitable approach for the consumer health information content (e.g., readability). However, by not to examining consumers' interactions with eHealth literacy resources and systems, they cannot help identify opportunities to lower system demands on consumers.

Krass et al., 2002 developed two tools specific to Consumer Medication Information (CMI). The first, the Medication Information Design Assessment Scale (MIDAS), is a tool used to guide the development of CMI, but only provides guidance about graphical properties (e.g., font size, line spacing; Krass et al., 2002). The second, the Consumer Information Ration Form (CIRF), is used to evaluate consumer perceptions about the comprehensibility, utility, and design quality of CMI (Krass et al. 2002). Thus, this chapter offered a discussion of different health and eHealth literacy topics, which can be used to inform and assess studies on Consumer Medication Information (CMI) such as the present study.

As discussed in Chapter 3, researchers have incorporated images, either to complement or in lieu of text, as a strategy to lower the demands of medication information for users with limited health literacy. However, these materials are rarely developed using the guidance of the existing domain of research on multimedia. Moreover, the proliferation of technology has made consumer health information readily accessible electronically which affords using other communications methods (e.g., audio, videos). Additionally, research needs to be conducted regarding which method of

presentation is most effective for consumer memory and comprehension. Thus, the next chapter will examine the existing literature on multimedia learning.

## **Chapter 5: Multimedia Learning**

A review of the literature was conducted to identify analytical frameworks for multimedia learning and identify research on multimedia presentations used to convey medication information. This information is of importance for laying out theoretically based approaches for evaluating different presentation formats for consumer health information and specifically medication information. Several frameworks and theories were found that theorized about how people construct knowledge or learn from multimedia presentations. One of the foremost theories in this domain is Mayer's (2001) Cognitive Theory of Multimedia Learning (CTML). As such, the CTML will be used as the framework for the current study. Principles for multimedia learning emerged from studies on CTML and the proposed study will specifically explore two of these principles: the multimedia and modality principles. Thus, this chapter seeks to orient the experiment proposed for this dissertation in the existing literature on multimedia learning and the multimedia principles.

### **5.1 Multimedia Instruction and Multimedia Learning**

Remembering and understanding are the two goals of multimedia instruction and multimedia learning has occurred when one or both of these goals has been achieved (Mayer, 2005a, 2014a). Mayer (2014a) defined remembering as the "ability to reproduce or recognize presented material" (p. 20), whereas understanding is the "ability to use presented material in novel situations" (p. 20). In turn, there are three potential multimedia learning outcomes of consumers experiencing multimedia instruction: no learning, rote learning, and meaningful learning (Mayer, 2005a). No learning is the result of no acquisition of knowledge from multimedia instruction (Mayer, 2005a). Rote

learning is a circumstance where consumers may be able to remember the instruction materials well, but they may not necessarily understand it (Mayer, 2005a). In contrast, meaningful learning is where people are able to both remember and understand the multimedia instruction and are unable to make abstractions (i.e., problem solve) from it (Mayer, 2005a).

## **5.2 Managing Cognitive Demands of Multimedia Instruction**

Cognitive capacity is limited. Building on previous work, Mayer (2014b) proposed three goals for multimedia instruction based on the three types of demands placed on cognitive capacity by multimedia instruction. That is, in order for people to remember and understand multimedia instruction, multimedia presentations should aim to reduce extraneous processing, manage essential processing, and foster generative processing (Mayer, 2014b).

Extraneous processing is “cognitive processing during learning that does not serve the instructional objective and is caused by poor instructional design” (Mayer, 2014b, p. 68). Mayer’s example of this was a figure and the figure description printed on different pages, whereby the learner may have to alternate back and forth and allocate unnecessary cognitive resources to connecting the two pages. Thus, “extraneous processing does not result in any useful knowledge being constructed in the learner’s working memory” (Mayer, 2014b, p. 59) and therefore this type of processing should be minimized whenever possible.

In contrast to extraneous processing, essential processing is “cognitive processing during learning that is needed to represent the essential presented material in working memory and is caused by the complexity of the material” (Mayer, 2014, p. 67). Mayer

described that a definition would require less essential processing than an intricate figure. Unlike extraneous processing, which has no related learning processes, essential processing is related to the selection of information (Mayer, 2014). “Essential processing results in the construction of verbal and pictorial representations in working memory that correspond to the presented material” (Mayer, 2014, p. 60). Thus, managing essential processing in multimedia instruction ensures that the processing the information does not exceed human capabilities.

Finally, generative processing is “cognitive processing during learning that is aimed at making sense of the essential material in the lesson and is caused by the learner’s motivation to exert effort” (Mayer, 2014, p. 68). Mayer (2014) suggested that learners may be more motivated to learn if they have likeable instructors. Generative processing is related to organizing and integrating information (Mayer, 2014). Thus, generative processing enables learners to express concepts in their own words rather than just rote memorization. Thus, both essential (selection) and generative (organization and integration) processing are necessary to achieve learning. However, extraneous processing is not necessary and in fact detrimental to learning.

### **5.3 Cognitive Theory of Multimedia Learning (CTML)**

The CTML frames multimedia learning using a human information-processing approach (Mayer, 2005b). The CTML depicts sensory memory, working memory, and long-term memory as the three systems or stores necessary for multimedia learning (see Figure 5). Exact representations of visual and auditory information (i.e., images and sounds) last very briefly in the sensory registers and must be transferred working memory for processing (Mayer, 2005b). Working memory is aptly named because it is

here that stimuli are organized into verbal and pictorial models and integrated with information from long-term memory or prior knowledge to make sense of the stimuli (Mayer, 2005b). Thus, working memory plays an imperative role in multimedia learning because this system is where the stimuli from sensory memory are transformed into meaningful representations and unified with previous knowledge. Working memory has a limited capacity (i.e., it can only process a limited amount of information simultaneously) and information within working memory is subject to rapid decay (Mayer, 2005b). However, the rate of decay of information in working memory is not as rapid as in sensory memory (Mayer, 2005b). Unlike sensory memory and working memory, long-term memory has a large capacity (i.e., can store high quantities of information) and has a very slow rate of decay; therefore, information persists over long durations (Mayer, 2005b).

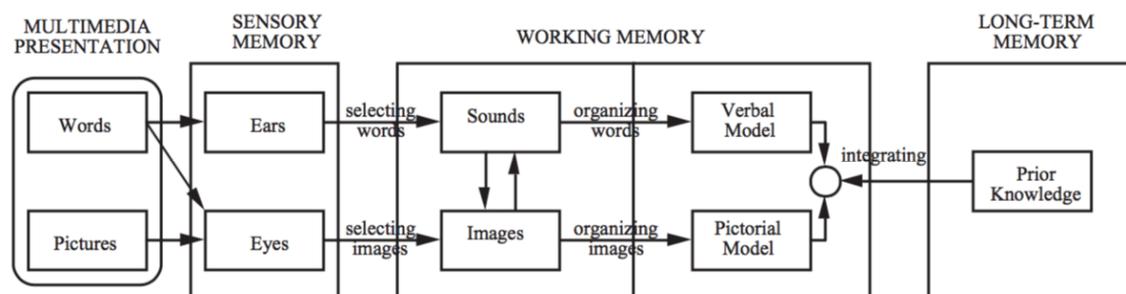


Figure 5. Cognitive Theory of Multimedia Learning (CTML; Mayer 2005b, p. 37)

The following three different types of cognitive processing must occur for multimedia learning to be successful: selecting, organizing, and integrating. Information must be attended to for it to be selected and used in subsequent processing (Mayer, 2005b).

Moreover, attention behaves like a filter or a spotlight: only portions of the visual and of the multimedia will be selected Mayer (2001; 2005b) outlined 5 processes (see the labeled arrows in Figures 1 and 2) in CTML:

1. Selecting relevant words

2. Selecting relevant images
3. Organizing relevant words
4. Organizing relevant images
5. Integrating word-based and image-based representations

## **5.4 CTML Assumptions**

CTML relies on three assumptions: (1) one channel processes audio/verbal information and an independent channel processes visual/pictorial information; (2) there are processing and capacity limits for both channels (3) to learn from multimedia, people must actively engage with the material (Mayer, 2001). Each of these assumptions will be elucidated in turn.

### **5.4.1 Dual Channel Assumption**

“Humans possess separate information processing channels for verbal and visual material” (Mayer & Moreno, 2003, p. 44.) is the premise of the Dual Channel Assumption. The cognitive phenomenon of independent stores and processors for two primary types of information (i.e., audio/verbal information and visual/pictorial) is well established in the psychology literature and most commonly associated with Paivio’s dual-coding theory (e.g., Clark & Paivio, 1991; Paivio, 1986; Paivio, 2006) and Baddely’s model of working memory (Baddeley, 1999; Baddeley, Eysenck, & Anderson, 2009). These theories were motivated by findings that visual processing tasks and a verbal processing task can be accomplished simultaneously; however, two simultaneous visual tasks or verbal tasks interfere with each other (Brooks, 1968). Thus, these two channels appear to operate independently to some extent. As can be

seen in Figure 5, CTML depicts the channels as two separate rows: the upper row is the auditory/verbal channel and the lower row is the visual/pictorial channel.

Using the CTML as a framework, the processing paths of different types of media can be shown. Here, the differences between how pictures, written words, and spoken words are processed will be described and depicted using the CTML. Processing of pictures (Figure 6a) begins with the eyes conveying pictures into sensory memory. Attention is used to select relevant images. Next, the images are organized into a pictorial mental model. The pictorial model is then integrated with existing knowledge drawn from long-term memory. In contrast, processing of spoken words (Figure 6b) begins with the ears transmitting words into sensory memory. Attention is used to select relevant words. Subsequently the sounds are organized into a verbal mental model. Then the verbal mental model is integrated with existing knowledge in long-term memory. Processing of pictures and spoken words are examples of information that activates a only a single channel (i.e., the visual/pictorial and auditory/verbal channels respectively). However, processing of written words requires a conversion of information from the visual/pictorial to the auditory/verbal channel (see Figure 6c). That is, the eyes initially receive written words using selective attention, but these images are converted to sounds in working memory and are then organized and used to generate a verbal mental model. As in the other examples, this mental model is then integrated with previous knowledge accumulated in long-term memory. Thus, representations can be processed in a single channel (i.e., either visual/pictorial or auditory/verbal) or be converted for processing in a different channel.

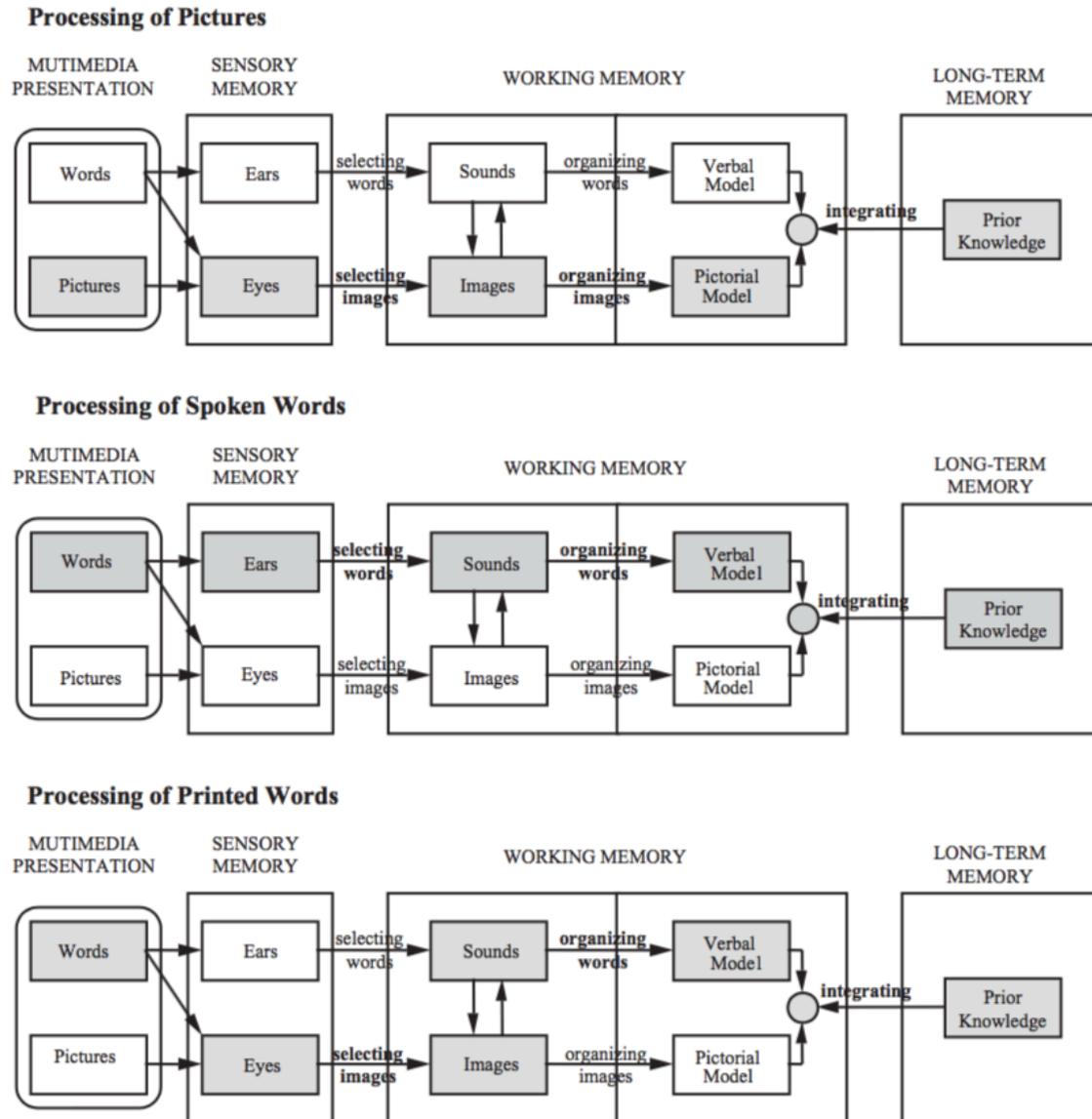


Figure 6. Processing of Pictures (a), Spoken Words (b), and Written Words (c) depicted using the Cognitive Theory of Multimedia Learning (CTML; reproduced with permission from Mayer 2005b, p. 43).

#### 5.4.2 Limited Capacity Assumption

The Limited Capacity Assumption is based on the notion that “there is only a limited amount of processing capacity available in the verbal and visual channels” (Mayer & Moreno, 2003, p. 44). Limited capacity is an assumption of the working memory model (Baddeley, 1992) and cognitive load theory (Chandler & Sweller, 1991; Sweller, 1999) in working memory as well. As previously noted, working memory is

limited in capacity and information decays from working memory rapidly (Mayer, 2005b) and these limitations affect multimedia learning. For example, presenting excessive amounts of information, or information too rapidly, can negatively impact learning, because the task demands exceed working memory resources (Mayer, 2001).

### **5.4.3 Active Processing Assumption**

The Active Processing Assumption surmises “learning requires substantial cognitive processing in the verbal and visual channels” (Mayer & Moreno, 2003, p. 44). More specifically, “humans actively engage in cognitive processing to construct a coherent mental representation of their experiences” (Mayer, 2001, p. 50). Active processing includes selecting (through attention), organizing, and integrating with existing knowledge to build mental models (Mayer, 2001). That is, “meaningful learning involves engaging in appropriate cognitive processes during learning” (Mayer, 2005a). Multimedia design attempts to facilitate learners build new mental models by presenting material with coherent structure and guiding users on how to build mental models of the material (Mayer, 2001).

### **5.4.4 The Cognitive Theory of Multimedia Learning for Multimedia Consumer Health Information**

Recently, Monkman and Kushniruk (2015b) modified the CTML to emphasize its potential utility for guiding the development of consumer health information (see Figure 7). Additionally, it was argued that the work on multimedia learning has not yet been leveraged in the development of consumer health information (Monkman & Kushnriuk, 2015b). Therefore, existing consumer health information materials are at risk of being suboptimal design (Monkman & Kushnriuk, 2015b). In summary, it was posited that the

CTML for Multimedia Consumer Health Information was a valuable framework for exploring the efficacy of multimedia consumer health information by grounding it in the multimedia learning literature.

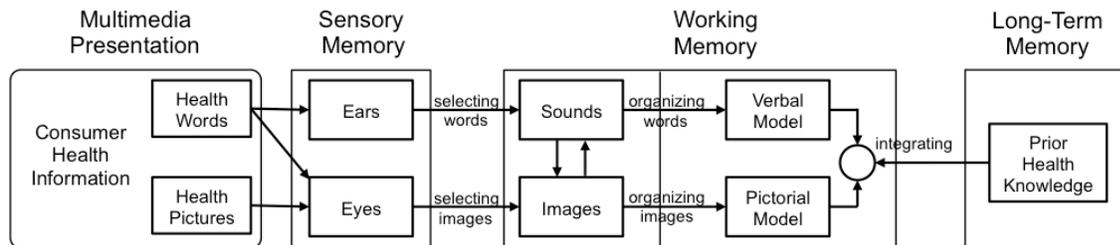


Figure 7. The Cognitive Theory of Multimedia Learning (CTML) for Multimedia Consumer Health Information (p. 288, Monkman & Kushniruk, 2015b)

## 5.5 Multimedia Learning Principles

Motivated by effects observed in cognitive psychology, Mayer (2001) conducted an extensive set of studies on multimedia learning. This amalgamation of studies provided evidence for the multimedia principles originally proposed by Mayer (2001) enhance cognitive processing through the design of multimedia presentations. That is, Mayer (2001) systematically explored different variables in multimedia presentations to determine what conditions facilitate or impair retention and transfer of information. This evidence was used to generate a set of principles to guide multimedia presentation design to optimize learning. Based on his research, Mayer (2001, adapted from p. 184) proposed the following seven research-based principles for multimedia learning:

1. *“Multimedia Principle:* People learn better from pictures and words than from words alone.
2. *Spatial Contiguity Principle:* People learn better when corresponding words and pictures are presented near rather than far from each other on the page or screen.

3. *Temporal Contiguity Principle*: People learn better when corresponding words and pictures are presented simultaneously rather than successively.
4. *Coherence Principle*: People learn better when extraneous material is excluded rather than included.
5. *Modality Principle*: People learn better from animation and narration than from animation and on-screen text; that is, people learn better when words in a multimedia message are presented as spoken text rather than printed text.
6. *Redundancy Principle*: People learn better from animation and narration, than from animation, narration, and text.
7. *Individual Differences Principle*: Design effects are stronger for low-knowledge learners than for high-knowledge learners and for high-spatial learners rather than for low-spatial learners.”

Since the inception of the multimedia learning principles, additional principles have been proposed. For example, Mayer (2008) proposed the Signaling Principle, Segmenting Principle, Pre-training Principle, Personalization Principle as additional principles for guiding multimedia design and others have suggested principles for specific populations (e.g., the Cognitive Aging Principle; Paas, Van Gerven, & Tabbers, 2005).

Two of Mayer’s multimedia principles were selected for investigation in the proposed study: the multimedia and the modality principle. Given their use in the proposed study, these two principles will now be explored in more detail.

### **5.5.1 Multimedia Principle**

At the crux of multimedia learning is the multimedia principle: complementing words with pictures results in more effective learning than words alone (Mayer, 2001). Butcher (2014) noted that many people self-identify as visual learners (Mayer & Massa, 2003), but there is no convincing evidence that aligning preferred learning styles with materials results in learning gains (Massa & Mayer, 2006; Pashler, McDaniel, Rohrer, & Bjork, 2008; Rohrer & Pashler, 2012). However, people benefit from multimedia presentations over text, regardless of their self-reported learning styles (Butcher, 2014). That is, both static images (Mayer, Bove, Bryman, Mars, & Tapangco, 1996) and animations (Mayer & Gallini, 1990) presented in combination with words have been consistently shown to enhance learning over text alone. The effect of multimedia is influenced by factors such as the relevance of the presented images (Levi & Lentz, 1982) and other multimedia learning principles (Butcher, 2014).

Research on using multimedia to benefit consumer health information is beginning to emerge (e.g., Houts, Doak, Doak, & Loscalzo, 2006; Katz, Kripalani, & Weiss, 2006). However, no studies were identified that explored the potential impact of the multimedia on Consumer Medication Information (CMI) by adding images to complement the text. Therefore, this study will explicitly investigate how multimedia affects memory for CMI as well as users' opinions of this type of information presentation.

### **5.5.2 Modality Principle**

Multimedia learning researchers make an important distinction between mode and modality. Mode (i.e., pictures, narration, printed text) refers to the representational format or how the information is presented (Paivio, 1986). In contrast, modality refers to

what channel (i.e., visual or verbal) processes the information (Penny, 1989). The modality effect is well evidenced in the cognitive psychology literature and emerged from the modality effect observed in several studies (e.g., Kalyuga, Chandler & Sweller, 1999; Kalyuga et al., 2000; Low & Sweller, 2005; Mayer & Moreno, 1998; Mousavi, Low, & Sweller, 1995).

Mousavi, Low and Sweller posited “the effective size of working memory may be increased by presenting information in a mixed (auditory and visual mode) rather than in a single mode” (Mousavi, Low, & Sweller 1995, p. 320). That is “multimedia presentation results in superior learning when pictorial information (i.e., visual modality) is accompanied by narration (i.e., auditory modality) rather than by on-screen text (i.e., dual verbal presentations in the visual and auditory modalities; Debusse, Hede, & Lawley, 2009, p. 749-750). Thus, leveraging the independent channel resources (i.e., auditory/verbal and visual/pictorial) enhances the processing efficiency of working memory.

Printed words and pictures are both processed by the visual system and have the potential to overload the visual/pictorial system and by competing for resources in this channel and impede learning. However, when words are spoken, they are processed by the auditory or verbal system instead which is independent from the visual/pictorial channel and therefore this information does not compete for the same resources. Therefore, according to the modality principle, learning is improved when verbal information is spoken narrative rather than text, so visual resources can be devoted strictly to the pictorial or image information.

Although evidence supports the modality principle in other domains, it has not been explicitly investigated using health information stimuli. Given the relative advantage narration has over printed text when other visual information is presented simultaneously, it is important to explore whether there is evidence of the modality effect for medication information, as it could be used as a strategy to enhance consumer understanding and memory. Clark and Mayer (2011) noted “there are times when the words should remain available to the learner for memory support – particularly when the words are technical, unfamiliar, not in the learner’s native language or needed for future reference” (p. 120). Therefore, a limited number of words were used in the stimuli representing the modality principle stimuli in this experiment. However, the proposed study will test whether using primarily narration paired with images to convey CMI will impact participants’ memory for the information contained therein. Additionally, the study will explore the participants’ opinions of this type of information presentation.

## **5.6 Summary of Multimedia Learning**

Multimedia learning has been thoroughly studied and principles have emergent to inform the design of multimedia principles to enhance their efficacy. There is a significant amount of research to suggest under what conditions people are most likely to understand and remember multimedia presentations. However, this body of work has largely investigated topics other than consumer health. Further, despite this large body of evidence, most multimedia consumer health information is rarely developed using this relevant evidence-based guidance (Monkman & Kushniruk, 2015b). Thus, the multimedia consumer health materials tested and disseminated may be suboptimal, as

they often fail to leverage principles on how to facilitate cognitive processing of multimedia presentations (Monkman & Kushniruk, 2015b).

## Chapter 6: Hypotheses and Research Questions

### 6.1 Purpose of This Research

Electronic methods for delivering health information are becoming more pervasive; however, information that is available cannot necessarily be equated with information that is accessed or understood. As such, it is important to explore methods that can improve comprehension and memory of information as well as new opportunities to disseminate Consumer Medication Information (CMI). Despite the proliferation of health information online, much of it has been designed with limited consideration for the needs of the consumer, and how to optimize comprehension and memory. Evidence is mounting in support of the multimedia principle (i.e., images and words facilitate learning more than words alone) in studies of medication information (refer to Katz, Kripalani, & Weiss, 2006 for review). However, the few studies on multimedia medication information have not framed their research within multimedia learning, not held other variables (e.g., font size, readability) constant, nor have they investigated other potentially beneficial multimedia principles. The one exception is King and colleagues' (2012), whose study was grounded in theory and held other variables constant, but it did not explore narration and the stimuli may have been too simplistic to generate results. Thus, opportunities may exist to leverage the findings in multimedia research from other domains to improve consumers' understanding of health information.

The preceding chapters outlined relevant topics and identified different sources of motivation for the proposed study. Initially, the argument of the importance of comprehension and memory of consumer health information was outlined. This was

followed by a discussion of how CMI is currently provided as well new methods of presentation being explored. Subsequently, health and eHealth literacy were discussed as these constructs warrant consideration during the development and assessment of CMI. Finally, as multimedia is one approach that has been gaining traction for improving consumer health information, especially for people with limited health literacy, the body of literature around multimedia learning was presented. The proposed study seeks to address gaps observed in the literature with respect to multimedia CMI.

Most studies to date have focused on testing techniques to increase understanding of different types of medication information. Many of the interventions modified the content and design of the text in an attempt to improve these materials (e.g., Boudewyns et al., 2015; Morrow et al., 2005; Wolf et al., 2014). While comprehension of materials is of primary importance, memorability, or the ability to remember information is another crucial factor that should be examined. Indeed, some studies have begun to investigate strategies to improve memory for consumer health information (e.g., Morrow et al., 2005). The ability of consumers to remember medication information can not only impact adherence, but also whether contraindications and side effects are recognized and responded to appropriately.

Most of the attempts to improve medication information have manipulated both design and content in an attempt to achieve results. However, modifying both content and design makes it difficult to isolate the contribution of each factor in any changes in performance. Some studies have used images to support the concepts in the text of medication information, but it was often limited to times when medications should be administered (e.g., Davis et al., 2009). No studies were found that used images to

complement text throughout (e.g., for indications, administration, side effects). Further, although studies have explored verbal communication of medication information (e.g., Thomson et al., 2001), the effects of narration (in lieu of text) with complementary images to communicate CMI does not appear to have been studied. Thus, this study will attempt to address gaps in research by a) controlling for content but manipulating design, b) using complementary images throughout the document, and c) using narration instead of text.

Currently, CMI provided to consumers by pharmacies is limited only to text. However, evidence from the domain of multimedia learning (e.g., Mayer, 2001) suggests an array of strategies that might bolster CMI communication. Two such strategies that might benefit CMI communication are: 1) using pictures to complement text (i.e., applying the multimedia principle) and 2) using narration rather than text and complementing the narrative with pictures (i.e., applying the modality principle). This study will explore the application of these two multimedia learning principles in the context of CMI.

The multimedia principle is grounded in evidence that people learn better from pictures and words than just words alone (Mayer, 2001). Adding images to other types of consumer health information (Houts, Doak, Doak, & Loscalzo, 2006), discharge instructions (Zeng-Treitler et al., 2014), and medication information (Katz et al., 2006) has been shown to be beneficial. However, there is a dearth of research on complementing text with images specifically using CMI (i.e., the information about new prescription medications dispensed by pharmacies). Moreover, the few studies identified exploring the potential of adding images to text for medication information,

only included images in a limited manner. Specifically, images were tested to convey medication administration timelines (e.g., Kripalani et al., 2007; Morrow et al., 1998a) or medication directives (King et al., 2012), but not many of the other topics included in medication information (e.g., suitable illnesses, benefits, possible side effects). To determine whether the multimedia principle holds true for CMI, images should be added to complement all CMI topics and compare it with the standard text only CMI currently dispensed.

The modality principle is based on evidence that people learn better from narration with pictures than text and pictures, because the cognitive processing of the former is more efficient than the latter (Mayer, 2001). Although there is a mandate for BC Pharmacists to provide verbal information about prescriptions (College of Pharmacists of British Columbia, 2015), no studies were identified using narration with complementary images to communicate CMI as a means to further support the verbal information provided by pharmacists at the time the prescription is dispensed. Thus, to determine whether the modality principle applies to CMI, CMI composed of text and images should be compared to the same information conveyed through narration and images.

## **6.2 Research Objectives**

This study sought to contribute to the design and delivery of CMI. Specifically, this study explored:

1. Effects of the multimedia (i.e., adding images to text) and modality (i.e., using narration in lieu of text) principles upon memory (i.e., recall) for CMI

2. Consumer perceptions of different CMI formats in terms of comprehensibility, utility, and design quality as well as potential preferences for CMI formats
3. Consumers' information needs with respect to CMI

A mixed methods approach was used to explore the above research areas.

Quantitative comparisons of participant CMI memory were used to determine if multimedia or modality affected memory for CMI. As they were exposed to them, participants rated different aspects of the CMI formats (i.e., comprehensibility, utility, and design quality) to collect quantitative data on their perceptions of the materials. Participants were asked general questions (typical of pharmacists testing consumers' comprehension) to explore their memory for the medications in different formats. After seeing all three formats, participants were asked to rate and compare the three CMI formats to garner a deeper understanding of their opinions of the three formats. Further, semi-structured interviews were used to gain insight on participants' information preferences and needs with respect to CMI.

### **6.3 Quantitative Research Questions and Hypotheses**

Mayer's (2001) set of multimedia principles offer a valuable framework for operationalizing the effects of multimedia presentation on retention, but they have yet to be explored with respect to CMI. Specifically, although some studies have explored the potential benefits of adding images to complement medication information, many simultaneously changed other aspects of the content (e.g., wording simplification, using active voice) and therefore the effects of adding images to text are often confounded with other modifications. One notable exception is King and colleagues' (2012) who

conducted a systematic investigation of the effect of adding pictographs on memory for medication information. King and colleagues (2012) found no impact of multimedia on memory. However, they only tested a subset of medication information rather than the content in its entirety. Further, the author identified no studies that explored the potential benefits of using narration for communicating medication information instead of text. Therefore, two of the multimedia principles, the multimedia principle and the modality principle, were tested in this research to determine their relative effects on memory for CMI. This study appears to be one of few that have systematically tested the multimedia principles using CMI or even more broadly, consumer health information. Given that consumer health information is unique from many other kinds of information due to characteristics such as the use of medical terminology, detailed instructions, and lengthiness, CMI may or may not perform as predictably as other types of multimedia presentations that have been tested. Thus, it is important to test whether multimedia principles such as the multimedia principle and the modality principles are applicable in the context of CMI. The multimedia principle predicts that adding images to complement text will result in learning gains because both visual and verbal channels of working memory will be activated (Mayer, 2001). Thus, the effects of CMI using both text and images on memory were tested.

1. Is there evidence of a multimedia effect for CMI on memory?

**H<sub>0</sub>:** There is no difference in CMI memory, regardless of whether it is presented as plain text or text with images.

**H<sub>1</sub>:** Memory of CMI is enhanced when it is presented as text with images compared to plain text.

The modality principle proposes that learning gains will be observed when narration is presented in conjunction with images over presentations comprised of text and images, because narration does not compete for resources in the visual channel (unlike text; Mayer, 2001). Therefore, narration plus images is thought to be a more efficient use of cognitive resources. Thus, the effects of text and images for medication information on consumer retention were tested.

2. Is there evidence of a modality effect for CMI on memory?

**H<sub>0</sub>:** There is no difference in CMI memory, regardless of whether it is presented as narration with images or text with images.

**H<sub>1</sub>:** Memory of CMI is enhanced when it is presented as narration with images than text with images.

In addition to determining if the aforementioned presentation modifications impact memory, it was also important to determine if there are any differences in participants' perceptions and preferences of the different formats. Consumers may prefer or dislike one format, which could potentially impact their likelihood of reading the materials. Further, participants may consider different CMI formats easier to understand and/or remember. To address these perceptions, findings were triangulated using both quantitative (i.e., rating and ranking questions) and qualitative (semi-structured interview responses) data.

3. Do participants perceive one CMI format as more comprehensible?

**H<sub>0</sub>:** There is no difference in perceived comprehensibility of CMI formats.

**H<sub>1</sub>:** Participants perceive at least one CMI format as more comprehensible than another format.

4. Do participants perceive one CMI format as having more utility?

**H<sub>0</sub>:** There is no difference in perceived utility of CMI formats.

**H<sub>1</sub>:** Participants perceive at least one CMI format as having more utility than another format.

5. Do participants perceive one CMI as superior in terms of design quality?

**H<sub>0</sub>:** There is no difference in perceived design quality of CMI formats.

**H<sub>1</sub>:** Participants perceive at least one CMI format as more appealing in terms of design quality than another format.

6. Do participants prefer one CMI format overall?

**H<sub>0</sub>:** There is no difference in CMI format preference.

**H<sub>1</sub>:** Participants prefer at least one CMI format to another format.

#### **6.4 Qualitative Research Questions**

Other important research questions stem from consumers' information needs and preferences with respect to how they receive and use CMI. This investigation begins by examining the current process of dispensing CMI and whether consumers feel it supports their needs. Then whether there were opportunities to improve the dissemination of CMI in terms of timing and medium is explored.

Participants may have ideas to improve the timing of CMI delivery to be more helpful in the safe and effective use of medications. For example, some (e.g., the Committee on Safety of Medicines, 2005) have argued that dispensing CMI before a medication is prescribed or purchased is worth exploring. That is, rather than providing the materials with the medication after it is purchased, CMI should be dispensed by the prescribing physician with (or before) the written prescription for the consumer to review

before filling the prescription. This approach would allow consumers to review the information, consider the risks of taking the medication, and prepare questions for their provider or pharmacist before beginning a new medicinal treatment.

#### 7. When do consumers want to receive CMI?

Additionally, consumers may prefer to receive CMI electronically or wish to continue the current standard by receiving it in hardcopy. Given its potential benefits (e.g., loss prevention, sharing with caregivers and family, reproducibility) consumers may be receptive to using electronic CMI. However, consumers may be less inclined to read the information if they receive it electronically or if it is too much work to access. In addition to exploring whether participants wanted electronic CMI, people may prefer a specific method (e.g., by email, online through a secure website, or in an application for medication management) of receiving or accessing this information electronically.

#### 8. How do consumers want to receive CMI?

Research questions seven and eight were investigated using qualitative approaches. The hypotheses and research questions taken together show how this study explored the potential benefits of delivering CMI electronically, both by determining whether images and/or narration to enhance memory or comprehension and identify opportunities to improve the design and dissemination of CMI to address needs and preferences of consumers.

### **6.5 Implications of the Proposed Research**

Currently in Canada, CMI is often only conveyed through text only. In an attempt to address the gap in research, this study sought to determine whether limiting information to text impedes memory or affects perceptions and preferences when compared with

multimedia medication information (e.g., Text + Images, Narration + Images). That is, does adding images and/or narration increase the likelihood that consumers will remember the CMI or consider it more favourable? If gains in memory were observed in this study due to complementary methods of information presentation (i.e., the addition of narration and/or images), it would motivate the development and distribution of multimedia medication information to enhance safe and effective medication taking. If gains in perceptions or preferences of multimedia CMI were observed, it may prompt the creation of these types of materials by increasing the likelihood that consumers will engage with them.

Further, the deployment of CMI online by the FDA is imminent (Pearsall et al., 2014), yet whether people are receptive to this type of dissemination, what their information presentation preferences are, and how and when they would like to access this information has yet to be explored. Given some of the shortcomings of paper-based CMI (e.g., easily misplaced, read once and then disposed of, not available when questions arise), electronically delivered medication information is appealing. However, benefits of electronic CMI delivery may not be realized unless how it is deployed aligns with consumers' expectations, needs, and preferences. Thus, findings from this study could be valuable in informing how to optimize the design of CMI online to correspond with consumers' information needs and preferences.

## Chapter 7: Experimental Methods

### 7.1 Ethical Approval and Data Collection

This University of Victoria's Human Research Ethics Review Board approved this study June 14<sup>th</sup> 2016 (see Appendix D). Data was collected began in July 2016. Data collection was completed in October 2016.

### 7.2 Participants

#### 7.2.1 Sample Size Calculation

The number of participants expected to achieve a significant difference between conditions in the proposed study was estimated based on findings from previous multimedia studies. Although there are published effect sizes summarizing performance over many studies, it may not be prudent to use this in calculations for the current study because they report the effect sizes of transfer tests (i.e., being able to generalize what was learned), not retention tests (e.g., Mayer, 2008; Mayer & Pilegard, 2014) and effect sizes for retentions test are generally more modest than for transfer tests (Butcher, 2014). For example, studies have reported the following median effect sizes for transfer (i.e., an index of comprehension): multimedia principle 1.39 based on 11 studies (Mayer, 2009); modality effect 0.76 based on support found in 52 of 61 studies (Mayer & Pilegard, 2014). More modest effect sizes require more participants to find significant differences. Therefore, the most prudent estimate of effect size useful for the proposed study was deemed to be from a meta-analysis comparing the effectiveness of static images vs. animations (Höffler & Leutner, 2007). Specifically, Höffler and Leutner, found that the mean weighted effect size was 0.44 for declarative knowledge (i.e., memory) in 40 studies. Thus, to calculate the number of participants for the proposed study, the

critical effect size of 0.45, the significance level of 0.05 and power of 0.8 will be adopted. Using the aforementioned parameters in consultation with Kraemer and Thiemann's table for one-tailed tests (p. 106), as memory hypotheses were directional, a sample size of 28 participants was suggested. However, given that conditions were counterbalanced, and equal numbers of participants should experience the orders of the conditions, to err on the side of caution (i.e., run one more participant in each sequence than suggested) 36 participants were recruited for this study.

### 7.2.2 Sample

A sample of adults (i.e.,  $\geq 18$  years old) participants ( $N = 36$ ) were recruited.

Participants were excluded from the study by self-report if they:

- a. Had a medical or health professional background (e.g., nurses, pharmacists, doctors)
- b. Were not proficient in English, and/or
- c. Had compromised visual or auditory acuity that is not effectively compensated for by assistive devices (e.g., glasses, hearing aids).

Two participants were identified as outliers due to their age (i.e.,  $> 3 SD$  from the mean age) and replaced with two new participants to maintain equal numbers of participants in each sequence (see Figure 12).

### 7.2.3 Recruitment

A multi-pronged approach was used to recruit participants for this experiment. A call for participants was sent out through the University of Victoria's School of Health Information Science listserve. Additionally, the investigator hung posters on campus to advertise the study.

#### **7.2.4 Remuneration**

To compensate participants for their time, each participant was given a \$20 gift card.

### **7.3 Materials**

#### **7.3.1 Stimuli Selection**

Many studies seeking to improve CMI use medications that are similar to or the actual medications their participants are prescribed (e.g., Koo et al., 2007, Morrow et al., 2005) However, Morrow and colleagues (2005) found that familiarity with a medication influences memory for information about that medication. Therefore, attempts were made to limit the familiarity of medications but preserve realism, so neither commonly prescribed nor rarely prescribed medications were used. Given that younger adults take relatively few prescription medications (26.2 % of 15 to 24-year olds and 28.0 % of 25 to 44 year olds; Rotermann et al., 2014), a broad range of medications were considered for inclusion.

A pharmacist and the investigator generated 23 medications to consider for use as stimuli. The pharmacist expert identified a Canada-wide community pharmacy chain as providing representative medication information to its consumers upon filling new prescriptions. The investigator requested, obtained, and reviewed the CMI for each of the 23 identified medications. Seven medications were subsequently rejected, because the CMI was drawn from an alternate database named Vigilance (<http://www.vigilance.ca/en/rx-vigilance/information-on-demand/>). Specifically, the following seven medications were rejected, because their CMI did not match the others: Allopurinol (Zyloprim), Ciprofloxacin + Hydrocortisone (Cipro hc), Hydromorphone

(Dilaudid), Ketorolac (Toradol), Prandase (Acarbose), Terbinafine (Lamisil), Ustekinumab (Stelara). These substitutions were rejected because the information was not consistent in terms of format and content with the other CMI acquired. The remaining 16 CMI sheets were transcribed and analyzed according to their treatment condition(s), routes, number of words, and readability (using an online SMOG calculator). Three medications (i.e., Betaderm, Cromolyn, Flovent) were selected based on their uniqueness from each other in terms of name, route, and content, as well as their similarity in length and readability (see Table 9). Three healthcare professionals (i.e., 2 nurses, one pharmacist) reviewed the final materials to ensure they were representative of typical CMI. Using experts to validate stimuli and experimental settings has also been used in other studies (e.g., Borycki, Lemieux-Charles, Nagle, & Eysenbach, 2009).

Table 8

Comparison of Candidate Stimuli Medications

<b>Medication Name</b>	<b>Condition Treated</b>	<b>Route</b>	<b>Word Count</b>	<b>SMOG Index</b>	<b>Selected</b>
Betaderm	Inflammation and itching	Cream	360	17.5	Yes
Cromolyn	Allergic conjunctivitis	Eye drop	406	17.7	Yes
Flovent	Asthma	Inhaler	377	17.2	Yes
Nasonex	Sinusitis or Allergic rhinitis	Nasal Spray	395	17.6	No
Avamys	Allergic rhinitis	Nasal Spray	377	17.3	No
Flonase	Allergic rhinitis	Nasal Spray	395	17.3	No
Zaditor	Allergic conjunctivitis	Eye drop	424	16.8	No
Sandoz-Timolol	Glaucoma	Eye drop	359	17.5	No
Zymar	Antibiotic for conjunctivitis	Eye drop	447	17.1	
Aldara	Genital warts Skin Cancer Actinic keratosis	Cream	270	18.6	No

Loprox	Antifungal	Cream	365	17.7	No
Asmanex	Asthma and prevent crisis	Inhaler	374	17.2	No
Onbrez	COPD	Inhaler	331	16.9	No
Lyrica	Nerve Pain	Pill	391	18.4	No
Parnate	Depression	Pill	445	18.7	No
Doxycycline	Infection	Pill	581	17.8	No

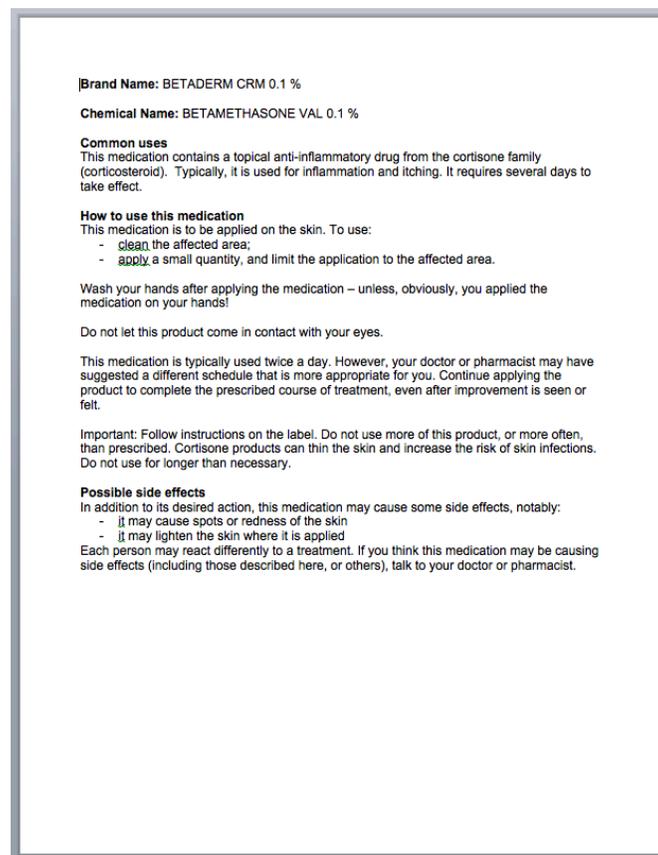
### 7.3.2 CMI Formats

Three different CMI formats were used as conditions in this study: Text, Text + Images, and Narration + Images. The three conditions were developed using the MIDAS as design guidelines, as this has been shown to correlate with more positive ratings in terms of comprehensibility, utility, and design quality on the CIRF (Krass et al., 2002). However, where the sample from the community pharmacy written information deviated from the MIDAS guidelines, the former was preserved to make the materials more realistic and consistent. Specifically, a sans-serif font was used and no bolding/box or summary to highlight important points was created. Three health professionals validated the representativeness of all three formats in a manner similar to Borycki and colleagues (2009). The following sections will describe in more detail how the three different formats were developed.

#### 7.3.2.1 Text (Control) Format

The Text format served as the control condition for this experiment. The Text format was based on the typical layout of paper CMI currently distributed by Canadian community pharmacies. The actual content from the CMI of a leading community pharmacy was transcribed and simplified slightly to create the Text format. Specifically, the date, Drug Identification Number (DIN), address and phone number of community

pharmacy, as well as other branding and logos were excluded from the Text format. The “general information” section and storage instructions for the CMI were excluded, as it was the nearly or virtually identical for all three medications. Therefore, these two topics provided no unique learning opportunities that would be more likely to be remembered in subsequent conditions because of repeated exposure. Arial 12-point font was used, and headings were bolded (see Figure 8 for example).



*Figure 8.* Text Format for Betaderm (Appendix A).

*Note.* Written content was developed by a leading Canadian pharmacy.

### 7.3.2.2 Text + Images Format

The Text + Images format was developed by complementing the Text format with images from the Internet and developed by the investigator (see Figure 9 for example) using PowerPoint®. This format was created based on the multimedia principle whereby

complementing text with images facilitates learning over text alone (Mayer, 2001). The page layouts were 11 inches in width and as long as necessary to convey all of the information. As in the Text format, Arial font was used. However, larger font sizes were used (i.e., 14 point for body text and 22 point for medication names) for the Text + Images format. Minor changes were made to punctuation (e.g., removing periods), few words were added (e.g., the name of the condition next to the picture of the condition), written numbers were replaced with Arabic numerals, medication names were emphasized headings were emphasized, and boxes were used to group topics information; however, the content (i.e., words) in the Text formats were identical to those in the Text + Images format. Text + Images formats were saved as PDF files.



**Brand Name: Cromolyn op drp 2%**  
**Chemical Name: Sodium Cromoglycate 2%**

**Common Uses**

This medication is typically used for allergic conjunctivitis (inflammation of the clear covering of the front of the eye, due to allergies). 

It requires several days to take effect. 

Allergic Conjunctivitis

**How to Use This Medication**

To use:  This medication is for the eye.

**1** Wash your hands as well as the skin surrounding the affected eye



**2** Shake the container



**3** Gently pull down the lower lid of the affected eye



**4** Apply 1 drop of the medication



**5** Close the eye for 2 to 3 minutes, while gently pressing on the inner corner of the eye



To avoid contaminating the medication, do not let the tip of the applicator touch your fingers or any part of your eye



Close the container tightly after each use.

This medication is typically used 4 times a day. However, your doctor or pharmacist may have suggested a different schedule that is more appropriate for you.

**1**



8 am

**2**



noon

**3**



4 pm

**4**



8 pm

Use it regularly and continuously to maintain its beneficial effects.

Everyday 

If you forget a dose, apply it as soon as you remember –



**Or**

Unless it is almost time for your next dose. In that case, skip the missed one. Do not apply more to try to catch up.



**Possible Side Effects**

In addition to its desired action, this medication may cause some side effects, notably:

When it is used, it may cause local irritation



When it is used, it may cause a temporary burning sensation



It may cause a stinging sensation.



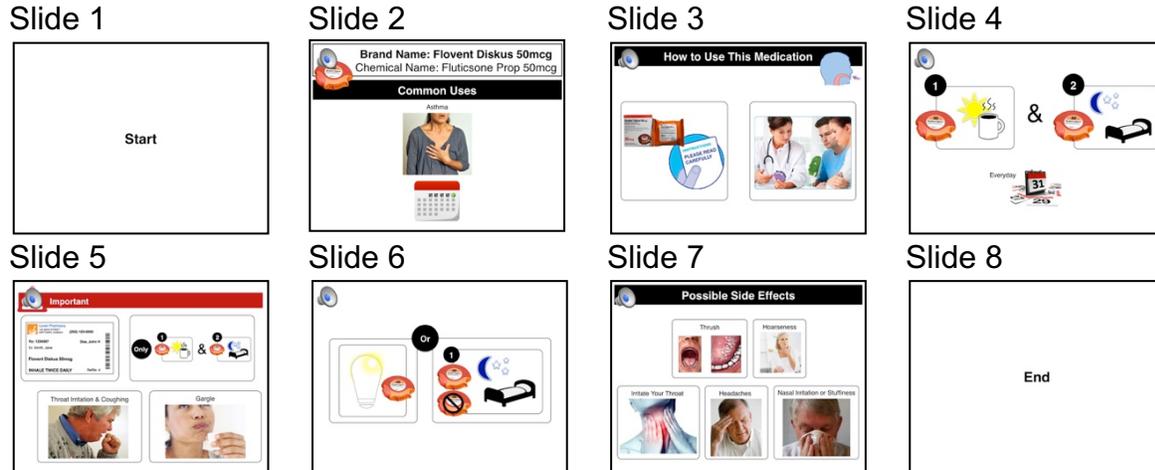
*Figure 9. Text + Images Format for Cromolyn (Appendix B).  
 Note. Written content was developed by a leading Canadian pharmacy.*

### 7.3.2.3 Narration + Images Format

The Narration + Images format was developed by audio recording a volunteer reading information from the Text format aloud and using the images from the Text + Images format and separating the content into a series of Powerpoint™ slides. This format was created based on the modality principle, whereby audio and images facilitate learning over text and images, as the latter two compete for visual resources (Mayer, 2001). The same font and sizes were used as the Text + Images format. However, the font size was reduced as a result of the width available for showing the video in the survey software. As the narration provided all the words from the Text formats, the majority of words from the Text format were excluded from this format. However, some words were retained, if they were considered to frame the presentation (e.g., the name of the medication, headings) or reinforce the meaning images (e.g., names of side effects). The images and audio were combined using Power Point™, and the entire sequence of slides were coordinated through timing intervals to match the image and heading appearances (i.e., they dissolved in) with the concurrent narration. To allow participants to be prepared for the onset of the presentation, each Narration + Images format begins with a 5 second “Start” screen. The Power Point® presentation was screen recorded with audio and will be played for participants using YouTube® (see Figure 10 for example).

Narration + Images Formats are available online:

- Betaderm - <https://www.youtube.com/watch?v=EVTvhRESwxA>
- Cromolyn - <https://www.youtube.com/watch?v=U8TNf49eLPo>
- Flovent - <https://www.youtube.com/watch?v=VEwU2m9BIBo>



*Figure 10.* Slides from the Narration + Images Format for Flovent (Appendix C)  
*Note.* Audio recordings were based on the written content developed by a leading Canadian pharmacy.

### 7.3.3 Apparatus

The Text format served as the control format for this experiment. In the Text format, participants were given paper hardcopies on A4 (8.5 x 11 inch) of the CMI to emulate current Canadian pharmacy dispensing practice. Three health professionals validated the representativeness of the Text format as emulating the current materials distributed by pharmacies in Canada. The remaining two formats were displayed on an Apple Macbook Air laptop computer with a 13.3-inch colour display. As the FDA is in process of moving toward providing medication information online in digital form (Pearsall et al., 2014), the researcher adopted a digital approach for conveying both the multimedia formats (i.e., Text + Images and Narration + Images). The Text + Images format was displayed on a single web page. If necessary, participants were shown how to scroll using the keyboard arrows or the mouse. The Narration + Images format was displayed as an embedded YouTube® video. To keep the exposure timing consistent, participants were only able watch the video once from start to finish. Therefore,

participants did not have the opportunity to interact (e.g., rewind, fast forward) with the Narration + Images video. QuickTime® was used to record the screens as well as the audio for the duration of the experiment, even when the computer was not involved (e.g., when participants were studying Text format). An additional audio only recorder was also used.

### 7.3.4 Setting

The experiment was conducted in a quiet office. Participants were seated comfortably at a desk and the experimenter sat alongside him or her with the experimental materials that were not currently in use (e.g., Text format; see Figure 11).

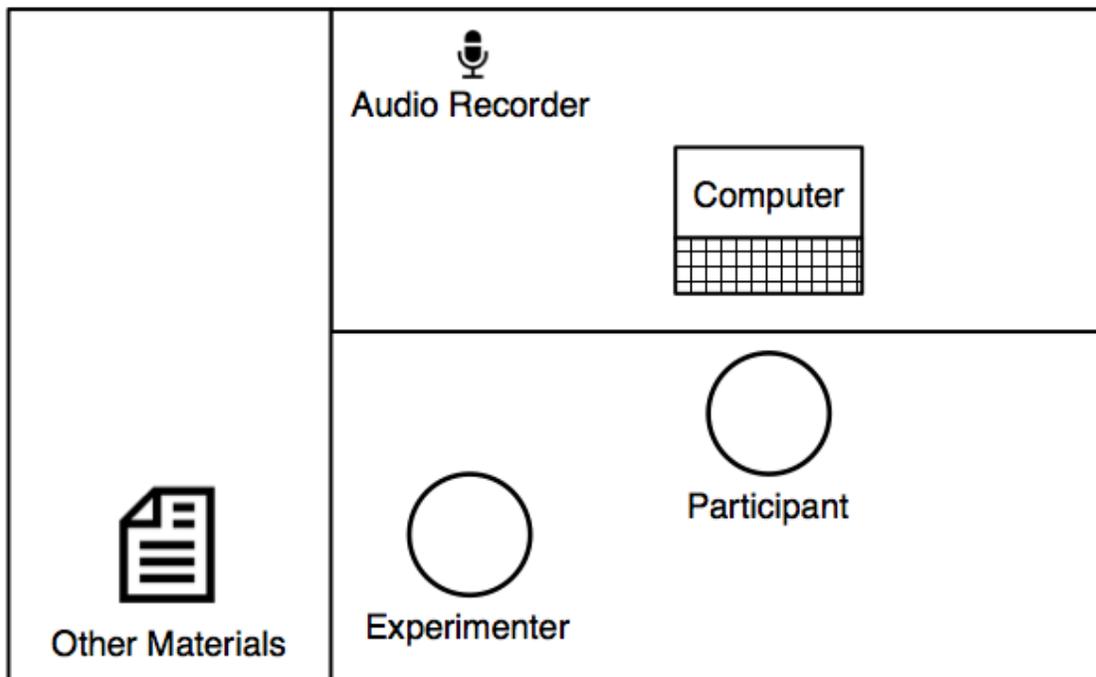


Figure 11. Top View of the Experimental Setting

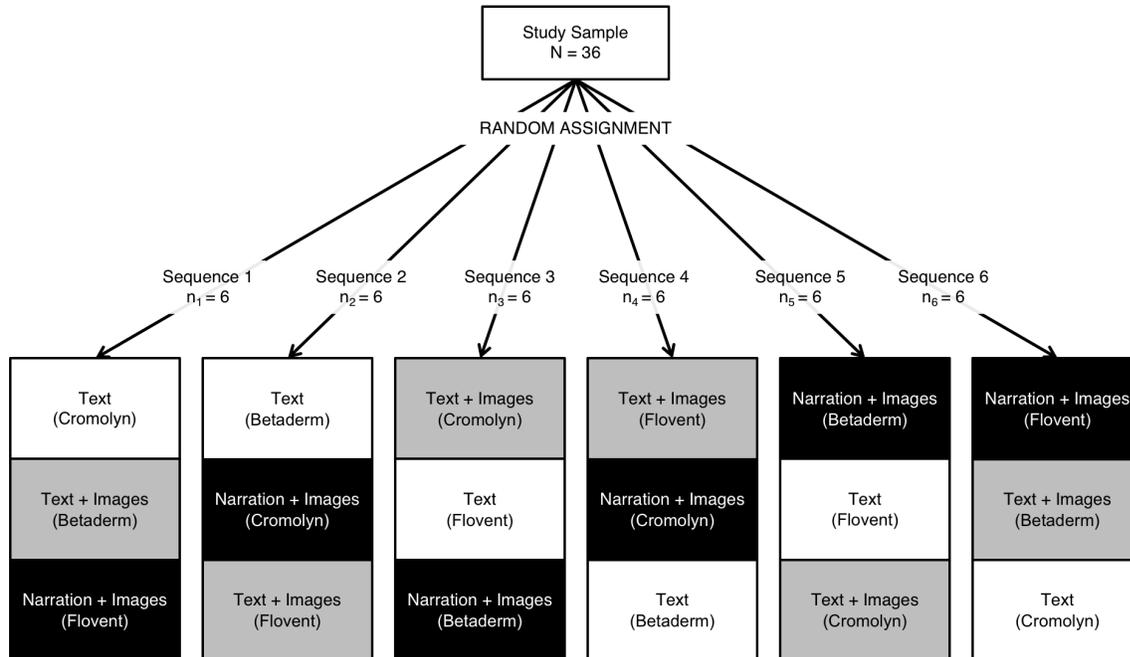
## 7.4 Procedure and Measures

### 7.4.1 Design

This experiment used a 1 x 3 randomized, counterbalanced design (Christensen, Johnson, & Turner, 2014). The single factor (i.e., independent variable) was CMI format and the three levels of CMI format were Text, Text + Images, Narration + Images. This study design was used to investigate the potential effect of multimedia CMI on memory, perceptions (i.e., comprehensibility, utility, and design quality), overall format preference, and/or information needs.

All 36 participants were each randomly assigned to one of the six unique presentation sequences (see Figure 12). Thus, each of the six sequences were completed by six participants (denoted by lowercase n's with subscripts corresponding to their sequence number). The numerals 1 to 6 (to represent each of the six sequences, see Figure 12) were each printed six times (i.e., one written six times, two will be written six times etc.). The 36 (i.e., one for each participant) printed numbers were cut into individual pieces of the same size, folded in the same way, and placed into a container. To ensure equal cell sizes, numbers were drawn without replacement.

Each sequence dictated which order the formats were presented as well as which medication was represented in each format. The order of both the CMI format and the medications were counterbalanced. These precautionary measures were taken in an attempt to minimize the potential for order effects, fatigue effects, and inherent memorability differences between medications (Christensen et al., 2014).



*Figure 12.* Experimental Design: Randomized, Counterbalanced for Formats and Medications (in brackets)

#### 7.4.2 Procedure

To begin, each participant read and signed the informed consent form outlining the details of the study. After consent was provided, each participant drew a piece of paper with a number on it from the container that determined his or her sequence (see Figure 13). After the participant's sequence was determined, the preliminary measures were administered online. The preliminary measures (represented on the first line of Figure 13) were used to collect data on the participants' demographics, health, and eHealth literacy levels for descriptive purposes. Thus, participants completed the demographic questionnaire (Appendix E) first, followed by the Newest Vital Sign (Weiss et al., 2005), and finally eHEALS (Norman & Skinner, 2006) online before they were exposed to any CMI (see Figure 13).

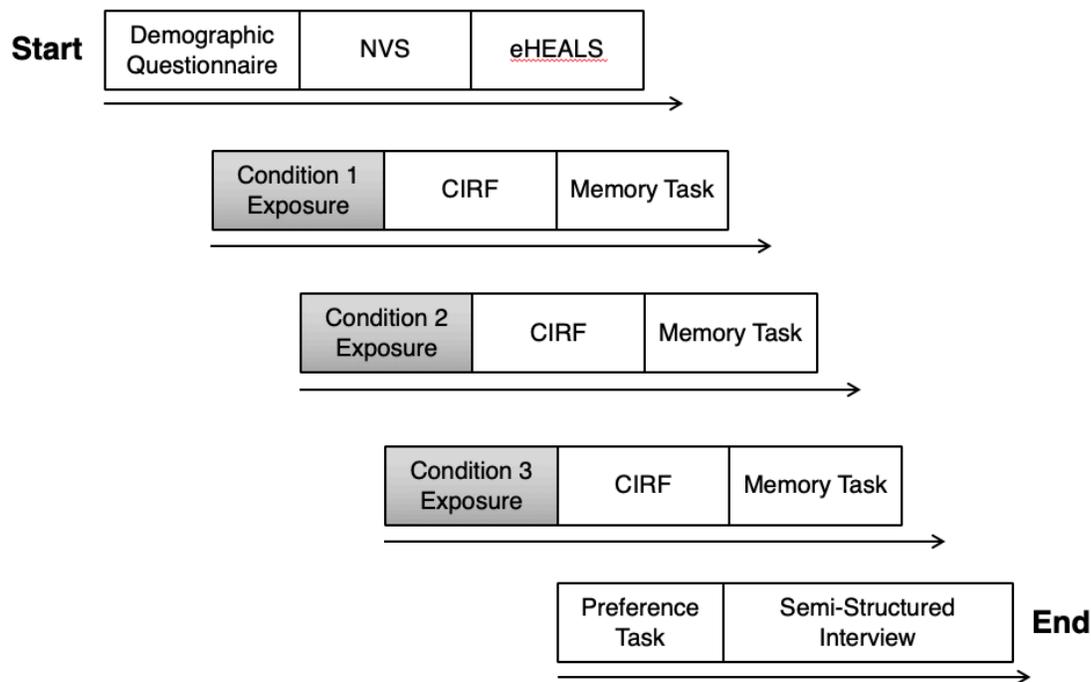


Figure 13. The Experimental Procedure

This procedure was adapted from methods used by Morrow and colleagues (2005). Morrow and colleagues' (2005) procedure was selected and adapted because their study tested the effects of patient-centered modifications to medication information on memory and the proposed study had a similar purpose. As in Morrow and colleagues (1991), participants were encouraged to create mental models by asking them to try and understand the medication information, rather than simply memorize it.

Following the administration of the preliminary measures, the procedure was identical for each format (refer to the middle three lines in Figure 13 beginning with condition 1, condition 2, condition 3). The randomly assigned sequence (see Figure 12) determined the format and medication pairing that is represented by condition 1, condition 2, and condition 3 in the experimental procedure (see Figure 13), but the

procedure for each condition was identical. The following steps occurred for each of the three conditions (see the three middle rows in Figure 13).

1. **Condition Exposure.** Text and Text + Images Conditions were shown for two minutes. The Narration + Images conditions were all approximately two minutes. Materials were removed after the exposure time has elapsed.
2. **The Adapted Consumer Information Rating Form (CIRF).** Participants were then asked to complete the adapted CIRF. The following minor modifications were made to the adapted CIRF (Koo, Krass, & Aslani, 2007) to make it more appropriate for the current study:
  - a. CMI was replaced with medication information to be more explicit
  - b. Alternatives (i.e., hear, watch, images) were added to make the questions relevant for the Text + Images Conditions and Narration + Images conditions.
  - c. Participants were asked if they were familiar with the medication.
3. **Memory Task** (Appendix F). The investigator introduced the task by saying “I will now ask you questions about the medication you just learned about. Please do your best to remember as much as you can. Some of the questions are not applicable to all of the medications. If you think the question is not applicable, please tell me and we will skip it.” and then pose the following questions to participants:
  - i. What were the two names of the medication?
  - ii. Why would you be taking this medication? That is, what condition or conditions is the medication usually used to treat?

- iii. How long does it typically take for the medication to start working?
- iv. Where do you apply or administer this medication?
- v. How would you take this medication? That is, what are the instructions and steps?
- vi. How many times a day is this medication usually taken?
- vii. What should you do if you missed a dose of this medication?
- viii. What are the potential side effects of this medication?
- ix. Is there any other important information to remember about this medication?
- x. Is there anything else you remember about this medication?

\*Additional explanatory question: If someone didn't know anything about this taking this medication, what would you tell them?

The aforementioned sequence of three steps were repeated until participants were exposed to all three conditions (see Figure 13). After completion, participants indicated their perceptions of comprehensibility, utility, and design quality as well as ranked the three formats for overall preference (see Appendix G). Other open-ended questions in the semi-structured interview (see Appendix H) were used to investigate participant CMI perceptions and information needs.

### **7.4.3 Measures**

An overview of the measures used in the study can be found in Table 10, including the names of the measures, what they measured, and what research area they addressed.

Table 9

*List of Measures*

<b>Measure Name</b>	<b>Measurements</b>	<b>Research Area</b>
Demographic Questionnaire (Appendix E)	Age, gender, occupation, salary, computer experience	Provided a description of the sample characteristics
The Newest Vital Sign (NVS; Weiss et al., 2005)	Suspected likelihood of limited health literacy	Provided a description of the sample characteristics
The eHealth Literacy Scale (eHEALS; Norman & Skinner, 2006)	Consumers self-reported eHealth literacy skills	Provided a description of the sample characteristics
The adapted Consumer Information Rating Form (CIRF; Koo, et al., 2007)	Consumers perceptions of: Comprehensibility <ul style="list-style-type: none"> <li>• Read / Hear</li> <li>• Understand</li> <li>• Locate</li> <li>• Keep</li> </ul> Utility <ul style="list-style-type: none"> <li>• Benefits</li> <li>• Contraindications</li> <li>• Directions</li> <li>• Precautions</li> <li>• Adverse Effects</li> <li>• Storage</li> </ul> Design Quality <ul style="list-style-type: none"> <li>• Organization</li> <li>• Attractiveness</li> <li>• Print / Image Size</li> <li>• Tone</li> <li>• Helpfulness</li> <li>• Spacing</li> </ul>	Served as a distractor task to allow time for information to decay from memory and familiarized participants with the concepts of comprehensibility, utility, and design quality
Memory Task (Appendix F)	Memory for medication information (e.g., how many questions about the medication were answered correctly)	Assessed memory (i.e., memory)
Preference Scale (Appendix G)	Comprehensibility (single item) Utility (single item) Design Quality (single item) Overall preference	Assessed perceptions of comprehensibility, utility, design quality and over CMI format preference
Semi-Structured Interview (Appendix H)		Investigated CMI information needs and preferences

The following three measures were administered prior to beginning the experimental cycles (see Figure 13) to collect background information and descriptive statistics from the participants:

- a. A demographic questionnaire (see Appendix E)
- b. The Newest Vital Sign (NVS; Weiss et al., 2005)
- c. The eHealth Literacy Scale (eHEALS; Norman & Skinner, 2006)

These measures were selected to collect demographic as well as health literacy and eHealth literacy information about the participants, to provide a detailed description of the sample characteristics. The investigator selected the NVS (Weiss et al., 2005) as a health literacy measure, as this tool requires a more analytical reasoning to generate the correct responses to questions regarding health information than some of the alternative health literacy tools. The investigator used the eHEALS to describe participants' perceived eHealth literacy skills.

The adapted CIRF (Koo et al., 2007) was primarily used as a distractor task to prevent rehearsal of medication information by participants and allow time for information to decay from memory. The adapted CIRF (Koo et al., 2007) was also used to familiarize participants with the concepts of comprehensibility, utility, and design quality (for the items associated with these three subscales, refer to Table 10). Participants rated each of the three CMI formats immediately after they had seen each format. Participants' memory was measured using the number of correct items of information they generated for each format using the Memory Task (Appendix F). A perceptions and preference scale (Appendix G) was administered after participants had seen all three as more general (i.e., single-items) measure of comprehensibility, utility

and design quality. The last question of the preference scale asked participants to rank the three formats from favourite to least favourite.

Each semi-structured interview (Appendix H) began by asking participants to rationalize their overall rankings of the three CMI formats (i.e., the last question of the preference scale) and provide suggestions for further improving their favourite format. The remaining questions were used to gain insight into participants' experiences filling prescriptions, medication information needs and preferences (e.g., how and when CMI should be delivered).

#### **7.4.4 Analysis**

##### **7.4.4.1 CMI Memory**

The audio recordings from the study were transcribed in full. The method of assessing memory was adopted from Patel, Kushniruk, Yang, and Yale (2000). Specifically, participants' responses to the free recall memory questions (Appendix F) were scored against the contents of CMI. That is, the CMI was divided into content items (i.e., individual items of information) and marks were awarded for each content item correctly generated by the participant. For an example of how memory marks were awarded for Cromolyn, see Figure 14. Points were only awarded once for synonyms (e.g., topical or applied to the skin) or information that was repeated in the CMI (e.g., prescription strength).

**Brand Name:** CROMOLYN OP DRP 2%

**Chemical Name:** SODIUM CROMOGLYCATE 2%

**Common uses**

This medication is typically used for allergic conjunctivitis (inflammation of the clear covering of the front of the eye, due to allergies). It requires several days to take effect.

**How to use this medication**

This medication is for the eye. To use:

- wash your hands as well as the skin surrounding the affected eye;
- shake the container;
- gently pull down the lower lid of the affected eye;
- apply 1 drop of the medication;
- close the eye for 2 to 3 minutes, while gently pressing on the inner corner of the eye.

To avoid contaminating the medication, do not let the tip of the applicator touch your fingers or any part of your eye. Close the container tightly after each use.

This medication is typically used 4 times a day. However, your doctor or pharmacist may have suggested a different schedule that is more appropriate for you. Use it regularly and continuously to maintain its beneficial effects.

If you forget a dose, apply it as soon as you remember – unless it is almost time for your next dose. In that case, skip the missed one. Do not apply more to try to catch up.

**Possible side effects**

In addition to its desired action, this medication may cause some side effects, notably:

- when it is used, it may cause local irritation
- when it is used, it may cause a temporary burning sensation
- it may cause a stinging sensation.

*Figure 14.* Memory Marking Scheme for Cromolyn.

*Notes.* Highlighting alternated to ease discrimination between each content item. Written content was developed by a leading Canadian pharmacy.

Omnibus Analysis of Variance (i.e., ANOVA) analyses were conducted on participants' memory scores to investigate whether CMI format influenced memory. When the omnibus tests were significant, pairwise comparisons using a Bonferonni correction (i.e.,  $\alpha = 0.05 / 3 = 0.017$ ) were used to identify significant differences existed. A between groups ANOVA was used to explore potential memory differences in the first condition, to avoid any potential influence of practice effects. A repeated measures ANOVA was used to determine whether memory was affected by CMI format across all three conditions.

#### 7.4.4.2 CMI Preferences

The adapted CIRF (Koo et al., 2007) responses were not analyzed for two reasons. First, this measure served as a distractor task and as such was administered between the stimulus exposure and the free memory task. Unlike Morrow and colleagues (2005) who had participants cancel each letter e in a written passage as their distractor task, this study used the adapted CIRF (Koo et al., 2008) as it provided a more naturalistic distractor task. Thus, participants were likely trying to maintain information from the stimulus in their working memory while completing the adapted CIRF which could affect their responses and performance trade-offs may have occurred. Second, true perceptions may have differed from ratings after participants had seen all three formats, because comparisons could be drawn. Thus, the perceptions and preference scale (Appendix G) was considered more prudent measure and analyzed as it provided ratings based on a more informed comparison of the three formats.

The perceptions and preference scale (Appendix G) collected ratings (i.e., ordinal data) on participants perceptions of comprehensibility, utility, design quality. Participants rated each of the three CMI formats on each of the three constructs (i.e., comprehensibility, utility, and design quality). Thus, the repeated measures design and ordinal nature of the data warranted using the non-parametric Friedman tests of difference among repeated measures, sometimes referred to as Friedman ANOVAs to explore potential differences in perceptions. As with above, where the omnibus tests were significant, Wilcoxon signed-ranks tests (i.e., pairwise comparisons) using a Bonferonni correction (i.e.,  $\alpha < 0.05 / 3 = 0.017$ ) were used to explore where differences existed between the groups. Similarly, to explore the overall preference rankings, a

Wilcoxon signed-ranks test (i.e., pairwise comparisons) using a Bonferonni correction (i.e.,  $\alpha < 0.05 / 3 = 0.017$ ) was used to investigate whether the mean ranks of each CMI format differed.

#### 7.4.4.3 Interviews

The qualitative data from the explanations of participants CMI preferences as well as the semi-structured interviews were analyzed using both directed and conventional content analysis (as described Hsieh & Shannon, 2005). Directed content analysis, a deductive approach, is most suitable for developing more comprehensive descriptions of partially explained phenomenon (Hsieh & Shannon, 2005). In this study, subscales and question items from the adapted CIRF (Koo et al., 2007) were used as a starting point to create themes and subthemes and serve as predetermined codes that guided the analysis of the transcripts.

The verbal rationale about favourite CMI format was used to complement their responses on the preference scale and determine why participants favoured one or more formats. Here the transcripts were analyzed to identify and code for instances of the major themes and subthemes established from the adapted CIRF (Koo et al., 2007). A hierarchical structure was used to analyse the preference portion of the data whereby, the three formats were used as the highest level of categories, followed by advantages and disadvantages, then the themes and subthemes. For example, the following quote by participant 13 “where text; that's always going to be there, and it's always going to have the exact information you need right there, and you can just spot it right away” was coded Text > Advantage > Comprehensibility > Easy to locate information.

Conventional content analysis (as described by Hsieh & Shannon, 2005) is an inductive approach and was used in complement with directed content analysis to identify emergent subthemes and themes as necessary. Conventional content analysis was used to categorize data that fell beyond the scope of the predetermined codes by creating additional subthemes and themes as necessary. Here, new themes and subthemes that emerged from analyzing the transcripts were identified and coded. For example, the following quote by participant 21, referring to the Narration + Images format, was not suitable for a predetermined theme or subtheme “because it's in the video, you can't keep it with you all the time. I guess if you had a phone you could, but for most people, having a piece of paper would be easier to have”. This quote illustrates how the CMI medium (i.e., digital vs. hardcopy), an aspect of provision (i.e., how CMI is obtained, stored, and accessed), is considered a disadvantage for the Narration + Images format. That is, the main theme of provision was coded for because the participant discussed a potential barrier impeding access to the CMI, if it were delivered digitally (i.e., the subtheme of medium). Thus, this quotation was coded as Medium < Provision < Disadvantage < Narration + Images.

After all of the data was coded, some of the predetermined subthemes from the adapted CIRF (Koo et al., 2007) were reallocated to different themes, as deemed appropriate. Coded segments were tabulated and used to generate percentages of the total number of participants reporting themes and subthemes to illustrate agreement or pervasiveness of topics.

## Chapter 8: Results

### 8.1 Participant Demographics

Participants ( $N = 36$ ) were on average 23.6 years old, ( $SD = 3.8$ , range = 18 – 35). With respect to ethnicity, most of the sample identified as Caucasian (23, 63.9%). Most participants in this study were female (26, 72.2%). Many participants also reported having part-time employment (14, 38.9%). With respect to socioeconomic status, most of the participants reported coming from or being middle class (30, 83.3%). Most of the participants first language was English (31, 86.1%). Table 11 contains a comprehensive summary of participants' demographic information.

Table 10

#### *Demographic Characteristics of Study Sample*

Descriptor	n	%
Gender		
Female	26	72.2
Male	10	27.8
Ethnicity		
Caucasian	23	63.9
Chinese	6	16.7
Japanese	1	2.8
South Asian	1	2.8
Southeast Asian	1	2.8
West Asian	1	2.8
Other ethnicity	1	2.8
Multiple (2 or more) ethnicities	3	8.3
Employment		
Full-time	4	11.1
Part-time	14	38.9
Socioeconomic Status		
Working class	30	83.3
Middle class	4	11.1
Upper class	2	5.6
First Language		
English	31	86.1

<b>Descriptor</b>	<b>n</b>	<b>%</b>
Other	5	13.9
<b>Level of Comfort Using Computers</b>		
Very comfortable	30	83.3
Somewhat comfortable	5	13.8
Not comfortable	1	2.8
<b>Reading frequency</b>		
Everyday	17	47.2
Several days a week	9	25.0
A few days a week	8	22.2
Once a week	2	5.6

All the participants in this study were students. Precisely, half of the participants' highest level of education completed was high school (18, 50%). The majority of participants were currently enrolled in school full-time (30, 83.3%). Participants were students of various faculties, but the three most common faculties were Science (9, 25.0%), Social Sciences (8, 22.2%), and Human and Social Development (7, 19.4%). More details about participants' educational history and current status can be found in Table 12.

Table 11

#### *Educational Characteristics of the Sample*

<b>Descriptor</b>	<b>n</b>	<b>%</b>
<b>Highest Completed Education Level</b>		
High School	18	50.0
Undergraduate	13	36.1
Graduate	4	11.1
Other	1	2.8
<b>Current Enrollment Status</b>		
Full-time	30	83.3
Part-time	3	8.3
Co-op	3	8.3
<b>Faculty</b>		
Science	9	25.0
Social Sciences	8	22.2
Human and Social Development	7	19.4
Education	4	11.1

<b>Descriptor</b>	<b>n</b>	<b>%</b>
Business	2	5.6
Engineering	2	5.6
Fine Arts	2	5.6
Law	1	2.8
Division of Medical Sciences	1	2.8

Participants reported using several different resources for medication information. The most commonly reported medication resource were physicians (27, 75%). An equal number of participants reported consulting pharmacists (16, 44.4%) and electronic resources (16, 44.4%) for information about medications. Many participants (16, 44.4%) reported not taking any prescription medications daily. However, over a third of participants (13, 36.1%) reported taking one medication daily. Nearly half of the participants (17, 47.2%) reported following medication instructions completely. See Table 13 for comprehensive details about participants use of medication resources, medications, and general reports of adherence.

Table 12

*Medication Related Characteristics of the Sample*

<b>Descriptor</b>	<b>n</b>	<b>%</b>
<b>Medication Information Resources Consulted*</b>		
Physician	27	75.0
Pharmacist	16	44.4
Electronic resources (e.g., Internet)	16	44.4
Family member	9	25.0
Other	1	2.8
<b>Number of Prescription Medications Taken Daily</b>		
None	16	44.4
One	13	36.1
Two	6	16.7
Three	1	2.8
<b>Follow Medication Instructions</b>		
Completely	17	47.2
Mostly	9	25.0

Descriptor	n	%
Somewhat	8	22.2

*Note: Sum exceeds 100% because participants could report using multiple medication resources.*

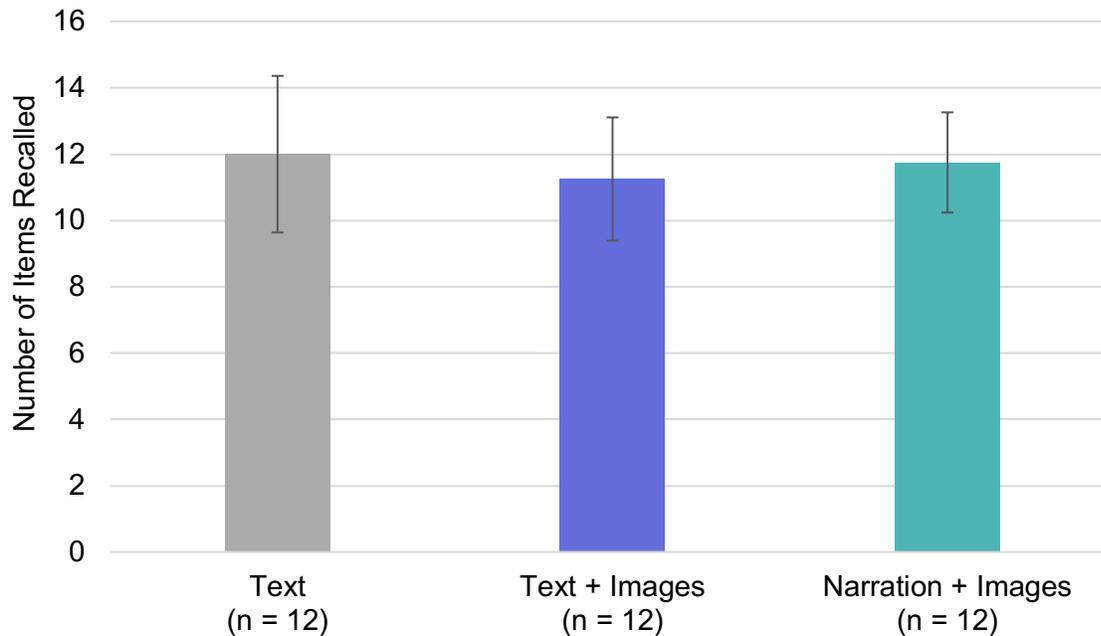
## 8.2 Health and eHealth Literacy Scores

This study used Weiss and colleagues' (2005) framework determine the likelihood that participants had limited health literacy based on participants' scores on the NVS. Most participants (30, 83%) had a very low likelihood of having limited health. Six participants (17%) were classified as possibly having limited health literacy and no participants had a high likelihood of limited health literacy. Monkman and colleagues (2017) developed a framework to classify self-perceptions of eHealth literacy using scores on the eHEALS (Norman & Skinner, 2006). The majority of participants reported moderate (21, 58%) or high (8, 22%) self-perceptions of eHealth literacy. However, seven participants (19%) reported low self-perceptions of eHealth literacy (Monkman et al., 2017). Interestingly, Monkman and colleagues (2017) found no correlation between participants' scores on the NVS (Weiss et al., 2005) and the eHEALS (Norman & Skinner, 2006), questioning the relationship between health literacy and eHealth literacy.

## 8.3 Effects of Multimedia on Memory for Consumer Medication Information (CMI)

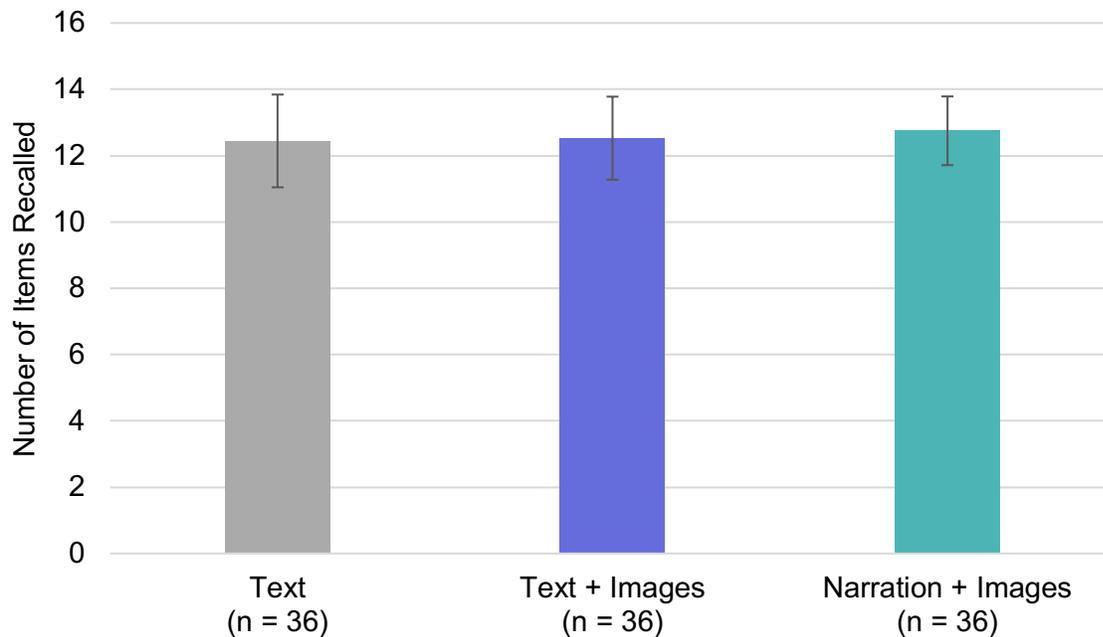
Omnibus analyses on participants' scores in the free recall task were conducted to explore whether CMI format influenced memory. Participants' memory for CMI in the Text, Text + Images, and Narration + Images formats was assessed in two ways. First, to negate any practice effects (e.g., studying focused on answers specific to recall questions) participants' memory in the only the first condition was examined. A one-way, between-subjects ANOVA yielded no indication of CMI format affecting memory,

$F(2, 33) = 0.19, p = 0.830$  (see *Figure 15*). Mean number of items remembered in the free recall task were 12 for the Text format, 11.25 for the Text + Images format, and 11.75 for the Narration + Images format.



*Figure 15.* Number of Medication Items Remembered in the First Condition as a Function of Consumer Medication Information Format (error bars represent 95% confidence intervals).

Second, to minimize the effect of individual differences (e.g., some participants having better memories) participants' memory in all three conditions was compared. A one-way, repeated-measures ANOVA determined there was not a significant effect of CMI format on memory,  $F(2, 70) = 0.1, p = 0.901$  (see *Figure 16*). Thus, there was no evidence to suggest CMI format affected memory in either the first condition or in the entire experiment. Mean number of items remembered in the free recall task were 12.44 for the Text format, 12.53 for the Text + Images format, and 12.75 for the Narration + Images format.



*Figure 16.* Number of Medication Items Remembered as a Function of Consumer Medication Information Format (error bars represent 95% confidence intervals).

In summary, there was no evidence to support either the multimedia principle or the modality principle. That is, participants remembered approximately the same amount of information regardless of whether the CMI was presented as Text, Text + Image, or Narration + Images.

#### **8.4 Perceptions and Preference of Multimedia Consumer Medication Information (CMI)**

The perceptions and preference scale (Appendix G) administered after participants were exposed to all three formats was used to compare perceptions of the CMI. Given the ordinal nature of the data, a series of non-parametric Friedman tests of difference among repeated measures were conducted to investigate whether participants rated CMI formats differently in terms of comprehensibility, utility, design quality, and overall

preference. Where Friedman tests were significant, pairwise Wilcoxon signed-ranks tests were used for pairwise comparisons.

#### 8.4.1 Comprehensibility Ratings

A Friedman test of difference comparing participants' perceptions of the comprehensibility of the three CMI formats was significant,  $\chi^2(2) = 26.5$ ,  $p < .001$ . Post hoc analysis with Wilcoxon signed-ranks tests were conducted with a Bonferroni correction applied, resulting in a significance level set at  $< 0.017$ . The median and interquartile range (IQR) were used as measures of central tendency because the scale is ordinal (i.e., non-parametric). Median (IQR) perceived comprehensibility of the Text, Text + Images, and Narration + Images formats were 3 (2 to 4), 4 (4 to 5), and 4 (3 to 4) respectively (see Figure 17). The Text + Images format was perceived as significantly more comprehensible than both the Text format ( $Z = -4.27$ ,  $p < .001$ ) and the Narration + Images format ( $Z = -3.12$ ,  $p = .002$ ). Additionally, participants perceived the Narration + Images format as significantly more comprehensible than the Text format ( $Z = -2.61$ ,  $p = .009$ ).

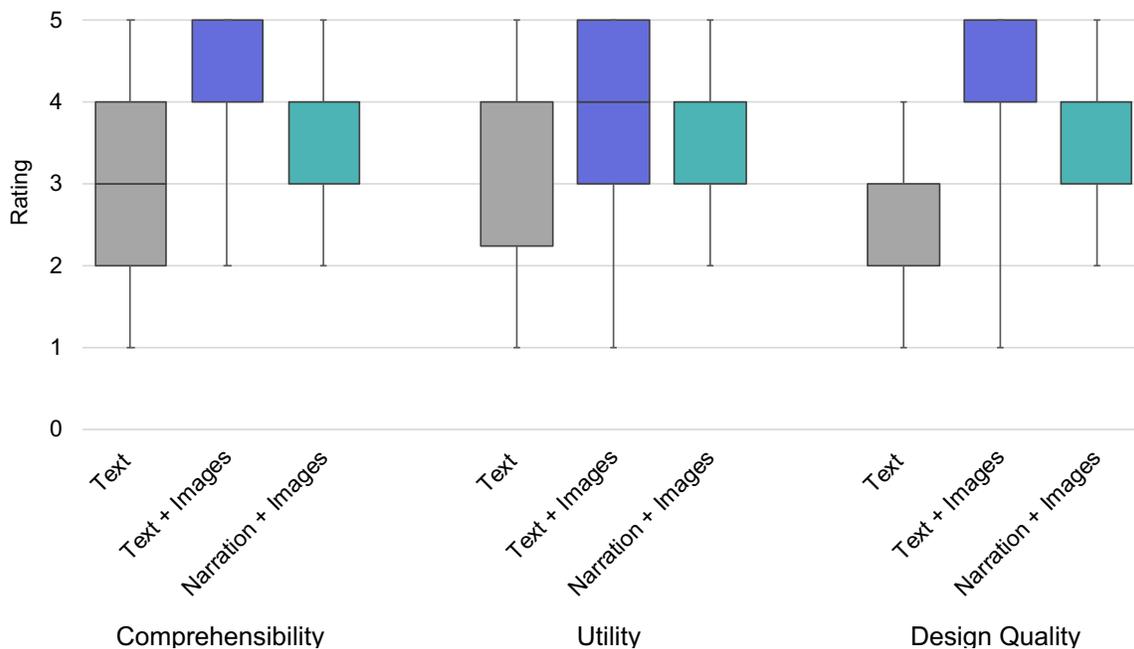
#### 8.4.2 Utility Ratings

Next, participants' perceptions of the utility of the three CMI formats were found to be significantly different using Friedman test of difference,  $\chi^2(2) = 8.21$ ,  $p < .016$ . The median (IQR) perceived utility of the formats were 4 (2.25 to 4) for Text, 4 (3 to 5) for Text + Images and 4 (3 to 4) for Narration + Images (see Figure 17). Despite the significant Friedman test of difference, the post hoc analysis with Wilcoxon signed-ranks tests using a Bonferroni correction setting the significance threshold at  $< 0.017$ , yielded

no significant differences amongst the perceptions of utility between the CMI format pairwise comparisons.

### 8.4.3 Design Quality Ratings

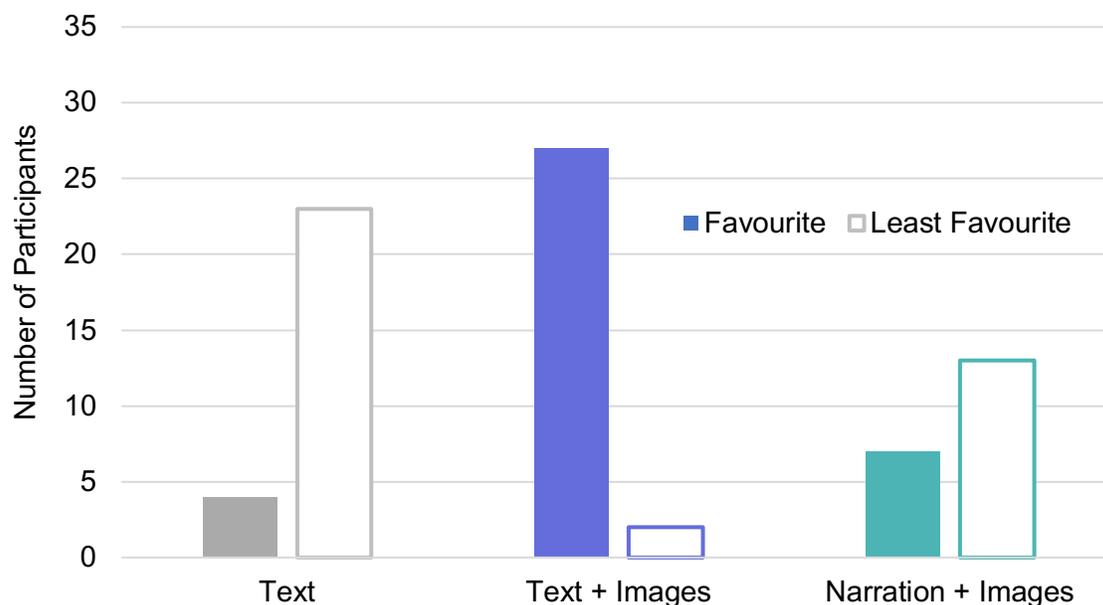
A Friedman test of difference comparing participants' perceptions of the utility of the three CMI formats was significant,  $\chi^2(2) = 35.69, p < .001$ . Post hoc analysis with Wilcoxon signed-ranks tests were conducted with a Bonferroni correction applied, resulting in a significance level set at  $< 0.017$ . Median (IQR) perceived design quality of the Text, Text + Images formats were 2 (2 to 3), 4 (4 to 5), and 4 (3 to 4) respectively (see Figure 17). A similar pattern of results to the comprehensibility findings was found for perceptions of design quality. That is, the Text + Images format was perceived as having significantly higher design quality than both the Text format ( $Z = -4.53, p < .001$ ) and the Narration + Images format ( $Z = -2.53, p = .011$ ). Participants also perceived the Narration + Images format as having significantly higher design quality than the Text format ( $Z = -4.50, p < .001$ ).



*Figure 17.* Boxplots of Depicting the Distribution of Comprehensibility, Utility, and Design Quality Perception Scores as a Function of Consumer Medication Information (CMI) Format

#### **8.4.4 Overall Preference**

To explore participants' overall preference, participants ranked the three CMI formats from their most to least favourite, no ties were possible. The majority of participants selected the Text + Images format as their favourite (27, 75.0%) and the Text format as their least favourite (23, 63.8%; see Figure 18). A Friedman test of difference comparing participants' rankings of the three CMI formats was significant,  $\chi^2(2) = 26.00, p < .001$ . To account for multiple comparisons, a Bonferroni correction was applied to the Wilcoxon signed-ranks tests, setting the threshold of significance to  $< 0.017$ . Median (IQR) overall perception of the Text format was 1 (1 to 2), Text + Images format was 3 (2 to 3), and Narration + Images format was 2 (1 to 2). As in the comparisons of the CMI formats based on comprehensibility and design quality, the Text + Images format was preferred overall to both the Text format ( $Z = -4.20, p < .001$ ) and the Narration + Images format ( $Z = -3.72, p < .001$ ). Additionally, participants preferred the Narration + Images to the Text format ( $Z = -1.57, p = .116$ ).



*Figure 18.* Frequency of Participants' Favourite and Least Favourite CMI Formats

In summary, despite the lack of evidence to support any differences in memorability between the CMI formats, participants did consider the Text + Images format the easiest to comprehend and the highest design quality. Further, participants perceived the Narration + Images format as both easier to comprehend and better designed than the Text format. However, with respect to the utility of the information, no significant differences between in perceptions were found among the three CMI formats were found. Finally, participants were most likely to select Text + Images as their favourite CMI format overall, followed by the Narration + Images, and their least favourite was the Text format.

### **8.5 Detailed Perceptions of Consumer Medication Information (CMI)**

To glean insight into reported format preferences, participants were asked to explain the rationale behind their choices of favourite and least favourite CMI formats.

Additionally, participants were able to report comments on each of the formats after viewing each format. The limited written comments were integrated into the participants' respective interview transcripts. The transcripts were thoroughly analyzed and MAXQDA (qualitative data analysis software) was used to code or label concepts identified in the interviews. Each of the three CMI formats were analyzed independently for concepts revealed in participants' comments. These concepts were categorized as being either advantages or disadvantages (i.e., whether a participant was reflecting on a strength or weakness). Subsequently, the individual conceptual codes were aggregated into themes within the existing categories.

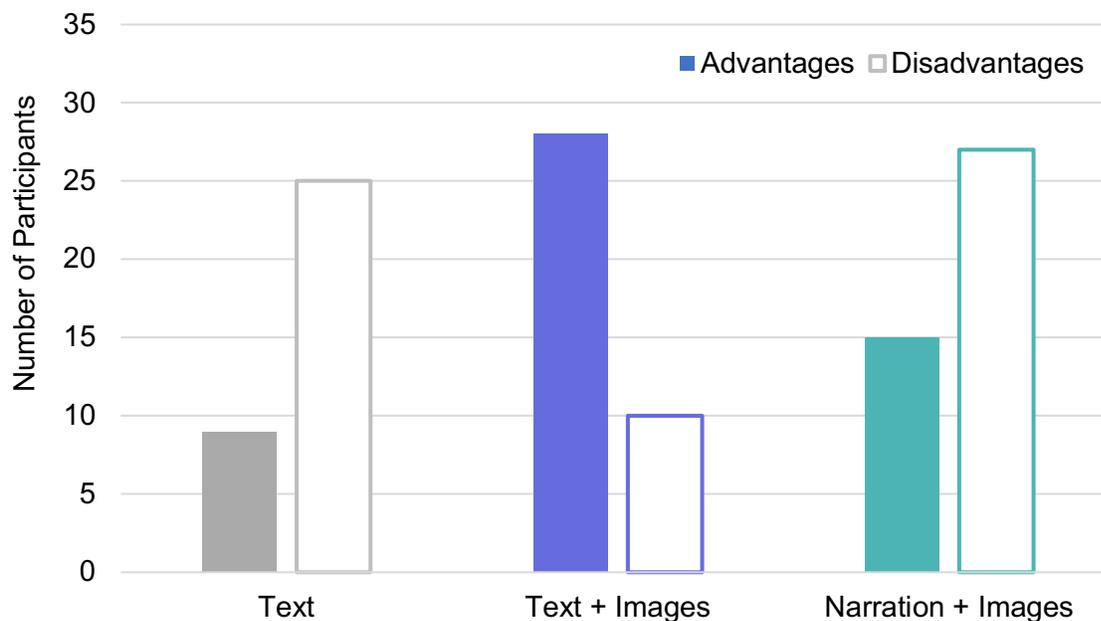
### **8.5.1 Advantages and Disadvantages of the Three CMI Formats**

When interviewed, participants described how various concepts were advantages and disadvantages for each of the four themes. Unsurprisingly, participants identified a variety of strengths and weaknesses of each of the three CMI formats. To begin this analysis, a holistic perspective will be presented. First, the number of participants who identified at least one advantage or disadvantage of each CMI format was explored (see *Figure 19*).

Although the Text format was generally the least liked of the formats, nine participants (25.0%) discussed perceived advantages of this format (see *Figure 19*). In contrast, a total of twenty-five (69.4%) participants identified disadvantages of the Text format in the interviews (see *Figure 19*). Most of the participants selected the Text + Images format as their favourite of the three CMI formats. Thus, unsurprisingly, twenty-eight participants (77.8%) identified perceived benefits of the Text + Images format, yet ten participants (27.8%) discussed disadvantages of the Text + Images format (see

*Figure 19*). Fifteen participants (41.7%) described strengths of the Narration + Images, whereas 27 participants (75.0%) identified weaknesses of this format (see *Figure 19*). Thus, the pattern of results that emerged from the participants who discussed advantages and disadvantages of each format closely resembled their preferences of favourite and least favourite CMI formats. That is, the number of participants who identified advantages for the Text + Images format exceeded those who reported disadvantages for this format. However, this was reversed for both the Text and Narration + Images formats whereby the number of participants who identified disadvantages of these formats exceeded those who identified advantages. Participants were free to discuss aspects of any of the three formats, regardless of their preference selections, which accounts for why the number of comments in each category often exceeds the number who identified a particular format as his or her most or least favourite. Although participants were encouraged to discuss the rationale behind their favourite and least selections, clearly some participants identified advantages and

disadvantages of the intermediate format as well.



*Figure 19.* Frequency of Participants Who Reported Advantages and Disadvantages of Each CMI Format

The total number of participants who generated strengths and weaknesses of each format paralleled the findings from the previous preference ratings. However, this high-level perspective does not provide insight into what motivated participant preferences. Thus, in an attempt to understand what compelled participants to make their selections, it was imperative to explore the data at a more detailed level. Specifically, the subthemes identified as advantages and disadvantages were combined into more meaningful, overarching themes.

### 8.5.2 One Meta Theme, Four Major Themes and Component Subthemes

One meta theme and four major themes were coded in the analysis of participants' verbal rationale of their CMI format preferences. The meta theme and the three of the

themes identified were based on Koo and colleagues' (2007) work. Specifically, the adapted CIRF (Koo et al., 2007) measures consumers' CMI use (i.e., the meta theme) as well as their perceptions of comprehensibility, utility, design quality (i.e., three of the four major themes). Provision, the remaining theme, originated from previous work by Koo, Krass, and Aslani (2002). The meta theme and the four major themes were reflected in participants' interview comments. This section will define each of the four major themes and their associated subthemes (for a summary refer to Table 14) and the meta theme.

Table 13

*Summary of the Four Major Themes and Subthemes of Consumers' Perceptions of CMI*

<b>Theme</b>	<b>Definition</b>	<b>Source</b>	<b>Subthemes</b>
Provision	Factors relating to how and when consumers obtain CMI and how they store CMI.	Reallocated from Design Quality in the adapted CIRF (Koo et al., 2007)	<ul style="list-style-type: none"> <li>• Ease of keeping CMI</li> </ul>
		Interviews	<ul style="list-style-type: none"> <li>• CMI medium (e.g., digital, hardcopy)</li> <li>• Method of digital distribution (e.g., email, mobile application, website)</li> <li>• Push or pull communication type</li> </ul>
		Koo, Krass, and Aslani (2002)	<ul style="list-style-type: none"> <li>• Timing of when CMI is provided (e.g., with the prescriber, when the prescription is dropped-off or picked-up)</li> </ul>
Comprehensibility	Factors contributing to how well consumers use and understand CMI.	Adapted CIRF (Koo et al., 2007)	<ul style="list-style-type: none"> <li>• Ease of reading CMI</li> <li>• Ease of understanding CMI</li> <li>• Ease of remembering CMI</li> <li>• Ease of locating information in CMI</li> </ul>

Theme	Definition	Source	Subthemes
		Interviews	<ul style="list-style-type: none"> <li>• Attention capturing capability of CMI</li> <li>• Ease of processing CMI</li> <li>• Ease of scanning CMI</li> <li>• Ease of reviewing CMI</li> <li>• Extent of multimedia use (e.g., images, narration)</li> <li>• Use of plain language principles</li> </ul>
Utility	Factors contributing to how useful consumers perceive the CMI content.	Adapted CIRF (Koo et al., 2007)	<ul style="list-style-type: none"> <li>• Included and excluded medication topics</li> <li>• Usefulness of information</li> <li>• Amount of information (too little, too much)</li> </ul>
		Interviews	<ul style="list-style-type: none"> <li>• Use of a CMI summary</li> </ul>
		Reallocated from Design Quality in the adapted CIRF (Koo et al., 2007)	<ul style="list-style-type: none"> <li>• Tone of the CMI (positive, negative)</li> <li>• Helpfulness of CMI</li> <li>• Information bias</li> </ul>
		Interviews	<ul style="list-style-type: none"> <li>• Familiarity with the format</li> <li>• Information clarity</li> <li>• Information tailoring</li> </ul>
Design Quality	Factors contributing to how aesthetically appealing consumers perceive the CMI.	Adapted CIRF (Koo et al., 2007)	<ul style="list-style-type: none"> <li>• Information organization</li> <li>• CMI attractiveness</li> <li>• Legibility and size of print and images</li> <li>• Spacing between lines and images</li> </ul>
		Interviews	<ul style="list-style-type: none"> <li>• CMI layout</li> <li>• Holistic impression</li> </ul>

*Note. There were three sources of subthemes: interviews, research by Koo and colleagues (2002), and the adapted CIRF (Koo et al., 2007). As indicated in the Source column, some subthemes from the adapted CIRF were reallocated to more suitable themes.*

#### 8.5.2.1 Provision

Provision, as defined here, is comprised of factors related to how and when CMI is obtained, stored, and accessed. Koo and colleagues (2002) posited that the provision of CMI could increase or decrease likelihood depending on whether or not it was provided

at the appropriate time. Thus, both the theme of provision and the subtheme of timing originated from Koo and colleagues' (2002) work.

In addition to timing and ease of keeping CMI, the interviews generated four other key provision subthemes. Specifically, participants discussed how the medium (i.e., paper vs. digital), method (e.g., email, mobile application), and type of communication, as well as the timing CMI was offered to them could affect their perceptions and use of CMI. The Text format was presented as a printed hardcopy, whereas the Text + Images and Narration + Images formats were presented digitally on the computer. Many participants envisioned how the method of digital delivery (e.g., email, website, mobile application) would impact how they received and/or accessed digital CMI. Push and pull communication are the two types of sharing information. Push communication refers to someone acting as the sender (e.g., pharmacist, prescriber) whose sends out the information to specific recipients (Schwalbe, 2016). Emails, digital alerts, and voicemails examples of push communications. In contrast, pull communication requires recipients to seek out and retrieve information of their own volition (Schwalbe, 2016). Examples of pull communication include websites, bulletin boards, e-learning resources. Participants also described advantages and disadvantages of receiving CMI at different times during the prescription process (e.g., with the prescriber, when the prescription is dropped off, when the prescription is picked up).

#### 8.5.2.2 Comprehensibility

Fundamentally, CMI comprehensibility is the ability for consumers to use and understand CMI. Koo and colleagues (2007) used how easy or hard CMI is to read, understand, remember, locate and keep information, as indices of comprehensibility in

the adapted CIRF. However, it is posited here that keeping CMI has limited relevance to how easy that material is to understand. Further, the factor loading of keeping CMI (0.42) was the lowest of the comprehensibility scale, suggesting it may belong in a different theme (Koo et al., 2007). Instead, the concept of keeping CMI was considered more appropriate in a theme encompassing how consumers obtain and store CMI, namely provision (refer to Provision section).

In addition to subthemes related to comprehensibility from the adapted CIRF (Koo et al., 2007), other subthemes were identified in the interviews that contributed to the comprehensibility of CMI. For example, participants reported varying levels of effort required to attend to, scan, and process the stimuli. Opinions of CMI were also influenced by the ability to review the material as well as its pace. Finally, participants discussed how different modes (e.g., text, images, narration) influenced their perceptions of comprehensibility independently and in combination in the multimedia formats (i.e., the Text + Images and Narration + Images formats).

### 8.5.2.3 Utility

Comprehensibility emphasizes use and understanding, whereas utility is concerned with the CMI content. There are two important aspects of CMI utility: the medication information topics and how the information is conveyed. Koo and colleagues (2007) proposed six medication topics important for safe and effective medication use (i.e., benefits, contraindications, directions, precautions, adverse effects, and storage). However, interviews in this study revealed that some participants want additional medication topics (i.e., cost, interactions, alternatives, how it works, what if it does not work) included in CMI.

The adapted CIRF (Koo et al., 2007) measures the utility of CMI as a function the perceived appropriateness of both the amount and usefulness of information. These facets of utility overlapped with participants reports about CMI in this study. Further, related to the theme of the amount of CMI information, several participants expressed wanting a brief summary of the CMI. The subthemes of tone (i.e., encouraging vs. alarming), helpfulness, and bias (i.e., unbiased vs. biased) also originated from the adapted CIRF (Koo et al., 2007) whereas the subthemes of clarity and tailoring the content were identified in the interviews. Interestingly, there was some evidence that CMI format affected perceptions of the amount and usefulness of information which will be discussed.

#### 8.5.2.4 Design Quality

Koo and colleagues (2007) measured design quality of CMI with assessments of the following factors: organization, attractiveness, print size, and spacing between lines. Given that images were included in the CMI stimuli in this study, this theme was complemented with image size and spacing between images. Further, layout and holistic impression were two subthemes that emerged from the interviews that were allocated to the design quality theme.

#### 8.5.2.5 CMI Use – The Meta Theme

CMI use, as defined here is the set of factors (i.e., the four major themes) affecting both whether or not consumers as intend to use CMI or actually used CMI. Intention to use CMI describes whether or not consumers report that if given the CMI they would use it whereas actual use is whether or not the CMI was used. Thus, intention to use CMI can be used as a proxy of actual use. However, it is not possible to determine how

strongly correlated CMI use intentions and actual use are. The adapted CIRF measured how likely consumers' felt they would read, use, and keep CMI that they rated, as indices of use intentions. The stimuli in this study presented participants with formats of CMI that are not currently available (i.e., Text + Images, Narration + Images). Further, other potential ways of providing CMI were explored. Thus, in these hypothetical scenarios, participants intentions to use the alternate formats or CMI received in a non-traditional way are the closest measure to use that can be achieved. In contrast, participants real life experiences with CMI can be used to reveal what motivates and deters them from actually using CMI. Evidence from this study suggests that providing CMI the four major themes all have the potential to influence whether or not consumers intend to use the stimuli CMI or actually used CMI they received from a pharmacy.

#### **8.6 Evidence of Thematic Advantages and Disadvantages of the Three CMI Formats**

In an effort to understand why participants preferred the Text + Images format over the Text and Narration + Images formats, the strengths and weaknesses of each format were collapsed into provision, comprehensibility, utility, and design quality themes. This analysis collapsed individual comments such that participants were counted once per advantage or disadvantage of each theme. That is, each participant was only counted once per theme regardless of how many individual comments he or she generated in that particular theme. For example, if a participant mentioned four utility advantages and only one disadvantage for the Text format, she would be counted once in the advantages and once in the disadvantages. This section will describe participant perceptions of advantages and disadvantages for each CMI format categorized by the four major themes: provision, comprehensibility, utility, and design quality.

### 8.6.1 Advantages of the CMI Text Format

The most participants made comments about the advantages of the Text format that were coded in the comprehensibility theme, followed by provision, design quality and utility themes (see *Figure 20*). Six (16.7%) participants generated comments that supported the comprehensibility of the Text format. Participants noted that it the text format was easy to scan, locate information, and review (i.e., re-read). The comprehensibility of the Text format is illustrated by participant 3 who reported “I like being able to go back and re-read things that I didn't understand or don't remember”.

Four participants (11.1%) discussed that the Text format would be easy to keep, which was coded as a subtheme of provision. For example, participant 32 described “I feel like it'd be easier to refer back to in the future if I, for some reason, forgot how to take the medication or had a side effect from it.” Further, one participant made an argument that the text format was the most portable, which was a provision benefit. Specifically, participant 25 reported:

“I found for the video and the text images on the computer that I was like if I was taking this medication, I would want to have it right there or somewhere that I could actually touch it and have it with me. I'd probably take the text one into the bathroom with me and read the instructions before I did it.”

With respect to the utility of the CMI in Text format, two (5.6%) participants made statements corresponding to subthemes such as having useful and clear information and the familiarity of the format. For example, the Text format was described by participant 32 as “clear to understand. It didn't have any graphic images on it”.

Two participants (5.6%) discussed advantages of the Text format from the perspective of design quality. For example, participant 19 commented on the simplicity of the Text format: “It’s just easiest for me. It’s not a sensory overload.”

In summary, the most participants described advantages of the Text format that were coded in the themes of comprehensibility and provision, but there were also comments coded in the utility and design quality themes (see Figure 20). Overall, despite some participants identifying strengths of the Text format, more participants discussed its weaknesses.

### **8.6.2 Disadvantages of the CMI Text Format**

The two most prominent themes that were identified when participants discussed weaknesses of the Text format were comprehensibility and design quality (see Figure 20). However, participants also noted disadvantages in terms of the utility of the Text format. No weaknesses of the Text format were categorized as provision issues.

Subthemes of the design quality theme were described by 17 participants (47.2%) when discussing shortcomings of the Text format. The most frequently coded design quality subthemes described as disadvantages by participants were the Text format’s attractiveness, layout, and organization. Many participants noted that the Text format was not attractive by using terms such as plain, boring, ugly, bland. The layout was also critiqued. For example, participant 1 noted that “the text is chunked together in sections, but it still looks like one big block of everything.” Further, one participant described that the disorganization of the Text format made it more challenging to read (a comprehensibility subtheme). Specifically, regarding the Text format participant 26

claimed “it was difficult to read, and it seemed like there was multiple places that certain important information was-- like it wasn't organized very strategically”.

Negative aspects of the Text format in terms of comprehensibility were described by 17 participants (47.2%). Specifically, participants noted that the Text format was harder to read, process, remember, and understand. For example, participant 10 noted “it requires kind of a lot of mental commitment to go through each line and understand each word”. Similarly, participant 22 asserted that the Text format:

“was really boring. When I was reading it, it felt like I was reading a textbook or something. So, I actually had to read it a few times because I just kept zoning out and I was like, ‘Oh, right. No, I've got to pay attention [laughter].’ ”

Interestingly, in contrast to those that identified the ease of scanning as a benefit of the Text format, several participants asserted that the ease of scanning was, in fact, a drawback for medication information. When documents are too easy to scan, and participants skim rather than process the information at a deeper level, important information could be missed. That is, participants expressed having to exert more concerted effort to maintain focus and process the information. This notion is illustrated by participant 7 who said, “it's just not appealing, so you sort of look at it and you're like, ‘I don't like this.’ So, you just want to, I think, scan over it, which is not always good when it comes to medications.” Thus, participants most common complaints about the comprehensibility of the Text format were related to subthemes of scanning, processing, understanding and remembering

In addition to the Text format having shortcomings in terms of design quality and comprehensibility, three participants (8.3%) also made comments about the utility of the

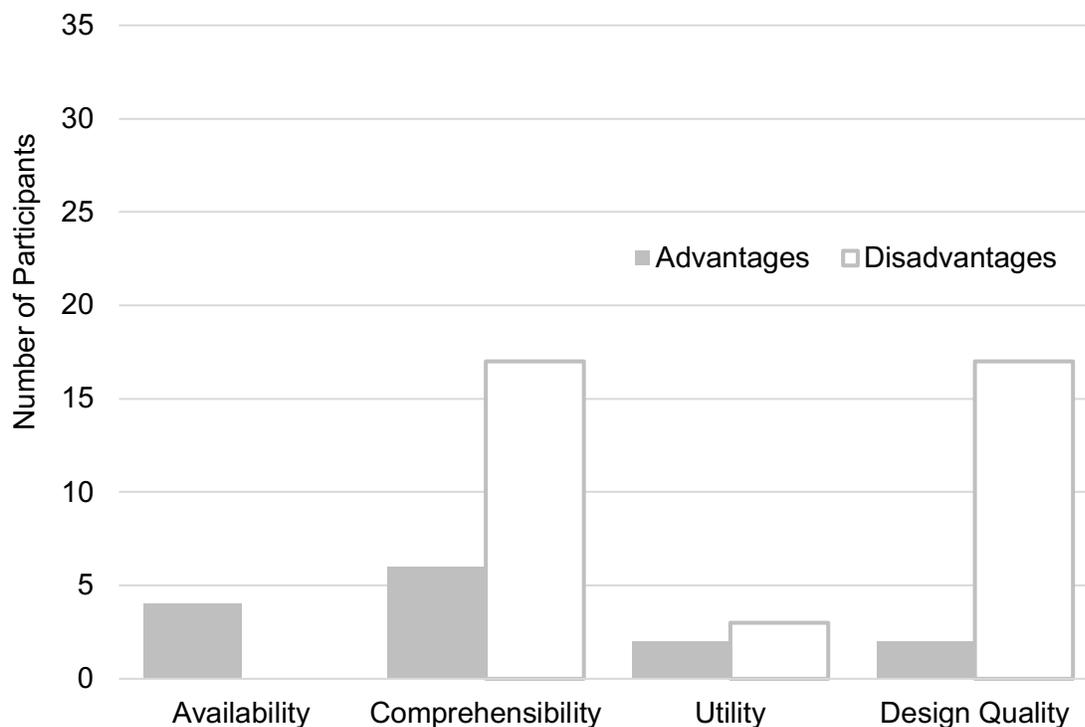
information in the Text format. Interestingly, their negative perceptions of the utility of the Text format appeared to influence their opinions on the comprehensibility of the CMI as well. That is, the format appears to have negatively influenced their perceptions of the amount and clarity of the information, which then in turn negatively impacted how comprehensible they considered the information. Specifically, participant 2 noted:

“I just felt like there was a lot of information, but in terms of being able to remember it and recall it, I think the visuals, for the other ones, made it a lot easier to help recall that information, and so it felt like there was a lot, when really it wasn't more, it just was harder to remember.”

Similarly, another participant questioned whether it was the medication or the format that made the Text format more difficult to process and remember than the multimedia formats. Specifically, participant 7 said:

“I don't know if it was because that medication was more complicated, but it was way harder to follow, and it was way harder to remember, so maybe the images actually helped a lot more than I had actually realized.”

In summary, disadvantages of the Text format discussed by participants were categorized into three of the four themes: design quality, comprehensibility, and utility. Thus, participants made no complaints regarding the provision of the Text format. Importantly, design quality and comprehensibility of the Text format were reported most frequently as problematic (see Figure 20). Moreover, the number of participants that discussed disadvantages of the Text format far exceeded the number that described its advantages (see Figure 20).



*Figure 20.* Frequency of Participants Who Reported Advantages and Disadvantages of the Text Format as a Function of Theme

### 8.6.3 Advantages of the CMI Text + Images Format

A number of subthemes in all fourth themes were identified as strengths of the Text + Images format. From most frequent to least frequent, comprehensibility, design quality, provision, and utility were coded in participant reports for the Text + Images format (see Figure 21).

Twenty-seven participants (75%) identified subthemes that were perceived to facilitate comprehensibility. Specifically, participants noted that the Text + Images format captured their attention and was easy to scan as well as locate information. For example, participant 1 said “you can just look at the whole picture and find what you’re looking for”. Additionally, evidence of comprehensibility in the Text + Images was also found in comments that this format was easy to read, understand, and remember. With

respect to reading the Text + Images format, participant 7 noted “I liked having both because I think the pictures and the text together just helps me read information”. Further, participant 6 described the Text + Images format as “really easy to understand. I really liked how it had the diagrams of how you actually apply it, that was really helpful.” Further, participant 14 illustrated Text + Images comprehensibility by reporting:

“I find that using visual cues really helps you remember, recollect stuff like although you asked me questions I wasn't able to answer a few. Like I'd remember images-- the steps to take, I remember there's going to be like three or four at the top -- at the bottom, based around six to eight steps. It just helps me remember a lot easier.”

One participant discussed how images in the Text + Images format helped them remember information that they may not have otherwise. Specifically, participant 16 said:

“it was nice with the text and images to have a bit of a visual as well, because that's kind of-- that's how I remembered the thrush was because they had a picture of what that looked like, whereas I feel like if it was just words I wouldn't have.”

In addition to those above, participants also discussed other ways that images seemed to facilitate comprehensibility. For example, several participants described how having images provided the gist or general meaning of the information more readily. For example, participant 5 described:

“when you first see the image, you can make that association right away and you know what the text is kind of going to be explaining... You can understand what the images are trying to convey a lot more quickly than reading a line of text.”

Some participants felt that the images made the concepts more concrete. As an example of how images support conceptual concreteness, participant 1 noted “I think having pictures is helpful instead of just thinking about it in an abstract way from reading text”. Thus, images supported the perceived comprehensibility of the Text + Images format in several ways.

In addition to comments supporting the comprehensibility of the Text + Images format, participants also noted two specific types of information that were best conveyed through imagery to enhance comprehensibility. Administration instructions or procedural images and dosing schedule images were noted for their benefits. For example, participant 9 described liking how “the image as can show you what to do, and also show the important points like, apply one drop, or three times a day”. One participant described how procedural images were easier than reading and more likely to capture one’s attention. Specifically, participant 27 described the images in the Text + Images format as:

“really helpful as far-- if you're just reading the instructions. And I feel like it's more-- if you just have to look at something and look at the steps, it's easier than reading all the steps. And I feel like people are more likely to actually pay attention to them if you don't have to read them if you just see them. So I kind of like the mix of that.”

Similar to the Text format, participants also appreciated being able to review the Text + Images format. For example, as participant 6 described “so you read it and then

you make sure that you understand it, and if you don't understand it then you read that section again before moving on the next one". As well as being easily able to review the information, participants also appreciated that they could use the Text + Images format at their own pace, unlike the Narration + Images format. Participant 4 liked the Text + Images format "because it showed me pictures and I could go at my own pace". Thus, proceeding through CMI at one's own pace and being able to review it as necessary were benefits perceived by participants.

Another advantageous subtheme of the comprehensibility theme was simply having the information conveyed in two ways: text and images. For example, participant 10 "as a visual person, the images grant a lot more understanding and then further understanding is provided by the text. Similarly, participant 12 said "pictures are just illustrative, so they just reiterate what the text is actually telling you". Thus, the Text + Images condition appears to have benefitted from using text and images to communicate the CMI content.

Although advantages in terms of comprehensibility were discussed by the most participants, they also made comments coded as favourable in the theme of design quality. Ten participants (27.8%) identified at least one design quality advantage of the Text + Images format and their comments were distributed between the subthemes of layout and attractiveness. The layout of the Text + Images format was considered advantageous by many participants. One participant spoke fondly of the distinctness of images and their associated information and that this felt that layout may have facilitated memory as well. Specifically, participant 13 noted:

“I know that a lot of people use literal borders that are drawn around, so they kind of delineate what text is associated with what image. I really like the-- I don't remember what point it was in the eye drop thing, but at one point, it really had boxes around, like, ‘Here's the image, here's the accompanying bullet point.’ And I think that that's a lot easier to remember rather than an image next to several bullet points.”

With respect to the attractiveness of the Text + Images format, one participant noted that its appeal may have also affected its memorability. That is, participant 21 said “I liked that it had color and images because it made it just a little bit more memorable, I guess, and attractive to look at”.

The third most number of participants made comments coded theme of utility in terms of benefits for the Text + Images format. Utility subthemes were identified that described advantages of the Text + Images format by seven participants (19.4%). Utility subthemes included the clarity, amount of information, and the holistic impression of the information. Containing the right amount of information rather than too little or too much is important for CMI. Participant 5 described that the Text + Images format provided “enough information to be useful, but not too much information that the user would get lost in”. In contrast, participant 15 noted that the being able to see the CMI as a whole is important by saying “it's better to have it all laid out”.

Comments made by four participants (11.1%) were coded as subthemes related to provision of the Text + Images format. All four participants commented on the Text + Images format being easy to keep. This subtheme was demonstrated by participant 7 who said, “I can always go back and refer to it” and participant 37 who noted “I think it's

something that as a brochure, you could keep it for longer”. Further, one participant even suggested being more likely to keep the Text + Images format than other CMI formats. Specifically, participant 6 said “I could see myself keeping this one, whereas the other ones, I think that you'd probably just throw it away, whereas this one might be easier to kind of keep on hand”.

In summary, participants identified benefits of the Text + Images in all four themes. The most notable finding was that of the 28 participants (77.8%) identified at least one advantage of the Text + Images format, 27 (75.0%) of them discussed comprehensibility as strength of this format. The second most common theme perceived as advantageous to the Text + Images format was its design quality. However, participants also identified other advantages of the Text + Images format in the utility and provision themes. Although various perceived benefits of the Text + Images formats were discussed by participants, some participants also noted weaknesses of this format.

#### **8.6.4 Disadvantages of the CMI Text + Images Format**

Compared with the advantages of the Text + Images format, fewer participants discussed its weaknesses. However, those participants did describe perceived disadvantages of the Text + Images format in relation to each of the four major themes (i.e., provision, comprehensibility, utility, and design quality). The most participants made comments that were coded as utility weaknesses, followed by comprehensibility, design quality and provision (see Figure 21).

The utility theme for weaknesses of the Text + Images format, reported by five participants (13.9 %) included subthemes of clarity and tone of the images. With respect to clarity, participant 10 commented the image with “usage info was far too small for me

to read”. With respect to tone, participants described that some images could be considered disturbing or juvenile and that the images selected be more racially diverse. Participant 27 described how some of the images gave the impression that the CMI was better suited to children by saying:

“stinging and stuff, probably wasn't necessary to have an image with it because that's almost childish, sort of. If I could say that. It's kind of a little bit like, ‘Okay. I'm an adult.’ Maybe for kids prescriptions, sure, because then the kids can even get involved, and be like, ‘Oh. That's stinging. Okay. Cool.’ But for adults, it's kind of like, ‘Okay. I'm not a child. I get that.’ ”

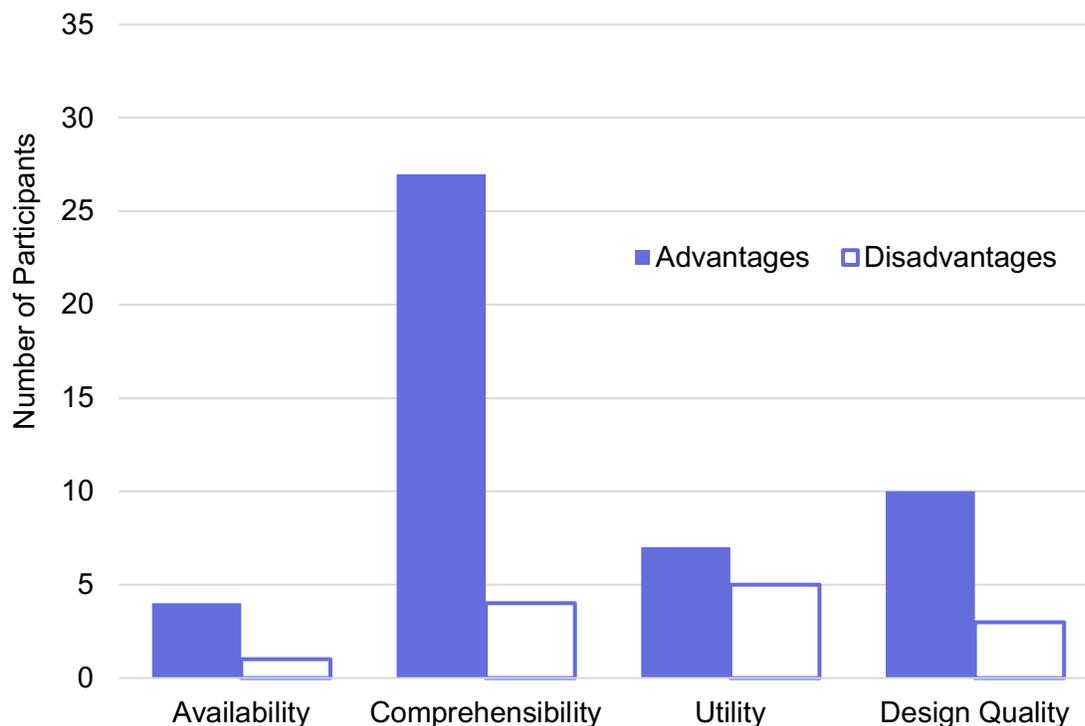
Although comprehensibility was the most popular strength of the Text + Images format, four participants (11.1%) also discussed comprehensibility weaknesses of this format. Remembering, locating information, and capturing attention were the three subthemes represented negatively in the comprehensibility theme. Participant 31 perceived the Text + Images format as “harder to remember than video/audio format”. Another participant described that this format made it more difficult to locate information. Specifically, participant 19 noted the Text + Images format “was the least favorite because, for me, it just presents too much information to pick [from and] take out.” Further, one participant indicated that the pictures were distracting from the actual content. That is, participant 32 described that the “images on it that just kind of made me forget about what was actually being said in the text”.

Three participants (8.3%) identified issues with the design quality of the Text + Images format. Layout and organization were the two themes of issues identified in the Text + Images format in terms of design quality. Some participants indicated that there

were too many images such. For example, participant 19 noted that the Text + Images was perceived as “a bit of image overload. Packed in terms of images”. Participants 32 described the Text + Images format as “poorly organized. It didn't outline the important information very well”.

Only one participant described an issue with the provision of the Text + Images format noted the provision challenge. This was participant 25's comment discussed previously about how the Text format was portable, whereas the Text + Images and Narration + Images formats were not.

In summary, although only few participants identified weaknesses of the Text + Images format, they were in four of the major themes. However, the issues were fairly evenly distributed amongst the themes and therefore there was no prevailing negative theme of this format. Further, although participants did identify weaknesses of this format, many more participants discussed the strengths of the Text + Images.



*Figure 21. Frequency of Participants Who Reported Advantages and Disadvantages of the Text + Images Format as a Function of Theme*

### **8.6.5 Advantages of the CMI Narration + Images Format**

Several benefits to the Narration + Images CMI format were discussed by participants. The most participants discussed items that were coded in the theme of comprehensibility with respect to advantages of the Narration + Images format. However, participants also noted other strengths of the Narration + Images format which were coded in the themes of design quality, utility, and provision (see Figure 22).

Twelve participants (33.3%) identified perceived comprehensibility benefits of the Narration + Images format. The most common subtheme was the advantage of having the combination of both audio and visual information. Participant 13 illustrated this subtheme by saying:

“I remember that guy's voice now. I remember what he told me. And then the images; that's helpful, because if don't remember what it actually said I can look back: ‘I remember there was a bee in the side effect.’ I'm like, ‘stinging.’ So, it's multiple cues of how to get to information.”

Another participant made a similar comment about combination of having audio and visual information. Specifically, as participant 22 described by “the good thing about [the Narration + Images format] is when you're hearing it and with the visuals -- I think that was the one I remembered probably the most. Just because it has those two factors, the visuals and the auditory”. Finally, a participant described how the narration facilitated processing by processing the visuals and images simultaneously “you can gather that information visually while listening”. Thus, participants described several perceived benefits to having both audio and visual information.

In addition to the combination of audio and visual information, some participants also spoke strictly about the benefits of narration. For example, participant 13 said, “I am very auditory. So, having the narration is really good for me”. Further, one participant explicitly noted that the narration seemed to enhance memory. That is, participant 36 described liking the Narration + Images because “I find it easier to remember auditory things. So that helped me more”. Finally, as in the other two formats, being able to review the information was considered a strength of Narration + Images. This subtheme is illustrated by participant 5 who said, “videos allow the user to pause and go back to certain sections if he [or she] missed something or didn't understand completely”.

After comprehensibility, design quality was the next most popular theme with four participants (11.1%) outlining perceived strengths of the Narration + Images format. A few participants appreciated the layout as illustrated by participant 4's comment “it just explained step-by-step.” Another participant also discussed the perceived benefit of observing images of naturalistic use of the medication. Specifically, participant 20 described liking images in the Narration + Images format as it showed “real-life humans using it”.

Two participants (5.6%) noted the utility of information were strengths of the Narration + Images. The subtheme of clarity is illustrated by participant 20 who described this format as “very clear and informative”. The amount of information also seemed appropriate in this format. As participant 18 noted “I do like the comprehensiveness of the narration and video instructions, so that's my favorite”.

Finally, one participant (2.8%) described perceived benefits of the Narration + Images format related to provision. The aspect of provision was merely the preference of this medium as an information source. Specifically, participant 16 noted “I do prefer watching information on videos versus maybe reading them from a book”.

### **8.6.6 Disadvantages of the CMI Narration + Images Format**

Although participants discussed some advantages of the Narration + Images format, many more participants discussed the disadvantages of this format. The most participants made comments that were coded in the theme of comprehensibility related to Narration + Images format issues; however, some participants also described provision, utility, and design quality shortcomings (see *Figure 22*).

Twenty-two participants (61.1%) discussed perceived issues with the comprehensibility of the Narration + Images format. The most prevalent comprehensibility subtheme identified in participant comments was the inconvenience of reviewing CMI in the Narration + Images format because it presented information sequentially. Specifically, 18 (50.0%) participants expressed discontent because this format was difficult to review. For example, participant 12 said of the Narration + Images format:

“it was informative, but I would have to absorb everything at once with just the narration, so I'd have to watch the whole thing again. I don't think I would remember where important information was, looking back at it. So, I'd have to re-watch the whole thing, which is just time consuming, whereas the text images, I could just be like, right here, this is what I can't remember, and I'd find it immediately, so that would be why.”

This finding that participants found the difficulty of reviewing the Narration + Images format a disadvantage complements participants' appreciation of being easily being able to review both the Text and Text + Images formats.

In addition to reviewing the Narration + Images format, another prominent comprehensibility weakness was the pace of this format. Interestingly, some participants considered the pace of the Narration + Images format too fast and others found it too slow. Participant 3, for example noted "I didn't like the pace. I felt like I had to wait and just hear what I actually wanted to hear". In contrast, participant 27 claimed the opposite by saying "I felt the pace was kind of fast". Other participants merely discussed needing to learn at their own pace.

The Narration + Images format was considered by some to be less comprehensible because it was perceived to be more difficult to pay attention to and also remember. Participant 14 described having a short attention span, which is illustrated by "when the person is speaking I just kind of turn off. I just kind of zone out." Further, another participant described that questions about how the information was going to be presented distracted from the actual content. Specifically, participant 20 said, "I was always wondering how long it was going to be or what was going to come up, and so I couldn't pay attention too much". The subtheme of difficulty of remembering the Narration + Images format is illustrated by participant 7, who said "I couldn't keep the information in my head as he was talking". Similarly, participant 17 described the difficulty of remembering in the Narration + Images format as "I feel like the narration, it doesn't stick to my memory as easily". Thus, difficulty maintaining focus as well as

remembering were subthemes of perceived comprehensibility disadvantages in the Narration + Images format.

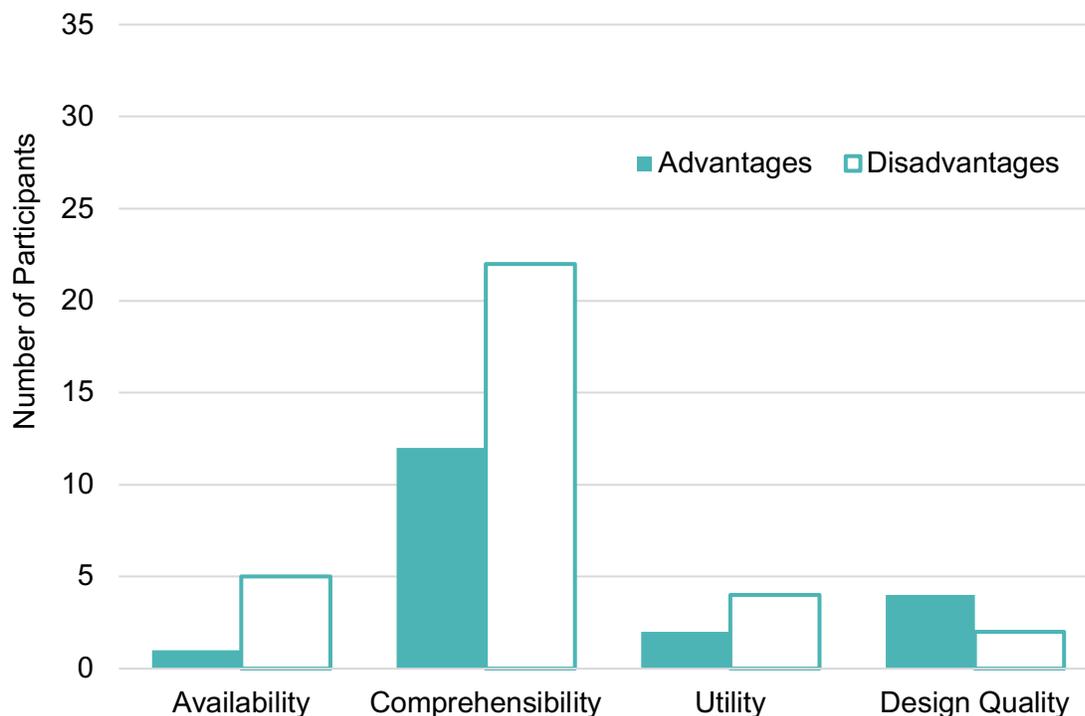
Five participants (13.9%) reported provision issues with the Narration + Images format. Provision disadvantages fell into the subthemes of medium and communication type. Participants noted that the Narration + Images format was potentially less convenient because it was digital. Participant 33 described the inconvenience of the digital format by saying “With the video, is pretty good. But when I want to review, I need to have the Internet and electric stuff with me”. Further, participant 33 argued that “people wouldn't refer back to” the Narration + Images format. Moreover, one participant noted that having been a pull communication (rather than push) was a disadvantage of the Narration + Images format.

The theme of utility of the Narration + Images format was also perceived as problematic by four participants (11.1%) in this study. As with the Text + Images format, participants noted that one image had text that was unreadable and some of the images could be alarming. Specifically, participant 38 described “fearful for many people to see the fire for explaining burning and wasp for stinging when describing possible side effects”. The tone of the narration was also described as an issue that may have deterred participants from the Narration + Images format. For example, participant 7 described the narrator's voice as “incredibly hard to listen to. He was just super-boring.”

Issues of the Narration + Images format were also identified by two participants (5.6%) in the final theme of design quality. Participants simply noted that this format did not appeal to them. Participant 7 illustrating how unappealing the Narration + Images format was by describing it as “something I would probably only ever watch once,

unless I absolutely had to, because the idea of watching a video about medication is very unappealing to me". Thus, for some participants, this format was not appropriate or even a deterrent for presenting CMI.

In summary, although weaknesses of the Narration + Images format were identified by participants in all four themes, comprehensibility of this format was the most frequently cited problem of this format. The primary reason participants disliked about this format was how difficult or inconvenient it was to review, corresponding to the subtheme of ease of reviewing. Further, five participants (13.9%) reported that they would be deterred from using the Narration + Images format because of the difficulty of reviewing the information in this format. Thus, Narration + Images appears to impede intention to use CMI. Interestingly, comprehensibility was the theme cited by participants most frequently for the Narration + Images format for both advantages and disadvantages.



*Figure 22. Frequency of Participants Who Reported Advantages and Disadvantages of the Narration + Images Format as a Function of Theme*

## **8.7 Consumer Medication Information (CMI) Information Needs**

In addition to reflecting on the CMI formats used in the experiment described in the previous sections, interviews were also used to garner insight into real life experiences with CMI. This exploration revealed a variety of CMI use patterns and information needs. Thus, the following sections will describe participants' experiences with CMI as well as how participants foresee the future of CMI. First, how participants reported using CMI will be discussed. This will be followed the perceived benefits, shortcomings, and recommendations for CMI generated by participants. Finally, how and when participants would like to receive CMI will be discussed.

### **8.7.1 Experiences with CMI**

This section explores participants perceptions of their previous experiences CMI. Whether participants received CMI, whether they used it, and whether they kept it were investigated.

#### **8.7.1.1 Provision: Obtaining, Accessing, and Storing CMI**

There were several interesting findings revealed regarding participants' when and how participants received CMI and whether or not they kept it. With respect to receiving CMI, two surprising findings emerged. Common Canadian practice is that CMI is given to consumers with new prescriptions (i.e., filled for the first time). However, eight participants (22.2%) did not remember CMI accompanying their most recent new prescription. Although it is not considered common practice, some participants described having received CMI from their prescribing physicians. Specifically, three

participants (8.3%) reported receiving CMI from their physicians. Contrary to common practice, it appears that a) not all participants received CMI when new prescriptions were filled, and b) some participants received CMI from their prescribers rather than at the pharmacy.

Whether participants kept CMI was also investigated in this sample of health consumers. Interestingly, 20 participants (55.6%) reported keeping CMI either temporarily or indefinitely. However, 10 participants (27.8%) reported recycling CMI almost immediately and five participants (13.9%) reported losing their CMI.

In summary, participants receipt and storage of CMI varied. According to participant reports, CMI distribution processes are not consistent. That is, in addition to common practice of providing consumer CMI with new prescriptions at the pharmacy, CMI may be given out by prescribers, or not given out at all. Further, participants had different CMI storage practices. Some participants kept CMI and others disposed of it almost immediately. Thus, participants reported that they obtained and stored CMI differently.

#### 8.7.1.2 Actual CMI Use

Another theme identified was whether or not participants actually used CMI. The extent to which participants reported reading CMI they had received varied. Ten participants (27.8%) reported that they typically read CMI they receive with new prescriptions. However, 10 participants (27.8%) described typically skimming CMI, but not thoroughly reading the information in depth. Further, it could be cause for concern that 12 participants (33.0%) admitted to not reading the CMI whatsoever. Thus,

participants had different practices of reading CMI. Specifically, some participants read CMI, others skimmed it, and some participants did not read it.

### **8.7.2 Opinions About CMI**

This section explores what participants considered strengths and weaknesses of the CMI they received for their prescription medications. Additionally, recommendations for improving CMI are discussed.

#### **8.7.2.1 CMI Strengths**

Eleven participants (30.6%) identified reasons they considered CMI beneficial. The themes identified were provision, utility, and comprehensibility. Unsurprisingly, no aspects of design quality or use were discussed by participants as benefits of currently available CMI. Several of the subthemes identified in different themes were related to participants appreciation of having CMI available as a complement to their interactions with healthcare providers about medications such as CMI as reference material.

All six participants (16.7%) who discussed benefits related to the subtheme of ease of keeping CMI in the theme of provision. Specifically, six participants described having CMI available after consultations with healthcare providers was helpful as a support in the event they wanted to review the information again or forgot some of the content. One participant even expressed that it was reassuring to have CMI. For example, participant 1 said of CMI “I could take it home with me instead of listening to the doctor and then being like, ‘I have to memorize what they’re telling me.’ It’s like, ‘Oh, I have the paper to take home.’” Thus, being able to keep CMI was important to consumers.

In addition to provision, four participants (11.1%) also discussed strengths of the utility of CMI. One subtheme identified was the amount of information, whereby CMI supplemented the medication information consumers received verbally from healthcare providers. Specifically, two participants asserted that CMI provided more information than their healthcare providers reviewed with them. A second subtheme was the usefulness of the information as implied by two participants who reported consulting CMI if they suspected they were experiencing side effects.

Comprehensibility was the third and final theme identified during the interviews. Only two participants (5.6%) generated comments on this theme. One participant noted that reading information, rather than only hearing it, facilitated memory. Specifically, participant 3 described how reading CMI facilitated memory by noting “I like the paper because I have an easier time remembering if I can see it written down”. The other participant described how easy information is to locate in CMI. To illustrate this, participant 29 said “if you're just looking for one thing, it's usually easy to find it, especially if they have it laid out in different sort of sub-categories.”

One participant generated a comment that was not an instance of any of the four major themes. This participant described that CMI may have the added benefit of empowering them and giving consumers a sense of responsibility. Participant 14 illustrated this by saying “I guess giving it to you sort of empowers you to take the initiative to actually take care of yourself”.

Reasons participants appreciated CMI were coded in the themes of provision, utility, and comprehensibility. An overarching theme was that CMI complemented verbal medication consultations by providing information they could keep, more detailed

information, and help them identify side effects. One participant discussed that using CMI hinged whether or adverse effects were experienced. Despite some participants recognizing the value of CMI, more participants discussed shortcomings of CMI.

#### 8.7.2.2 CMI Weaknesses

Nineteen participants (52.8%) identified at least one drawback of CMI, as currently distributed. Utility was the most commonly discussed theme followed by provision, design quality, comprehensibility weaknesses. Fourteen participants (38.9%) identified at least one utility issue with CMI. The most common subtheme of utility was the amount (either too much or too little) of information, which was discussed by 13 participants (36.1%). Other subthemes discussed by a minority of participants included the tone, helpfulness, and clarity of CMI.

As described, the amount of information was the most problematic subtheme of the utility theme for participants. The most frequently cited criticism, cited by 12 participants (33.3%), was that CMI had too much information or was too long. The issue of the excessive length of CMI is illustrated in by several participant quotes in Table 15. Three participants (8.3%) described that CMI contained too much information about adverse effects in particular. One participant noted that reading the adverse effects facilitated experiencing psychosomatic side effects. In contrast, participant 7 described presenting so many side effects reported it impedes the usefulness of this information:

“a lot of times it gives you a stinky list of every single side effect. So, it goes anywhere from you could be drowsy to you could be hyperactive to you could die to-- and you're like, ‘Okay, well. I feel like that's every medication’, so it's not really useful anyway.”

Table 14

*Participant Quotes Illustrating the Perception that CMI is Too Long*

<b>Participant #</b>	<b>Quote</b>
3	"I dislike how I get like three sheets for one medication. I think they could really pare it down to one sheet. And I feel like the stickers they put on the bottle, those are the important things. So, it's just a lot of information, and I just toss it, usually."
15	"I feel like there's too much information for an average user. About ingredients, or non-active ingredients, and stuff like that. That's not necessarily a thing for me to know. And if it's a real drug that you only get prescribed usually they don't even have dosage on there either because the doctor can vary it."
25	"It was really dry. It was a lot of information and not a whole lot of really anything else. It was just kind of like this, and this, and this. It's not a super-strong medication so there wasn't a whole ton of side effects or anything. But yeah, I don't know. It was really boring. I honestly can't remember much of it because I was just like, 'I know I have to read this in case there's something important,' but—"

However, in contrast to the participants who argued CMI was too long, three participants (8.3%%) reported that CMI does not provide enough information. Using medications off-label caused concern for one participant, because her condition was not listed in the CMI.

Not only did participants discuss the amount of information in CMI, but they also discussed negative aspects of the tone, clarity, and usefulness of the material. Two participants perceived CMI as primarily a legal document to limit liability rather than a tool oriented towards helping the consumer. For example, participant 3 said "I feel like they use a template just to cover their bums". One participant comment that the tone of CMI is predominantly negative with very limited if any positive content. Interestingly, one participant commented that punctuation impacted the credibility of CMI. Additionally, one participant did not feel that CMI was useful. Participant 2 described the limited usefulness of CMI by saying "I always keep them, just in case I need them for later if

something happens, but most of the time I just don't think they're that useful." Another participant mentioned that CMI was not very clear. Thus, the amount, tone, and usefulness of the clarity were subthemes exhibited as weaknesses in the theme of utility.

Eight participants (22.2%) discussed shortcomings of CMI with respect to provision. Three subthemes related to provision of CMI were identified. First, participants noted the negative impact distributing paper CMI had on the environment by wasting paper. Second, participants described that it was difficult to keep CMI. As participant 23 described "it's nice when they give you a sheet, but obviously you're prone to losing it".

Third, participants described that CMI was unnecessary because the information was available online. Participant 6 described how CMI is redundant with what is available online by saying "I don't know if the paper one is necessarily necessary, because that's something you can just Google. You can get it online." Similarly, participant 23 described that finding relevant information may be easier online than parsing through the paper in the following quote "normally, I go online to try figure out information on it because all the paper-- and just like there's multiple pages and some of it just didn't seem really applicable to that specific drug." Thus, the provision weaknesses participants described were that CMI wastes paper, is difficult to keep, and is unnecessary.

Seven participants (19.4%) commented on the issues with the design quality of CMI. Six participants felt that CMI was unappealing. For example, participant 6 referred

to CMI as “like that very bland white sheet of just taxes. It's ugly”. Further, some participants discussed that its lack of appeal deterred participants from reading CMI. One participant considered CMI font too small. Thus, design quality shortcomings of CMI included small font but were mostly related to its lack of aesthetic appeal.

Four participants (11.1%) discussed CMI comprehensibility issues. Each participant identified a different weakness. Participants described CMI as hard to read, understand, and locate information. One participant described the issue of plain language. Specifically, participant 7 described CMI as having “a lot of wording and jargon in there that I don't fully understand”. Thus, participants perceptions of comprehensibility weaknesses in CMI varied and there was no predominant subtheme.

In summary, issues in all four themes were identified with CMI. The most common criticism related to the utility theme and it was that CMI was too long, which some participants considered a deterrent from reading CMI (i.e., negatively impacting intention to use CMI). Participants also described various issues with the tone of CMI. Distributing CMI as paper was considered unnecessary, harmful to the environment, and easy to lose. Finally, participants found CMI unappealing and some expressed not reading it as a result. Thus, design quality can also be argued to impact the intention to use CMI.

### 8.7.2.3 CMI Recommendations

Participants generated recommendations for CMI in relation to all four major themes. Participants made the most recommendations for the utility of CMI, followed by comprehensibility, provision, and design quality.

#### 8.7.2.3.1 *Utility Recommendations*

Twenty-three participants (63.9%) discussed opportunities to improve the utility of CMI. Interestingly, despite complaints that CMI was too long, the most popular recommendation, made by 19 participants (52.8%) was to include more information. Participants expressed wanting more information about traditional medication topics such as those in the adapted CIRF (Koo et al., 2007) as well as five new potential medication (see Table 16) information topics which will be discussed here.

Table 15

*Common and Potential Medication Topics*

Source	Medication Topics
Common topics from the adapted CIRF (Koo et al., 2007)	<ul style="list-style-type: none"> <li>• Benefits</li> <li>• Contraindications</li> <li>• Directions</li> <li>• Precautions</li> <li>• Side effects</li> <li>• Storage</li> </ul>
Potential topics identified from the interviews	<ul style="list-style-type: none"> <li>• Cost</li> <li>• Interactions</li> <li>• Alternatives</li> <li>• How it works</li> <li>• What if it does not work?</li> </ul>

Side effects, directions, and storage were three of Koo and colleagues' (2007) medication information topics participants wanted more information about. Interestingly, in contrast to those participants who wanted less information about side effects, eight participants (22.2%) wanted more explicit information about potential adverse effects. For example, participant 8 wanted the likelihood of experiencing in the CMI by having it list "the percentage of people who experience known side effects just to see how common it is". Some participants wanted more information than the generic script of contacting your healthcare provider if an adverse effect occurred. Participant 24 wanted CMI to include how to respond, "if you're the .5% that gets the possible side effects".

Further, participant 26 argued that CMI may not always include all of the adverse effect information and present a false sense of safety:

“They don't always tell you all the information. It will say on the bottom, ‘For more information go to this web page,’ or whatever, that has all the side effects. So that's kind of [mis]leading, so you see that there are some side effects, which makes you think the medication is safe, and if you really went on to the website and knew how many problems could there potentially be by taking this medication.”

Participants also discussed the need for more information about topics included in the adapted CIRF (Koo et al., 2007) such as directions and storage. Additional information about directions was wanted by four participants (11.1%) which might include answers to questions such as those asked by participant 9: “When should I take it? Can I take it before meal or after meal?”. With respect to storage, one participant wanted to know if it was harmful to refrigerate an eye drop to increase its soothing effects. As participant 18 described “because I know with eye drops it makes your eyes feel really nice if you put it in the fridge first”. However, the CMI did not contain this information, but he refrigerated it.

In addition to wanting more comprehensive information about adverse effects, directions, and storage, the following new medication information topics were identified by participants in this study that may be beneficial if included CMI: cost information, alternatives, interactions, how the medication works, and what to do if it does not work.

Five participants (13.9%) recommended that CMI included cost information. For example, participant 38 reported “I think finance is a big part of it for a lot of people”. As

described previously, consumers may want alternative options because of financial considerations. For example, one participant described a scenario whereby she had to go between the pharmacy and the physician multiple times to determine an affordable medication option. The initial prescription was cost prohibitive and she was asked to get advice on alternatives from the pharmacist to convey back to the physician. Specifically, participant 13 explained the disconnect by noting that they told her:

“the doctor will know what other options you might have, but you won't have any idea about what they cost, whereas the pharmacy will. So, you should ask the pharmacy whether there are alternatives that they know of that are less expensive.”

Thus, cost information, potentially including alternatives for comparison, is an important part of medication information that is not currently included in CMI but would add to its utility.

Four participants (11.1%) also described a shortage of information about interactions in CMI, another new topic not included in the adapted CIRF (Koo et al., 2007). Multiple participants reported turning to online information to find information about interactions. For example, participant 8 described:

“I think that that's probably the one time that I do actually look things up online, is if it doesn't explicitly say anything about interactions with alcohol for example or antibiotics. And then I'm kind of like, “Well, I don't know if this is great information.” And it would be nice if it was just more explicit.”

Participant 21 described a similar situation in the following quote:

“I Googled if it interacted with something because this was the first time I ever took a prescription and I was wondering if it like-- because I got a cold, so I wanted to take a Sudafed® and I didn't know if it interacted, and then it said it had a mild interaction, but I didn't really know what that meant.”

Although some participants actively seek out information about interactions with common substances (e.g., alcohol, ibuprofen, cold medication), one participant was confident prescribers would know if they were prescribing a medication that interacted with another prescription a consumer was taking. Specifically, participant 27 described “if it was two medications that you were taking interacted somehow, and, I mean, your physician would hopefully catch that”.

The mechanisms by which some medications work interested two participants. For example, participant 27 wanted to know “What is this actually doing in my body?”. One participant wanted more information about what steps should be taken if the medication has no observed effect. That is, participant 17 said “they don't tell me what if it doesn't work”. Thus, participants reported wanting more information in CMI about adverse effects, medication costs, interactions, administration, alternatives, how medications work and what to do in the event that they do not work.

Although many participants reported wanting more information in CMI, the second most common recommendation was having a concise summary, which was discussed by seven participants (19.4%). Participant 2 wanted CMI to be “one page that has all the key information kind of like bullet form. Very easy to find the information”. Similarly, participant 8 proposed “Perhaps a summary table at the end would be helpful”. One participant suggested that having a summary may encourage consumers to read CMI

and the longer form CMI could still be available as well. Specifically, participant 27 said that the first page should be a:

“one-page summary. Couple pictures. And, then, if you're interested or if you need more information, it could be, that's what this booklet is for. You do this. I think that would probably make it better. Because, honestly, I feel like not a lot of people have time to sit down and read through all that.”

Another participant suggested providing links in CMI to access more detailed or different information such as a video of the medication being administered. Thus, several participants recommended including a concise summary, covering all of the most important aspects, at the beginning of CMI. However, participants also conceded that more detailed CMI should still be available.

The final subtheme related to the utility of CMI was that the information should be tailored, which was expressed by two participants (5.6%). CMI is general and usually reports the typical dosage and conditions it is used to treat. However, it does not provide information relevant to particular consumers in terms of their prescribed dose, allergies, what other medications they are taking, etc. As described earlier, participant 7 was concerned when her condition was not listed on the CMI. Further, participant 7 asserted “if there would be a way to get the instructions that were more specific and simplified to me, I would prefer that”. Thus, participants would appreciate if CMI was tailored to them individually.

In summary, participants suggested several ways the utility of CMI could be improved. Recommendations were that CMI should provide more information, one-page summary, and use tailored content.

#### 8.7.2.3.2 *Comprehensibility Recommendations*

Ten participants (27.8%) generated recommendations to improve comprehensibility by including images or using plain language principles.

Participants' appreciation of images was discussed previously, so it is unsurprising that including images that seven participants (19.4) believe CMI could be improved by adding images. For example, one participant described how images could enhance the clarity of CMI. Specifically, participant 14 said:

“I like procedural. If there's anything ambiguous said, I guess an image could be there too, pop out maybe just for a side effect. If you describe something and it could be taken different ways, could have an image there to really reinforce your point. Saying 'it could look like this.'”

Participants also stressed that images should not be overused as illustrated by participant 23 who said “I don't know if I want a bunch of images and texts and videos and stuff like that, but maybe a little sketch. To show someone that's administering the drug, that sort of thing”.

Using plain language principles was another comprehensibility subtheme for CMI recommended by four participants (11.1%). Participants suggested making CMI briefer, include more bullet points, avoid jargon, and explain relevant terminology. One participant described receiving CMI that included the word “paresthesia”. She suggested either replacing the term with a consumer translation (i.e., numbness in arms and legs) or include a consumer-oriented definition of the term in the body of the text or in a glossary. Participant 20 illustrated the need for incorporating plain language principles in the following quote:

“I like more information, but also not the scientific jargon because that goes over my head, so it needs to be – I understand why you will need the scientific stuff on there, but also the layperson's version of it would be nice.”

Thus, participants felt that CMI could be written better and include particularly procedural images, to improve the clarity of CMI and be more readily understood.

#### *8.7.2.3.3 Provision Recommendations*

Four participants (11.1%) also made suggestions about how to improve the provision of CMI, which fell into two categories CMI medium (i.e., distributing CMI digitally) and the timing of distributing CMI. Participant 38 asserted to providing CMI digitally would reflect changes in media consumption:

“It kind of just feels like the way this age is going. And with people so connected to electronic devices, and really visual in wanting that stimulation, I think it probably fits the niche of how people are starting to learn now.”

Thus, participants suggested that distributing CMI digitally would be keeping pace with the increasing adoption of digital devices and consumption of multimedia.

The other recommendation made to improve the provision of CMI was to increase access by offering CMI more frequently (i.e., provide CMI with prescription refills as necessary) Participant 19 suggested offering CMI with prescription refills in addition to first time prescriptions would be beneficial:

“I think it's probably good for each time you renew prescription, just to make sure that you – I don't know, sometimes you develop weird habits that are not supposed to be going away. So, I think each time you have to renew a prescription probably.”

Thus, the two recommendations to improve CMI provision were to distribute CMI digitally and offer it to consumers more frequently.

#### *8.7.2.3.4 Design Quality Recommendations*

Only one participant (2.8%) made recommendations for improving the design quality of CMI. Additionally, participant 3 suggested increasing the font size, including icons and links, as well as images of the medication itself would be beneficial.

In summary, participants explicitly described several opportunities to improve the utility, comprehensibility, provision, and design quality of CMI. The majority of these recommendations sought to improve the utility of CMI by including more detailed information, but also providing a brief summary of the content. Participants also suggested that comprehensibility of CMI could be improved by incorporating images rather than relying strictly on text. Provision recommendations were to distribute CMI digitally. CMI could benefit from design quality improvements. Finally, using multimedia and a digital medium could increase the appeal of CMI thereby increase the likelihood that consumers would use it.

### **8.8 Potential Options for Providing CMI**

This section explores how participants would like to receive CMI. First, different potential formats are explored. Second, the theme of provision is explored more in depth. Specifically, participant impressions of different provision options in terms of medium, method, and timing will be discussed.

### 8.8.1 CMI Format

Participants in this study were asked ideally what format would be best for CMI. Given the preference patterns of the three format types observed in this study, it is unsurprising that only two participants (5.6%) expressed wanting CMI to continue to be delivered in a strictly text format. The majority of participants, 26 (72.2%) to be precise, expressed wanting CMI with both text and images. Seven participants (19.4%) wanted to receive CMI with narration and images. However, participants did not limit their ideas to the formats presented in the study but rather combined them into a new format.

Interestingly, seven participants (19.4%) suggested that instead of any of the three formats presented in this study, the ideal format for CMI would be to have all three communications modes (i.e., text, images, *and* narration). Some participants envisioned the proposed format as a slide show or video with subtitles, but others believed that providing options to three independent formats would be better, or potentially toggling the each of the three communication modes on or off. This notion is illustrated in the following quote by participant 13:

“Apart from having somebody literally who pays all their attention to you, and literally walks you, individually, through something, I think what works best for me is-- I was kind of raised on audiobooks, and how I learned to read was by listening to an audiobook and following along. And if information websites had a little button that you could click where a narrator - not a robot, but a person with inflection in their voice that you can remember - a real human being-read text, while you read the text and saw the images next to it, that would be all the things that I would need. Yeah. And I mean, in terms of administration, it'd be nice to have a video, but not everything needs that.”

Additionally, another participant argued that it is important to include options for consumers to have control over the different communication modes. Specifically, participant 20 described:

“In an ideal world, there would be all the ways and then I could choose or pick. And then if I still want more, then I'd go to the other version. If I read with the images and then I think I would benefit from seeing the video, then I would do that in addition. Or if I want my partner to administer the information and I know he's a visual guy who doesn't want to read it, well, I'd just show him the video and then that just takes a few minutes. So especially if it's not just me, if there's other people involved, then it's nice to have those different formats.”

Thus, participants suggested that providing CMI through a combination of text, audio, and visual information would be ideal.

In summary, similar to preferences discussed earlier, most participants considered the best text with images the best format for CMI. However, other participants argued for the benefits of giving consumers control over the format by allowing them to turn different aspects on and off (e.g., audio, images, closed captioning).

### **8.8.2 CMI Provision**

As previously described, the theme of provision was used to account for comments and subthemes relating to how participants obtain, access, and store CMI. This section explores participant opinions potential ways CMI could be distributed with respect to medium, method, and timing.

### 8.8.2.1 Medium

In addition to their preferred CMI format, participants were also asked to discuss what medium would be best for distributing CMI. Many participants had more than one opinion on this subject. Participants considered digital distribution of CMI the most ideal followed by, paper and digital options, paper, and one participant was undecided (see Figure 23). The undecided participant will be disregarded from this analysis.

Beginning with the distribution method selected by the fewest, some participants believed that the current practice was the most effective way to provide CMI to consumers. That is, six participants (16.7%) reported that traditional paper hardcopies are the best way to provide CMI (6). Two of those six participants argued that providing CMI on paper may compel consumers to read it. For example, participant 6 said “I'd probably read it just because it's there. So I'm like, 'I should read this because they've given it to me, so obviously it's important.’”

Sixteen participants (44.4%) believed that giving consumers the option of receiving CMI digitally, on paper, or both would be ideal. The two reasons participants gave as benefits of having both options available were having a copy of the CMI in the event the paper was lost or inaccessible (e.g., while away from home) and addressing different consumers' preferences and needs. One participant likened the proposed process to what currently happens with receipts whereby you can choose whether to have one printed or sent to your email.

Several participants discussed how having a digital version would be convenient in different situations. One participant noted that digital CMI may be helpful as a backup, but that she tends to read materials more thoroughly in hardcopy. This is illustrated in participant 8's quote:

“It might be nice to have that [a digital version] in addition to a paper copy, just in case, like I said, you would misplace the [paper copy] – but I also find that reading things on screens sometimes is harder. I don't know. Sometimes I just skim things more.”

Further, participant 26 illustrated the convenience of having a digital copy of CMI in the following quote:

“I think having a paper as well as an email just so I can have it like quick reference at home. I think email is great if I was out and I just needed to quickly check to make sure I remember, but to have it on me would possibly be good.”

Other participants discussed how options may be suitable for different age demographics or user preferences. Participant 19 described how different consumer demographics may have distinct preferences and needs with respect to CMI medium and format (e.g., text, video):

“I think it really depends on the user group you're trying to get at. I don't know. I feel like maybe me who's a bit more old-school like the written version, probably my parental generation would prefer that to whatever. But then if you're talking about kids, and especially young kids, you obviously need to get them engaged and excited about whatever they need to take. So, for them a video, or whatever, and animation will probably work best. Yeah. That's all.”

Another participant shared a similar sentiment but emphasized different learning style preferences and age differences. Specifically, participant 35 said:

“Well, I know some people are more receptive to digital information. There are different type of learners and whatnot. Because definitely, my grandma would not

want it this way because she doesn't own a computer, right? So I think the option would be good.”

Thus, participants described how letting consumers have the choice between receiving CMI digitally and/or in printed hardcopy would satisfy different consumer needs and preferences as well as be a valuable and convenient backup.

The most popular choice was to provide consumers CMI digitally. Thirty-two participants (88.9%) considered digital distribution of CMI the most effective method (see Figure 23). Participants generated several benefits of providing CMI digitally. The most common suggestion would be that the mechanism for digital CMI distribution could serve as a support tool and facilitate communication between consumers and healthcare providers. Generally, the onus is on participants for following up about medications. However, participants argued that that a digital messaging system to support medication use would make this process more convenient and easier. For example, participant 7 described how digital communication with healthcare providers about medications would be valuable in the following scenario:

“If they were able to somehow create some sort of app or email, if I knew that I was able to respond to that email and be like, ‘I’m having this reaction. Should I go to the doctor?’ Or, ‘Is this normal?’ Or have some easier access to the information that I know that I can trust as opposed to going into a pharmacy or having to go back to a walk-in clinic.”

This is further illustrated by participant 20’s following quote:

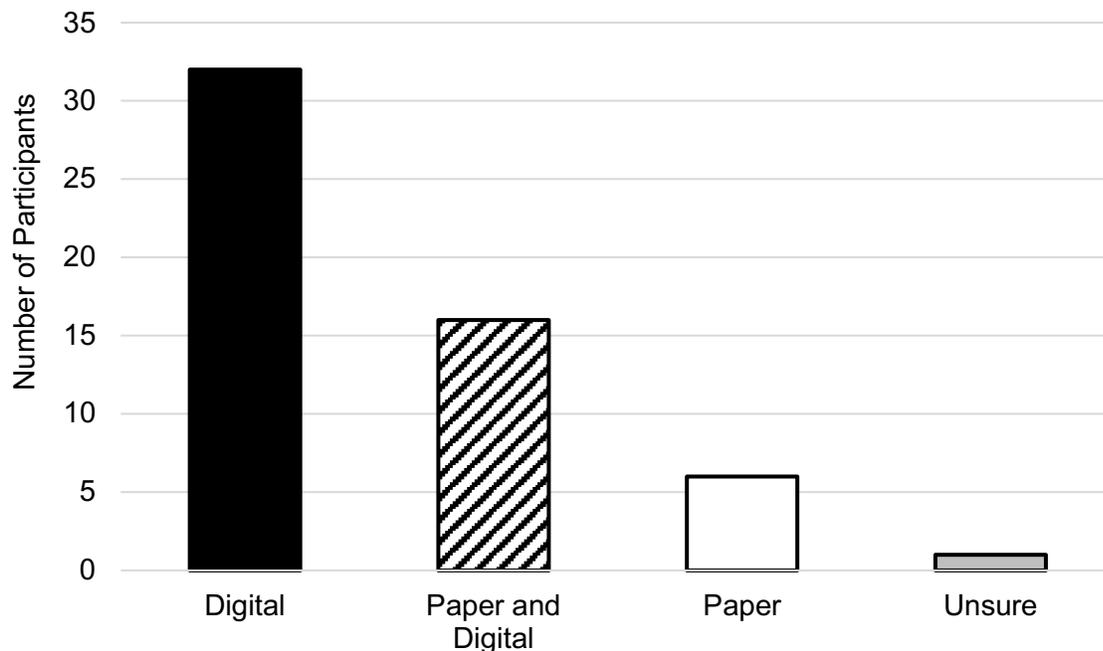
“a check in. Often you start this prescription, and you do this, but then your doctor doesn’t call you, your pharmacist doesn't call you, so you're left doing it

without-- if you have questions then, yeah, I don't know if there's a way to get-- like if you do get it by email, to get a reminder or something.”

Participants generated several other potential benefits in addition to secure consumer-provider messaging. First, digital distribution of CMI could be leveraged to include medication reminders and potentially improve medication adherence. This notion is illustrated by what participant 10 said: “If it had links to a calendar system [laughter] then it could definitely provide people with alerts and notifications and therefore provide a lot of...self-directions and support to properly dose yourself.” Second, given participants’ complaints about the environmental impact of CMI, it is unsurprising that one of the benefits cited was that digital CMI distribution would be more environmentally friendly. Third, corresponding with previous comments, participants also recognized the benefits in terms of provision and loss prevention. Fourth, participants described the benefits of having digital CMI that not only originated from a reputable and trustworthy source but was also kept current. Finally, participants also discussed the opportunity for providing additional information not typically included in CMI that some consumers may also want to know such as including links to empirical evidence of the medication efficacy as well as having reviews from other people who have used it.

In summary, participants described an array of potential benefits of digitally distributing CMI with the most common advantage being incorporating a communication tool to support consumers. Participants were also asked to describe precisely how they would like to access digital information (e.g., by email, a mobile application, a website)

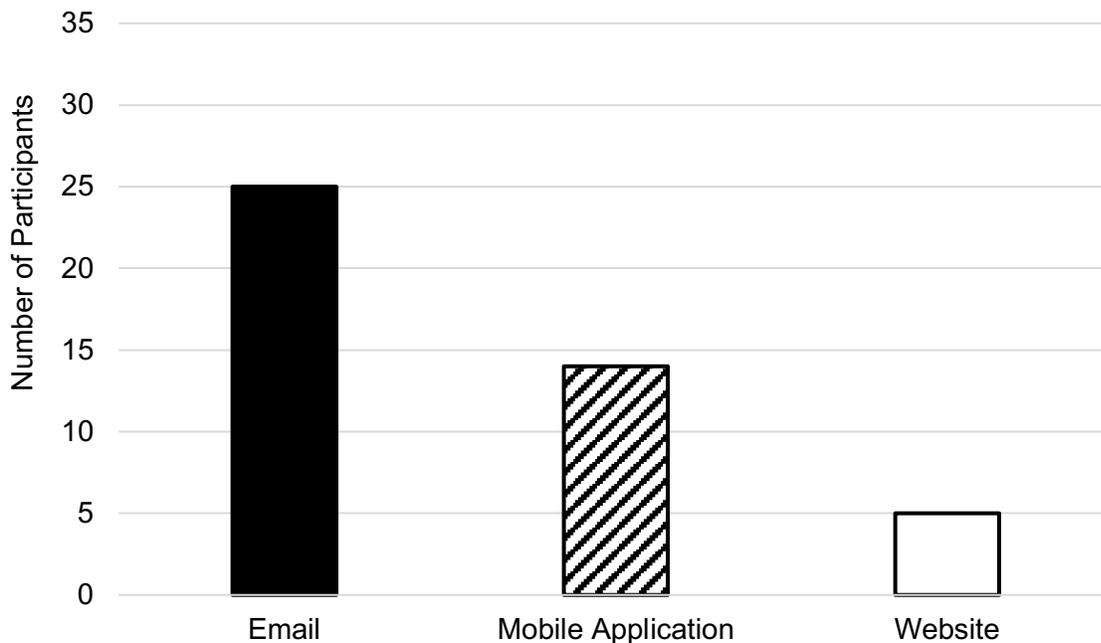
as well as their respective benefits and drawbacks. Participants' opinions about what method would be best to distribute digital CMI will be discussed below.



*Figure 23.* Frequency of Participant Reports of the Ideal Medium for Distributing CMI

#### 8.8.2.2 Method

As described above, there was clear support for distributing CMI digitally. However, participants' opinions of the best method to distribute it was somewhat divided between email and a mobile application (see Figure 24). The most participants discussed advantages of emailed CMI, yet many participants also identified strengths of a mobile application. Few participants considered a website a suitable distribution method of CMI. Participants' perceptions of the advantages and disadvantages for each potential CMI distribution method will be described below.



*Figure 24. Frequency of Participant Reports of Advantages for Each Method for Distributing CMI*

#### *8.8.2.2.1 Distributing CMI by Email*

Twenty-five participants (69.4%) of participants generated at least one advantage sharing CMI with consumers by emailing it directly to consumers. Eighteen participants (50.0%) cited provision themed reasons as to why email would be the best method. Participants suggested email would be best because it easy to keep emails indefinitely and CMI would be easy to find in their inbox. For example, participant 4 described:

“I think because my email is connected to everything, so if I have it on my phone then I can just search it up quickly. Whereas, if I had a paper copy I'd probably leave it at home. And if I'm out and I want to know, so I can easily just search.”

In addition to having nearly ubiquitous access, participants also described that they can access their email accounts almost anywhere, anytime, and without needing additional login information. That is, emailed CMI would be easy to retrieve. This is

illustrated by participant 1's following quote: "I think in an email, where it's like, I don't have to make extra accounts for logging into a patient portal or anything like that. And just having it on my email, then I can access it wherever, whenever". However, one participant disagreed and mentioned that having to search through emails to find it could be tedious.

In addition to reasons related to provision, participants also provided reasons related to comprehensibility and utility to explain why CMI is well suited for email delivery. Specifically, participants described that locating information would be particularly easy because consumers could use search functions. For example, participant 2 said "I can also search in it, if it's a PDF, for specific things so it's easier to find what I'm looking for". Additionally, one participant posited that an email could potentially individually tailored content. This is illustrated by participant 7's quote:

"I think maybe an email. I think that would be probably the easiest. I feel like if it was an app or a website, it would get right back to that really medically, jargony, generic information. Whereas if there would be a way to get the instructions that were more specific and simplified to me, I would prefer that."

Thus, comprehensibility and utility were also themes considered as potential benefits of sharing CMI through email.

One participant provided several reasons why she considered email the most suitable option for her to receive CMI. Specifically, participant 13 described a preference for email because it is a pull communication, it would not require a secure login, it would not require storage space on a mobile device, and it could be printed and saved:

“Personally, I prefer an email, because I wouldn't like the idea that the only way for me to get my prescription medication [information] would be for me to make an account with a username and a password that I have to remember, and I have to remember the website. And I wouldn't like the idea of having to have a specific app that takes up space on my phone, just so that I could look up these things. For instance, if I thought I had them memorized, I might be tempted to delete that information. And then, if you need it again, it's a hassle to get it back. Whereas if it's on your email, then you could potentially print it out. You could back it up. You could save it to a Google drive. You could do a lot of things with it.”

In summary, the most common reasons participants considered email the best method of distributing CMI were associated with provision. Examples of email provision benefits included being readily available, as well as easy to find, retrieve, and store. Further, participants considered being able to search an electronic document for specific information would be beneficial, which is a comprehensibility benefit. Finally, one participant reported wanting emailed CMI to be individually tailored.

#### *8.8.2.2.2 Distributing CMI Using a Mobile Application*

With 14 participants (38.9%) discussing its advantages, a mobile application was the second most popular method for CMI digital dissemination. The primary advantage of using a mobile application for CMI was in the utility theme. Specifically, participants envisioned CMI in a mobile application that provided comprehensive information about their prescription medications. Participants also described that as with emailed CMI, CMI on a mobile application would make CMI readily accessible and easy to keep.

The potential utility benefit of using a mobile application to deliver CMI was that it could be complemented with other information about prescriptions and become a comprehensive tool. That is, a mobile application could aggregate all of one's medications into a single repository and provide access to CMI as well as complementary information such as reminders to take medications and order refills. For example, participant 2 described "If there was an app that had a record of all of my medications, so I could just look things up... it would be pretty useful". Although one participant did not consider a mobile application ideal for herself, it was recognized as something that consumers with different needs might find valuable. Specifically, participant 16 said:

"Maybe if I had something chronic that I did need reminders, and it was a little bit more encompassing, like I don't know, diabetes or something, where I needed to do the tests and it was a bit more complicated, maybe an app would be useful."

Participants had other ideas for features to further enhance a comprehensive mobile application as well. One participant suggested that consumers could choose tailor the level of detail of the information based on their needs and preferences. This notion is illustrated by participant 27's following quote:

"You could go on there and see all your current medications, and then you could go on and be like, 'Okay. This is what I'm on.' And then even that could have a simplified version-- you know when you go online, and you can now have that new - I think it's on your phone or maybe your computer as well - but it can be a bunch of text and pictures and stuff, and you can click the button and it simplifies everything. You can always have something like that, that's just like, 'Here's the

basic points,' and then another tab that's like, 'Here's the really detailed information.' So, I think an app would be kind of cool.”

Participant 10 suggested that a mobile application could provide valuable information to first responders in emergency situations:

“I think that a key feature for that actually might be that the app would push a link directly to a phone's home screen. So, if someone needed to respond to an emergency, like an outside person, they could find this phone and then they'd have access to this information without knowing the password of this individual's phone. They could just click on it and presented with the emergency procedures for dealing with that situation.”

Thus, participants described how a mobile application would be beneficial from a utility perspective because it would serve as a centralized source of different kinds of medication information and could offer other useful features, especially for those with chronic illnesses or more complex medication regimens.

In addition to utility advantages, participants also identified provision advantages of providing CMI on a mobile application. That is, similar to emailed CMI, two participants discussed how having a mobile application would make CMI easy to keep and access from anywhere using their mobile devices. Specifically, participant 21 said “I like the idea of the app because then it would be saved somewhere on my phone”.

Although participants identified several potential benefits of using a mobile application for CMI, shortcomings of this method were also discussed. Specifically, six participants discussed two key drawbacks of using a mobile application for CMI distribution. First, participants did not see value in this method because they would use

the CMI so infrequently. For example, participant 6 reported that using a mobile application would not be ideal because she “would use it so infrequently”. Similarly, participant 35 considered this method impractical because she does not “have very many prescriptions”. Second, on a related theme, participants did not want to have a mobile application for CMI using up storage space on their mobile devices. For example, participant 13 said “I wouldn't like the idea of having to have a specific app that takes up space on my phone, just so that I could look up these things”. Thus, participants would be deterred from using a mobile application because it would rarely be used and consumer storage space on their mobile devices.

#### *8.8.2.2.3 Offering CMI on a Website*

The fewest participants were interested in getting their CMI from a website. Specifically, only five (13.9%) participants discussed advantages of using a website to provide CMI to consumers. Participants described provision and utility advantages of accessing CMI on a website. As with the previous two methods, participants considered easy to access. For example, participant 6 said “if there was a master website that you could always you could just Google and find out, then that would be nice. Further, participant 8 described how a website would be valuable as a backup to printed CMI: “I think if maybe the same information that they will give you in a packet, like a paper packet, was available online, maybe that would be nice to refer to if you don't hold on to the paper package”.

Participants also discussed utility advantages because the information would be trustworthy and offer enhanced security. That is, participant 32 described liking the possibility of an “online format that I knew was reliable, because it was from my

pharmacy or Health Canada or something”. One participant expressed concern over security and privacy of medication information and suggested a secure login should be necessary for the website. Specifically, participant 8’s concern for privacy and security are illustrated in the following quote:

“I think if there was a database that you could look up, or some kind of secure access point, just because-- I don't really care, personally, but I would be concerned about confidentiality for other people. If you're emailing things to people it's not really secure, and then people can potentially find out what kind of medications you're taking and all that, so.”

Although advantages of accessing CMI from a website were generated, more participants identified provision disadvantages of this method. Specifically, nine participants (25.0%) discussed shortcomings of using a website for CMI distribution in the theme of provision. The most frequently cited shortcoming of a website for sharing CMI was that it is a pull rather than push communication method. That is, pull communication requires consumers to seek out the information of their own volition. In contrast push communication allows consumers to passively receive the information (e.g., email). For example, participant 2 said “if it was just found online, I probably wouldn't take it upon myself to go look for it”. Similarly, participant 15 described “you would actually have to-- it's not like it's coming to you, you have to go to it, and I don't think I would do that yet”. Participants also noted that a pull communication requires more effort and they would be less likely to access the CMI. For example, participant 38 said “I think even having an email link, a lot of people probably wouldn't click on it. So, by having people search a link themselves, without an email sent to them, I think it's

even less people that would go to it". Thus, participants regarded the effort required to seek out and pull CMI from a website unnecessarily tedious and potentially not worthwhile to pursue.

The other provision deterrent was specific to websites or portals that require consumers to have an account and password. This is illustrated in the following quote by participant 3:

"I wouldn't like the idea that the only way for me to get my prescription medication would be for me to make an account with a username and a password that I have to remember, and I have to remember the website."

Thus, participants do not want additional steps required to access CMI.

In summary, most participants were supportive of distributing CMI by email, primarily for provision benefits. For example, emailed CMI would be easy to keep and access anywhere, anytime. Further, CMI would be sent directly to consumers without requiring them to seek it out. Some participants were also fond of the idea of a comprehensive medication mobile application that included CMI as part of a suite of features. The fewest participants identified advantages of using a website to share CMI with consumers. Disadvantages of a website were complementary to the advantages of emailing CMI. That is, participants did not want to have to seek out CMI nor did they want to have to have to login to a system to access their CMI. Thus, it is apparent that the both the method and medium of CMI distribution can either facilitate or impede intentions and actual use of CMI.

### 8.8.2.3 Timing

Currently, CMI is given to consumers after their new prescriptions have been filled and they are picking them up. However, there are other opportunities earlier in the prescription process (e.g., when the prescription is written, when the prescription is dropped off at the pharmacy) that may be more effectively to provide this information, in terms of timing. Indeed, the results suggest many participants would prefer receiving CMI earlier in the prescription process than the current practice (see Figure 25).

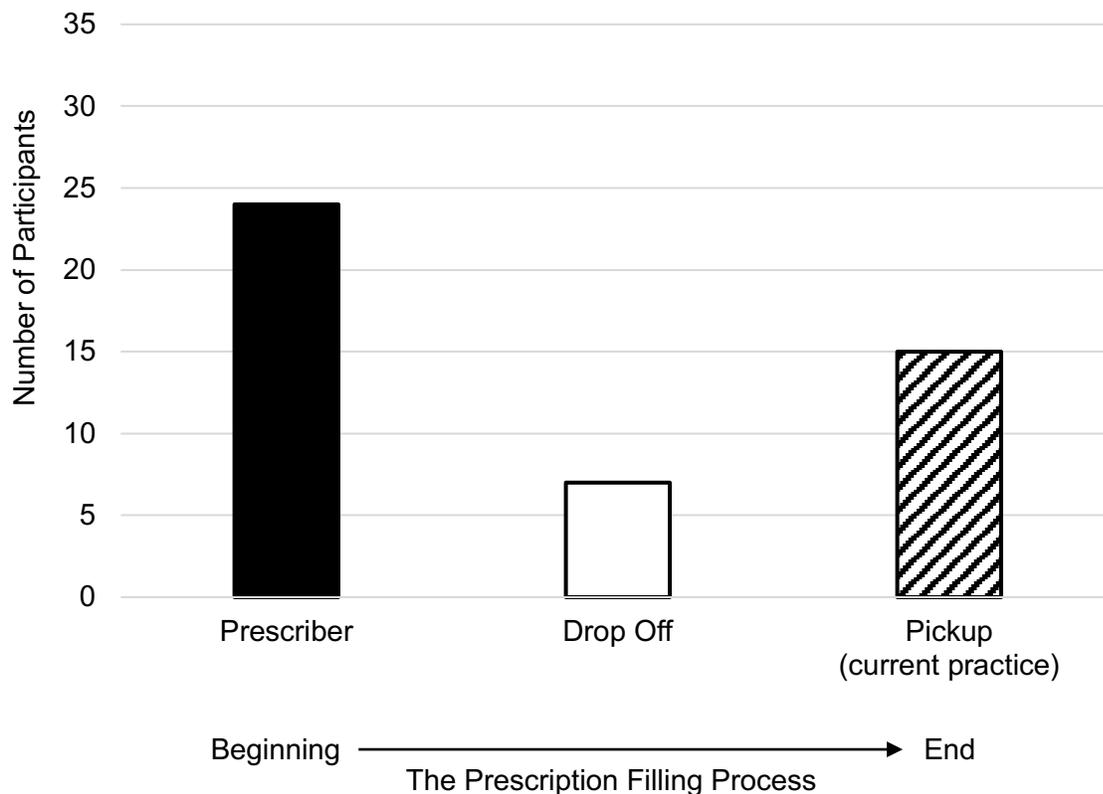


Figure 25. Frequency of Participant Reports of Ideal Timing for CMI Distribution

The majority of participants thought that CMI should be given to consumers earlier in the prescription process. Specifically, 24 (66.7%) participants argued that the best time to receive CMI would be when consumers are with their physicians and new

prescriptions are being written. The most common reason cited by 14 (38.9%) participants (33.3%) wanted to receive CMI while with the prescriber was having a more informed choice about the prescription. This subtheme is illustrated by several different quotes from participants (see Table 17). The current practice of disseminating CMI when new prescriptions are filled is too late for participants to have a say in whether or not they feel comfortable with the potential adverse effects or can afford the medications. Thus, many participants expressed wanting CMI while there was still an opportunity for them to participate in medication decision-making and discuss alternatives.

Table 16

*Participant Quotes Illustrating Wanting CMI Earlier to Facilitate Participation in the Prescribing Process*

<b>Participant #</b>	<b>Quote</b>
7	"A lot of times, you have a choice between what type of medication you're taking for a certain thing, in which case I'd rather have that conversation with my doctor to make choosing what or whether I should go on medication a collaborative process as opposed to my doctor just saying, "You need to take this." So, I think it would be good to have that discussion in the doctor's office."
8	"I guess it would be best to receive it in the doctor's office, given that at that point then you could make a decision about whether you want to fill the prescription or not, just because it's, kind of, a waste in terms of your finances, and also the medications, and the labor itself if you don't end up taking it because of some adverse side effects or something, so."
10	"I believe the best time is as early as possible. So, when you're talking to the doctor, he should be able to provide you with options if possible, and then you can understand this prescription before even accepting it. As soon as you accept it there's kind of this inherent assumption where they assume you're going to be taking it if you've filled the prescription. However, if you're receiving this information after you've filled it and then decide you're not comfortable with it, then you have this weird kind of backwards conflict to have either corrections made or if there's money involved, then there's definitely more issues of finances."

Participant #	Quote
13	<p>“I would like mine with my doctor, before I even go and get it... Because if you don't know when you're filling it, what your medication is going to entail, then that may be something that you wish you had known, so that you can say, 'Oh but wait, I see something that isn't going to work for me,' or, 'I have a question about how I'm going to tailor this to myself.' And I think that deciding with your doctor, whether you even want to fill that prescription is a lot better, because sometimes, they just kind of prescribe you something and then send you on your way. And you're like, 'I didn't get the chance to tell you that there's no way I'm going to take a medication like that.' And now I'm left without an option. So, I think it should be right then and there.”</p>
23	<p>“I think as early as possible because I think it's good to know what you're getting yourself into. Because some last several weeks and you don't know where you're going to be, what you're going to be doing. Like for drinking, what if you already planned to drink on the weekend? You might wait and fill your prescription after the weekend because you realize that those two don't mix together, but if you didn't realize that, you could set yourself up for [laughter] trouble. Because I know my friends and myself, you don't really think about that right away. So that could be kind of important, just knowing the dos and don'ts of your drug and what it consists of, I think, as early as possible is the best.”</p>
26	<p>“I think with the doctor because I think that would open more communication because maybe there's an alternative medication that he could take if you're not comfortable with the information that he's giving or she's giving. But, I mean, now it's just after you've picked up your medication, you're kind of like, "Okay, now I have these pills or whatever, and now I have to make sure that I do it correctly." If I had that beforehand, then I would either be able to read that before I even had the prescription filled.”</p>

Participants also discussed that getting CMI from their prescribers would be beneficial because they could because they trusted their prescribers most about medications. For example, participant 9 said “I trust more doctors because she knows my condition and what's happening. So, when she gave the prescription and at the same time told me, what should I do. What should I not do. I feel more comfortable”. Similarly, participant 31 described “the doctor's probably the one who's most knowledgeable on what exactly you should be doing”. Further, two participants implied that they had different expectations about prescriber and pharmacist roles. For

example, participant 37 said “people go to the doctor for advice when it comes to medication. And they go to the pharmacy to pick up their drugs. So, they're not looking for the information when they go to the pharmacy”. This is also illustrated by participant 18 in the following quote:

“Just because I think that's when you talk about the side effects. That's when you talk about all of the important stuff. And then for me, at least after I leave the clinician's office a little bit like it's a relief, like it's done, and then I'm just going to simply-- people always say, ‘Drop off your medication,’ or, ‘Drop off your prescription,’ rather. So, for me, it literally does just seem to be like it's dropping off a prescription I guess.”

Participants also described that receiving CMI earlier would allow them to read it in advance and prepare questions before seeing a pharmacist. For example, participant 32 said “because then if I had any questions, I could ask the pharmacist when I'm getting the medication”.

Although many participants wanted to receive CMI from their prescribers, two participants discussed reasons why this timing would not be suitable. Specifically, one participant described that knowing about serious adverse effects would deter her from filling the prescription. Another participant described that having CMI too early may overwhelm consumers.

In sum, participants reported wanting to receive CMI from their prescribers, which occurs earlier in the prescription process than currently. The primary rationale behind why this would be a more suitable time was that it would allow consumers to become more active participants and make informed medication choices. Other reasons this

timing would be beneficial included that they trust their prescribers most about prescriptions and that they perceive the role of the pharmacy and pharmacist as more post hoc. Participants also suggested that receiving CMI earlier would allow them to review the material and pose questions to a pharmacist. Finally, not all participants were in favour of receiving CMI earlier because it may deter them from getting the prescription filled or they may be overwhelmed.

The least popular time identified by participants for providing CMI to consumers was when prescriptions were dropped off at the pharmacy. Specifically, seven participants (19.4%) identified advantages to receiving CMI when a prescription is the prescription at the pharmacy for filling. Similar to rationale provided for receiving CMI with a prescriber, two participants noted that receiving CMI while the prescription was being filled at the pharmacy would allow consumers to prepare questions for the pharmacist when they receive their prescriptions. This is illustrated in the following quote by participant 1:

“I think at the time you drop off your prescription, then you should get the paper. That way, while you're waiting to pick up your prescription, when they fill it out, then you have that time to read it and go over any part that you might not understand. Then you know what questions to ask your pharmacist when you're ready, and when he's ready.”

Another participant also suggested that receiving CMI when the prescription is dropped off would be best because it would not overwhelm consumers with too much information at once. Specifically, participant 38 said:

“I think as you drop off the prescription. I think when people receive it, it might get a little overwhelmed of trying to remind themselves what they need to do with it. So maybe if you give them the information just prior, like minutes or hours, but within close timing of when they receive the actual medication. But if you do it when they're with their doctor, it might be too far in advance for them to remember that.”

Thus, some participants considered receiving CMI when they dropped off their prescription the most ideal time because it would give them a chance to review the information while waiting for the prescription to be filled and they would not be overwhelmed with too much information.

Although most participants wanted CMI earlier, many participants believed that current distributing practice was suitable in terms of timing. That is, fifteen participants (41.7%) reported that receiving CMI when picking up their new prescriptions worked well. Participants suggested that receiving CMI with new prescriptions would complement verbal information from their prescribers, facilitate comprehensibility, and be stored easily with their medications.

Participants described that they expected to be verbally informed about the medication by their prescribers but receive CMI and more specific information from pharmacists. As participant 14 described “I feel like the, your physician should have, sort of have the duty of saying what it's going to be used for, how often you should take it, but at that point, you haven't fully got it”.

Additionally, participants discussed that receiving CMI with the prescription is best for comprehensibility, precisely learning and remembering CMI. For example,

participant 11 wanted to receive CMI “at the pharmacy, when I pick up the drugs, so I can be reassured and confident in how I'm going to take it, and then that's it.” Another participant described that when delays occur between seeing a prescriber and getting a prescription filled, consumers are more likely to forget. Specifically, participant 27 said:

“Not everyone goes straight from the doctor and drops it off. So then by the time you drop it off you're like, "What is this meant for again?" So, I'd say, in order to maximize remembering it, I'd say when you pick it up.”

Participant 30 expressed a similar sentiment:

“I feel like I want information with the physician and, as well, again, when I pick up the information. So, if I, in between, had forgotten anything it would be covered again. Just people can tend to forget things in between.”

Further, participants discussed that this time would facilitate them keeping the medication and the CMI together. This is illustrated by participant 20's following quote:

“If I get it with the medication, I usually keep it together wherever I keep it in the drawer or something. So, it kind of goes always in the same side spot. Whereas if I get it from the-- well, I usually fill it the same day, so it's not too much of a problem if I get it from the doctor as well.”

Thus, participants suggested that the current timing of CMI distribution was beneficial because it could provide additional information over and above what their prescribers told them verbally, improve comprehensibility, and make it easy to store alongside their medications.

In addition to one of the three aforementioned specific times, some participants felt that CMI should be distributed by both prescribers and pharmacists. For example, participant 30 said:

“I feel like I want information with the physician and, as well, again, when I pick up the information. So, if I, in between, had forgotten anything it would be covered again. Just people can tend to forget things in between.”

In summary, most participants believed that contrary to current practice, CMI should be provided to consumers by their prescribers to facilitate and informed discussion and explore potential alternatives if necessary. Participants felt that their prescribers were the most informed about their medical history and were trusted. Having time to prepare questions for pharmacists was discussed as a benefit of providing CMI earlier (i.e., either from the prescriber or when the prescription was dropped off at the pharmacy). Participants were also wary of providing CMI too soon in case the information was forgotten. Thus, a benefit to the current practice was that the information was given with the verbal consultation by the pharmacist and when the medication was received. Further, storing the CMI and the medication together was beneficial for some and therefore receiving them together was most ideal. The fewest participants considered when the prescription is dropped off at the pharmacy the most ideal time to receive CMI.

### **8.9 CMI Use: Intention to Use and Actual Use**

Explicit questions exploring factors affecting usage were not posed during the interviews (e.g., how likely would you be to use this CMI, if it were given to you). However, throughout the interviews, many comments about intention to use and actual

use of CMI were observed. Participants discussed how their intentions to use CMI or their actual use of CMI were impacted by provision, comprehensibility, utility, and design quality. Participants in this study explicitly reported that the lack of aesthetic appeal, difficulty of keeping CMI, pull communication type, the tediousness of reviewing a video, and the amount of information deter them from using CMI (see Table 18). According to the interviews, currently one of the biggest deterrents hampering actual CMI use is its length and whether or not it was available. If CMI is lost, it cannot be used. Further, participants described how a video format or an online resource were not suitable for CMI, due to them being pull communications (i.e., consumers would have to seek it out). Further, CMI in a video format was also considered too tedious to review. In contrast, one participant described how the usefulness of the information and specific circumstances impacted whether or not she used CMI. Specifically, participant 27 described she used CMI only if a potential side effect was experienced:

“The only time I'm actually ever really-- only thing I ever really read through is side effects. And normally, the only time I read side effects is if I'm having something weird going on, and I'm like, 'Oh, okay. Maybe this is coming from this sort of thing.' But even from my doctor, I don't think I've ever been told, 'These are the possible side effects,' or even from the pharmacist. I don't think.”

Table 17

*Potential Deterrents of Intention to Use or Actual Use of CMI*

<b>Theme Subtheme</b>	<b>Participant #</b>	<b>Quotation</b>
<b>Provision</b> <i>Ease of keeping CMI</i>	38	"It's just a bother to have to carry it around, especially if it's medication that you're taking for an extended period of time. You kind of feel like you need to have the paper with you in order to reference it if any future questions come up but, yeah, they just get lost and crumpled."
<b>Provision</b> <i>Communication type</i>	5	"I don't think people who are taking medication frequently would be going out and searching for the video, so that might be a less attractive way of presenting the information, because it is available, but you'd have to go looking for it or save it somewhere and, yeah, then go looking for it there."
<b>Comprehensibility</b> <i>Ease of reviewing CMI</i>	3	Regarding the Narration + Images Format: "and if I didn't understand it, I just missed it. I couldn't go back. And I just don't see myself ever looking at a video to learn how to use a medication".
<b>Utility</b> <i>Amount of information</i>	27	"It's a lot of information. It's multiple pages. So, it's like, I don't have time in my life to sit down and read multiple pages of, 'This is the drug, this is all its chemical names, this is what it does.' It's a lot, so I think maybe you could even-- sure, maybe some people love that. And I could imagine my grandpa sitting down and reading that kind of stuff. So, I mean, some people might want that... honestly, I feel like not a lot of people have time to sit down and read through all that."
<b>Utility</b> <i>Amount of information</i>	32	"I feel like they're too lengthy. That's maybe part of the reason why I never read them [laughter]."
<b>Design Quality</b> <i>Aesthetic appeal of CMI</i>	15	"Okay, but they're usually just text, so I don't know how many people would actually read it".
<b>Design Quality</b> <i>Aesthetic appeal of CMI</i>	37	"That I didn't even look at. That it was so easy to not look at. That there was nothing that kind of, piqued my interest. If it had some kind of visual aid, or color, or something like that, it maybe would've been more likely that I would've looked at it."

Logically, whether or not CMI is available, comprehensible, useful, and appealing would affect whether or not consumers use CMI. It is plausible that improving the alignment between consumers information needs and preferences would increase the usefulness and appeal of CMI and potentially increase the likelihood that consumers use it. Advantages and disadvantages of the three CMI formats of the experiment as well as the strengths, weaknesses and recommendations identified by participants could also act as facilitators or obstacles impacting intentions to use CMI as well as its actual use. That is, different CMI features and or deficits could either facilitate or impede consumers' intentions to use CMI or has impacted their actual use of CMI in the past.

Three participants (8.3%) generated recommendations specifically aimed at increasing the use of CMI. Two participants suggested that reviewing CMI should be mandatory. One participant went so far as to suggest standardizing CMI and making reviewing it mandatory could be more efficient and potentially offload some responsibility from healthcare providers. This notion is illustrated by participant 10's following quote:

"The video would be very effective if it was part of a requirement to get the medication, like, 'Here's your medication. Please step behind this. Watch this short video and then you can have it.' That way it's no-- rather than depend on the prior body - from the perspective of the pharmacist, the doctor would be this former body - to describe what this medication does, doesn't do, who should take it, and all these kinds of relevant facts. That this video could be pre-formatted and pre-made, and then it takes responsibility and time commitments away from

pharmacists and doctor. And also provides a lot of information in a short amount of time.”

This finding is supported by Koo, Krass and Aslani (2002), whose participants did not feel there was enough emphasis on the importance of reading CMI before using prescription medications.

Additionally, one participant described that providing CMI digitally and improving its design could potentially increase the likelihood that consumers would use it. Thus, both multimedia and medium may positively impact intention to use CMI. This is illustrated in participant 18’s quote:

“I haven't actually received prescription where I get instructions in the form of in a video or even a nice kind of print out package like that, but I definitely notice the efforts. Like I said if I receive something like that to my inbox then I'd be sure to use it I think.”

Thus, participants suggested that mandating the use of CMI, distributing it digitally and using multimedia may increase the likelihood of consumers using it.

## **8.10 Summary of Results**

Several interesting findings were observed in this study. Contrary to expectation, there was no evidence found to support the multimedia or modality effect in CMI. Interestingly, although objectively all three formats were nearly equivalent in terms of memory, participants did perceive the formats differently. Specifically, participants perceived the Text + Images format as significantly easier to understand and having higher design quality than the other two formats. Additionally, there was some evidence that participants perceived the Text + Images format to have more utility, but this finding was not significant, once corrected for multiple

comparisons. Finally, in terms of overall preference, most participants preferred the Text + Images format and liked the Text format the least.

Directed content analysis (Hsieh & Shannon, 2005) allowed for the use of both pre-existing and emergent coding of the data. This approach led to the development of one meta theme and four main themes. The meta theme was CMI use (i.e., of CMI in past experiences), which also encompassed intention to use CMI (i.e., hypothetical situations with different formats of CMI or different methods of provision). The main four main themes that appeared to facilitate or deter CMI use or were provision, comprehensibility, utility, and design quality (refer to Table 14 for subthemes).

This thematic framework assisted in examining participants CMI format preferences as well as their information needs (e.g., how and when they want to receive CMI). With respect to CMI format preferences, contrary to the lack of objective memory findings, participants reported the Text + Images format as being easier to remember, as well as understand. Further, as revealed through the interviews, participants primarily disliked the Text format based on issues with comprehensibility and design quality. Regarding information needs, many participants indicated that instead of receiving CMI from their pharmacist when a new prescription is picked up, they would like to receive CMI earlier (i.e., before the prescription has been filled). Additionally, although participants were receptive to the option of receiving CMI electronically (ideally by email), they did not want it to eliminate the existing paper-based process. Instead they argued that electronic CMI should be available in different ways to suit the needs of different consumers.

## Chapter 9: Discussion and Conclusions

As previously described, this study had three research objectives:

1. Investigate the potential effects of multimedia and modality on CMI memory
2. Explore consumer perceptions and preferences of different CMI formats
3. Identify consumers' CMI information needs

These three objectives as a framework, whereby the results and key findings from this study will be discussed and conclusions will be drawn. There were several important findings from this study. To begin, the use of multimedia (e.g., images, narration) did not appear to have any effect on memory for CMI. However, multimedia did influence perceptions and preferences of CMI. Specifically, statistically significant differences were observed whereby the Text + Images format was rated higher in terms of design quality and comprehensibility and was selected most often as participants' favourite format. The results of this study indicate that CMI is not currently fulfilling the needs of consumers. A variety of reasons consumers were deterred from using CMI were revealed and potential opportunities for encouraging CMI use were identified. Finally, consumers were receptive to receiving CMI digitally rather than (or in addition to) hardcopy. Following discussion of these results, a new model is proposed inspired by existing research but enhanced with evidence from this study, attempting to describe relationships between some of the factors that influence whether or not CMI is used by consumers.

Table 18

*Summary of Research Questions and Findings*

<b>Research Area</b>	<b>Research Question</b>	<b>Finding</b>
Memory	1. Is there evidence of a multimedia effect for CMI on memory?	Not supported. No differences in memory were observed between the Text and Text + Images CMI formats.
Memory	2. Is there evidence of a modality effect for CMI on memory?	Not supported. No differences in memory were observed between the Text + Images and Narration + Images CMI formats.
Perceptions	3. Do participants perceive one CMI format as more comprehensible?	Supported: Participants perceived the Text + Images CMI format as the most comprehensible.
Perceptions	4. Do participants perceive one CMI format as having more utility?	Partially supported: Participants perceived the Text + Images format as more comprehensible, but after adjusting for pairwise comparisons, it was not significant.
Perceptions	5. Do participants perceive one CMI as superior in terms of design quality?	Supported: Participants perceived the Text + Images CMI format as the most comprehensible.
Preferences	6. Do participants prefer one CMI format overall?	Supported: Participants preferred the Text + Images CMI format to both the Text and Narration + Images formats.
Information Needs ( <i>Exploratory</i> )	7. When do consumers want to receive CMI?	Contrary to current practice, many participants would like to receive CMI <i>before</i> receiving their prescription.
Information Needs ( <i>Exploratory</i> )	8. How do consumers want to receive CMI?	Contrary to current practice, participants would like the <i>option</i> to receive CMI electronically, preferably by email. However, participants still want the paper practice continued for those who prefer it.

### 9.1 Discussion of the Memory Results

Participants' means for memory for items in the free recall task for each of the three formats ranged from 11.25 – 12 items in the first condition of this study and 12.44 – 12.75 items overall. Miller (1956) asserted that short term memory capacity is typically

seven meaningful chunks of information (ranging from five to nine). Gobet and colleagues (2001) defined a chunk as “a collection of elements having strong associations with one another, but weak associations with elements within other chunks” (p. 236). Thus, it appears that participants in this study were able to combine, or chunk, smaller items from the CMI together to effectively exceed the limitations of working memory. Despite having high general memory performance, participants’ memory performance did not provide evidence to suggest either multimedia or modality effects.

This study corroborates King and colleagues’ (2012) lack of findings that multimedia affects memory for multimedia for medication information. Although King and colleagues’ (2012) study limited their test stimuli to medication directives (i.e., directions and precautions), this study used multimedia to complement as much of the written content in CMI as possible. Corresponding to this, more memory items were tested thereby reducing the opportunity of ceiling effects. Participants had even higher average rates of recall in this study than in King and colleagues’ (2012) study. However, this study did not use a sample of consumers with limited health literacy, whereas King and colleagues (2012) did. Additionally, this study also investigated whether narration had an impact on CMI memory, which did not have evidentiary support.

If, as hypothesized, the multimedia principle and the modality principle from Mayer’s Cognitive Theory of Multimedia Learning (CTML; 2001, 2005, 2014) were observed in CMI memory performance in this study, the expected pattern would have been that participants would remember the least in the Text format, more in the Text + Images format, and remember the most in the Narration + Images format (see Figure

26). Performance in the Text + Images format was expected to enhance memory, because of the multimedia principle which asserts that the use of images facilitates learning. Further, memory in the Narration + Images condition was expected to be better than both the Text and Text + Images conditions because of the modality principle. That is, in an attempt to bolster learning, the Narration + Images condition had images and reduced visual processing by presenting written information directly to the auditory channel. Therefore, the Narration + Images format should have facilitated cognitive processing, understanding, and memory of the information.

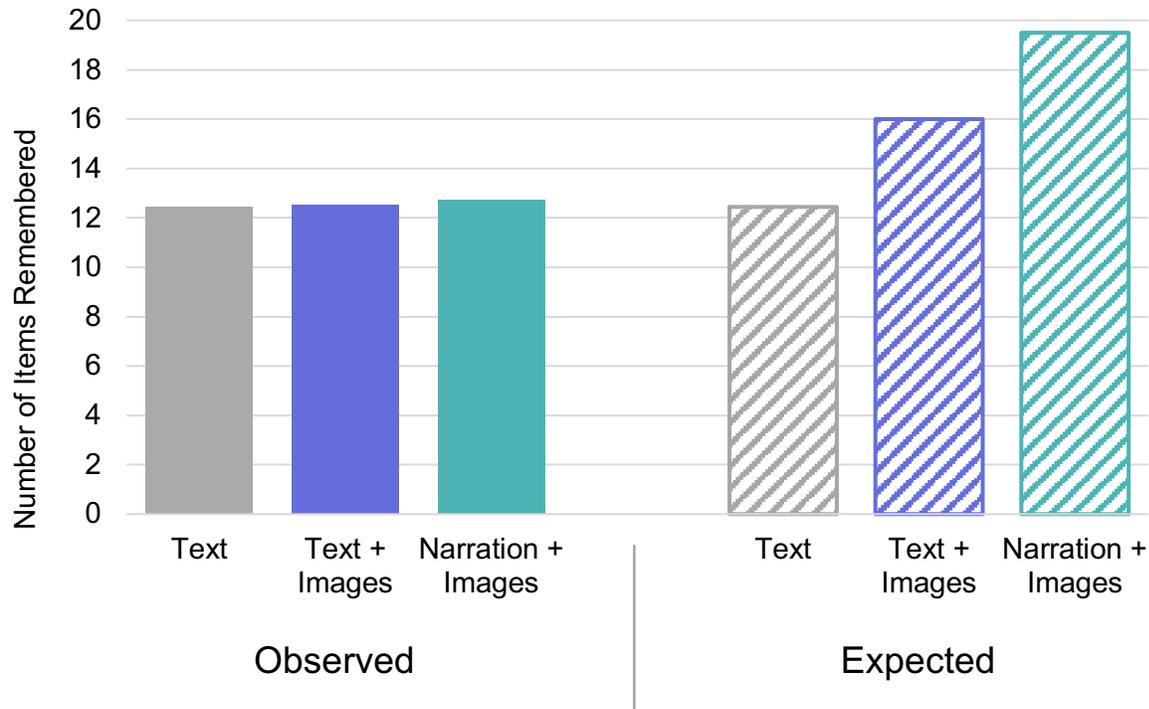
### **9.1.1 Is there evidence of a multimedia effect for CMI on memory?**

Participants did not remember significantly more items in the Text + Images format than the Text format and therefore, there is no evidence to suggest multimedia played a role in CMI memory in this study.

### **9.1.2 Is there evidence of a modality effect for CMI on memory?**

Participants did not remember significantly more items in the Narration + Images format than in the Text + Images format and therefore there is no evidence supporting the role of modality in this study.

Participants' memory in all three formats was so similar there was no evidence to support the multimedia or modality principles in this study (see Figure 26). Thus, the results from this study suggest that the Cognitive Theory of Multimedia Learning (CTML; Mayer, 2005, 2014) does not apply to CMI. This evidence opposes previous assertions made by Monkman and Kushniruk (2015b). However, given the abundance of evidence supporting the multimedia and modality principles in other domains, it is not immediately apparent why no evidence was found in this study.



*Figure 26.* Observed vs. Expected Patterns of Results Based on Mayer's (2001) Multimedia Principles

It cannot be determined from the available data precisely why this pattern or results observed without additional research. However, three potential theoretical explanations as to why there was no evidence supporting the multimedia or modality principles in this study will be presented:

1. Memory Not Comprehension
2. CMI is Descriptive Not Explanatory
3. Multimedia Benefits Some People More Than Others

First, the absence of expected learning gains due to multimedia, may be attributable to only testing memory and not understanding as well. Second, the inherent content of CMI may not be a good candidate for multimedia instruction because it requires learning discrete types on information rather than an integrated process of connected information. Fourth, no gains in memory in this study may be attributable to

participants being younger and/or having adequate health literacy. Thus, the first explanation is related to the performance tested, the second pertains to inherent characteristics of the stimuli, and the final explanation due to the characteristics of the study sample.

#### 9.1.2.1 Memory Not Comprehension

The first possible explanation of why no evidence of either the modality or multimedia principles were found pertains to the type of task used as an index of learning. As previously described, the two primary goals of multimedia instruction are for learners to remember and understand (Mayer, 2014a). Mayer (2014a) defined remembering as the “ability to reproduce or recognize presented material” (p. 20) or retaining the information. Recognition (i.e., choosing a correct response from a set containing lures) and recall (i.e., generating a response) are tests of memory or retention. In contrast, Mayer (2014a) defined understanding as the “ability to use presented material in novel situations” (p. 20) or apply the information to solve problems. Thus, asking participants to solve problems by extrapolating upon multimedia presentations are tests of understanding or transfer (Mayer, 2014a).

Many researchers of multimedia learning emphasize transfer because it is an index of comprehension rather than memory (Mayer, 2014b). For example, Mayer (2014b) asserted “Our focus is on transfer test performance because we are mainly interested in how words and pictures can be used to promote understanding” (p. 44). However, the emphasis on transfer performance in multimedia learning may also be due to it providing more consistent results than those of retention. That is, evidence on whether multimedia facilitates memory is mixed. Some studies have reported memory

gains due to multimedia presentations (e.g., Mayer & Moreno, 1998; Moreno & Mayer, 1999). In comparing age performance, some studies have shown benefits for older and younger adults (e.g., Bol et al., 2015) but others have only found memory gains in older not younger adults (e.g., Morell et al., 1990). Interestingly, two of Mayer and Moreno's studies (Mayer & Moreno, 1998; Moreno & Mayer, 1999) found evidence of a modality effect in retention *and* transfer results, whereby narration and animation were remembered and understood better than written text and animation.

In contrast, to multimedia learning studies reporting gains in retention, other studies have found no benefits of multimedia presentations on memory (e.g., Bol et al., 2014). Mayer and Anderson (1991, 1992) found no evidence of improved retention, only improved transfer due to multimedia instruction. To demonstrate retention of the instruction materials, participants were asked to provide a written description of how a bicycle pump works for a layperson (Mayer & Anderson 1992). To demonstrate transfer (i.e., understanding), participants answered questions such as "Suppose you push down and pull up on the handle of a pump several times but no air comes out? What could have gone wrong?" (Mayer & Anderson, 1991, p. 487). An accurate response to the previous question was "Look for a hole or stuck valve to explain a malfunction" (Mayer & Anderson, 1991, p. 487).

Mayer and Anderson (1991) found evidence that participants who saw words-*with*-pictures understood the material better than participants who saw words-*before*-pictures. However, there were no significant differences in memory between the two groups (Mayer & Anderson, 1991). Further, Mayer and Anderson (1991) reported that participants who were instructed by words-*with*-pictures understood more than those in

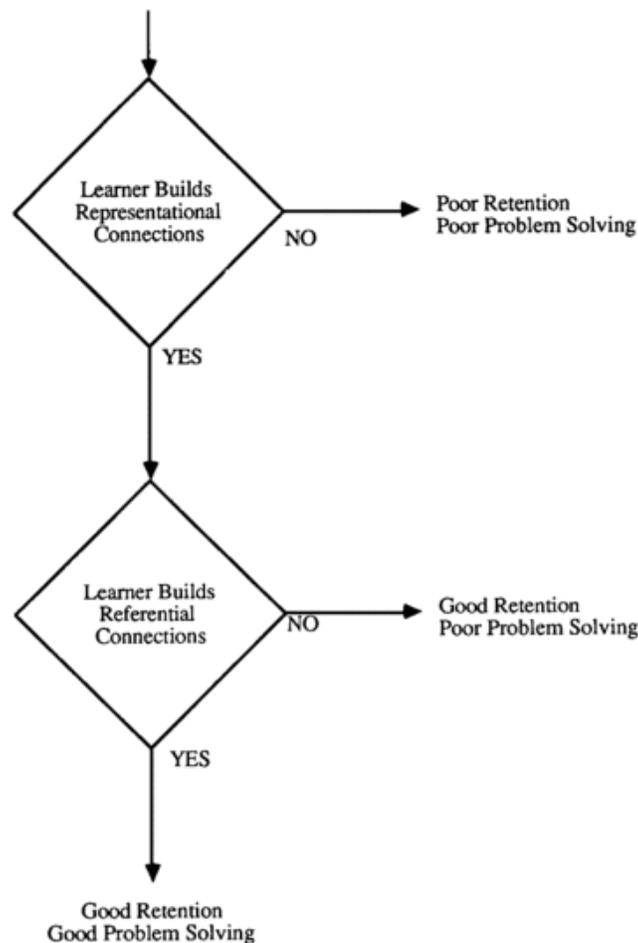
the control (i.e., no instruction), words-only, and pictures-only groups. Moreover, there were no differences in memory observed between the words-only, pictures-only, or words-with-pictures groups. Using a more elaborate experimental design, Mayer and Anderson (1992) found similar results. That is, participants understood more if animation and narration were presented concurrently rather than successively, but there was no observable impact on memory.

Mayer and Anderson's (1991, 1992) explained their results using three possible connections that can be constructed during multimedia learning:

“(a) Connection 1 involves building representational connections between verbal information that is presented and the learner’s verbal representation of that information; (b) Connection 2 involves building representational connections between pictorial information that is presented and the learner’s visual representation of that information; and (c) Connection 3 involves building referential connections between corresponding elements in the learner’s verbal and visual representations” (p. 444)

Mayer and Anderson (1991, 1992) posited that single mode, successive, and concurrent presentations provided equal opportunity to create representational connections. That is, learners are all receiving the same verbal information. However, only concurrent presentations would enable representational connections because the verbal and visual content were presented simultaneously (Mayer & Anderson, 1991, 1992). Thus, Mayer and Anderson (1992) asserted that differences between memory and comprehension performance are attributable to differences between representational connections (i.e., constructed independently for verbal and visual

information) and referential connections (i.e., integrating verbal and visual information). Specifically, Mayer and Anderson (1991, 1992) argued that participants who only generated representational connections would perform relatively well on retention tests, but not on transfer tests because no referential connections were made to deepen their learning (see Figure 27). In contrast, those that created both representational and referential connections would perform well on both retention and transfer tests (see Figure 27; Mayer & Anderson, 1991, 1992).



*Figure 27.* Predictions of a dual-coding model of learning from words and pictures (Mayer & Anderson 1992, p. 447)

In this study, memory (an index of retention) was tested to see how well participants were able to remember the CMI. Given that all three conditions contained

the same verbal information (either written or narrated), according to Mayer and Anderson (1991, 1992) all participants had an equal opportunity to construct representational connections of the CMI. Therefore, their performance on the recall task was approximately the same despite the differences in format. However, differences in learning attributable to multimedia presentation of CMI may have been observed if transfer had been tested.

It is difficult to test for transfer of CMI because CMI is inherently unique to each medication and it is rarely prudent to apply the knowledge about a medication broadly to a novel medication situation. For example, if a medication is not working, it is not advised that a person adjust their dosing schedule, as these adjustments should be made only by healthcare professionals. As a result, it is challenging to distinguish between what information consumers truly understand as opposed to what they simply remember. Indeed, Houts and colleagues (2006) also noted that several studies in their review “purported to assess comprehension but, in fact, studied recall since they only asked respondents to repeat information they heard or read” (p.178). Thus, it is unsurprising that some researchers have conflated memory, understanding, and other cognitive abilities in medication information.

Boudewyns and colleagues (2015) described that their comprehension measure assessed memory *and* understanding using true and false as well as multiple answer questions on three subscales: “(a) side effects and risks; (b) benefits and uses; and (c) topics to discuss with a doctor before taking Rheutopia” (p. 1595). However, given the sample questions included in their article, it appears that very limited if any extrapolation of the CMI information was required to answer these questions (Boudewyns et al.,

2015). Similarly, based on Koo and colleagues' (2007) adapted CIRF, items such as combined aspects such as information location, readability, and memorability were aggregated with understandability into the category of "comprehensibility" in this study. However, given Mayer and Anderson's (1991, 1992) findings, it may be more prudent to examine and address these cognitive abilities (e.g., information location, memory, comprehension) independently, using objective measures.

Although a true comprehension test that is naturalistic has been used by Morrow and other researchers (e.g., Morrow, Leirer, Andrassy, Hier, & Menard, 1998b; Morrow et al., 1998a; Morrow et al., 1998b; Morrow et al., 2005), because of the generic nature of CMI, it not considered an appropriate test. Specifically, the inference (i.e., comprehension) task charged participants to determine how many tablets would be consumed daily calculated by multiplying how many tablets were taken at once and how many times a day they were taken (Morrow et al., 2005). Thus, the inference task is a comprehension task, as it requires combining the information in a novel way to solve a problem. However, this task has limited value in the context of testing CMI, as CMI currently conveys "typical" dosage frequency but not necessarily dosage amount. For example, the CMI in this study described that Flovent was typically used twice a day, but there was no information about how many puffs should be administered each time. The specific details of dose and time are prescribed uniquely, which often conveys more details and further may vary from what is described in the CMI.

#### 9.1.2.2 CMI is Descriptive Not Explanatory

The third possible explanation of why participants demonstrated similar memory for all three CMI formats is that the CMI content is not a suitable candidate for

multimedia instruction and learning. Typical multimedia learning experiments explain processes (i.e., sequences of actions) such as how lightning works (Mayer et al., 1996), the mechanics of pulleys (Hegarty & Just, 1993), and the principles of flight (Cuevas, Fiore, & Oser, 2002). However, the stimuli in the present study were more descriptive than explanatory. That is, although medication administration procedures are processes, most of CMI is separated into discrete packages of information that from the consumer perspective would likely appear unrelated. This might also explain why King and colleagues (2012) failed to find any differences in memory associated with adding pictograms to medication information.

As previously described, it is difficult to test for CMI understanding and CMI should generally not be used to make inferences. Mayer and Anderson (1992) also noted how differences in content making information more or less suitable for multimedia instruction. Specifically, Mayer and Anderson (1992) described how the instructional material, or inherent characteristics of the stimuli, may play a role in multimedia learning:

“we used materials that explained how a system works; that is, we focused on "how-it-works" explanations that could be used to make inferences. If we had focused on material consisting mainly of arbitrary facts, we would not have been able to test for understanding. In short, our results may be limited to expository passages that describe how concrete physical, biological, or social systems work rather than descriptive or narrative passages.” (p. 451)

Thus, CMI is more aligned with Mayer and Anderson’s (1992) notion of arbitrary facts that cannot be tested for understanding and are more descriptive than expository in

nature. Thus, it is not unreasonable to assume that no differences were observed in memory because CMI is poorly suited for gains associated with multimedia instruction.

Evidence from memory studies using simple stimuli have shown that memory for image pairs is superior when images interact with each other (e.g., a hammer is hitting a nail) than when they are separated (e.g., a hammer resting next to a nail) either in the image or in participants' imagination. For example, Bower (1970) asked participants to learn pairs of words in one of the following three ways "(a) overt rote repetition of the word pair, (b) construction of an interactive scene in imagery, or (c) imagery of the objects noninteracting and separated in 'imaginal space'" (1970, p. 530). Bower found that participants were almost equally likely to recognize the first word of the pair. However, when asked to generate the second word, memory was significantly better in the interactive imagery condition than the separation imagery and rote repetition conditions, but no difference between the latter two conditions (Bower, 1970). Thus, Bower's (1970) results provide evidence that imagining interaction (or a relationship) between pairs of words facilitates memory. McGee (1980) performed a similar experiment but used words as stimuli and had similar findings. Further, Bobrow and Easton (1972) also found benefits of relational organization when pairs of images were depicted interacting with each other rather than having participants imagine them interacting.

The notion of relational organization could be extrapolated and potentially present an interpretation of why the multimedia effect was not observed in the present study. It could be argued that most multimedia studies use stimuli that are inherently relational. That is, the component concepts and items interact rather than being disparate pieces

of information. Further, multimedia presentation may further enhance memory by depicting these relationships, rather than having people imagine relationships amongst them. This rationale suggest that participants did not create interactions between the items in the CMI and further the images added to the Text + Images condition did not facilitate interactive relationships between the items either. Thus, imagery in traditional multimedia learning studies may be enhancing relational organization, but not in the present study.

#### 9.1.2.3 Multimedia Benefits Some People More Than Others

The participants in this study were younger ( $M = 23.6$  years old,  $SD = 3.8$  years), well-educated, and had adequate health literacy (i.e., 83% had low likelihood of having limited health literacy). One or all of these sample characteristics may have limited the potential benefits of multimedia presentation of health information or specifically CMI in this study.

Multimedia may be more beneficial for older people compared with younger people. Many older people are affected by a decline in one or more cognitive capabilities which can create negative implications for learning (Paas et al., 2005; Van Gerven, Paas, & Tabbers, 2006). Age related cognitive decline includes reduced processing capacity, reduced cognitive speed, reduced inhibition, reduced coordination and integration (Van Gerven, et al., 2006). The cognitive aging principle (Paas et al., 2005), however, asserts that the application multimedia strategies can help older learners overcome obstacles due to age related limitations in cognitive capabilities. Some studies have found more pronounced benefits (i.e., interactions) of multimedia instruction for older people than for younger people (e.g., Paas, Camp, & Rikers, 2001;

Van Gerven, Paas, Van Merriënboer, & Schmidt, 2002). Thus, the benefits of multimedia instruction for CMI may only apply to older adults. However, the evidence is mixed as other studies have found that both younger and older people benefit equally from multimedia instruction (e.g., Van Gerven, Paas, Van Merriënboer, Hendriks, & Schmidt, 2003; Van Gerven, Paas, Van Merriënboer, & Schmidt, 2006) suggesting that despite the younger sample in this study, benefits due to multimedia instruction still should have been observed.

Benefits due to multimedia instruction may be more pronounced for people with limited literacy than those who have adequate literacy. In a review of 55 studies comparing text alone with illustrated text, Levie and Lentz (1982) found that there was some evidence to support the argument that illustrations are more helpful for poor than adequate readers. Further, in their review, Houts and colleagues (2006) reported that people with low literacy levels were more likely to benefit from multimedia instruction in consumer health information. Although literacy itself was not measured in this study, the high levels of health literacy and education in this sample likely precludes these participants from having literacy issues. Thus, the current sample may not have benefitted from multimedia instruction because of their adequate levels of literacy.

### **9.1.3 Conclusion: Memory for CMI**

Participants in this study generally demonstrated strong memory for the CMI. However, contrary to expectation, participants' performance did not vary as a function of CMI format. Thus, there was no evidence to suggest that the Cognitive Theory of Multimedia Learning (CTML; Mayer, 2005, 2014) applies to CMI.

Four possible theoretical explanations for the absence of differences in memory were presented. First, participants' may have remembered all three formats equivalently because memory of CMI was tested but comprehension was not. Other studies have only found differences in comprehension but not memory using multimedia (e.g., Mayer & Anderson 1991, 1992). Second, the images added to the multimedia CMI formats (i.e., Text + Images and Narration + Images) may have actually impeded memory by providing redundant information and therefore counteracted gains due to multimedia. Third, CMI is inherently different from typical multimedia stimuli. CMI is more descriptive and disparate in nature whereas a typical multimedia stimulus is explanatory and based on a process of interrelated events. Fourth and finally, the young, well educated, health literate participants in this study may not have been good candidates for reaping the benefits of multimedia instruction. Thus, there are several potential reasons why no differences in memory were observed despite the format manipulations in this study. However, additional research is required to determine the cause of these findings with any certainty.

## **9.2 Discussion of the Perceptions and Preferences Results**

A previous study found to find conclusive evidence that multimedia medication information affects perceptions of the materials (Advani et al., 2013). Advani and colleagues' (2013) attributed their inconclusive multimedia medication information preference results to a sample site with potentially high levels of health literacy who appeared to appreciate text-only materials. Interestingly, the objective and subjective data in this study were not consistent in this study. That is, despite the lack of differences in memory between the three CMI formats, participants' clearly favoured

multimedia CMI, particularly the Text + Images format. Moreover, this study sample exhibited high levels of health literacy, and participants consistently rated multimedia CMI more favourably on individual factors and preferred it to plain text overall.

### **9.2.1 Do participants perceive one CMI format as more comprehensible?**

Participants found the Text + Images format the most comprehensible, followed by the Narration + Images format, and the Text format was considered the least comprehensible. Thus, images appear to have bolstered the impression of comprehensibility, despite their lack of impact on memory.

### **9.2.2 Do participants perceive one CMI format as having more utility?**

No significant differences in participants rating of the utility of each of the three CMI formats were observed in this study. However, the omnibus test did suggest there were difference but after adjusting for multiple comparisons, none of these differences were significant. This suggests that CMI format may in fact influence perceptions of CMI utility but that the difference was not robust enough to be significant in this sample size. Further, it would have been if surprising if the utility of any of the formats was perceived differently than the others because the content was held constant between the three formats.

### **9.2.3 Do participants perceive one CMI format as having higher design quality?**

Similar to the comprehensibility findings, participants rated the Text + Images highest in terms of design quality, followed by the Narration + Images format, and the Text format had the lowest design quality. It is unsurprising that the Text format had the lowest design quality ratings. These findings are interesting in that given the

proliferation of short informational videos, it might be more reasonable to expect the Narration + Images format to outperform the Text + Images format in terms of design quality.

#### **9.2.4 Do participants prefer one CMI format overall?**

The majority of participants in this study shared the same opinions in terms of overall preferences of their most and least favourite CMI formats. Overall preferences aligned with the patterns of comprehensibility, utility, and design quality ratings. Specifically, participants were most likely to rank the Text + Images format as their favourite, followed by the Narration + Images format, and select the Text format as their least favourite. The following sections will highlight the most prevalent themes and subthemes emphasized which are assumed to have influenced participant perceptions the most.

##### **9.2.4.1 Impressions of the Text Format**

Comments from participants suggest that the disfavour of the Text format was primarily due to perceived design quality and comprehensibility disadvantages. Many participants used adjectives such as plain, boring, ugly and bland to describe the unattractiveness of the Text format. Additionally, participants critiqued the layout and organization of the Text format. With respect to comprehensibility, many participants described that the Text format was more cognitively taxing to attend, process and remember. However, this subjective finding from participant reports was not supported in the objective memory results.

#### 9.2.4.2 Impressions of the Text + Images Format

Interestingly, favourable comments of these same two factors (i.e., comprehensibility and design quality) appeared to drive the positive impressions of the Text + Images format. Counterintuitively, more perceived comprehensibility benefits were discussed more frequently than design quality benefits. Three out of four participants made a positive comment about the Text + Images format. In contrast to the Text format, participants reported the Text + Images format captured attention, facilitated scanning, facilitated information location, was easy to read, easy to understand, and easy to remember. Again however, these subjective perceptions of the superiority of the Text + Images format was not supported by improved memory.

#### 9.2.4.3 Impressions of the Narration + Images Format

The most prevalent theme, of the Narration + Images format, both positively and negatively, was comprehensibility. Participants reported perceived comprehensibility benefits of having the combination of narration and images. However, this format made it difficult to reviewing this CMI which negatively affected comprehensibility. Further, the difficulty of reviewing the Narration + Images format reduced intentions of using this format. Accordingly, the segmenting principle claims that “people learn more deeply when a multimedia message is presented in learner-paced segments rather than as a continuous unit” (Mayer & Pilegard, 2014, p. 317). The segmenting principle is supported by evidence from 10 studies comparing segmented and continuous multimedia presentations (Mayer & Pilegard, 2014). Thus, a linear presentation that is not self-paced, as used in the Narration + Images format, is suboptimal. However, despite the subjective shortcomings of the lack of learner control, memory performance

in the Narration + Images was equivalent to the other two formats. Therefore, the lack of learner control did not appear to impede memory in this study similar to other research in this area. However, implementing segmentation in the Narration + Images format may have improved memory.

### **9.2.5 Conclusion: Perceptions and Preferences of CMI Formats**

Participants in this study clearly preferred CMI in the Text + Images format. This format was also perceived as more comprehensible and of higher design quality than the Text and Narration + Images formats. Further, multimedia did appear to play a role in perceptions as both the Narration + Images format was also rated more highly in terms of comprehensibility and design quality than the Text format. However, the linear presentation of the Narration + Images format created challenges in reviewing the CMI for clarity and enhanced understanding, which negatively impacted perceptions of this format and whether participants imagined themselves using CMI in this format. Despite the lack of differences in memory between the formats, there were significant differences in participant perceptions and preferences of the Text, Text + Images, and Narration + Images formats.

### **9.3 Discussion of the Results on CMI Information Needs**

Participants' comments revealed several interesting CMI information needs. According to participant reports, CMI distribution practices vary more than expected. Further, consumers are heterogeneous in terms of whether they use CMI, what information they want in CMI, whether they keep CMI, how much information they want included in CMI, what CMI format they want, and how they want to receive CMI. This

section begins with the findings of the two information needs research questions and followed by other key findings and how they support or oppose other studies.

### **9.3.1 When to participants want to receive CMI?**

Participants recognized potential benefits of having access to CMI earlier in the prescriptions process, as it would allow them to make a more informed choice about whether or not to actually fill the prescription. This finding suggests that consumers want the opportunity to consider options and to have conversations about medications, rather than the traditional paternalistic process of passively receiving and filling a prescription. This finding is supported by the Australian Committee on Safety of Medicines (2005), who urged the exploration of providing consumers CMI earlier in the prescription process and the need to improve CMI provision more generally. Koo and colleagues (2002) reports of consumers in their focus groups resonated with the findings from this study:

“Many consumers preferred to receive a CMI together with their medication to prevent losing the CMI. However, the majority preferred to receive the CMI prior to paying or taking the medication and a few preferred to receive a CMI from the doctor. Some consumers commented that CMIs could be wasted if given when they were feeling physically unwell or emotionally upset.” (112)

This theme of provision is consistent with international agencies and research. The United States is moving towards a single online source of medication information for consumers (Pearsall et al., 2014). This approach will allow physicians, pharmacists, and consumers access to the same CMI and will provide consumers with CMI earlier in the prescription process. Wali and colleagues (2016) also echoed the benefits of having

medication information available when participants needed it for consumers with limited health literacy.

### **9.3.2 How do participants want to receive CMI?**

Perhaps the transition from paper to electronic CMI is considered an inevitability, given that most other paper documentation has transitioned or is transitioning to electronic transmission. For example, Pearsall and colleagues (2014) discussed the FDA's planned move towards a single online repository for medication information for consumers. However, studies around consumers' opinions about this transition are limited. Hammar and colleagues (2016) examined this topic in a sample of Swedes and found that only a minority of participants (17%) would prefer to receive medication information electronically than paper. Unsurprisingly, younger participants were more receptive to electronic medication information (Hammar et al., 2016).

Findings from this study support Hammar and colleagues' findings with respect to their younger participants. Specifically, nearly nine out of ten participants in this study were receptive to receiving CMI electronically for themselves. However, participants also argued for the continuation of paper CMI distribution as an option for those consumers who prefer it in hardcopy. Thus, the participants in this study were open to receiving CMI electronically, but more as an additional option to the current paper-based practice than an alternative.

In terms of options for electronic distribution of CMI, emailing CMI and including it in a mobile application were both popular options with participants in this study. Generally, email was considered the most convenient method as it was easy to keep indefinitely and find in their inbox and it was received passively. Thus, if CMI were more

readily accessible consumers may be more likely to use it. A mobile application was slightly less popular with participants in this study, but given the characteristics of this sample (i.e., relatively young and healthy), they also recognized that it might be a more useful tool for people with complex medication regimes. Participants doubted whether consumers would have the impetus to seek out CMI on their own if it was on a website and therefore it was the least popular method of offering CMI. Indeed, this finding aligns other reports that participants indicated that they were very unlikely to seek out written medication information on their own (Koo et al., 2006). Further, participants discussed that having CMI accessible only through a secure account (i.e., requiring a user name and password) would also deter them from using it. Thus, both the medium and method can either facilitate or impede consumers from using CMI.

Participants also generated several other interesting ideas related to how CMI should be obtained, accessed, and stored. For example, some participants envisioned CMI as a component of a more comprehensive prescription medication tool. Participants also expressed that consumers need to feel more supported in their use of prescription medications by being able to pose questions to a professional easily (e.g., through a chat feature) and having reminders to facilitate adherence.

In addition to addressing the information needs research questions about when and how consumers want to receive CMI, other interesting findings were generated in this study based on participants' previous experiences with CMI.

### 9.3.3 Experiences with CMI

This study explored whether people remembered receiving CMI and from whom as well as whether they reported using and keeping it. Additionally, participants discussed reasons they were deterred from using CMI as well as opportunities to improve it.

#### 9.3.3.1 Receiving CMI

Findings from this study suggest that consumers' receipt of CMI is varied. Corresponding with common practice, most participants noted that they had received CMI with their new prescriptions. Interestingly, some participants reported receiving CMI from their prescribers rather than pharmacists. It is concerning that some participants claimed that they had not received CMI with their new prescriptions. However, Gibbs and colleagues (1989a) found that 11- 40% of participants who had received CMI in their study, did not remember having received it. Thus, it would appear that whether CMI is dispensed and by whom are inconsistent, but due to the retrospective self-report nature of this study it is difficult to determine distribution numbers with any certainty.

#### 9.3.3.2 Actual CMI Use

Based on participants in this study, it seems that consumers have three approaches to using CMI: those who read CMI thoroughly, those who skim it or read only specific sections, and those who do not read it whatsoever. Participants were relatively equally divided amongst these three types of CMI use.

Present reports of not reading CMI are consistent with other research in this area, but there are some conflicting reports. In the United Kingdom, Raynor and Knapp (2000) found that only 21% of their participants reported reading all of the CMI and 40% read parts of it. Of the participants who received the CMI with a new prescription ( $n =$

43), 74% read it while 11% did not. In an American study, the majority of patients (70.4%) reported reading CMI with new prescriptions always or often (Nathan et al., 2007) and the minority (29.7%) read it seldom or never. Of those who reported reading CMI, the majority (56.9%) reported reading the CMI in its entirety and the remainder only read select portions (Nathan et al., 2007). Wolf and colleagues (2006) also found that many of their participants (23.0%) did not read medication guides, especially if they were males and/or had limited health literacy. A Belgian study also found that only approximately one in four consumers read the entire CMI with a new prescription (Leemans et al., 2011). Further, women were more likely to read CMI than men (Leemans et al., 2011). In another study, the majority of participants in focus groups reported reading CMI but to various extents, focusing on directions and side effect information (Koo et al., 2002). Most of Koo and colleagues (2005a) participants reported reading CMI in its entirety (61%) but some read specific sections (17%) or skimmed it (22%). Thus, all of the participants in Koo and colleagues' (2005a) study expressed at least minimal engagement with the CMI (i.e., scanning it), but others have found that a considerable portion of consumers often ignore written medication information completely.

In the present study sample, there were a limited number of males, no participants were identified as having a high likelihood of limited health literacy, participants were younger and well educated. Thus, it is unlikely that these factors played a role in low reported usage of CMI. Moreover, participants may have even over-reported reading CMI because of the experimental setting. These factors combined suggest that the

practice of not reading medication information is likely more pervasive than previous reports.

#### 9.3.3.3 CMI Storage

Participants in this study also varied as to whether or not they kept CMI and if they kept it for how long. Just over half of the participants in this study reported keeping CMI. More than one in four participants in this study recycled CMI almost immediately and more than one in ten reported losing their CMI. These present findings align with Koo and colleagues (2005a) who found that after reading the CMI, the majority of participants (58%) kept CMI with their medications until the course of medication was complete (Koo et al., 2005a). Other participants (21%) either kept the CMI for future reference, shared it with a friend who was also prescribed the medication, or did both (Koo et al., 2005a). The remaining participants (21%) disposed of the CMI (Koo et al., 2005a). In an early study, Gibbs and colleagues (1989a) found that 66.7%-82.4% participants reported keeping CMI. Similarly, Raynor and Knapp (2000) reported the majority of participants (74%) who received CMI (n = 161) kept it. Thus, it appears that there may be a reduction in the likelihood of keeping CMI.

#### 9.3.4 Deterrents from Using CMI

Several weaknesses of CMI were discussed by participants and it some of these shortcomings appeared to contribute to consumers being deterred from using CMI. Findings from this study suggest that the utility and specifically the lengthiness of CMI dissuades consumers using CMI. This notion endorses others who have previously proposed the value of including summaries for CMI (e.g., Nathan et al., 2007), medication information (e.g., the Committee on Safety of Medicines, 2005; Wolf et al.,

2006; Wolf et al., 2012) and health information more generally (e.g., Doak et al., 1996, Berkman et al., 2011). Moreover, a couple of participants in this study wanted more information in CMI, which would also support those who argued for the summary to preface more comprehensive information. Shorter versions of CMI have also been shown to benefit memory (e.g., Boudewyns et al., 2015). Thus, the utility (e.g., amount of information) appears to influence whether or not consumers use CMI and how well they remember it.

Although some participants described that CMI could serve support tool and provide additional information and reassurance, others advocated for changes to make it better suited for consumers in terms of its tone, clarity, and usefulness. Several other studies have reported that CMI use can be worrying or anxiety inducing (e.g., Koo et al., 2002, Koo et al., 2005a). In Gibbs and colleagues' (1989a) first study, participants who reported that reading CMI resulted in worry ranged from 10.8% for bronchodilators up to 27.9% for NSAIDs. Similarly, Kish-Doto and colleagues (2014) reported that approximately a third of participants were concerned about the warning section. Many would avoid using a medication because of the risk of death outweighing potential benefits of taking the medication (Kish-Doto et al., 2014). Koo and colleagues (2005a) found that some participants (21%) had questions or concerns as a result of reading CMI, which often led to consulting a healthcare professional (Koo et al., 2005a). Further, only a small portion of their sample reported ceasing their medication use as a result of reading the possible side effects (12%) or drug interactions (9.5%) in the CMI. Generally, participants who had received CMI considered it informative and useful (Gibbs et al., 1989b; Koo et al., 2002; Nathan, Zerilli, Cicero, & Rosenberg, 2007).

In the theme of provision, participants described several weaknesses of distributing CMI in paper. First, this practice is a perceived waste of paper. Second, hardcopies were prone to being lost. Third, CMI was considered redundant with medication information available online. Thus, it can be inferred that participants would be welcome to new distribution practices for CMI which would overcome these shortcomings and increase the provision of CMI and potentially increase the likelihood that consumers would use CMI.

Participants also discussed the lack of aesthetic appeal, or design quality, as a contributing factor to not using CMI. Additionally, some comprehensibility issues were discussed that created barriers to using CMI. In summary, participants described a range of weaknesses of the current CMI distribution practices and the material themselves and many of these related directly or indirectly to whether or not participants used CMI.

### **9.3.5 Improving CMI**

Participants generated a variety of recommendations which might improve CMI. Intuitively, incorporating these recommendations might increase the likelihood CMI would be used by consumers.

Interestingly, over half of the participants wanted more information. For example, participants asserted that side effect information was somewhat ambiguous which limited its usefulness. Kish-Doto and colleagues (2014) also reported that some of their participants did not find this section informative either. Thus, providing more explicit information about the frequency side effects occur in the population would improve CMI. A potential approach to resolving this ambiguity is currently implemented by Denmark

on their min.medicin.dk website. Specifically, min.medicin.dk lists the possible side effects of a medication in a tabular format categorized by the ordinal frequency (e.g., general, rare, very rare) and the corresponding probability (e.g., 10 out of 100 people; 1 in 1,000 people; 1 in 10,000 people). Moreover, evidence from a meta-analysis suggests that using numbers rather than words for side effect probabilities increases the accuracy (i.e., reduce overestimation) of risk estimates, satisfaction, and likelihood of using medications (Büchter et al., 2014).

Some potential new medication topics were generated that may make CMI more useful for consumers (i.e., cost, interactions, alternatives, how it works, what if it does not work?). For example, participants asserted that cost information was important to determine whether or not they could afford the medication. Indeed, research has shown approximately 8.2% of Canadians who take prescription medications, suffer from medication affordability issues (Law et al., 2018). Moreover, these issues force choices between medications and other basic needs and also result in increased healthcare services (Law et al., 2018). Currently, Pacific Blue Cross (a health insurance company) offers a website called Pharmacy Compass (<https://www.pac.bluecross.ca/pharmacycompass>) which provides the cost of some prescription medications (i.e., cost per pill for both generic and brand name) as well as the pharmacy's dispensing fee to allow consumers to compare the prices between local pharmacies. However, Pharmacy Compass only provides information for pharmacies in British Columbia, Canada and it does not have a comprehensive database. Further, it is not known how many physicians or consumers are aware of Pharmacy Compass. Moreover, physicians are usually under time constraints during appointments which

may make searching for a medication unfeasible. Thus, it is assumed that the typical scenario is that consumers are unaware of the cost of a prescription medication until they attempt to pay for it.

This scenario is a waste of resources that could be avoided if cost information was available when prescriptions are written. With regards to interactions, one participant was confident that prescribers would identify interactions. Again, prescribers may not always have access to comprehensive medication information about their patients. Thus, prescribers may not always be able to detect potential interactions with new prescriptions, so it would be useful for consumers to have access to this information as an additional safety measure.

Although only corroborated by two participants in this study, the value of CMI for consumers called into question because of its legal tone. That is, these participants considered CMI more as a medico-legal document than one that is a tool aimed for use by consumers. Findings from other studies (i.e., Pollock and colleagues, 2004; Raynor et al., 2004) led Grime and colleagues (2007) to report

Patients queried the independence of information in leaflets produced by pharmaceutical companies with a vested interest in promoting their products, and the content of medicine leaflets was thought to be dictated more by medico-legal issues than the needs of patients (p. 292)

Thus, the question of whether CMI is a tool developed for consumers or to provide legal assurance is not a new debate.

Adding images to CMI, especially for directions, could benefit the comprehensibility of CMI. This improvement is supported by Health Canada's (2016)

suggestion that illustrations are helpful for demonstrating self-administered medications. However, Health Canada also asserted that images should be avoided for purposes other than directions. However, participants were more in favour of using images conservatively and judiciously. Typical Canadian CMI does not include any images. Monkman and Kushniruk (2017a) have previously argued that this practice is a missed opportunity and that images for directions would be beneficial, especially for medications such as inhalers. Thus, some recommendations to improve CMI were to include more and different information, tailoring the information, and adding select, complementary images for directions.

#### 9.3.5.1 Tailoring CMI

Participants also suggested that tailoring CMI content might increase the utility of CMI. In contrast to a generic or one-size-fits materials, tailored health communications are “are intended to reach one specific person, are based on characteristics that are unique to that person, are related to the outcome of interest, and have been derived from an individual assessment” (Kreuter, Strecher, & Glassman, 1999, p. 276). Traditionally, investigations of tailoring health information seek to explore the effects of individualized content relevant to the characteristics (e.g., demographics, illnesses) of the user. Some researchers posit that tailored health information should positively impact behavior change more than generic content (e.g., Kreuter et al., 1999; Rimer & Kreuter, 2006). Counterintuitively, evidence suggests that tailoring provides negligible, if any, benefits with respect to behaviour change (e.g., Noar, Benac, & Harris, 2007). However, based on their systematic review, Grime, Blenkinsopp, Raynor, Pollock, and Knapp (2007) posited that tailored information tailored to health conditions increased

the perceived value of the information. Further, Wali and colleagues (2016) reported that evidence supported the benefits of personalizing medication information for increasing knowledge and potentially adherence for people with limited health literacy.

In addition to tailoring based on user characteristics, how the information is presented can also be tailored to suit modality (i.e., mode) preferences or learning styles. Pashler, McDaniel, Rohrer, and Bjork (2008) defined learning styles as “the concept that individuals differ in regard to what mode of instruction or study is most effective for them” (p. 105). Studies on matching instructional mode (e.g., text, audio, visual information) to preferences has failed to produce compelling evidence to support any learning advantages of this type of tailoring (Pashler et al., 2008). Although matching instruction to learning styles may not produce benefits in learning, it appears to positively impact perceptions of health materials.

Tailoring has been shown to positively affect perceptions of health materials. For example, Nguyen and colleagues (2018) found that mode-tailoring health information (i.e., allowing participants to choose which format they saw) resulted in improved perceptions of both the attractiveness and comprehensibility of the materials for both older and younger participants. However, benefits in attention and memory were only observed in older but not younger adults due to mode-tailoring (Nguyen et al., 2017). Thus, research is warranted to investigate what may be more added or removed to positively influence the likelihood CMI is used and make it a more useful tool for consumers.

### 9.3.6 Conclusion: CMI Information Needs

Participant experiences with CMI revealed that CMI use is limited. Interviews with participants revealed a variety of ways in which CMI could be augmented to better suit consumers' needs. Additional exploration is warranted to examine which topics should be included or excluded from CMI. Evidence from this study suggests there are ample opportunities to improve CMI by addressing consumers' needs and incorporating their feedback. Arguably, CMI that is better aligned with consumer needs and preferences is more likely to be used.

## 9.4 A Novel Model Explaining CMI Use

As previously argued, memory of CMI is an important aspect to safe and effective medication use and overcoming memory limitations associated with CMI can be accomplished in two ways: 1) make CMI more memorable 2) make CMI more readily available. This study sought to explore these two opportunities to overcome memory limitations associated with CMI. Despite efforts to apply multimedia learning principles to improve memory for CMI, no gains in memory were observed. However, there were observable differences in perceptions of the different CMI formats. Moreover, evidence from this study suggests that consumers recognize the potential benefits of having CMI more available and are receptive to receiving CMI digitally to realize these benefits.

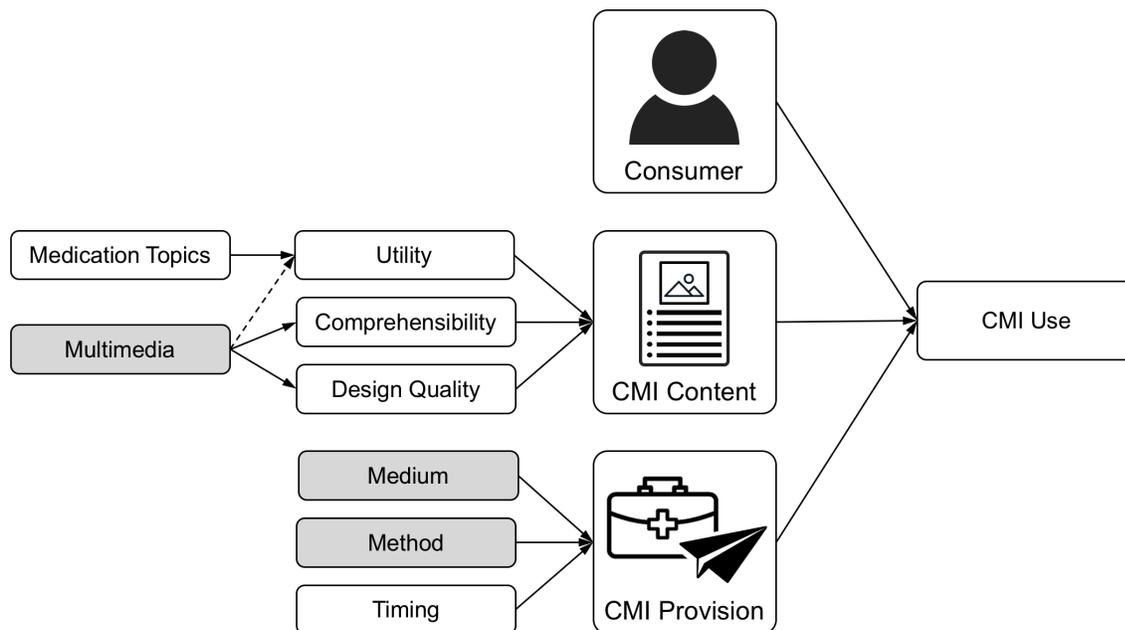
Although CMI influences safe and effective medication use, any potential benefits of CMI hinge on it actually being used. However, evidence from this study and others indicates that use of CMI is limited. Thus, perhaps the most fundamental and important question is actually a precursor to exploring comprehension and memory: *how can the use of CMI materials be increased?* Evidence from this study and others might provide

insight on how to increase the use of CMI and may be applicable to medication information targeted at consumers more generally (e.g., paper package inserts, medication guides).

This present study did not explicitly investigate CMI in naturalistic settings. Participants were not asked to rate how likely they would be to use any of the stimuli or CMI they had received from a healthcare provider for medications they were prescribed. However, in participants' comments about the advantages and disadvantages of the CMI stimuli as well as CMI for their prescriptions in the past, several opportunities to potentially encourage CMI use were identified. Further, existing properties of CMI and how it is provided to consumers were reported that appeared to discourage consumers from using CMI. Thus, CMI use emerged as an important consideration inadvertently and factors were identified that could encourage or discourage CMI use.

A model was developed to describe the findings of this study and other research on CMI use. This model is based on Koo and colleagues' (2002, 2003) work which generated three types of factors that potentially influence CMI use: those related to the consumer, the CMI document, and the provision of CMI (see Figure 28). It should be noted that the category labels used here are a combination of the those used in Koo and colleagues (2002; i.e., consumer, CMI format, and provision of CMI) and Koo and colleagues (2003; i.e., the patient, the written information document, and the environment). In addition to the three primary factors, contributing factors were also identified in Koo and colleagues' (2005a, 2005b, 2006, 2007) work which aligned with the results of this study. For brevity, only factors investigated in this study were included in the model (see Figure 28). Some of these factors (i.e., medication topics, utility,

comprehensibility, design quality and timing) have been previously investigated with respect to their potential influence on CMI use. The present study generated several new subordinate factors that arguably have the potential to influence CMI use as well, such as multimedia, the medium and method of CMI provision. Evidence from other studies describing the influence or potential influence of the factors in this model will be described and the findings from this study will be integrated with the existing research.



**Figure 28. Potential Factors Affecting CMI Use.**

*Note:* Grey boxes indicate factors originating from the present study. White boxes indicate factors based primarily on research by Krass, Svarsted, and Bultman (2002) and Koo, Krass, and Aslani (2002, 2003, 2005a, 2005b, 2006, 2007).

#### 9.4.1 CMI Use

Having consumers use CMI thereby bolstering safe and effective medication taking practices, is a primary goal of distributing CMI to consumers. In this model, CMI use is comprised of both intentions to use CMI and actual CMI. However, intention to use CMI may be an imperfect proxy for actual CMI use because consumers may report

that they will use CMI but not end up actually using it. This model also aggregates initial and subsequent CMI use into one outcome variable. However, CMI use may vary over time and thus it may be worthwhile to explore CMI use with a time component. For example, using CMI initially (i.e., the CMI has been received but the medication has not yet been taken) may be predicted by different factors than using CMI in the future (i.e., the CMI has been received and the medication has been taken for some time). Thus, there are four possibilities with respect to actual CMI use: consumers may or may not use CMI initially and they may or may not use CMI in the future and these types of CMI usage are independent (i.e., any combination of CMI use is possible). Arguably, initial use of CMI is a more proactive strategy, whereas future use of CMI is typically reactive. That is, using CMI after the medication has been taken is typically motivated by something forgotten about the medication or an unexpected event such as a side effect. Therefore, initial and future CMI use timepoints may warrant further investigation and may have different predictors.

#### **9.4.2 The Consumer**

Undoubtedly, there are an array of factors unique to each individual which will motivate or deter CMI use which belong to the “Consumer” box of the proposed model (see Figure 28). Evidence from an exploratory study using focus groups led Koo, Krass, and Aslani (2002) to propose a variety of consumer related factors that might increase or decrease the likelihood of using CMI. Specifically, consumers were more likely to read CMI if they perceived their illness as severe, felt responsible for their own well-being, had had a negative experience with a medication, coped by seeking information, or were in a caregiver role (Koo et al., 2002). In contrast, consumers were less likely to

read CMI if they perceived their illness as minor, trusted their healthcare provider(s), and had no previous issues taking medications (Koo et al., 2002) In a subsequent quantitative study, consumer factors accounted for three out of four factors explaining attitudes towards CMI (Koo et al., 2005a). That is, Koo and colleagues (2005a) reported that attitudes towards CMI were explained by the perception of disease/condition, role of carer, health locus of control, as well as readability and presentation (i.e., a document factor).

Another investigation in a large sample of consumers ( $N = 479$ ), found that interest in reading written medication information (e.g., CMI, paper package inserts) and information seeking were distinct constructs with unique predictors (Koo et al., 2006). Although participants expressed high interest in reading written medication information, they were very unlikely to seek it out for themselves (Koo et al., 2006). Further, interest in reading written medication information was predicted by coping style, health literacy levels, and occupation (Koo et al., 2006). In contrast, information seeking behaviour was best predicted by disease state, health locus of control, and health literacy levels (Koo et al., 2006).

Koo and colleagues (2005b) specifically investigated perceptions of CMI intentions of using CMI in the future using the adapted CIRF (Koo et al., 2007). Participants' reported likelihood of using CMI in the future was influenced by their levels of health literacy (i.e., a consumer factor) as well as ratings of CMI comprehensibility and utility (i.e., document factors; Koo et al., 2005b). As argued by Koo and colleagues (2005b), alternative methods of communication medication information should be explored.

Studies of predictors of CMI use have generated conflicting results. For example, Ramia and colleagues (2017) reported predictors of CMI use in their Lebanese sample were: age, gender, education, and adverse drug reaction awareness (i.e., whether or not healthcare providers had counseled consumers about potential side effects). In contrast, an investigation of American CMI found that only education was a significant factor in CMI use, but neither age nor gender were associated with CMI use (Nathan et al., 2007). Thus, it is presently unclear exactly which consumer factors and their relative influence, but it does appear that consumer factors influence CMI use (see Figure 28).

In summary, a variety of consumer specific factors have been found to influence information seeking, interest in reading CMI, attitudes towards CMI, and intentions to use CMI in the future, which all in turn may affect CMI use. Although demographic information was collected, this study did not explore relationships between consumer factors and intentions to use CMI specifically and therefore cannot elucidate consumer factors related to CMI use other than comments generated during the interviews.

In addition to consumer factors predicting intentions of using CMI in the future, consumer factors were also found to predict ratings of comprehensibility, utility and design quality (i.e., document factors). Specifically, Koo and colleagues (2003) found that participants' age and number of medications they were taking influenced their perceptions of CMI utility. Ratings of design quality were predicted by age, gender, and education level (Koo et al., 2003). Perceived comprehensibility was influenced by speaking primarily English at home, health literacy and education levels (Koo et al., 2003). Thus, consumer factors have the potential to impact intentions to use CMI in the

future both directly and indirectly as comprehensibility and utility were found to predict intentions to use CMI in the future (Koo et al., 2003).

### **9.4.3 CMI Content**

In addition to factors unique to the consumer, various aspects of the CMI document itself may influence whether or not consumers use CMI. In their early exploratory work, Koo and colleagues (2002) posited that CMI that was concise, written in simple language and used large print would be more likely to be read than CMI that was long, full of technical jargon, or used small print. Based on findings from the literature, Koo and colleagues (2003) posited both readability and presentation as factors that could influence the use of CMI. With respect to presentation, Koo and colleagues (2003) argued “the overall presentation or mode of delivery of the WDI [written drug information] itself (e.g., package insert or computer-generated leaflet), as well as the details of its presentation (e.g., font size, paper quality), can influence its use by consumers” (p. 261).

Subsequently, Koo and Colleagues (2005a) found that readability and presentation (assessed as a single factor) influenced attitudes towards CMI as well as three consumer factors which were previously described. Other perceptions of CMI were also found to influence whether or not participants intended to use CMI in the future. Specifically, Koo and colleagues’ (2005b) found that comprehensibility and utility ratings were positively correlated with intentions of future use (Koo et al., 2005b). However, there was no evidence that design quality influenced intentions of using CMI in the future (Koo et al., 2005b). Although Koo and colleagues (2005b) noted that it was surprising that design quality did not influence future use and argued that “patients were

not given a choice between the 2 CMI types they were asked to evaluate; thus, having any type of CMI, albeit poorly designed, may have been deemed better than having no CMI at all” (p. 1437). Alternatively, poor design may simply not be that influential provided the CMI content is useful and understandable (Koo et al., 2005b).

It is important to reiterate the difference between intentions of using CMI in the future (i.e., revisiting the material) compared with using it initially and how different factors may influence these behaviours. Although design quality did not influence evaluations of future use, it is plausible that it could affect whether or not CMI is used initially. For example, comments from participants in this study suggest that the lack of aesthetic appeal of current CMI served as a deterrent from using it. Further, Nathan and colleagues (2011) found that some participants (15.7%) in their study reported print size too small as the reason behind not always reading CMI. Results from this study concur with the findings of other studies (e.g., Koo et al., 2002; Nathan et al., 2011) such that the length of CMI (i.e., an index of utility) dissuaded participants from using it.

Several different comprehensibility issues were reported by participants in Nathan and colleagues’ (2011) study as reasons for not always reading CMI. Specifically, some participants (8.6%) expressed that CMI was difficult to understand or there was a language barrier and other participants considered the information confusing (5.6%) or too technical (4.5%; Nathan et al., 2011). Thus, comprehensibility can be considered to play a role, to some extent, in whether or not consumers use CMI.

As previously argued, the utility of CMI content can influence intentions to use CMI in the future, but some medication topics may only influence initial use. For example, including the cost of a medication in CMI may only influence whether or not CMI is used

initially, as this information is only pertinent in as a deciding factor of whether or not a medication will be taken. Also, in agreement with Koo and colleagues (2002), participants in this study recommended that CMI incorporate plain language principles. Further investigation is required to determine whether multimedia and medication topics affect initial use CMI as well as intentions to use it in the future.

#### 9.4.3.1 Medication Topics

Intuitively, what medication topics are selected for inclusion directly impact consumer perceptions of how useful (i.e., utility) CMI is. Based on evidence in this study, some consumers would like additional topics included in CMI to complement those measured in the adapted CIRF (see Table 12). Various agencies and researchers have stated different perspectives on what topics should and should not be included in medication information (e.g., the Committee on Safety of Medicines, 2005; Health Canada 2016; Monkman & Kushniruk, 2017b). However, Grime and colleagues' (2007) reported topics based on consumer reports of information needs in three studies. It has also been shown that prescribers and pharmacists' opinions of important medication topics vary from consumer perspectives (Nair et al., 2002).

Some topics suggested by participants in this study corroborate the perspectives of other agencies and research. For examples, others have also suggested that interactions (the Committee on Safety of Medicines, 2005; Health Canada, 2016; Grime et al., 2007; Monkman et al., 2017b), alternatives (Grime et al., 2007), and what to do in the event the medication does not work (the Committee on Safety of Medicines, 2005) should be included in CMI. However, new topics (i.e., cost and how it works) were also generated that may be worth exploring for their potential value in increasing the utility of

CMI which may increase the use of CMI. Taken together, the medication topics currently included in CMI are failing to meet the information needs of consumers. By improving the alignment between CMI medication topics and consumer information needs, CMI utility could be improved which could then influence CMI use (see Figure 28).

#### 9.4.3.2 Multimedia

Despite not affecting memory, CMI in multimedia formats (i.e., Text + Images and Narration + Images) positively influenced participant perceptions of both comprehensibility and design quality in this study. Further, there was some evidence that in a larger sample, multimedia may even influence the perceived utility of CMI. It is proposed that the perceived benefits of multimedia CMI may propagate through to positively influence CMI use (see Figure 28).

Interestingly, this study found that multimedia CMI formats positively affected participants' perceptions of not only design quality but also comprehensibility. CMI content was not manipulated in this study and therefore format manipulations should not have affected the utility of the information. Medication topics included and excluded as well as the amount of information can impact the utility of CMI. Findings from the interviews suggest that additional topics may be worth including in CMI and could potentially increase the utility of CMI. Koo and colleagues (2005b) found that higher ratings of CMI utility and comprehensibility were associated with higher ratings of future use. By extrapolating, it is plausible that the effects of multimedia on comprehensibility and potentially utility as found in this study would positively affect intentions to use CMI in the future. The argument that multimedia has the potential to bolster CMI use is also

supported by other studies which have demonstrated multimedia materials are more likely to be used than plain text alternatives. Findings supporting this argument include increased reading rates of discharge materials with pictures (Delp & Jones, 1996) and increased likelihood of referring to medication information with pictograms in the future (Advani et al., 2013). Although, Koo and colleagues (2005b) failed to find a relationship between design quality and intention to use CMI in the future, their stimuli did not appear to include multimedia. Thus, multimedia is likely to have positively influence CMI use both directly and indirectly.

#### 9.4.3.3 Utility

Fundamentally, utility is consumers' perceptions of how useful CMI content is. The amount and usefulness of information in CMI appear to play an important role in whether or not consumers will use CMI or not. Specifically, the lengthiness of current CMI was cited as a deterrent from using it. Similarly, Koo and colleagues (2002) reported that the length of CMI influenced reported CMI use, such that more concise materials were more likely to be read. Evidence from the interviews supports the Committee on Safety of Medicines' (2005) position that CMI length deters consumers from using CMI and consumers appear to want a CMI summary such as the Committee's proposed "headlines" approach. In theory, minimizing CMI content may make it easier to read, understand, and remember. Indeed, Reder and Anderson (1980) found that memory for summaries are better than the longer versions of texts and that these effects persist over time. Further, participants in Gossell-Williams and colleagues (2012) study remembered CMI better and rated it as easier to read and more attractive than the standard (lengthier) drug monographs in their study. Therefore, brevity may not

only affect the appeal and intention to use CMI but also its comprehensibility. Moreover, it was not just the conciseness that improved memory but Reder and Anderson (1982) found the spacing (i.e., design quality) was also found to be a beneficial factor in memory.

Although many argue that CMI should be more concise, some participants in this study wanted additional information or wanted existing information to be more explicit instead. As previously described in the medication topics section, new categories of information might be worthwhile exploring for their potential to increase the perceived utility of CMI. Additionally, including more precise information about side effects (i.e., specific proportions of people who experience side effects rather than verbal labels such as common or rare), similar to Denmark's `min.medicin.dk` approach, may make CMI more useful. Thus, evidence from this study and others suggests that the utility of CMI could be improved by including a summary and incorporating new or improving existing content. Moreover, improving the utility of CMI has the potential to impact whether or not consumers use CMI (see Figure 28).

#### 9.4.3.4 Comprehensibility

How well consumers understand CMI, or comprehensibility, can be affected by a variety of factors. Findings from this study support Koo and colleagues (2007) position that how easy information is to read, understand, remember and locate information affect comprehensibility perceptions. However, additional factors were identified in this study that also appeared to influence perceptions of comprehensibility (i.e., ease of capturing attention, processing, scanning, reviewing, and multimedia). Further, Koo and colleagues (2002) reported that excessive technical language deterred consumers from

using CMI. Comments from this study also suggest that CMI comprehensibility could be improved by using plain language principles (e.g., avoiding jargon). Thus, an array of factors from this study and others have the potential to impact CMI comprehensibility which could then influence whether or not consumers use CMI (see Figure 28).

Given that being able to understand and use CMI to address potential issues that may arise while taking a prescription medication, comprehensibility has been studied widely. This experiment did not manipulate CMI content, but as several other studies have explored how CMI comprehensibility could be improved (e.g., Morrow & Conner-Garcia, 2013, Morrow et al., 2005). Further, as previously argued, comprehensibility is often dependent on other factors (e.g., utility, design quality). For example, Morrow and colleagues (2005) modified the font-size (i.e., design quality), readability scores and length (i.e., utility factors) as well as incorporated multimedia.

Comprehensibility is an important aspect of CMI and consumer health information more generally. Lampert, Wien, Haefeli, and Seidling (2016) recently proposed a four-step process for achieving comprehensible patient information leaflets:

“(i) an initial requirement analysis specifying the needs and constraints of the target population and evidence-based preparation of the leaflets, (ii) a readability assessment, (iii) the Suitability Assessment of Materials instrument and (iv) iterative consumer test in the target population” (p. 634)

Thus, Lampert and colleagues proposed a user-centred design approach to focus on users' characteristics and needs and tests these materials with target users. Additionally Lampert and colleagues (2016) provided examples of test questions about the materials for target users that covered layout and typography (i.e., design quality), general and

specific comprehension, as well as illustrations. Again, it can be observed that comprehensibility is reliant on other factors as well.

Perceptions of comprehensibility are related to the notion of fluency. Fluency is "the subjective experience of ease or difficulty associated with completing a mental task" (Oppenheimer, 2008, p. 237). A variety of factors (e.g., readability, legibility) can influence perceptions of fluency which in turn impact judgements. Studies have shown that positive perceptions of fluency can make messages seem more truthful (e.g., Reber & Schwarz, 1999) and authors seem more intelligent (Oppenheimer, 2006). Thus, based on fluency research perceptions of comprehensibility may impact other perceptions as well.

#### 9.4.3.5 Design Quality

Design quality, or the aesthetic appeal of CMI, also has a variety of contributing factors. Koo and colleagues (2007) measured perceptions of organization, attractiveness, print size, and spacing as indices of design quality. Comments by participants in this study also suggest that aesthetic appeal influences CMI use, whereby current CMI is unattractive and deters use. This finding aligns with Koo and colleagues (2002) who reported that CMI's unattractiveness and small font hindered CMI use. Additionally, results from this study also suggest that multimedia impacts perceptions of design quality, which may in turn influence whether consumers use CMI. Specifically, some participants in this study reported that the aesthetic appeal of the multimedia formats, particularly the Text + Images format, may make them more likely to use the CMI than traditional text only CMI. Thus, poor design quality of existing CMI

appears to deter users, whereas incorporating multimedia and improving the aesthetic appeal of CMI may encourage its use (see Figure 28).

#### **9.4.4 CMI Provision**

Provision of CMI is comprised of factors related to how and when consumers obtain, access, and store CMI. Results from this study suggest that there are several provision factors which relate to which could plausibly affect CMI use. The factors explored in this study related to the provision of CMI were around when CMI is provided (i.e., timing) as well as how CMI is provided (i.e., the medium and the method) to consumers can influence whether or not it is available when consumers need it and therefore affect whether or not CMI is used (see Figure 28).

Koo and colleagues (2002) used provision of CMI as a category to describe how certain factors could increase or decrease the likelihood of consumers using CMI. For example, consumers might be less likely to use CMI if it was not provided or if the healthcare provider failed to emphasize the importance of the CMI (Koo et al., 2002). Further, the timing of when CMI was provided was also identified as having the potential to increase or decrease the likelihood of whether consumers would use it. Specifically, some participants described that giving them CMI when they were physically or emotionally unwell would negatively impact its use (Koo et al., 2002). Moreover, as in the present study, the majority of participants in Koo and colleagues' (2002) preferred receiving CMI prior to getting their prescriptions filled. However, in subsequent work, instead of using the term provision, Koo and colleagues (2003) referred to a similar concept as "the environment". Koo and colleagues (2003) defined the environment as comprised of factors "related to the environment in which WDI [written drug information]

is or was given or used” (p. 274). Further, Koo and colleagues (2003) posited that positive experiences with written drug information (e.g., CMI, paper package insert) with respect to the usefulness of the document, or the experience with the healthcare provider when the information is provided, is more likely to respond positively to this written drug information in the future.

#### 9.4.4.1 Timing of CMI Provision

Timing was previously identified as a provision factor with the potential of influencing CMI use (Koo et al., 2002, 2003). Koo and colleagues (2002) reported that consumers might be more likely to use CMI use if it was provided at the appropriate time. For example, “some consumers commented that CMIs could be wasted if given when they were feeling physically unwell or emotionally upset” (Koo et al., 2002, p. 112). Thus, the emotional and physical state of the consumer is important to consider and determine whether it is an appropriate time to provide CMI. Concurring with the findings from the current study, Koo and colleagues (2002) reported that the majority of their focus group participants preferred receiving CMI prior to paying for or taking the medication and a few even wanted to receive CMI from their prescriber. However, many participants wanted to receive CMI at the same time as their medication to prevent loss (Koo et al., 2002). However, Koo and colleagues (2005a) reported only minor differences between consumers timing preferences. In their sample ( $N = 226$ ), participants were almost equally divided between wanting to receive CMI from their prescribers (29%) or at the pharmacy after the prescription was dispensed (27%; Koo et al., 2005a). Thus, it is unclear when the most appropriate time to provide consumers CMI is.

#### 9.4.4.2 Medium of CMI Provision

It is argued here that there are other important components of the provision as well. Specifically, results from this study suggest that both the medium and the method are additional factors which should be considered with respect to CMI provision. For the purposes of this discussion, the medium is whether CMI is provided digitally or in printed hardcopy. Thus, to some extent the medium influences whether or not certain multimedia can be used (i.e., video, narration). For example, participants in this study felt that a video was not a suitable way to deliver CMI and some expressed that this format would deter them from using it. Although a video may be appropriate as the sole means of providing CMI, it may be beneficial if offered in complement to a static version or for select CMI information such as directions. Further, having the capability of narration may be an important feature for consumers who have vision impairments.

Participants discussed that logically, losing hardcopy CMI prevented them from using it. Therefore, providing CMI in a way that can be readily stored or accessed (i.e., digital) could facilitate consumers using it. Thus, CMI medium has the potential to influence the possible features of CMI (e.g., video, narration, collapsible categories) as well as how easy CMI is to keep and access when necessary, which all could impact CMI use (see Figure 28).

#### 9.4.4.3 Method of CMI Provision

Based on evidence from this study all digital distribution methods (e.g., an email, a website, a mobile application) are not considered equal by consumers. Participants in this sample did not consider either mobile application or a website as suitable methods for providing CMI. Whether CMI was provided as a push or pull communication method

also influenced whether participants' reports of whether or not they would use CMI. Concurring with Koo and colleagues (2006), participants in this study were not motivated to seek out CMI. Participants in this study considered email to be most suitable method for distributing CMI, as it was sent directly to them and easy to store. Participants also recognized that consumers with more complex health issues may have different preferences on how best to receive CMI and that CMI should not necessarily be a standalone item. That is, it may be worthwhile integrating CMI into an application that facilitates communication between consumers and pharmacists and remind them of when their medications should be taken. Results from this study suggest that the timing, medium, and method of CMI provision all have the potential to influence whether or not consumers use CMI (see Figure 28).

## **9.5 Limitations**

### **9.5.1 Sample Limitations**

There were several limitations that may affect the generalizability of the results of this study. Opinions and performance of young, educated, generally healthy, adults, such as those in this sample of participants in this study, may not be representative of other groups of consumers, or consumers as a whole.

This study may have been affected by sampling error. First, this study used a convenience sample, whereby provided they met the eligibility criteria, participants were included in the sample. Unfortunately, this approach resulted in a higher percentage of female (i.e., 72.2%) than male (i.e., 27.8%) participants (see Table 11). Second, participants in this study had higher rates of prescription medication use than would be expected based on Canadian population data. Specifically, 55.6% of participants

reported using one or more medication (see Table 13). However, Statistics Canada (2014) found that approximately 26.2% of adults between the ages of 15 – 24 years old and 28.0% of those between 25 – 44 years old reported taking at least one prescription medication in the past two days. Thus, this may be an anomalous sample or perhaps medication use is more prevalent in the academic setting than in the population more broadly. The investigator found no reports of prescription medication use specific to the academic setting, with the exception of a study Patel and colleagues (2018). Patel and colleagues' sampled American university students (N = 306, mean age = 23.6) and had more female than male participants (62% vs. 38%), similar to the present study. This study asked only about current use of prescription medications. However, Patel and colleagues asked whether the students were currently taking or had ever taken a prescription medication. Thus, it is not prudent to compare Patel and colleagues' findings that 73% of the sample had taken or was currently taking a prescription medication with the 55.6% of this sample currently. Thus, Patel and colleagues' more precise approach would be a more prudent approach in the future. Thus, potential sampling error (i.e., substantially more females and higher rates of medication use) may have affected the results and therefore somewhat limits the generalizability of the study findings.

There may have been a Hawthorne effect (French, 1953) also referred to as the observer effect in this study. That is, participants' performance in the proposed study may have been better than memory for medication information in naturalistic conditions, because of the experimental context and observation by the researcher. However, although participants may have recalled more information because of the Hawthorne

effect (French, 1953), participants may have recalled less medication information because the medication stimuli were not necessarily relevant to them. For example, Patel and colleagues (2018) found that participants performed better when they imagined themselves in scenarios where they had a serious illness and the medication had the potential for severe side effects. This study attempted to minimize potential effects due to familiarity with the stimuli medications, but consumers may be more motivated to remember medication information when it is a prescription they are taking due to potential implications of taking the medication.

### **9.5.2 Stimuli Limitations**

There were several limitations of the CMI stimuli in this study. Firstly, none of the medications in this study were pills (i.e., pills, tablets, capsules). Pills are likely the most frequently prescribed and used medications. However, attempting to select equivalent medications for the three formats all pills and tablets (i.e., the most commonly dispensed forms of medications) were excluded. CMI for pills generally does include limited or no information whatsoever about administration. In contrast, nasal sprays, eye drops, and inhalers such as the stimuli in this study, require more detailed administration instructions. More complex administration methods may have artificially increased the perceived benefit of images. However, CMI for inhalers does not typically include administration steps, but instead refers consumers to patient package inserts, an approach criticized for its potential to compromise the efficacy of inhaler use (Monkman & Kushniruk, 2017a).

Thirdly, the attempt to select equally memorable medications was unsuccessful. Specifically, the three medications were not equivalent but rather significantly different

(i.e., not equivalent) in terms of memorability, as revealed by a one-way, repeated-measures ANOVA,  $F(2, 70) = 15.47, p < .001$ . Post hoc comparisons using a Bonferroni correction revealed that participants remembered significantly more about Cromolyn ( $M = 14.50, SD = 3.00$ ) than either Betaderm ( $M = 1.44, SD = 2.67$ ) or Flovent ( $M = 11.78, SD = 3.38$ ). However, there was no evidence to suggest a difference in memorability existed between the Betaderm and Flovent stimuli.

This study was a repeated measures design which allowed participants to make informed comparisons between the three formats because they had exposure to all of them. Unsurprisingly, participants did exhibit learning or practice effects whereby more information was recalled in subsequent conditions. Participants likely used the questions from the first condition to guide their attention and studying to improve their performance during the second and third condition. However, counterbalancing mitigated the impact practice effects could have on recall results.

### **9.5.3 Methodological Limitations**

Familiarity with a medication (e.g., having been prescribed it previously) has been shown to facilitate memory (Morrow et al., 2005). Despite attempts to minimize familiarity through stimuli selection, some participants were familiar with the medication stimuli. Specifically, 17 of the 108 (3 conditions x 36 participants) or 15.7% of the trials were potentially affected by familiarity. However, the familiarity with medication stimuli question did not ask how recently the medication had been used and thus, it is difficult to ascertain whether familiarity would have had any impact on the present results. That is, if medications had been used temporarily a long time ago, advantages in recall would be unlikely whereas the opposite would be true if the medication was currently used.

With regards to format, Text, Text + Images and Narration + Images Format were familiar in five, three, and nine trials respectively. Unfortunately, this means Narration + Images trials may have had a slight memory advantage. With respect to medications, Betaderm, Cromolyn, and Flovent were familiar in four, six, and seven trials respectively. However, these values cannot account for evidence that Cromolyn was remembered better than the other two medications, given that more participants reported being familiar with Flovent. Thus, some participants expressed familiarity with the medication stimuli in this study, which may have created memory advantages, but it cannot be determined the extent, if any, to which familiarity had an impact on memory.

The NVS (Weiss et al., 2005) has only been validated using paper administration not online administration as was used in this study. Further, for some questions, the survey software and size of the ice cream label image prevented participants from being able to see the label and the question simultaneously. This may have increased the demands on working memory. For example, as participants would have had to remember the question while scrolling up to see the label and search for the relevant information and then remember the response while navigating back to answer the question.

The adapted CIRF was administered after each exposure to a stimulus and primarily served as a distractor task and to familiarize participants with the concepts of comprehensibility, utility, and design quality. Single-item measures of these three concepts were used to compare of perceptions between the three formats. However, single-item measures are inherently less detailed and thus it is difficult to determine with certainty which to what extent individual factors influenced these perceptions. Further,

each format was paired with a different medication. To some extent these two components (i.e., format and medication) may be inextricable and therefore difficult for participants to rate perceptions of the format without taking the content of the CMI for a specific medication into consideration. Thus, this study precluded making detailed inferences based on the item level of each of the subscales and further there was some variation due to the medications themselves.

Although the model developed seeks to attribute CMI use to various different factors, actual CMI use was not assessed in this study. That is, unlike other studies which examined CMI use shortly after participants received CMI, this study asked about participants' previous experiences with CMI. Therefore, a substantial amount of time may have elapsed between when the participants last received a new prescription and the study, which may have impacted the accuracy of their memory of the events. The time elapsed between receiving CMI and study participation was likely variable. Thus, some participant reports may not have been entirely accurate. Therefore, further investigation is required whereby consumers are studied near the time of receiving CMI to assess how well the factors in this model reflect real world CMI use.

## **9.6 Contribution to Science**

This study systematically explored the potential effects of multimedia on CMI and the findings make important contributions to the domain of multimedia learning as well as health informatics. Unlike most studies exploring strategies for improving memory and comprehension of medication information, this study held content constant to isolate the potential unique contributions of images and narration (i.e., multimedia). Findings from this study suggest that using multimedia does not impact memory for

CMI. Specifically, neither the addition of images nor narration to CMI resulted in any observable memory gains. Although multimedia has proven beneficial in a variety of studies, it did not facilitate memory for CMI in this experiment. As discussed, there are several potential reasons for the lack of evidence to support the multimedia or modality effects in this study (i.e., comprehension was not tested, the descriptive nature of medication information, multimedia benefits limited to specific types of consumers). However, without additional research, it cannot be determined with certainty whether multimedia impacts consumers' ability to learn CMI or not.

This study also explored the potential impact of multimedia on consumers' perceptions and preferences of CMI. Interestingly, despite the lack of performance gains (i.e., memory), multimedia significantly impacted participants' perceptions of the materials and their preferences. Specifically, pairing traditional CMI content with images resulted in higher ratings of both comprehensibility, design quality, and to a limited extent, utility. These positive ratings also translated into the highest preference overall for the text and images format, whereas participants selected the plain text format as their least favourite most often. Thus, CMI conveyed using narration and images was neither highly favoured nor extremely disliked by participants. Deeper qualitative exploration into the rationale behind their ratings and choices revealed interesting sentiments about CMI, which could benefit the design of CMI.

In addition to investigating subjective and objective aspects of multimedia CMI, this study explored consumers' information needs specific to when and how (i.e., medium and method) CMI should be provided. Similar to Koo and colleagues (2002), many participants in this study indicated that having CMI before filling a new prescription

would be beneficial. In contrast to previous reports that only a minority of consumers were interested in electronic CMI (Hammar et al., 2016), participants in this study were very interested in electronic CMI. This may have been attributable to the notion that participants in this study did not see electronic CMI as a replacement for paper, but instead it would be an optional medium for receiving it. Moreover, this sample considered email the most suitable method of receiving electronic CMI for various reasons (e.g., no additional login, easy to save, easy to search).

Finally, the results from this study were synthesized to develop a new model attempting to explain various factors associated with CMI use. Although previous studies have identified factors potentially contributing to CMI use, these factors were not organized into a unified model. This model could be a valuable framework for future studies to systematically examine the strength of different factors that influence CMI use and guide evidence-based interventions to increase CMI use.

Results from this study contribute to the domain of health informatics as they can be used to guide the design, development, and distribution of CMI. Despite the lack of impact memory, multimedia did positively affect perceptions of the comprehensibility and design quality of CMI. Although some might argue that failure to find memory effects suggests that using multimedia for CMI is unnecessary, it is argued here that the gains observed in preferences as a result of using multimedia are important as they have the potential to increase the use of CMI and therefore increase the safety and efficacy of medication use. Findings from this study and others (e.g., Leemans et al., 2011; Wolf et al., 2006) suggest that a considerable portion of consumers ignore CMI. As Leemans and colleagues (2011) argued, efforts should be made to make CMI more

appealing and more useful to increase the likelihood that consumers will use it. Findings from this study were integrated with other evidence and used to develop a new model, which could be used to explore the extent to which different factors influence CMI use. Many of the findings from this study were qualitative in nature but serve to establish a foundation for further investigation of what motivates and deters consumers from using CMI.

### **9.7 Future Directions**

The absence of any effect of multimedia on memory was surprising. Several potential explanations for the lack evidence supporting either the multimedia or modality effects in this study. Moreover, it cannot be determined with certainty that multimedia does not affect learning for CMI only that the this was not observed in the present experiment. To further explore the potential of multimedia to affect learning a between subjects' design using a single medication (control for differences found and practice effects) using a comprehension task should be conducted. Additionally, learning should also be explored under more naturalistic conditions (i.e., with participants' own prescription medications).

The model developed here was inspired by other research but could prove to be a useful tool for investigating the potential factors affecting CMI and for driving and informing the design of new forms of CMI. The relative strengths of the various consumer, document, and provision factors require investigation to reveal which factors affect CMI use more than others and whether or not these factors differ for consumer groups or are generalizable should be explored. Thus, a randomized controlled trial using a larger more diverse sample of consumers should be used to test the validity of

this model and actual CMI use rather than historical experiences with CMI should be examined. Although in its nascent stages this new model provides a framework that can be used to categorize research on different variables that affect CMI use. Ultimately, CMI needs to be redesigned and evaluated so that it aligns with users' needs and preferences to make it into a valuable tool, rather than one that is often overlooked.

In an effort to improve medication safety, countries have been making efforts to improve the quality and provision of CMI internationally. Canada is currently in the process of rolling out a national electronic prescribing (i.e., ePrescribing) tool in an attempt to increase the safety and efficiency of the prescribing process (PrescribeIT, n.d.). Thus, the timing is optimal to determine how many Canadians actually use CMI, what factors influence CMI use, how CMI can better address CMI information needs, as well as how to improve the provision and memory of CMI to improve medication safety. Moreover, it would also be worth exploring a single standardized form of CMI as it is unclear the extent to which consumers are aware how much CMI varies between pharmacies or even that it varies at all.

## **9.8 Conclusion**

This study examined participants' memory, perceptions, preferences and information needs for CMI. Although CMI is meant to improve the safety and efficacy of taking prescription medications by educating consumers, as it is currently designed and distributed, it fails to meet consumers' needs. This misalignment limits potential benefits associated with providing CMI to consumers. Findings from this study should be leveraged to examine consumers' perceptions, preferences, and information needs in a

broader sample of Canadians to determine how CMI can improved to ensure it is used, understood, and benefits people taking prescription medications.

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## Appendices

### Appendix A Text Format for Betaderm

Written content was developed by a leading Canadian pharmacy.

**Brand Name:** BETADERM CRM 0.1 %

**Chemical Name:** BETAMETHASONE VAL 0.1 %

**Common uses**

This medication contains a topical anti-inflammatory drug from the cortisone family (corticosteroid). Typically, it is used for inflammation and itching. It requires several days to take effect.

**How to use this medication**

This medication is to be applied on the skin. To use:

- clean the affected area;
- apply a small quantity, and limit the application to the affected area.

Wash your hands after applying the medication – unless, obviously, you applied the medication on your hands!

Do not let this product come in contact with your eyes.

This medication is typically used twice a day. However, your doctor or pharmacist may have suggested a different schedule that is more appropriate for you. Continue applying the product to complete the prescribed course of treatment, even after improvement is seen or felt.

Important: Follow instructions on the label. Do not use more of this product, or more often, than prescribed. Cortisone products can thin the skin and increase the risk of skin infections. Do not use for longer than necessary.

**Possible side effects**

In addition to its desired action, this medication may cause some side effects, notably:

- it may cause spots or redness of the skin
- it may lighten the skin where it is applied

Each person may react differently to a treatment. If you think this medication may be causing side effects (including those described here, or others), talk to your doctor or pharmacist.

## Appendix B

### Text + Images Format for Cromolyn

Written content was developed by a leading Canadian pharmacy.



**Brand Name: Cromolyn op drp 2%**  
**Chemical Name: Sodium Cromoglycate 2%**

**Common Uses**

This medication is typically used for allergic conjunctivitis (inflammation of the clear covering of the front of the eye, due to allergies).  Allergic Conjunctivitis

It requires several days to take effect. 

**How to Use This Medication**

To use: This medication is for the eye. 

**1** Wash your hands as well as the skin surrounding the affected eye



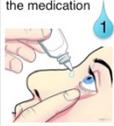
**2** Shake the container



**3** Gently pull down the lower lid of the affected eye



**4** Apply 1 drop of the medication



**5** Close the eye for 2 to 3 minutes, while gently pressing on the inner corner of the eye



To avoid contaminating the medication, do not let the tip of the applicator touch your fingers or any part of your eye



Close the container tightly after each use.

This medication is typically used 4 times a day. However, your doctor or pharmacist may have suggested a different schedule that is more appropriate for you.

**1**



8 am

**2**



noon

**3**



4 pm

**4**



8 pm

Use it regularly and continuously to maintain its beneficial effects.

Everyday 

If you forget a dose, apply it as soon as you remember –



Or

Unless it is almost time for your next dose. In that case, skip the missed one. Do not apply more to try to catch up.



**Possible Side Effects**

In addition to its desired action, this medication may cause some side effects, notably:

When it is used, it may cause local irritation



When it is used, it may cause a temporary burning sensation



It may cause a stinging sensation.



### Image Credits for Cromolyn

The following images were used to create the Text + Images & Narration + Images conditions, from left to right, top to bottom:

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“Pull down lower eyelid” by <https://www.wikihow.com/> is licensed under Creative Commons [CC BY-NC-SA 3.0 License](https://creativecommons.org/licenses/by-nc-sa/3.0/).

“Pull down lower eyelid” by <https://www.wikihow.com/> is licensed under Creative Commons [CC BY-NC-SA 3.0 License](https://creativecommons.org/licenses/by-nc-sa/3.0/).

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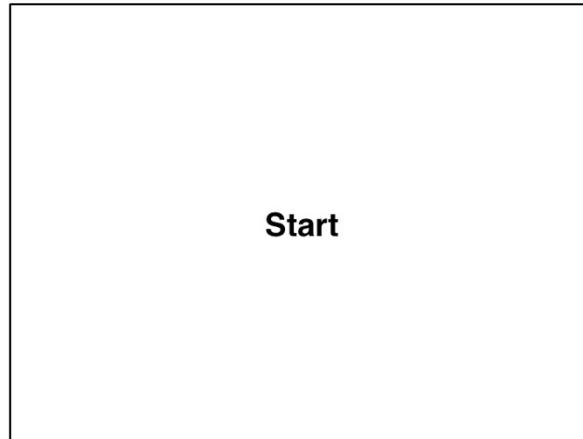
Purchased from iStock by Getty Images. Monster Wasp – Stock Image. Retrieved from <https://www.istockphoto.com/gb/photo/monster-wasp-gm139262382-322068>

## Appendix C

### Narration + Images Format Slides for Flovent

Audio recordings were based on the written content developed by a leading Canadian pharmacy.

Slide 1



Slide 2



 **Brand Name: Flovent Diskus 50mcg**  
Chemical Name: Fluticasone Prop 50mcg

**Common Uses**

Asthma



Slide 3

### How to Use This Medication

Slide 4: How to Use This Medication. This slide features a speaker icon in the top left and a person's head with an inhaler in the top right. The main content is divided into two panels. The left panel shows a box of Flovent Diskus 50mcg and a hand holding a diskus with a speech bubble that says "INSTRUCTIONS PLEASE READ CAREFULLY". The right panel shows a photograph of a doctor in a white coat and a patient in a blue shirt, both looking at a purple inhaler.

Slide 4

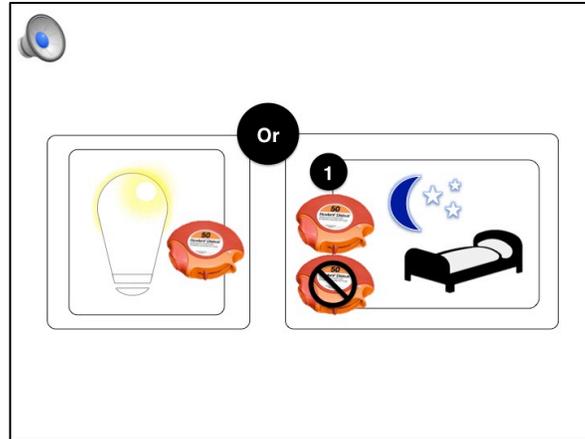
Slide 5: Medication schedule. This slide shows two inhaler icons. The first is labeled '1' and is associated with daytime icons: a sun and a coffee cup. The second is labeled '2' and is associated with nighttime icons: a moon, stars, and a bed. An ampersand (&) is placed between the two inhalers. Below the inhalers is a calendar icon with the word "Everyday" written above it, and the numbers 29 and 31 visible on the calendar pages.

Slide 5

### Important

Slide 6: Important information. This slide has a red header with a speaker icon and the word "Important". Below the header is a pharmacy card for "Local Pharmacy" (123 MAIN STREET, ANYTOWN, CANADA, (250) 123-5555) with a prescription for "Flovent Diskus 50mcg" and the instruction "INHALE TWICE DAILY". To the right of the card is a diagram of the inhaler steps labeled '1' and '2' with the word "Only" in a black circle. Below the pharmacy card are two panels: "Throat Irritation & Coughing" showing a patient coughing, and "Gargle" showing a patient gargling.

Slide 6



Slide 7

**Possible Side Effects**

<p>Thrush</p>	<p>Hoarseness</p>	
<p>Irritate Your Throat</p>	<p>Headaches</p>	<p>Nasal Irritation or Stiffness</p>

Slide 8

**End**

## Image Credits for Flovent

The following images were used to create the Text + Images & Narration + Images conditions, from left to right, top to bottom:

Drugsdepot.com. Flovent Diskus 250mcg Inhaler 1X60 each Mfg.by: Glaxo Smithkline USA. Retrieved from [http://www.drugsdepot.com/catalog.php/drugsdepot/ct13758/Generic\\_Items\\_Otc](http://www.drugsdepot.com/catalog.php/drugsdepot/ct13758/Generic_Items_Otc)

“Woman holding chest” by <https://www.wikihow.com/> is licensed under Creative Commons [CC BY-NC-SA 3.0 License](https://creativecommons.org/licenses/by-nc-sa/3.0/).

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“Coffee mug” created using Microsoft PowerPoint.

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## Appendix D Human Research Ethics Board Certificate of Approval



Office of Research Services | Human Research Ethics Board  
Administrative Services Building Rm B202 PO Box 1700 STN CSC Victoria BC V8W 2Y2 Canada  
T 250-472-4545 | F 250-721-8960 | uvic.ca/research | ethics@uvic.ca

### Certificate of Approval

<b>PRINCIPAL INVESTIGATOR:</b> Helen Monkman <b>UVic STATUS:</b> Ph.D. Student <b>UVic DEPARTMENT:</b> HEIS <b>SUPERVISOR:</b> Dr. Andre Kushniruk	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: right;"><b>ETHICS PROTOCOL NUMBER</b></td> <td style="text-align: left;"><b>16-198</b></td> </tr> <tr> <td colspan="2" style="text-align: center; font-size: small;"><i>Minimal Risk Review - Deidentified</i></td> </tr> <tr> <td style="text-align: right;"><b>ORIGINAL APPROVAL DATE:</b></td> <td style="text-align: left;">14-Jun-16</td> </tr> <tr> <td style="text-align: right;"><b>APPROVED ON:</b></td> <td style="text-align: left;">14-Jun-16</td> </tr> <tr> <td style="text-align: right;"><b>APPROVAL EXPIRY DATE:</b></td> <td style="text-align: left;">13-Jun-17</td> </tr> </table>	<b>ETHICS PROTOCOL NUMBER</b>	<b>16-198</b>	<i>Minimal Risk Review - Deidentified</i>		<b>ORIGINAL APPROVAL DATE:</b>	14-Jun-16	<b>APPROVED ON:</b>	14-Jun-16	<b>APPROVAL EXPIRY DATE:</b>	13-Jun-17
<b>ETHICS PROTOCOL NUMBER</b>	<b>16-198</b>										
<i>Minimal Risk Review - Deidentified</i>											
<b>ORIGINAL APPROVAL DATE:</b>	14-Jun-16										
<b>APPROVED ON:</b>	14-Jun-16										
<b>APPROVAL EXPIRY DATE:</b>	13-Jun-17										
<b>PROJECT TITLE:</b> Consumer Medication Information: Memory, Perceptions, Preferences, and Information Needs of Consumers  <b>RESEARCH TEAM MEMBER:</b> None   <b>DECLARED PROJECT FUNDING:</b> None											
<b>CONDITIONS OF APPROVAL</b>											
<p>This Certificate of Approval is valid for the above term provided there is no change in the protocol.</p> <p><b>Modifications</b> To make any changes to the approved research procedures in your study, please submit a "Request for Modification" form. You must receive ethics approval before proceeding with your modified protocol.</p> <p><b>Renewals</b> Your ethics approval must be current for the period during which you are recruiting participants or collecting data. To renew your protocol, please submit a "Request for Renewal" form before the expiry date on your certificate. You will be sent an emailed reminder prompting you to renew your protocol about six weeks before your expiry date.</p> <p><b>Project Closures</b> When you have completed all data collection activities and will have no further contact with participants, please notify the Human Research Ethics Board by submitting a "Notice of Project Completion" form.</p>											
<b>Certification</b>											
<p>This certifies that the UVic Human Research Ethics Board has examined this research protocol and concluded that, in all respects, the proposed research meets the appropriate standards of ethics as outlined by the University of Victoria Research Regulations Involving Human Participants.</p>   <hr style="width: 20%; margin: auto;"/> <p style="text-align: center;">Dr. Rachael Scarth Associate Vice-President Research Operations</p>											

Certificate Issued On: 14-Jun-16

16-198  
Monkman, Helen

## Appendix E Demographic Questionnaire

1. What is your date of birth? \_\_\_\_\_
2. Are you: Female      Male
3. Which one (or more) of the following ethnic groups do you most identify with?
 

<input type="checkbox"/> Aboriginal	<input type="checkbox"/> Latin American
<input type="checkbox"/> Black	<input type="checkbox"/> South Asian (e.g., East Indian, Pakistani, Sri Lankan, etc.)
<input type="checkbox"/> Chinese	<input type="checkbox"/> Southeast Asian (e.g., Vietnamese, Cambodian, Malaysian, Laotian, etc.)
<input type="checkbox"/> Filipino	<input type="checkbox"/> West Asian (e.g., Iranian, Afghan, etc.)
<input type="checkbox"/> Japanese	<input type="checkbox"/> Caucasian / White
<input type="checkbox"/> Korean	<input type="checkbox"/> Other
4. What best describes your current employment status (select all that apply):
  - Employed Full-Time
  - Employed Part-Time
  - Self-employed
  - Not employed
  - Homemaker
  - Retired
  - Student
  - Prefer Not to Answer
  - a. [If a student = yes], what is your current enrolment status:
    - Full Time     Part Time     Co-op       Other
  - b. [If a student = yes] What faculty are you in?  
\_\_\_\_\_
  - c. [If a student = no] What is (or was) your profession?  
\_\_\_\_\_
5. What is the highest level of education you completed?
  - High School Diploma
  - Undergraduate / College Certificate, Degree, or Diploma
  - Graduate or Professional Degree
  - Other
  - d. In what area or speciality? \_\_\_\_\_



## Appendix F Memory Task

I will now ask you questions about the medication you just learned about. Please do your best to remember as much as you can. Some of the questions are not applicable to all of the medications. If you think the question is not applicable, please tell me and we will skip it.

1. What were the two names of the medication?
2. Why would you be taking this medication? That is, what condition or conditions is the medication usually used to treat?
3. How long does it typically take for the medication to start working?
4. Where do you apply or administer this medication?
5. How would you take this medication? That is, what are the instructions and steps?
6. How many times a day is this medication usually taken?
7. What should you do if you missed a dose of this medication?
8. What are the potential side effects of this medication?
9. Is there any other important information to remember about this medication?
10. Is there anything else you remember about this medication?

\*Additional explanatory question: If someone didn't know anything about this taking this medication, what would you tell them?

## Appendix G Perceptions and Preference Scale

Based on the adapted CIRF (Koo et al, 2007) scales.

### Comprehensibility

Overall, how would you rate the **comprehensibility** of each format?

Comprehensibility: Easy to read/hear, understand, remember, locate important information, keep for future reference

	Very poor	Poor	Fair	Good	Very good
 Text					
 Text + Images					
 Narration + Images					

### Utility

Overall, how would you rate the **utility** of each format?

Utility: how appropriate (not too much or too little) was the amount of information and how useful was the information about the medication benefits, precautions, instructions, warnings, side effects etc.

	Very poor	Poor	Fair	Good	Very good
 Text					
 Text + Images					

 <p>Narration + Images</p>					
---	--	--	--	--	--

### Design Quality

Overall, how would you rate the **design quality** of each format?

Design Quality: organization attractiveness, print size, tone, helpfulness, bias, line spacing

	Very poor	Poor	Fair	Good	Very good
 <p>Text</p>					
 <p>Text + Images</p>					
 <p>Narration + Images</p>					

### Overall Preference

1. Please rank the 3 formats from your most favourite to your least favourite:

Most favourite		Least Favourite

- Why was that format your **favourite**?
- Do you have any suggestions to make it even better?
- Why was that format your **least favourite**?

2. Do you have any other comments about the any of the medication formats?

## Appendix H Semi-Structured Interview

1. Think of a recent time you got a prescription for a new medication from your doctor.
  - a. Please step through the process starting from getting the prescription and going to the pharmacy.
  - b. How was the medication information presented to you?
  - c. Was the information you received useful and understandable?
  - d. Did you have any problems using or understanding the medication information?
  - e. What did you like or dislike about the process?
  - f. What did you like or dislike about the information?
2. How do you normally get information about your medications and what format is used?
3. Have you ever looked up a medication for you or someone you know is taking on the internet?
4. What do you usually do with the paper information sheet you get when you fill a new prescription?
5. Do you ever have problems **reading** the instructions? Can you provide an example?
6. Do you ever have problems **understanding** the instructions? Can you provide an example?
7. Do you ever have problems **remembering** the instructions? Can you provide an example?
8. Do you ever have problems **following through** with the instructions? Can you provide an example?
9. Would you like to receive medication information digitally (e.g., by email, online)? Why or why not?
10. If you were to receive digital medication information, how would you like to receive it (e.g., online, email, mobile app)? Why?
11. Ideally, what format would you like medication information to be in?

12. When would you like to receive medication information about a new prescription?
  - a. With your doctor when it is prescribed? When you drop off the prescription and are waiting for it to be filled? Right after you get your new prescription? Why do you think this time is best?
  
13. Would you like to get medication information using multimedia (e.g., with images and/or narration)? If so, how do you imagine this process working?