# Exploring the Requisites and Design Requirements for Adding 'Reason for Use' Information to Prescription Labels

by

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# AUTHOR'S DECLARATION

This thesis consists of material all of which I authored or co-authored: see Statement of Contributions included in the thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

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# Abstract

Individuals with multiple medical conditions and polypharmacy are at higher risk of inappropriate prescribing and consequent adverse drug events. Moreover, individuals may not adequately understand the therapeutic intention of their medications as this information is conveyed to patients inconsistently from their healthcare providers. One way to address this problem is to inform the patient of the reason for using a prescribed medication. The present research is an initial attempt to design a prescription label that incorporates Reason for Use (RFU) by first understanding how patients are currently receiving RFU information, their feelings of being provided with that information in a future health care system, and secondly, exploring their design preferences for this newly designed prescription label. Twenty patients (10 female; 10 male) throughout the Kitchener-Waterloo region were interviewed using a semi-structured questionnaire and 15 (9 female; 6 male) of these individuals participated in a design workshop that aimed to understand where the RFU information should be placed on a prescription label, the amount of detail, language, and overall layout of the label. Participant responses were analyzed thoroughly to discover important and/or frequent themes. Results from the study revealed that all 20 patients are in favor of having RFU information shared with their pharmacist and overall, would feel more informed if they were provided with RFU information from their healthcare providers. Results from the design workshop revealed that patients preferred RFU information printed in one to three words (80%) with its placement underneath the dosage instructions (33.3%) and/or next to the drug name (46.7%) because it felt the most 'logical' (73.3%). The participants showed a high preference for adding RFU to the prescription label for sake of being better-informed and more capable of participating fully in health decisions. Results from this study suggest a need for including RFU into the Ontario medication prescribing practices and adopting recently released United States Pharmacopeia (USP) patient-centered prescription label standards, which also include adding RFU to the labels.

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*You da best ☺I love you!*

# Dedication

This master's thesis is dedicated to every individual who has ever believed in me. Thank you for pushing, thank you for supporting me, and thank you for never casting doubt on me. Without you, I could not accomplish this. Thank you all…

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# List of Abbreviations

| | |
|---|---|
| **AARP** | American Association of Retired Persons |
| **ANSI** | American National Standard Institute |
| **APhA** | American Pharmacist Association |
| **FDA** | Food Drug Administration |
| **IOM** | Institute of Medicine |
| **ISMP** | Institute for Safe Medication Practices |
| **ISO** | International Standards Organization |
| **NABP** | National Association of Boards of Pharmacy |
| **OCP** | Ontario College of Pharmacist |
| **PL** | Prescription Label |
| **Pt** | Participant |
| **RFU** | Reason for Use |
| **RTU** | Reason to Use |
| **Rx** | Prescription |
| **USP** | United States Pharmacopeia |
| **WRAP** | Waterloo Research in Aging Participants Pool |

# Chapter 1 Introduction

The 2006 Institute of Medicine Report, "Preventing Medication Errors," cited inadequate patient comprehension and subsequent inadvertent misuse of prescription drugs as a root cause of medication error, meager adherence, and worse health outcomes (Institute of Medicine, 2006). Adverse drug events are the cause of one in every nine emergency room visits (Zed et al., 2008) and the Canadian health care system spends over $2 billion each year on preventable medication-related hospitalizations (Hohl et al., 2011). In Canada, 7% of patients, including 30% of older adults, take 5 or more medications; a situation commonly referred to as polypharmacy (Rotermann, Sanmartin, Hennessy, & Arthur, 2014). Individuals with multiple medical conditions and polypharmacy are at higher risk of inappropriate prescribing and consequent adverse drug events. With an aging population, the risk associated with adverse drug events and preventable health care expenditures will only escalate. As the current Ontario health system stands, patients play a major role in accurately transferring and communicating medication information; particularly those with complex polypharmacy needs must coordinate medications over multiple specialists and settings by either providing their own medication lists or bringing in their medications when they visit new clinical services. There is a serious potential risk to this approach in that patients, particularly in cases of polypharmacy, may not understand the therapeutic intention of their medications or they may fail to remember the constituent of these discussions. Without a proper understanding of the reason a medication is prescribed, healthcare providers are not able to assess if a prescription is appropriate or safe. If the patient cannot convey the information to their pharmacist or clinician, this jeopardizes the effectiveness of their next health treatment or can contribute to medication errors.

When healthcare providers are unable to adequately counsel patients on their prescribed medications, or if they forget the constituents of these discussions,

patients may turn to other sources to understand their medications, such as their prescription label (PL). Prescription labels are used to communicate key information such as medication name, dosage, directions and precautions; they are an immediate and important source of medication information to patients, especially when a pharmacist, physician or other healthcare professional is not readily available (Law & Zargarzadeh, 2010). Labels may supplement or complement healthcare provider instructions and medication information leaflets; hence their significance is highlighted when either of these two sources of information is not adequate. Prescription drug labels, however, are the root cause of a large proportion of outpatient medication errors and adverse drug events (Institute of Medicine, 2006). A major problem with these labels is that they seldom communicate the reason why the drug is being prescribed, also known as Reason for Use (RFU). Prior studies have shown that one in eight patients cannot accurately communicate what a medication has been prescribed for (Persell et al., 2004); this is almost one in three for older adults (Guénette & Moisan, 2011). Most medications have multiple reasons for use which have implications for the dose, route, duration, frequency of use, or monitoring.

Since the label typically stays on the medication container throughout the entire treatment, the RFU is a useful way of communicating this information to patients and helping patients recall the reason they use their medication. Having RFU on the prescription label may improve patients' understanding of their medication use and medication-taking behavior, which has the potential to lead to improved safety and a reduction in medication errors. The inclusion of RFU would support a better-informed patient who is more capable of participating fully in health decisions. The need for adding RFU has been corroborated in the literature, however, the inclusion of such information has yet to be adopted by standardization practices (Institute of Medicine, 2006).

The objective of this master's research was to investigate patients' understanding and feeling towards the inclusion of RFU on medication labels,

through semi-structured interviews and exploring the design requirements for an improved prescription label, which includes RFU through a design workshop. This is the first study to address the design requirements for a prescription label which includes RFU, therefore, involving the patients' views and preferences throughout this process is a crucial factor for eliciting a truly patient-centered design.

The following sections of the thesis are briefly introduced below:

Chapter 2 introduces the different design requirements for prescription labels which are used to inform the porotype of a newly designed prescription label. This chapter also explores how patients are commonly comprehending prescription labels, the need for adding RFU on the labels, and the importance of involving the stakeholder in such a task.

Chapter 3 discusses how the research methodology used and how the investigation was set up and executed.

Chapter 4 presents and discusses the findings from the semi-structured interviews with the patient stakeholders.

Chapter 5 presents and discusses the findings from the design workshop with the patient stakeholders.

Chapter 6 draws conclusions from the current research project and discusses suggestions for future research.

# Chapter 2 Background

## 2.1 Introduction

The purpose of this chapter is to present the current literature of various fields of study related to this thesis such as the requirements and the design of prescription labels, how patients comprehend labels, and to assess the need for adding RFU onto prescription medication labels. Providing consumers with patient-friendly labels that include information about indications related to their use has the potential to enhance patient safety through the minimization of unanticipated side effects and adverse events (Barr et al., 2002). The RFU information, specifically speaking, provides pharmacists, patients, and other healthcare professionals with useful information that should be considered as a part of supporting the patient's well-being (Veronin, 2011). Standardizing this process is advantageous because medications have multiple reasons for use, and the RFU will influence a medication's route of administration, dosing, duration, the frequency of use, and monitoring needs (Wolf, Curtis, et al., 2011).

The benefits associated with adding RFU to the label allows patients to gain a better understanding of why they are being given a medication by their doctors, and this enables them to ask questions or refuse the medication if they feel that it is unsafe (McNaughton, Huet, & Shakir, 2014). In addition, patients over the age of 65 are more likely to have multiple medications for multiple conditions, a condition known as 'polypharmacy'. Polypharmacy makes it even more challenging for patients to track the purposes of each drug (Burnside et al., 2007). Thus, implementing RFU enables patients to collect critical information they need to make decisions about their medications by simply looking at the label.

## 2.2 The Design of Prescription Labels

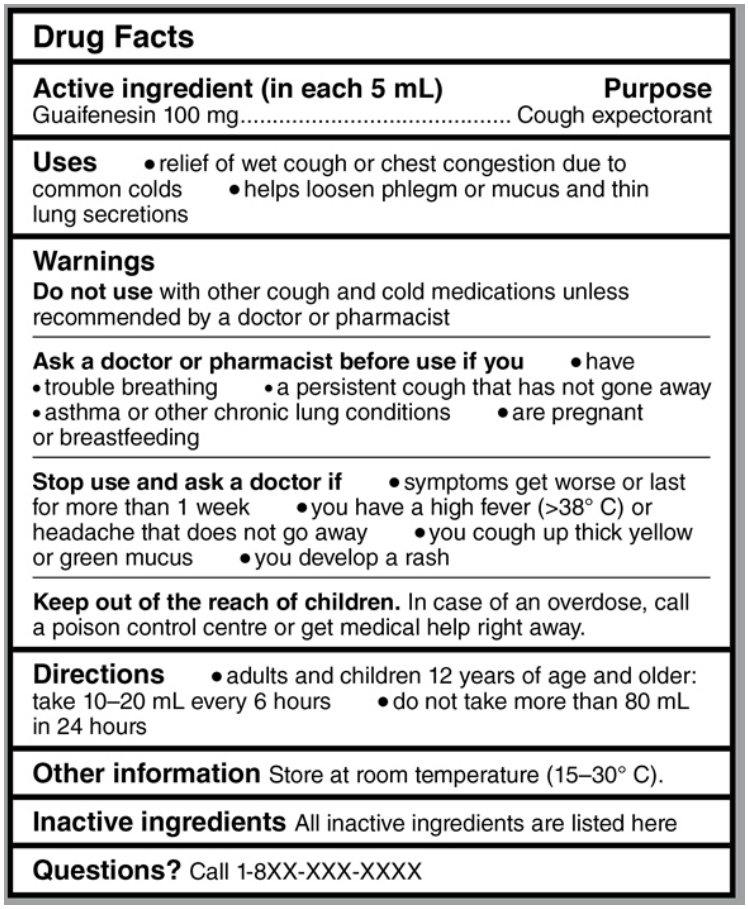
Currently, in Canada, the Consumers Packaging and Labeling Act is the legislation that guides the requirements as to what information needs to be placed on pharmaceutical labeling (U.S. Embassies Abroad, 2017). Additionally, Health Canada has published guidance documents to aid healthcare professionals on how to comply with these governing statutes and regulations (Minister of Health, 2013). At the provincial level, the Ontario College of Pharmacists (OCP) provides supplemental guidance to pharmacists and pharmacy technicians around labeling and packaging prescription drugs (Ontario College of Pharmacists, n.d.). These guidelines are put in place to increase the ability of consumers to make informed decisions about their use. In particular, the labels must be created in French and English to provide all users with an understanding of this information; details about the dealer's name and location of the business, the net quantity of the drug, and the product identity declaration must be included. Similar requirements have been established by the Food and Drug Administration (FDA) in the United States (Carpenter, 2014; Institute of Medicine, 2006). However, RFU,' also known as the drug's indication, is not included. Some medication labels in the U.S. may include a note indicating that the patient should consult the pharmacist or physician with questions, but this does not ensure that the information can be accessed quickly and as-needed.

Existing recommendations for the optimal design of medication labels are based on expertise and sound human-centered design principles (Endestad, Wortinger, Madsen, & Hortemo, 2016). When variability is seen between nations, as well as deviations from best practices in labeling, there is a need to assess why this is the case as well as what could be done to improve the safety of consumers. The United States Pharmacopeia (USP) is a standard-setting body that is able to offer information about the golden standard of practice in labeling. However, there are about 500 standard-setting bodies in the United States, contributing to this variability (U.S. Pharmacopeia, 2010). Three hundred or so are accredited by the American National Standard Institute (ANSI), which is a professional association that watches over all the

U.S. standard-setting bodies (ANSI, 2018). At the global level, there is the International Standards Organization (ISO) in Geneva, Switzerland (ANSI, 2018; Institute of Medicine, 2006). A recent meeting held by the Brookings Institution in July 2014 interestingly shared findings from multiple independent trials that identified discordance in recommendations for a single standard in the format and organization of patient medication information (S. C. Bailey, Navaratnam, Black, Russell, & Wolf, 2015). It is therefore valuable to assess how medication labels could be designed to better meet the needs of patients and to achieve safety as a part of prescribing practices.

### 2.2.1 Format, White Space, and Headers

The literature has revealed that patients prefer that information be organized in a schematic, coherent manner (Batchlor & Laouri, 2003; Kalichman, Ramachandran, & Catz, 1999; Peterson, Aslani, & Williams, 2003; Rosenthal, Berndt, Donohue, Frank, & Epstein, 2002; W. Shrank, Avorn, Rolon, & Shekelle, 2007). The logical organization of material on the label is critical; both young and older patients tend to prefer information organized schematically, with information about the drug, effectiveness, followed by warnings and side effects. Some suggestions that patients have offered to researchers pertaining to how these labels should be organized have been published in the literature. The most commonly, the preferred format for medication labels is the list format as they improved patient understanding and recall (Harvard Health, 2007; Hassell, Noyce, Rogers, Harris, & Wilkinson, 1998; Melin et al., 2004; W. Shrank et al., 2007; Svarstad, Bultman, Mount, & Tabak, 2003). Only one study was found where patients preferred the tabular format as shown in Figure 1 (Schwartz, Woloshin, & Welch, 2009).



**Drug Facts**

**Active ingredient (in each 5 mL)** **Purpose**
Guaifenesin 100 mg..... Cough expectorant

**Uses** • relief of wet cough or chest congestion due to common colds • helps loosen phlegm or mucus and thin lung secretions

**Warnings**
**Do not use** with other cough and cold medications unless recommended by a doctor or pharmacist

**Ask a doctor or pharmacist before use if you** • have • trouble breathing • a persistent cough that has not gone away • asthma or other chronic lung conditions • are pregnant or breastfeeding

**Stop use and ask a doctor if** • symptoms get worse or last for more than 1 week • you have a high fever (>38° C) or headache that does not go away • you cough up thick yellow or green mucus • you develop a rash

**Keep out of the reach of children.** In case of an overdose, call a poison control centre or get medical help right away.

**Directions** • adults and children 12 years of age and older: take 10–20 mL every 6 hours • do not take more than 80 mL in 24 hours

**Other information** Store at room temperature (15–30° C).

**Inactive ingredients** All inactive ingredients are listed here

**Questions?** Call 1-8XX-XXX-XXXX

**Figure 1** Example of drug information organized in a tabular format (Minister of Health, 2017)

An additional study that surveyed both older and young adults found that patients, particularly the older adults, could more easily read labels that sensibly used white space by separating related sections and grouping related material together (Harvard Health, 2007; W. Shrank et al., 2007). Ultimately, this space enables the patients to separate concepts and to process the information in a manner that is meaningful to them in practice (Sansgiry, Cady, & Sansgiry, 2001; Svarstad et al., 2003). For instance, it is essential for patients to be able to locate the expiration date on the medication label at all times. When it is expired, it should no longer be used, either because the expired formula has the potential to make the patient sick, or because the expired medication no longer has the same level of effectiveness as it once did, and it is no longer able to produce a treatment

effect (Lohiya, 2004). Furthermore, Svarstad et al. (2003) found that patients are able to locate information more readily when the different required sections are clearly labeled with headers (Hassell et al., 1998; Svarstad et al., 2003; Thomas & Corwin, 1998). Overall, when optimizing label format, lists, headers, and white space enhance readability, and content should be organized to follow the schema that patients use to understand medication information.

### 2.2.2 Language

Although there is no legal specification for wording or directions, the complexity of written medication information is problematic since patients regularly depend on these materials to figure out how to safely and appropriately take prescribed drugs, particularly in the event that physician and pharmacist counseling on proper medication use is suboptimal. Therefore, the use of plain or lay language on medication labels is highly recommended (S. C. Bailey, Sarkar, Chen, Schillinger, & Wolf, 2012; Davis et al., 2009; Dowse & Ehlers, 2001; Gibbs, Waters, & George, 1990; M. G. Katz, Kripalani, & Weiss, 2006; Kroner, Kelley, & Baranowski, 1994; Mohan et al., 2013; W. H. Shrank et al., 2007; Wolf et al., 2010; Wolf, Curtis, et al., 2011; Zargarzadeh & Law, 2011).

### 2.2.3 Text Orientation

The orientation of labeling is important to consider as well. It is important for all information to be facing the same direction because this offers the consumer with a better understanding of what the information says (Joolaee, Hajibabaee, Peyrovi, Haghani, & Bahrani, 2011). It is challenging to physically move the orientation of a product to gain an understanding of what the text says, and some will not do this and will simply miss information. According to Sanders et al., (1993), the use of knowledge about human factors on this subject suggests that it is beneficial to have all of the information on the label oriented in the same direction while the user is performing the same task (M. S. Sanders & McCormick, 1993).

### 2.2.4 Contrast/Material

The literature suggests that the contrast and material may be relevant to understanding as well. Haegerstrom-Portnoy et al. (2005) concluded that, "the use of high-contrast and nonglossy paper is essential for older adults, considering the loss of low-contrast acuity, low-lighting visual acuity and the increased sensitivity to glare with age" (Haegerstrom-Portnoy, 2005).

### 2.2.5 Use of Images

Although it is advantageous to consider the needs of patients from a broad perspective, people who take medications often have a range of disabilities, and some may prevent them from correctly interpreting the labels (Merry & Anderson, 2011). For instance, it is thought that implementing the use of pictures and symbols could be useful for those with vision impairment, and it is also practical to use these images as a way to better communicate with those who have difficulty reading. Pharmacist guidelines for making medication information accessible for patients with vision loss recommend the use of pictures and symbols (American Society of Consultant Pharmacists Foundation & American Foundation for the Blind, 2018). Results of a recent study ran counter to the hypothesis that older adults would find the use of these images more helpful than younger patients (Blenkiron, 1996). Instead, young patients reported a greater benefit from the combination of images and pictures.

One potential explanation for the benefits observed by the younger population is that symbols used in a mixed format require higher processing demands to interpret the information accurately (Burke, 2000; Morrell, Park, & Poon, 1990). Additionally, it was thought that young subjects were more proficient at integrating the verbal and visual information into a single, consistent storage format for later access. Older adults may have also found this more troublesome,

potentially on the ground that the distinctive picture- and word-based formats competed with one another (Morrell et al., 1990).

In contrast to the aforementioned studies, Wolf et al. (2010) showed that not all pictures are effective at improving patient's understanding of warning information and may not improve the safe administration of medicines (Wolf et al., 2010). Ultimately, these findings demonstrate that the addition of a graphic aid to support comprehension among the young adults, older adults, or those with limited literacy provided no additional benefit and may even impede comprehension (Wolf, Davis, et al., 2011). Thus, this specific information should be provided in a clearer manner, rather than simply implied on the basis of the additional information, such as graphics, placed on the label. As there is currently a disagreement in the literature on the use of icons, particularly among older adults, to convey medication use (Houts, Doak, Doak, & Loscalzo, 2006; Kutner, Greenberg, Jin, & Paulsen, 2006; Morrell & Park, 1993; Daniel G Morrow, Leirer, & Andrassy, 1996; Park, Morrell, Frieske, & Kincaid, 1992) there is a need to determine how to best resolve these concerns.

### 2.2.6 Font

The preceding sections provided an overview of the considerations that should be made when determining whether the medication labels are able to provide the necessary information to users in a proper format. A particular concern that arises when determining if this is accomplished is whether the font being used for labeling is clear and understandable by patients from a variety of age groups and demographic backgrounds (Odegard & Gray, 2008). The font is one of the elements that should be considered as a part of this process.

#### *2.2.6.1 Font Type*

Shank et al. found that when assessing patients' preferences for three font styles for medication labels (Century Schoolbook, Helvetica, and Courier), patients preferred Century Schoolbook (Shrank et al., 2007). In this case, each letter appeared more distinct, and the participants reported that it was easier to read. Additionally, a descriptive survey of 60 older patients presented to labels written with five different fonts, the Scriptwriter font was considered the most difficult to read (Shrank et al., 2007). Ultimately, this was concluded because participants reported that fonts that appeared larger were considered easier to read (Shrank et al., 2007). The literature has also revealed that sans-serif fonts (versus serif fonts) may be more legible by sanctioning improved horizontal movement, which is imperative for adults, especially those with low vision (Arditi & Cho, 2007; Connolly, 1998). The legibility and recommendation of sans-serif fonts is consistent with the results of additional studies (Davis et al., 2006; Filik, Purdy, Gale, & Gerrett, 2004; Gerhart et al., 2015; Harvard Health, 2007; Institute of Medicine, 2006; Latham, Waller, & Schaitel, 2011; Leat, Ahrens, Krishnamoorthy, Gold, & Rojas-Fernandez, 2014; Rosenthal et al., 2002; Sansgiry et al., 2001; W. Shrank et al., 2007; W. H. Shrank et al., 2010; Smither & Braun, 1994; Wogalter & Vigilante, 2003).

#### *2.2.6.2 Font Size*

Medical education guidelines explicitly propose that font size must be 12-point or larger to optimize the patients' ability to read health information (Doak, Doak, & Root, 1996), but it is worthwhile to consider if it should be even larger to better meet the needs of patients with vision problems (Smither & Braun, 1994). In an experiment conducted with 19 young and 20 older patients, patients of all ages preferred labels written in a larger font and reported that 14-point font was easier to read than 12 point, which was easier for them to read compared to the 9-point. This survey also found that patients read labels with

a larger font more quickly and precisely than labels with smaller font (Shrank et al., 2007). By and large, discoveries in the literature suggest that larger text dimension is ideal (Harvard Health, 2007; Institute of Medicine, 2006; Kalichman et al., 1999; Latham et al., 2011; Law & Zargarzadeh, 2010; Leat et al., 2014; Rosenthal et al., 2002; Sansgiry et al., 2001; W. Shrank et al., 2007; W. H. Shrank et al., 2009, 2010; Wogalter & Vigilante, 2003; Wolf et al., 2007; Zargarzadeh & Law, 2011).

*2.2.6.3 Tall Man Lettering and Capitalization*

An additional font suggestion that has been made in the literature is regarding the use of tall man lettering. Tall man lettering is the practice of writing part of a drug's name in upper case letters to highlight its primary dissimilarities and to help distinguish sound-alike, look-alike drugs from one another in order to avoid medication errors (Grissinger, 2012). For example, "prednisone" and "prednisolone" in tall man lettering would be "predniSONE" and "predniSOLONE", respectively. A 2004 study demonstrated that when patients are presented with 'tall man" letters, they are half as likely to incorrectly identify the information, (Filik et al., 2004), suggesting that capitalizing sections of potentially confusing drug names improves identification and readability. The Institute for Safe Medication Practices (ISMP), FDA, and other safety-conscious organizations such as the National Association of Boards of Pharmacy (NABP) have recommended the use of tall man letters as one means of reducing confusion between similar drug names (Institute for Safe Medication Practices, 2002, 2003; National Association of Boards of Pharmacy, 2008; U.S. Food and Drug Administration, 2009).

One other study found that the use of capital letters may result in speedier reading when comparing equivalent size in point print in sentence case for both people with and without visual impairment (Arditi & Cho, 2007). However, this same study also stated that capital letters may reduce the clarity

of the label. The general guidelines from professional organizations also recommend conflicting results (Canadian National Institute for the Blind, n.d.; Royal National Institute for Blind People, 2014; U.S. Pharmacopeia, 2012), therefore, the optimal use of sentence case versus capital is still not confirmed (Leat et al., 2014).

#### *2.2.6.4 Legibility*

Furthermore, the legibility of information is a clear concern (Leat et al., 2014). In spite of the fact that there are rules for general print intelligibility from nongovernmental associations and particularly for medication labels from some pharmaceutical and health organizations, they may not be applied consistently to medication labels (Leat et al., 2014; Punsongserm, Sunaga, & Ihara, 2017). In some instances, guidelines are considered suggestions rather than required practices, which contributes to this challenge. For instance, in Ontario, there are no legal prerequisites regarding the legibility of print, although the content of what must be included on the label is specified (Service Ontario, 1990). This means that different pharmacies are able to follow different labeling standards, and this has the potential to contribute to confusion among patients. Research has demonstrated that many of the current labels use sans-serif fonts, nonglossy paper, and a high contrast (Leat et al., 2014), however, the points discussed in the following sections are highly variable from pharmacy to pharmacy. Generally, the literature agrees upon the importance of increasing legibility of the fonts to support the reading abilities of patients who have visual impairment (Arditi & Cho, 2007; Connolly, 1998; Latham et al., 2011; Leat et al., 2014; Lohiya, 2004; Punsongserm et al., 2017; W. Shrank et al., 2007; Smither & Braun, 1994; Wogalter & Vigilante, 2003).

### 2.2.7 Emphasis

Label items that are most emphasized are those that enrich the practice of the pharmacist, and not the items that patients need to safely and appropriately administer medication (Shrank et al., 2010). Shrank et al. inspected the variability in label content and format when identical prescribed medications were dispensed at 85 different pharmacies. The study found that the current labeling system highlighted material important to the provider (e.g., pharmacy logo and prescription number rather than information that supports understanding and proper use of the medication (W. Shrank et al., 2007). The inclusion of such distracting material may be exceptionally problematic for patients with limited literacy, who face greater reading difficulty in less familiar and technical contexts (Doak et al., 1996). Ultimately, different providers place different levels of emphasis on the information related to medication use, so these challenges can vary.

#### *2.2.7.1 Bolding*

In the study conducted by Leat et al. (2014), "bolding was used in 95.6% of the labels, but was not used to strictly emphasize the patient- critical information, as recommendations would suggest. All of the labels that used bolding had at least one of the patient-critical components bolded; however, none of the labels bolded only the patient-critical information" (Leat et al., 2014). It is reasonable to use the bolding technique in order to help patients understand what information is absolutely essential, such as safety information. However, it is necessary for this to be consistent because if the information is bolded using different patterns at different pharmacies, then it will be challenging for patients to gain a true understanding of how to use this information to take their medications properly. As a result, it might be advantageous to limit the use of bolding and highlighting, because any information placed on the label is important to the patient.

#### *2.2.7.2 Italics and Underlining*

Just as bolding is not highly recommended by professionals in the literature, italics and underlining are not either (American Society of Consultant Pharmacists Foundation & American Foundation for the Blind, 2018; Canadian National Institute for the Blind, n.d.; I. R. Katz et al., 1998; Royal National Institute for Blind People, 2014). Although these are alternative methods for emphasizing information, it is apparent that emphasizing any information could detract the reader from additional information that may not be emphasized using these methods (Wallace, Keenum, & DeVoe, 2010). As such, the use of italics and/or underlining does not fall into the suggestions for labeling by common guidelines in North America (Leat et al., 2014). A summary of the generally agreed upon guidelines for designing prescription labels can be found in Table 1.

**Table 1** Summary of prescription label design guidelines

| Characteristic | Guideline |
|---|---|
| Format | List<br>Headers<br>Maximize white space<br>Logical Organization |
| Language | Plain/lay language |
| Text orientation | Horizontal |
| Alignment | Left justification |
| Paper material | Nonglossy |
| Contrast | High |
| Font type | Sans-serif |
| Font size | Minimum 12 or 14 points |
| Font color | Black |
| Emphasis | Bolding or highlighting (only for most important information) |

## 2.3 Comprehending Prescription Labels

Given that the health information label is an important component of health care practice, it is important to ensure that the information could be used by patients. Several studies determined that patients most often had questions about adverse effects, indication, and dosing frequency (B. J. Bailey et al., 1997; Lyons, Rumore, & Merola, n.d.; Morris, Tabak, & Gondek, 1997; Shrank et al., 2007; Sleath, Roter, Chewning, & Svarstad, 1999) which demonstrates that even though the information is consistently found on the medication label (excluding indication), patients don't understand it or know where to find it (Lyons et al., 1996).

Some patients believe that comprehending a prescription label is a simple task, as a result, they may not allow adequate time to process and understand the information (Wolf et al., 2007); it is also important to consider the perspective of the patients that may experience extreme difficulty in doing so. Related to this concern, Morrell et al. (1990) determined that older adults, a population that is more likely to be taking multiple medications, are at an increased risk for safety concerns related to pharmaceutical use because they do not necessarily take the amount of time that is needed for them to fully understand the labels (Morrell et al., 1990). By thinking from the perspective of the patients rather than the healthcare professionals who write and fill these prescriptions, it is possible to better meet the needs of the patients. This lack of comprehension is more common than healthcare professionals may expect (Rapp & Samuel, 2002; Rapp & Van Den Broek, 2005; Van Den Broek & Kremer, 2000).

The particular features that should be considered as a part of the comprehension process include the cognitive skills of the patients, especially those of older age as aging reduces information processing capacity. Furthermore, there may be physical constraints that block the person from being able to read the label, such as the lighting in the room. It is important for labels to be designed in a manner that allows the information on them to be accessible by

patients in a range of situations. Formatting and organizational issues should also be considered.

An additional concern is that there is some confusion about dosage information. Some healthcare providers use abbreviations for this purpose, but the average person doesn't understand what these mean (Wolf et al., 2010). Thus, all abbreviations should be written out, rather than using the medical abbreviations used to prescribe them. It is important for patients to comprehend the need for them to review these labels when they are being given new drugs or being presented with changes to their existing medications. This will help them avoid errors that could cause harm to their health.

An interesting issue that is related to the topic of labeling relates to not only the presence of this information, but how it might be interpreted by the patient (Wolf et al., 2010). Failure may occur if instructions are not explicit, or if purpose is not evident, such as providing an indication for use on the bottle label itself (i.e. ''take for diabetes''); including such information is not part of routine practice for either physicians (to add to the prescription send to the pharmacist) or pharmacists (to include on the dispensed container label). Even when an indication is included, it still is not explicit enough. In particular, something that says it should be taken for diabetes does not provide the user with an understanding of what the medication is explicitly treating. One may assume that it is an insulin treatment and it is meant to treat diabetes itself, or it may be an antibiotic that was prescribed to help resolve an infection related to diabetic ulcers. By providing patients with at least a simple understanding of the mechanism of action in addition to this information, it is possible to increase the safety of use.

## 2.4 Improving Prescription Labels

To transition to the practice of providing clear and detailed labels on medications, it is necessary for professionals to recognize that there is a gap between what the field could accomplish and the problems that are inherent in the present labeling processes. Although the literature has shown that patients heavily refer to their prescription label for key information and that a piece of information that they would like to see on the label is RFU (American Pharmacists Association, 2017; Basara & Juergens, 1994; Burnside et al., 2007; Cardarelli et al., 2011; Institute of Medicine, 2006; Law & Zargarzadeh, 2010; Luscombe, Jinks, & Duncan, 1992; Mohan et al., 2013; Rosenthal et al., 2002; Sakharkar, Zargarzadeh, & Law, 2014; Schiff, Seoane-Vazquez, & Wright, 2016; W. H. Shrank et al., 2010; U.S. Pharmacopeia, 2010; Zargarzadeh & Law, 2011). In recognition of this, the United States Pharmacopoeia (USP) published, in November 2010, a General Chapter on prescription container labeling, stating the label should include a "purpose for use" based on patient preference (U.S. Pharmacopeia, 2010), however, there is no study conducted on the design of implementing such. When patients are asked whether they want to better understand the use of a medication or the information on a label, most patients report that they do, Thus, it is important to consider how specifically to change labels to offer a consistent and clear way to provide patients with more information about their medications.

## 2.5 Implementing Reason for Use on Prescription Labels

To understand the impact of placing reasons for use on prescription labels in a clear manner, it is first necessary to define the extent to which patients require these labels to gain an understanding of essential information from these bottles. It is still possible for patients to access information about RFU, but one of the most common ways that they accomplish this is by asking it of their physicians (Yi et al.,

2015). Given that physicians have a limited amount of time to accomplish this, these individuals may not be getting the information that they need to take their medications safely.

To characterize this problem, research was conducted to determine the length of time physicians spend communicating with their patients about their prescription drug use. It was determined that these sessions lasted approximately four minutes long. In addition, half of the patients tend to not ask questions about drug use, but of those who do, it was determined that their questions primarily pertained to information already present on the label. However, 80% of patients had questions about use, demonstrating that this information represents the greatest source of missing information for patients (Chovil & Altekruse, 1986). While patients ideally should receive information about their medications from physicians and pharmacists, there is considerable evidence that physicians and pharmacists frequently miss opportunities to adequately counsel patients on newly prescribed medicines (Law & Zargarzadeh, 2010; Makoul, Arntson, & Schofield, 1995; Metlay et al., 2005; Morris et al., 1997; Scherwitz, Hennrikus, Yusim, Lester, & Vallbona, 1985; W. Shrank et al., 2007; Sleath et al., 1999; Stevenson, Cox, Britten, & Dundar, 2004; Tarn et al., 2006).

Conversations with the patient are helpful because they promote clarification of their understanding in a manner that contributes to better outcomes. Although physicians, pharmacists, and other healthcare providers may have limited time to spend with individual patients in many cases, it is reasonable for them to provide patients with handouts with additional information. However, these documents are helpful only when they are able to provide information that is easily understandable by the patient. Some of these documents use medical terminology which consists of Latin derivatives and additional words that are not spoken in the vernacular (Mitrovic, 2014) meaning they are fairly challenging to comprehend for the average patient (Bernardini, Ambrogi, Perioli, Tiralti, &

Fardella, 2000; Buck, 1998; Dickinson, Raynor, & Duman, 2001; Estrada, Hryniewicz, Higgs, Collins, & Byrd, 2000; Gustafsson, Kalvemark, Nilsson, & Nilsson, 2005).

When patients cannot access RFU information from healthcare professionals, they may attempt to do so in an informal manner. For example, the Food and Drug Administration (FDA) website or the American Association of Retired Persons (AARP) Guide to Pills serve as excellent resources for patients who may have additional questions to make them feel confident about their pharmaceutical use. However, some individuals may not able to access these resources based on their technological capabilities, and some may have difficulty understanding the information available on the website (Ayantunde, Welch, & Parsons, 2007). Therefore, the container label plays an important role in the appropriate administration of prescription medication (Shrank et al., 2007). Unlike the supplemental leaflets, which patients can easily discard or ignore (Institute of Medicine, 2006), the container label usually remains with the medication during the course of therapy. They often serve as the only or "last line" source of medication information (Wolf et al., 2007) and, undoubtedly, play an vital role in increasing patients' understanding of their medication (Hong, Liu, Tak, & Vaidya, 2013; Mohan et al., 2013; Shiyanbola, Smith, Mansukhani, & Huang, 2016; Zargarzadeh & Law, 2011). This demonstrates that the labels serve as a source of important information in many cases, and this information may prompt the patient to do additional research of their own when they are not certain about the RFU.

Thus, it is apparent that healthcare professionals, as well as federal agencies, may not be fully considering the needs of the patient when considering what requirements should be in place for medication labeling (Wolf, Curtis, et al., 2011). When considering the specific needs of patients, it is worthwhile to consider that aging has a negative impact on memory, and older patients are not always going to be able to recall the RFU information from a visit with a physician (Gustafsson et al., 2005). It is important for healthcare professionals and those responsible for

labeling to understand that patients need a reminder of use in order to ensure that they are compliant with instructions. Helping patients understand what medications they are on and why can increase outcomes in this manner.

## 2.6 Involving the Stakeholders

The stakeholders involved in this issue includes the physicians and prescribers, non-prescribing healthcare professionals, patients, governments, and pharmacists. Opinions from healthcare professionals and patients may lead to improved labels by providing their understanding of medication information (American Pharmacists Association, 2017; Andre & Wickens, 1995; S. C. Bailey et al., 2015, 2012; Davis et al., 2006; Gerhart et al., 2015; Hong et al., 2013; Leat et al., 2014; Mohan et al., 2013; Shiyanbola, Smith, Huang, & Mansukhani, 2017; Wolf, Curtis, et al., 2011; Zargarzadeh & Law, 2011). Physicians and prescribers have found that increasing the detail and accuracy of medical labeling for products that they are responsible for administering helps reduce medication errors (Bauer & Guerlain, 2011). Since physicians benefit from increased accessibility to RFU information, it is intuitive that patients would benefit from this change as well. Nurses and other healthcare professionals are typically responsible for providing patients with information about their medications and instructions for use during discharge, and this effort is more likely to be effective if patients are reminded of this information when they are accessing their medications (Bekker, van den Bemt, Egberts, Bouvy, & Gardarsdottir, 2018).

Patients are impacted because it is expected that they will be able to experience an improved quality of care through reduced errors and increased safety (Bauer & Guerlain, 2011). The government also plays a key role in the regulation of prescription medications through the Food and Drug Administration (Stafford, 2008). A decision that all prescription medications must contain the RFU

would, therefore, occur at this level and have the potential to impact the other stakeholders. Finally, pharmacists and pharmacy employees play a key role because they would be responsible for transferring the information that the prescriber gave them about RFU onto the prescription label, and they must do so accurately and in a manner that helps the patient notice this information (W. H. Shrank et al., 2009). It is expected that including the RFU on the labels will reduce medical costs for patients, as well as limit readmissions in a manner that allows healthcare professionals to respond to fewer cases related to accidents (Bauer & Guerlain, 2011). The pharmacies may incur small costs associated with this change, but it will allow for a better long-term benefit (W. H. Shrank et al., 2009). Thus, the federal regulators such as Health Canada and the U.S. FDA may need to become involved to mandate this change, since there is little incentive for pharmacies to implement this change independently.

## 2.7 Conclusion

Overall, the literature has revealed that there should be a place for the RFU on the labels of all medications and that it is necessary to do so in a manner that is understandable for all patients. It is necessary for Health Canada, the FDA, and other regulatory agencies to collaborate and identify the best methods to ensure clear communication of the medication name, dose, use, and safety information, in addition to other features to patients. Furthermore, given that people who use medication are more likely to have impairments than those who don't, it is essential to consider the difficulty that patients with age- and disease-related disabilities may have in terms of their abilities to access the information on a label. Having the information available in a large font with the use of simple vocabulary will promote this purpose. While there is a growth in the popularity of accessing online information to learn more about the function of a drug as well as additional information, this data is not always presented in a way that the average user could

understand. When this information is not placed adequately on the prescription label, patients may be missing this information, leading to noncompliance. It is therefore essential to put forth efforts to address these issues to promote better patient safety and outcomes.

Ultimately, by defining the specific changes that should be made by evaluating an improvement in patient understanding based on the labeling practices applied, it will be possible to confer a significant increase in practice quality that could lead to improved health for all patients. Treatment compliance is necessary to see these improved outcomes, and the understanding and accessibility of information on the basis of how it is labeled for consumers have the potential to cause a drastic positive change. While a barrier to implementation may be the cost of the research process needed to accomplish this at the policy level, it is possible to use recommendations from the literature as well as information from consumers to gain a better understanding of how these needs could be addressed by professionals in practice.

# Chapter 3 Method

To be able to design a patient-centered medication label which includes RFU, it is imperative to involve the principal stakeholders, which are the patients. Co-design is a user-centered design approach which involves stakeholders (businesses or customers) working together in the design development process to collectively develop new solutions (E. B.-N. Sanders & Stappers, 2008). Recent research suggests that designers working within a co-design environment create more innovative concepts and ideas than they do when creating ideas on their own (Mitchell, Ross, May, Sims, & Parker, 2016; Trischler, Pervan, Kelly, & Scott, 2018).

The co-design approach used for this project reconciles the user's tacit knowledge and preferences in hopes to build an improved, patient-friendly medication label. This design approach is customarily an iterative method which judiciously assesses the impacts of these incremental design changes. The process of such, involves the following: 1) an initial exploration of work where designers and users familiarize themselves with one another, 2) a discovery process in which the designer and users employ various techniques to understand the problem, and 3) a prototype stage in which the designers and users iteratively shape artifacts to solve the aforementioned problem (Spinuzzi, 2005). The co-design process used for this research study will solely focus on a discovery stage through a semi-structured interview and a prototyping stage through a design workshop.

## 3.1 The Participants

Between March 2018 and July 2018, two researchers (including the author of this thesis and one other research student) recruited a convenience sample of twenty individuals (10 females; 10 males) throughout the Kitchener-Waterloo region in

Ontario, Canada. Participants were recruited through emails, posters, and through the Waterloo Research in Aging Participants Pool (WRAP). The age of the participants ranged between 23 and 89. On average, the participants were currently taking 4.65 medications.

## 3.2 Materials

18 of the 20 interviews and design workshops took place in an empty room located in EC4 at the University of Waterloo; the remaining two sessions were conducted at the participants' preferred location in the Kitchener/Waterloo region. Each of these locations was chosen for the sake of maximizing privacy and minimizing distractions. An audio recorder was used through the entire session. During the design workshop phase, participants were provided with sharpies, markers, scissors, tape, glue, a blank, prescription label template and a prescription label prototype which was created following the guidance obtained from the literature (see Appendix G), and cut-outs of common prescription label elements (see Appendix H). Once all the interviews and workshops were completed, the audio recordings were uploaded to a password-protected file and deleted from the audio recording device; pictures of the design creations were taken and uploaded to a secure online location and the physical materials were stored securely in a locked cabinet at the University of Waterloo.

## 3.3 Procedure

Each session began with providing the participants with a copy of the information and consent form (see Appendix D and E) and offering them an opportunity to ask any questions or express any concerns. After obtaining consent, the researchers indicated to the participant that the audio recorder would be turned on, signifying that the session would officially commence. The duration of the sessions ranged from as short as 10 minutes to as long as 68 minutes.

### 3.3.1 Discovery through Semi-Structured Interview

All 20 participants took part in the semi-structured interviews. Individual interviews were conducted with each participant and two researchers (including the author of this thesis). Interview questions were formed and validated by the author of this thesis and research experts at the University of Waterloo's School of Pharmacy and Systems Design Engineering Department. The questions were divided into three sections (see Appendix G). The first section focused solely on the participant's demographics and medication history. If the participant had a medication list and was comfortable with sharing this information with the research team, the researchers took a picture with all identifying information removed. The next phase of questions was regarding how patients interact with the current health care system, with a keen emphasis on RFU. The last phase of the interview portion focused on a future health care system that would, hypothetically, include the RFU. All questions were designed to be open-ended to provide the participants with more autonomy to share their experiences, desires, and concerns. Throughout each phase of the interview, when appropriate, the researchers would ask probing questions to clarify about specific details, and/or to elicit deeper discussions.

### 3.3.2 Prototyping through a Design Workshop

A modification for this study, which requested for the inclusion of a design workshop (see Appendix I), subsequent to the semi-structured interview, was solicited and approved on May 11$^{th}$, 2018. Of the 20 participants, 15 also took part in this design workshop. The workshop phase of the study focused primarily on prescription labels which included adding the RFU and rearranging the label to better cater to patient needs and preferences. The workshop and interview questions were formed by the author of this thesis and validated by research experts at the University of Waterloo's School of

Pharmacy and Systems Design Engineering Department. Workshop tasks specifically aimed to explore the following: the language, amount of detail, location, the presentation of the reason for use information, and the overall layout preference of prescription labels. Participants were encouraged to talk aloud during the workshop to assist the researchers in understanding their design-decision making processes. After the design portion, a semi-structured interview was carried out in regards to adding RFU onto prescription labels.

Lastly, participants were given the opportunity to express their final thoughts, comments, and/or concerns or return back to a discussion which they felt they had more to say about. At the completion of the sessions, the participants were thanked, provided with a feedback form (see Appendix J), and provided with a $25 honorarium.

## 3.4 Data Analysis

Since this work is highly qualitative in nature, an analysis framework (Braun & Clarke, 2006) was applied to discover important, frequently mentioned responses. The analysis strategy conducted by the author of this thesis included: 1) carefully listening to and recording verbatim participant responses, 2) categorization of major problems/responses, and 3) recording the frequency of problems/responses for each question. By using this analysis framework to distill data, the researcher determined broad patterns that allowed for the transmission of more granular research and descriptive, statistical analysis (percentage, mean). That being said, the frequency of participants responses was statistically analyzed to understand the how patients currently interact with the system and the bearings of adding RFU into the health care system (Chapter 4). Design outputs from the workshop were analyzed and compiled into a single pictorial; frequency of participants responses was statistically analyzed to understand the design and associations of adding RFU onto prescription labels (Chapter 5).

# Chapter 4 Discovery Findings from Semi-Structured Interviews

In the following chapter, a detailed analysis of this qualitative research study is presented which sets out to understand the background behind RFU, supporting the primary research question of how to add RFU onto prescription labels. The purpose of this study is to understand how RFU information can be included in Ontario's health care system to enhance patient understandings of their medication and to improve shared decision making among pharmacist, physician, and patients

## 4.1 Results

### 4.1.1 Description of the patient stakeholder sample

A total of 20 participants took part in the semi-structured interview. Half of the participants were female and half were male; the mean age of the participants was 59 years. As seen in Table 2, 10% of the were currently taking one or two prescribed medications, 35% were currently taking three or four prescribed medications; 30% were currently taking five or six prescribed medications; 20% were currently taking seven or more prescribed medications. Participants were currently taking an average of 4.65 prescription medications. Fourteen (70%) participants provided a list of their prescribed medications. Patients were further tested on their understanding of their own medications by going through each one independently and stating the RFU; of those taking one or more prescribed medications, seventeen (86.7%) assuredly stated the RFU for their medications

**Table 2** Stakeholder demographics (n=20) from semi-structured interviews

| | **Frequency (%)** |
|---|---|
| **Age (in years)** | |
| 21-30 | 3 (15%) |
| 31-40 | 3 (15%) |
| 41-50 | 2 (10%) |
| 51-60 | 0 (0%) |
| 61-70 | 3 (15%) |
| 71-80 | 4 (20%) |
| 81+ | 5 (25%) |
| *Mean* | *59 years* |
| **Gender** | |
| Male | 10 (50%) |
| Female | 10 (50%) |
| **Number of current prescribed medications** | |
| 0 | 1 (5%) |
| 1 | 1 (5%) |
| 2 | 1 (5%) |
| 3 | 5 (25%) |
| 4 | 2 (10%) |
| 5 | 3 (15%) |
| 6 | 3 (15%) |
| 7+ | 4 (20%) |
| *Mean* | *4.65* |
| **Keeps a list of medications** | |
| No | 6 (30%) |
| Yes | 14 (70%) |
| **Assuredly states RFU of their medications (n=19)** | |
| No | 2 (10) |
| Yes | 17 (85) |

### 4.1.2 Current Ontario Health Care System

The majority of participants (N=16, (80%)) stated that they usually receive RFU information from the prescribing physician; eight (40%) stated that they receive this information from the pharmacist; seven (35%) shared that they retrieve this information from supplemental materials given from the healthcare providers or online. Upon receiving this information, 85% of the participants stated they store this information in their memory and 25% shared they keep a medication list handy, or store this information in a file at home. As shown in Table 3, participants recalled that RFU information was shared with them in the past by physicians (80%) and/or the pharmacist (60%); but three (15%) participants disclosed that they did not recall this information being shared with them. The participating patients recalled that the RFU information was openly communicated by the physician (75%) or pharmacist (50%) when it was a newly prescribed medication. Seven (35%) stakeholders only recalled receiving this information from healthcare providers upon asking. Six (30%) stakeholders recalled receiving RFU information freely from a healthcare provider while 12 (60) expressed that they had to 'sometime' or 'always' ask for this information. The majority (85%) of the participants recalled receiving this information in laymen terms and could not recall a time that the information was not clear or useful (75%). Sixteen (80%) of the stakeholders could recall a time that learning about RFU was helpful for them and 15 (75%) could not recall a time when they did not know the reason for using a medication. The majority (80%) of the participants shared RFU information with their family and/or partner. On average, the stakeholders rated the importance of knowing RFU as 4.9 out of five (on a Likert scale from 1 to 5, with 5 being "very important").

**Table 3** How stakeholders interact with the current Ontario health care system

| Question | Frequency (%) |
|---|---|
| *Responses to interview questions* | |
| **How do you currently find out what your medications are for?** | |
| From physician | 16 (80) |
| From pharmacist | 8 (40) |
| Supplemental material (from healthcare provider) | 2 (10) |
| Online | 5 (25) |
| **Where do you place this information?** | |
| Memory | 17 (85) |
| File at home | 4 (20) |
| Medication List | 1 (5) |
| **In the past, has the reason for use information been shared with you? If yes, by who?** | |
| Never shared | 3 (15) |
| Yes, by the physician | 16 (80) |
| Yes, by the pharmacist | 12 (60) |
| **When did they share it?** | |
| Physician, new med | 15 (75) |
| Pharmacist, new med | 10 (50) |
| Pharmacist, refill | 1 (5) |
| Pharmacist, annual review | 3 (15) |
| Upon asking | 7 (35) |
| **Did you have to ask to find out or was this information provided freely?** | |
| No | 6 (30) |
| Sometimes | 9 (45) |
| Always | 3 (15) |
| 'I do not ask' | 2 (10) |
| **Type of language used to explain RFU** | |
| Lay Language | 17 (85) |
| Medical Language | 5 (25) |
| **Was there a time that the reason for using a medication a professional provided was not clear or useful?** | |
| No | 15 (75) |
| Yes | 5 (25 |
| **Can you recall a time that learning the reason for using a medication was particularly helpful for you?** | |

| | |
|---|---|
| No | 4 (20) |
| Yes/always | 16 (80) |
| **Can you recall a time when you did not know the reason for a medication?** | |
| No | 15 (75) |
| Yes | 5 (5) |
| **Who else is aware of the reasons you are taking your medications?** | |
| Family/Partner | 16 (80) |
| Friends/Coworkers | 3 (15) |
| Nobody | 1 (5) |
| **On a scale of 1 to 5, with 5 being "very important," how important is it for you to know what your medications are for?** | |
| *Mean* | *4.9* |

### 4.1.3 Adding RFU into the Ontario Health Care System

All of the stakeholders felt positive about the sharing of RFU information by a pharmacist. Sixteen (80%) preferred getting this information on a printed medication list; thirteen (65%) stated they would like to have access to their medical record online through a website and/or an app; seven (35%) would appreciate having the RFU information on their prescription label. Having access to their RFU information would make all stakeholder feel more informed; eleven (55%) felt like having access to this information would help them weigh their medication options or affect the adherence to the drug regimen. Fourteen (70%) would like other medical staff (beyond their physician and pharmacist) and emergency personnel to have access to their RFU information; eleven (55%) would like their family and/or partner and five (25%) felt it was vital for caregivers to have access to their RFU material

**Table 4** Stakeholder's views on a future health care system which includes RFU

| Question | Frequency (%) |
|---|---|
| *Responses to interview questions* | |
| **How would you feel if the reason for use was shared with your pharmacist on every prescription, including refills?** | |
| Negative | 0 (0) |
| Positive | 20 (100) |
| **How should the reason for use information be presented to you?** | |
| On printed medication List | 16 (80) |
| On pharmacy receipt | 0 (0) |
| On an online medical record | 13 (65) |
| Through email | 1 (5) |
| Mentions prescription label | *7 (35)* |
| **How would the reason for use information affect your ability to make decisions about your medications?** | |
| 'Be more informed' | 20 (100) |
| Weigh options | 5 (25) |
| Adherence | 6 (30) |
| **Who else should have access to your RFU information?** | |
| Medical staff (outside of the primary physician or pharmacist) | 7 (35) |
| Emergency personnel | 7 (35) |
| Caregivers | 5 (25) |
| Family/partner | 11 (55) |

## 4.2 Discussion

In this qualitative study, patients discussed how they interact with the current Ontario health care system and their views on a future system that would include RFU. Given the growing challenges of polypharmacy and the increasing older adult population, patients need to be key members of the decision-making team. Shared decision-making refers to a form of health care decision-making where the patient

and the practitioner make a choice together that is informed by both the available evidence and the patient's values and preferences (Charles, Gafni, & Whelan, 1999; Towle & Godolphin, 1999). It can be as complex as choosing a new treatment or as simple as adjusting the time of day of a medication. a crucial step in recommending the right treatments to patients is for healthcare providers take the time to identify the patient preferences and values (Mulley, Trimble, & Elwyn, 2012). Although the research from the literature has shown that physicians and pharmacists do not adequately assist their patients due to time constraints, the majority of participants stated that they receive RFU information from their physician, or receive this information from the pharmacist upon pick up. What's unique about these occurrences, however, is that the healthcare professionals are only providing this information when a medication is newly prescribed. This a major problem, especially for individuals who are taking the same medications for multiple years, in some cases "over 10 years ago" (Pt. 11), and are not being reminded of the medication's RFU, its benefits, and/or its potential conflicts with newer prescribed medications.

Furthermore, the results from this study showed that RFU information is not consistently being provided to patients; the majority of the participants stated that they must ask the physician and/or pharmacist for the information, rather than it being provided openly. Some of the participants described this issue stating:

> "The doctors don't tell you, they just prescribe it. They tell you to take it at such and such time, but they don't tell you what they are for, unless you explicitly ask them. Even when you explicitly ask them some don't tell you. So, you end up Googling it" (Pt. 3).

> "They usually give a very brief intro, 'this is your problem and this is what can solve it', but they don't go into detail unless I ask" (Pt. 5).

> "I didn't want to (ask) because she (physician) seemed very rushed. To her, my condition seemed very minor…she seemed almost dismissive and didn't want to help" (Pt. 6).

Conversations with the patient are helpful because they can enhance patient understanding in a manner that contributes to better outcomes. Weston (2001) has argued that shared decision making is the crux of patient-centered care so when RFU information is provided to patients, it should be done in an appropriate manner. As professionals in the field, healthcare providers should check to make sure patients are understanding the drug regimen and RFU information adequately.

A previous study conducted at the University of Waterloo identified patients as the key point for transferring information on medications from the physician to the pharmacist (Grindrod, Tran, & Burns, 2015); this is especially difficult when patients do not adequately understand RFU and increasingly difficult for patients, particularly those with complex polypharmacy, who must coordinate medications over multiple specialists and settings. This is an exceptionally cumbersome task for these individuals, with substantial leeway for errors. One stakeholder described the situation as:

> "I switched pharmacies for that very reason. I was connected with a large multinational chain and I was just a number to them. Every time I went in, I had to retell my story, re-ask my questions, so I switched to a much smaller tinier pharmacy" (Pt. 7).

Several of the participants expressed that they would not take a medication without knowing the reasoning behind it; if for some instance the participant was not counseled properly on RFU, it could potentially affect their adherence to the drug regimen. Patients provided with RFU information has been shown to help facilitate

patient adherence and fewer errors (Kuntz et al., 2014; Schiff et al., 2016). Some of the participants described this issue stating:

> "I think it would mostly just reemphasize the importance of me taking the medication because it would be a good way to remind myself of why I'm taking it if for some reason I've been on it a very long time" (Pt. 2).

> "It will help me prioritize medications. Like if it's an antibiotic, I can't miss it, skip that, or break the course, I have to take it through the entire thing, otherwise, it would make the antibiotic ineffective and create more problems. So, it's absolutely important to know what I can't skip. It's worth knowing the information of what it's for" (Pt. 3).

While providing RFU information is undoubtedly an important factor in increasing patients' understanding of their medications, professionals (healthcare providers and government agencies) should take in account that only providing this information only verbally may not be sufficient. Results from this showed that many of the participants rely on their memory for storage and retrieval of RFU information. Given that memory and information retrieval decrease with age and the likelihoods of polypharmacy increasing with age, it is important to consider other channels of sharing RFU, such as pharmacist printing out a medication list with RFU included, providing patients with an online portal to access their medication history, or printing RFU on the patient's prescription label (Chapter 5).

Overall, results from this study showed that patients are very positive about including RFU into the current Ontario health care system. There are several reasons why knowledge of a medication's reason for use would be beneficial for all stakeholders (patients, physicians, and pharmacists); reasons confirmed from this study include:

A. *Off-label use* – Off-label use is the use of pharmaceutical drugs for an unofficial indication and/or in an unapproved age bracket, dosage, or method of administration (Stafford, 2008). Prescription drugs can be used in off-label manners. In a Quebec electronic health record, it was found that 1 in 10 prescriptions were written for off-label use and a large majority of these prescriptions (79%) lacked strong evidence for use (Eguale et al., 2012).

B. *Identification* – Knowing a medication's purpose reduces errors due to look-alike/sound-alike medications (e.g., hydrochlorothiazide for hypertension vs. hydroxychloroquine for rheumatoid arthritis). When RFU information is added to a prescription, pharmacists are able to identify twice as many discrete medications with look-alike names (Kennedy, Littenberg, Callas, & Carney, 2011). This same notion can assist patients in discerning between their prescribed medication that look-alike/sound-alike.

C. *Patient Knowledge* - Almost 1 in 8 patients cannot accurately communicate what a medication has been prescribed for (Persell et al., 2004). Patients are able to remain safer in terms of their prescription use and adherence when they have been provided with RFU information (Kuntz et al., 2014; Schiff et al., 2016).

Schiff and colleagues are presently working to design a particular type of RFU field known as "indication-based prescribing." It is assumed that the RFU information is the "link connecting a patient with a given drug," and that health systems need to incorporate this missing link (Schiff et al., 2016). Thus, incorporating RFU into the Ontario health system is an undeniably virtuous opportunity for improving the safety and quality of patient care. Accordingly, this research study serves as an important contribution to patient-centered health care literature.

### 4.2.1 Limitations

This study had some limitations. First, there was a small sample size for the patient interviews. We used a convenience sampling, as an unintended result, generalizability and representativeness may be limited (not all the participants are considered polypharmacy patients), Thus, the views expressed in interviews do not necessarily represent those of the broader community. Also, our study did not include significant numbers of low English proficient individuals or patients with low educational and/or health literacy skills; therefore, the study needs to be extended to these populations. Although pharmacist and physicians were not included in this research study, their views on the inclusion of RFU are needed; they are key members of the shared decision-making process, therefore future studies should include their opinions on the augmentation of RFU.

# Chapter 5 Prototyping Findings from Design Workshop

In the following chapter, an analysis of this exploratory research study is presented which sets out to answer the primary research question by understanding the design and preferences of RFU onto prescription labels through involving the key stakeholders: patients. Similar to the previous chapter, the purpose of this study is to understand how the RFU information can be included onto prescription labels to enhance patient understandings of their medication and to improve shared decision making among pharmacist, physician, and patients.

## 5.1 Results

### 5.1.1 Description of the patient stakeholder sample

15 participants took part in the design workshop portion of the study. 9 (40%) participants were female and 6 (40%) were male; the mean age of the participants was 68.7 years. As seen in Table 5, Five (33.3%) individuals were currently taking three or four prescribed medications; six (40%) were currently taking five or six prescribed medications; five (26.7%) were currently taking seven or more prescribed medications. Participants were currently taking an average of 5.6 prescription medications. Twelve (80%) participants keep a list of their prescribed medications. Patients were further tested on their understanding of their own medications by going through each one independently and stating the RFU. Thirteen (86.7%) assuredly stated the RFU for their medications.

**Table 5** Stakeholder demographics (n=15) from the design workshop

| | Frequency (%) |
|---|---|
| **Age (in years)** | |
| 21-40 | 1 (6.7%) |
| 41-60 | 2 (13.3%) |
| 61-80 | 7 (46.7%) |
| 81+ | 5 (33.3%) |
| *Mean* | *68.7* |
| **Gender** | |
| Male | 6 (40%) |
| Female | 9 (60%) |
| **Number of prescribed medications** | |
| 3 | 3 (20%) |
| 4 | 2 (13.3%) |
| 5 | 3 (20%) |
| 6 | 3 (20%) |
| 7+ | 4 (26.7%) |
| *Mean* | *5.6* |
| **Keeps list of medications** | |
| No | 3 (20%) |
| Yes | 12 (80%) |
| **Assuredly states RFU of their medications** | |
| No | 2 (13.3) |
| Yes | 13 (86.7) |

### 5.1.2 Adding RFU onto prescription labels

Results from the design workshop revealed that stakeholders preferred adding RFU onto prescription labels in the following locations: the top of the label (6.7%0, above the dosage instructions (13.3%), next to the dosage instructions (13.3%), underneath the dosage instructions (33.3%), and next the drug name (46.7%). As seen in Table 6, the majority (73.3%) of stakeholders felt that these locations were the most logical. Twelve (80%) of the participants would like the RFU detail to be written in short-hand (one to three words). As for rearranging the prescription label layout, the results were split with eight (53.3%) feeling that no changes were necessary and seven (46.7%) feeling like

the addition, removal, or rearrangement of information was necessary. The majority (86.7%) of the stakeholders had no concerns with adding RFU onto their prescription labels. Stakeholders would appreciate having RFU on their labels 'always' (53.3%), the first time a medication is filled (13.3%). Eight (53.3%) of the stakeholders expressed that other individuals may feel having such information on their prescription labels would invade their privacy. Stakeholders felt that the following individuals would benefit from having the RFU on prescription labels: family and/or partner (20%), older adults/cognitively impaired (33.3%), health providers (13.3%), and caregivers (13.3%). All but one stakeholder preferred the phrase 'reason for use' over 'reason to use.'

**Table 6** Stakeholder prescription label design preferences and insights

| Question | FREQUENCY (%) |
|---|---|
| *Responses to interview questions* | |
| **RFU location preference** | |
| Top of label | 1 (6.7) |
| Above dosage | 2 (13.3) |
| Next to dosage | 2 (13.3) |
| Underneath dosage | 5 (33.3) |
| Next to drug name | 7 (46.7) |
| **Location reasoning** | |
| Logical | 11 (73.3) |
| Visible | 2 (13.3) |
| Grabs attention | 2 (13.3) |
| More space | 3 (20) |
| **RFU detail** | |
| Short | 12 (80) |
| Long | 2 (13.3) |
| Depends | 1 (6.7) |
| **Label rearrangement** | |
| No | 8 (53.3) |
| Yes | 7 (46.7) |
| **Concerns** | |
| None | 13 (86.7) |

| | |
|---|---|
| Privacy | 1 (6.7) |
| Abuse | 1 (6.7) |
| **When RFU is wanted on the label** | |
| Always | 8 (53.3) |
| First fill (new medication) | 2 (13.3) |
| Unsure | 4 (26.7) |
| Not wanted | 1 (6.7) |
| **When RFU is not wanted on the label** | |
| Privacy (for self) | 1 (6.7) |
| Privacy (for others) | 8 (53.3) |
| Unsure | 6 (40) |
| **Who would benefit** | |
| Family/partner | 3 (20) |
| Older adults/cognitively impaired | 5 (33.3) |
| Health providers | 2 (13.3) |
| Caregivers | 2 (13.3) |
| Everyone | 5 (33.3) |
| **'Reason for use' vs. 'Reason to use' (RTU)** | |
| RFU | 14 (93.3 |
| RTU | 1 (6.7) |

## 5.2 Discussion

To the best of the researcher's knowledge, this is the first study that has examined the preference of the patient stakeholders for a newly designed label that includes RFU. The design requirements for adding RFU information onto prescription labels were explored, following the guidance obtained from the design workshop. The design workshop aimed to explore the language, amount of detail, location, the presentation of the reason to use information, and the overall layout preference of prescription labels. The results from this study showed that patients prefer RFU underneath the dosage instructions or next to the drug name, as shown in Figure 2. The stakeholders felt these locations were "almost logical" (Pt. 6). One participant who preferred RFU next to the dosage instructions supported their design choice by stating:

"I think that's where I would go because that really tells you-I mean this is the important stuff. You need to know how many times and for how long and then that's for why" (Pt. 10).

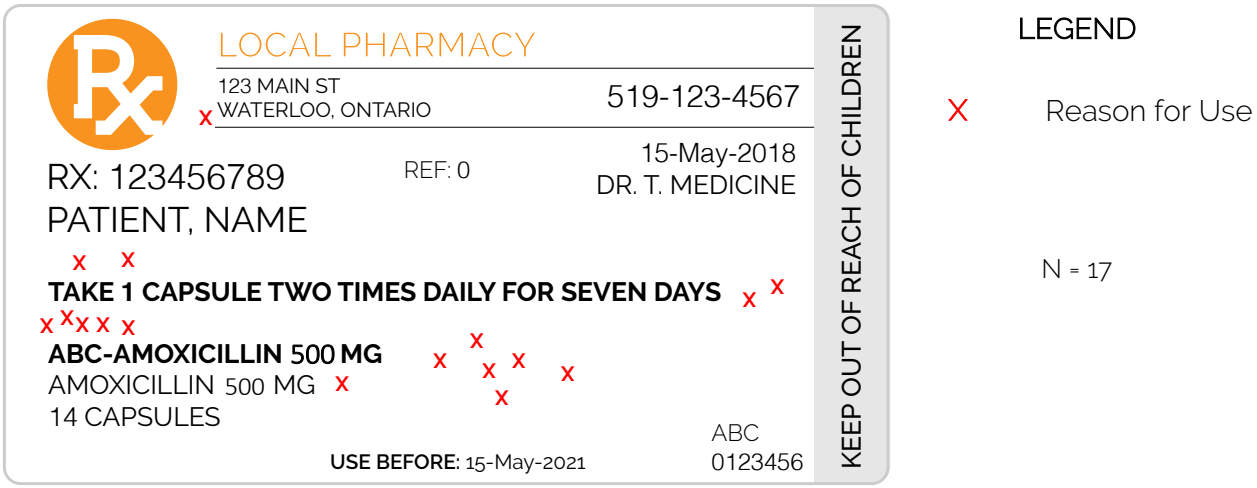



**Figure 2** Participants preferred RFU Location

Findings from the discovery phase (Chapter 4) and literature (Chapter 2) suggest avoiding medical jargon on prescription labels and that same principle should be applied to implementing RFU on prescription labels. Results from this study showed that the RFU language should be concise (one to three words) to serve as a "memory trigger" (Pt. 6). If the RFU information is too long, there's a risk that patients will not read it or understand it completely. One stakeholder described this situation as:

"If it gets too long or complicated, there would be some people that do not grasp it all" (Pt. 17).

Aside from implementing RFU onto prescription labels, results from this study showed that some stakeholders preferred the content on the label to be removed, rearranged, or emphasized; some individuals desired for the inclusion of certain

information as shown in Figure 3. The majority of the participants found nothing that was 'not useful' with the prescription label. One study found that the average patient found their own prescription labels generally easy to read, understand and useful (Law & Zargarzadeh, 2010). Similarly, older patients have a schema that they use to understand drug information, and they prefer information to follow in that order (D G Morrow, Leirer, Andrassy, Hier, & Menard, 1998; William J. Vigilante & Michael S. Wogalter, 1997). It is posited that the findings from this study were partially due to familiarity with existing label formats. However, the results from this study also suggest that improvements could be made that may help all patients. These changes need to be tested for efficacy in general and in susceptible populations for conclusive evidence.

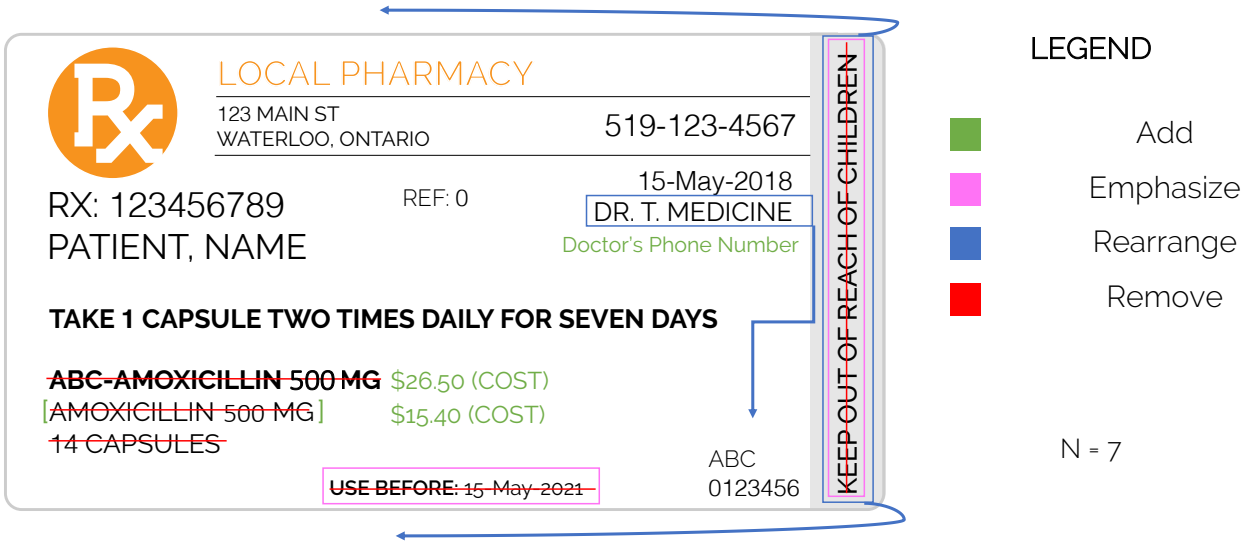



**Figure 3** Participants preferred prescription label changes

Although the benefits of having RFU have been detailed throughout this thesis, there are some concerns about the inclusion of such information on prescription labels. The most prominent concern amongst the participants pertains to privacy. Privacy concerns were more evident amongst the younger participants (age 40 and below) and such concerns manifested from how others would perceive and/or judge

the use of medications that may have a stigma associated with them. One participant stated that,

> "If somebody sees this in my medicine cabinet, they don't necessarily know what it's for but, with RFU it's more obvious to others. So, if I am carrying something that says 'for depression,' I am not comfortable sharing that I suffer from depression or battle depression. It takes that freedom to share or not away" (Pt. 6).

The implications of RFU associated with the treatment of depression, HIV/Aids, STDs, and condition alike should be assessed more carefully (Law & Zargarzadeh, 2010; Sakharkar et al., 2014). One way to afford these privacy concerns is giving the patient the option to not disclose this information on their prescription label.

Ultimately, the benefits associated with adding RFU to the label allows patients to gain a better understanding of why they are being given a medication by their doctors, and this enables them to answer questions or deny the medication if they feel that it is unsafe (McNaughton, Huet & Shakir, 2014). The design of RFU should use lay language, be simple (containing one to three words, e.g. 'for strep throat'), and should be placed in a sensible location either underneath to the dosage instructions or next to the drug name.

### 5.2.1 Limitations

This study had some limitations. First, there was a small sample size for the patient interviews. We used a convenience sampling, as a result, generalizability and representativeness may be limited (not all the participants are considered polypharmacy patients), Thus, the views expressed in interviews do not necessarily represent those of the broader community. Also, our study did not include significant numbers of low English proficient individuals or patients with low educational and/or health literacy skills; therefore, the study needs to be extended to these populations. We cannot

assume that patients fully understand the RFU information on prescription medication containers, because their appearance suggests that they are simple and clear., therefore, further research needs to be done to clarify the real value and comprehensibility of RFU on the label for patients and their impact on final health outcomes. Lastly, although pharmacist and physicians were not included in this research study, their views on the inclusion of RFU onto prescription labels are needed; they are key members of the shared decision-making process, therefore future studies should include their opinions on the augmentation of RFU onto prescription labels.

# Chapter 6 Conclusion and Future Work

This research was an initial attempt to understand the need for adding RFU onto prescription labels and the design of such. This exploratory study employed co-design strategies through semi-structured interviews and a design workshop with patient stakeholders was conducted to investigate design requirements for this patient-centered label. When patients are not clear about what their prescriptions do, it is possible that they are being treated for symptoms that deviate from their main complaints, and this limits their ability to discuss the matter further with their prescribers (Hassell, Noyce, Rogers, Harris & Wilkinson, 1998).

The data gathered through the semi-structured interviews and design workshop indicated that RFU may have an important role in increasing patient understanding of their medication and ultimately, increase patient-safety. Results from the first part of the study showed that patients are currently receiving RFU information verbally from their physician and/or pharmacist when it a newly prescribed medication and/or upon asking. Currently, participants rely on their memory for the storage and retrieval of RFU information, but would like to have this information provided to them in a written manner (i.e. a printed medication list, an online health portal, or on their prescription labels). Participants were generally receptive of including RFU into the health care system, concluding that access to such information would increase their understandings of their medications. Requirements for adding RFU to prescription labels should meet the following criteria: be placed underneath the dosage instruction or next to the drug name; be written in one to three words; and written in lay language as shown in Figure 4.

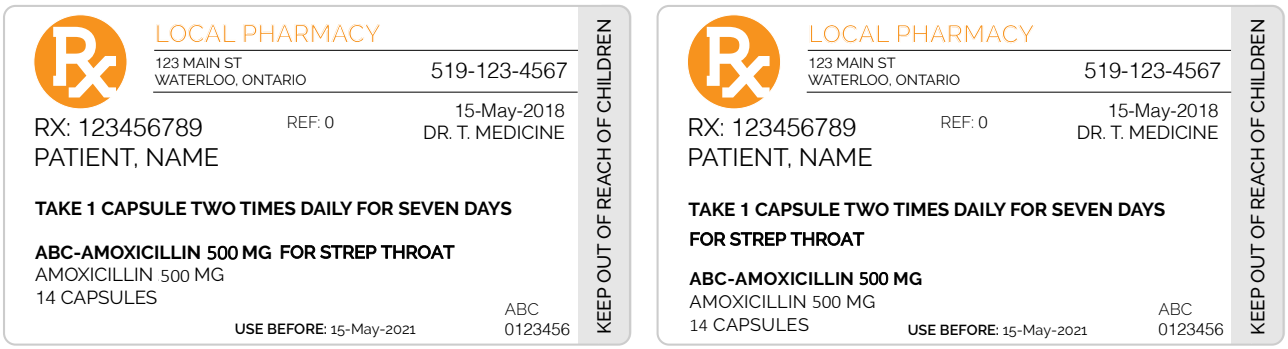



**Figure 4** Examples of prescription labels with RFU design requirements

Picking up a pill bottle and following the instructions for use is a patient-centered activity. It is important to note, however, that the inclusion of RFU on prescription labels may not meet the wants and needs of every patient or may not be appropriate in all patient care situations (American Pharmacists Association, 2017; Shiyanbola et al., 2016). Designers focused on implementing RFU on prescription labels should prioritize designs that provide the best features in terms of efficiency and safety, rather than only focusing on the design that is most preferred by users as it has been noted in human factors and systems design that there may be dissociations between performance and user preferences (Andre & Wickens, 1995).

Previous research has also shown that the other stakeholders may benefit from the inclusion of RFU in the Ontario health care system. Including RFU as a part of medication ordering practices ensures that the RFU will be accurately transcribed by the pharmacists or members of the pharmacy staff who are tasked with printing labels (Schiff et al., 2016). As the current Ontario health system stand, patients are the fundamental source for the accurate transfer of information between different physicians, pharmacist, and other healthcare providers they are working with. By providing patients RFU on their prescription labels, the exactitude of transfer such information may be enhanced, which ultimately benefits the healthcare providers in ensuring a proper drug regimen and consultation.

The American Pharmacist Association (APhA) encourages pharmacists to include RFU on prescription labels, stating that "when such information is included by the prescriber on the prescription order or can be otherwise clearly and accurately discerned per the professional knowledge and judgment of the pharmacist" (American Pharmacists Association, 2017). Future studies should include the opinions of pharmacist because are they are the health providers who would ultimately dispense and elucidate the revised labels during medication counseling and they may be the first health provider to notice a patient's misunderstanding on how to safely use their prescription medications (American Pharmacists Association, 2017).

It has been found that pharmacists view this change favorably to improve patient understanding and medication adherence, but have some hesitations due to implementation costs (Institute of Medicine, 2006; Mohan et al., 2013; Sakharkar et al., 2014). Considering the practice and policy implications of this research, the cost attached to adding RFU into the health care system, changing the prescription label, and how these changes may impact policy implications in terms of state-board-regulated content and label design needs to be examined.

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# Appendix A Semi-Structured Interview

# Recruitment Poster

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**Department of Systems Design Engineering University of Waterloo**

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**PARTICIPANTS NEEDED FOR**
**RESEARCH ON PHARMACY MEDICATION LABELS**

We are looking for volunteers to take part in a study, "exploring reason to use." As a participant of this study, you would be asked questions regarding how medication labels can include the reason a drug is being used.

Your participation would involve a 45-minute interview.

In appreciation for your time, you will receive **$25 cash!**

Participants must meet the following criteria:
be 18 years and older, be able to speak English fluently,
are currently taking 3 or more medications.

For more information about this study, or to volunteer for this study, please contact:

Reicelis Casares Li

PhD, Systems Design Engineering
Email: rcasares@uwaterloo.ca

Or

Catherine Burns, Professor
Executive Director, Centre for Bioengineering and Biotechnology
at 519-888-4567 Ext. 33903 or

Email: catherine.burns@uwaterloo.ca

This study has been reviewed by, and received ethics clearance through the University of Waterloo Research Ethics Committee.

# Appendix B Design Workshop Recruitment Email

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Hello (insert name),

My name is Thana and I am a graduate researcher at the University of Waterloo with the Systems Design Engineering Department. We are conducting a study regarding adding indication, what we refer to as "reason for use" onto prescriptions that are sent from physicians to pharmacist and furthermore, adding "reason for use" information onto prescription labels. *We are looking for individuals who take 3 or more prescribed medications.*

Your participation would involve an interview and a design session, which in total will take 45 minutes. In appreciation of your time, you will be given $25 cash.

Would you be interested in participating in this study? Feel free to reply to this email with your answer If you have any further questions please do not hesitate to contact me.

Looking forward to hearing from you.

Thank you,

**Thana G. Hussein**
MASc Candidate Systems Design Engineering
*Advanced Interface Design Lab*
University of Waterloo

# Appendix C Design Workshop Recruitment

# Poster

# Appendix D Project Summary

Dear Potential Participant,

This letter is an invitation to consider participating in a research study we are conducting in the Department of Systems Design Engineering and the School of Pharmacy at the University of Waterloo under the supervision of Dr. Catherine Burns and Dr. Kelly Grindrod

The purpose of this study is to understand how "reason to use" information can be shared amongst pharmacist, physician, and patients to improve decision making. The term reason for use it is used to convey why the medication it is prescribed. The rationale is that 7% of the population takes at least one medication, and almost a third of seniors take 5 or more medications. Nearly half of the population do not or cannot take their medications as prescribed, causing many preventable medication-related hospitalizations. Adverse drug events are the cause of one in every nine emergency room visits, costing the Canadian health care system over $2 billion each year. With an aging population, medication risks will only escalate. Poor knowledge-sharing within health care teams is a vital factor of medication mismanagement. One potential solution for these mishaps is to include the "reason for use" information with the prescriptions given to pharmacists and patients.

Participation in this study is voluntary. Participation requires an interview and a design workshop of approximately 45 minutes at a mutually agreed upon location. You may decline to answer any of the interview questions if you wish. Furthermore, you may decide to withdraw from this study without any negative consequences by advising the researcher; you will have up to two months after the interview has been conducted to do so. With your permission, the interview will be audio recorded to

facilitate collection of information, and later transcribed for analysis. The dataset without identifiers may be shared publicly. Your identity will be confidential, it will not appear in any thesis or report resulting from this study, however, with your permission anonymous quotations may be used. Please be advised, however, that confidentiality will be in accordance to Article 5.1 of the of the Tri-Council Policy Statement. Confidentiality will be balanced against competing ethical considerations or legal or professional requirements that call for disclosure of information obtained or created in this research context. Data collected during this study will be retained for a minimum of 7 years in a locked office. Only researchers associated with this project will have access. Your name and any identifying data will not be shared with the study sponsors.

There are no known or anticipated risks to you as a participant in this study. There are unlikely to be any direct benefits to the participants of this study. The intention of this project is to use the information gathered to help Electronic Health Record (EHR) vendors redesign their electronic medical and pharmacy records. The ultimate beneficiaries will be patients and clinicians who will use the new systems that are designed for medication management.

Once all the data collected from this project has been analyzed thoroughly, I plan on sharing the results with the research community through seminars, conferences, presentations, and journal articles.

Each participant will receive an honorarium of $25.

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee (ORE# 22713). If you have questions for the Committee, contact the Office of Research Ethics by phone at 1-519-888-4567 ext. 36005 or by email at ore-ceo@uwaterloo.ca.

For all other questions, or, if you would like additional information to assist you in reaching a decision about participation, please contact me, Reicelis Casares Li, by email at rcasares@uwaterloo.ca. You can also contact my supervisor, Dr. Catherine Burns by phone at 519-888-4567 ext. 33903 or by email at catherine.burns@uwaterloo.ca.

I hope that the results of my study will be of benefit to those organizations directly involved in the study, as well as to the broader research community.

I look forward to speaking with you, and thank you in advance for your assistance in this project.

Yours Sincerely,

**Reicelis Casares Li, PhD**
*Postdoctoral Fellow*
Advanced Interface Design Lab
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**Catherine Burns**, PhD, Professor, Systems Design Engineering, University of Waterloo. Tel: (519) 888-4567 ext. 33903. Email: catherine.burns@uwaterloo.ca

**Kelly Grindrod**, BScPharm, MSc, PharmD, Assistant Professor, University of Waterloo School of Pharmacy, 200 University Avenue West, Waterloo, ON N2L 3G1. Phone: 519.888.4567 ext. 21358. Email: kgrindrod@uwaterloo.ca

# Appendix E Participant Consent Form

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

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I have read the information presented in the information letter about a study being conducted by Catherine Burns, Kelly Grindrod, of the Department of System Design engineering and the School of Pharmacy at the University of Waterloo. I have had the opportunity to ask any questions related to this study, to receive satisfactory answers to my questions, and any additional details I wanted.

I am aware that I have the option of allowing my interview to be audio recorded to ensure an accurate recording of my responses.

I am also aware that excerpts from the interview may be included in the thesis and/or publications to come from this research, with the understanding that the quotations will be anonymous.

I was informed that I may withdraw my consent without penalty by advising the researcher, it was communicated to me that I have 2-months after my interview was conducted for it.

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee (ORE# 22713). If you have questions for the

Committee contact the Chief Ethics Officer, Office of Research Ethics, at 1-519-888-4567 ext. 36005 or ore-ceo@uwaterloo.ca.

For all other questions contact Catherine Burns by phone at 519-888-4567 ext. 33903 or by email at catherine.burns@uwaterloo.ca.

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

☐YES ☐NO

I agree to have my interview audio recorded.

☐YES ☐NO

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

☐YES ☐NO

Participant Name: _____ (Please print)

Participant Signature: _____

Witness Name: _____ (Please print)

Witness Signature: _____

Date: _____

# Appendix F Semi-Structured Interview Questions

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*First, we are going to ask you a few questions about yourself.*

**Demographic questions**:

1. What is your age?

2. What is your gender?
    a. Man
    b. Woman
    c. Non-binary

**Questions related to your medication history**:

1. How many medications do you take regularly?

2. In the last month, can you tell me what medications you took and why you took each of your medications?
3. Do you keep any lists of these medications (in a file, on a computer, etc.)?

4. Would you be comfortable with us taking a picture of these records? We will ensure that all identifying information is kept confidential and protected.

*We are going to talk about how you interact with the current system. In particular we are interested in something called "reason for use". This is the reason a medication was prescribed to you. For example, the reason for use with Tylenol may be "a headache" our "arthritis pain".*

**Questions related to how you function in the current system**:

1. How do you currently find out what your medications are for?

2. Where do you place this information? (Potential probes: Do you write it down? Do you keep it put in your phone? Do you make medication lists?)

3. In the past, has the reason for use information been shared with you?
    a. Who shared this type of info with you? Pharmacist? Physician?
    b. When did they share it? Did you have to ask to find out or was this info provided?
    c. Please provide an example of what type of language was used to explain a medication. How useful was this?
    d. Was there a time that the reason for using a medication a professional provided was not clear or useful? Please explain.
    e. Can you recall a time that learning the reason for using a medication was particularly helpful for you? Please tell me more.

4. Who else is aware of the reasons you are taking your medications?

5. Can you recall a time when you did not know the reason for a medication? What implications did this have?
    a. What did you do to find out (if appropriate to ask)? (ask user to draw out the steps they took to find out the reason for use information)

6. On a scale of 1 to 5, with 5 being "very important," how important is it for you to know what your medication are for? Please tell us more.

*We are going to talk about what would happen if the "reason to use" was added to the computer systems that doctors, pharmacists, and nurses use to help you manage your medications.*

**Questions related to being provided with "reason to use" information:**

1. How would you feel if the reason for use was shared with your pharmacist on every prescription, including refills?

2. How should the reason for use information be presented to you? (Probing questions: Would you like it to be on your prescriptions? Receipts? Medication lists? In an app or website that you use to view or access your prescriptions?)

3. How would the reason for use information affect your ability to make decisions about your medications?

4. Who else should have access to your reason for use information? This can be anyone in your life such as healthcare professionals, care providers, or family members. Why?

# Appendix G Design Workshop Prescription Label Template

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LOCAL PHARMACY

123 MAIN ST
WATERLOO, ONTARIO

519-123-4567

RX: 123456789
PATIENT, NAME

REF: 0

15-May-2018
DR. T. MEDICINE

**TAKE 1 CAPSULE TWO TIMES DAILY FOR SEVEN DAYS**

**ABC-AMOXICILLIN** 500 **MG**
AMOXICILLIN 500 MG
14 CAPSULES

**USE BEFORE:** 15-May-2021

ABC
0123456

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN

# Appendix H Design Workshop Prescription

# Label Cut-Out Information

| | |
|---|---|
| Pharmacy Name | **LOCAL PHARMACY** |
| Pharmacy Address | **123 MAIN STREET<br>WATERLOO, ONTARIO** |
| Pharmacy Phone Number | **519-123-4567** |
| Prescription Fill Date | **15-MAY-2018** |
| Name of Prescriber | **DR. T MEDICINE** |
| Prescription Number | **RX: 123456789** |
| Your name (patient's name) | **PATIENT, NAME** |
| Number of refills remaining | **REF: 0** |
| Directions on how to take the medication | **TAKE 1 CAPSULE THREE TIMES DAILY FOR TEN DAYS** |
| Brand name of medication | **ABC-AMOXICILLIN 500 MG** |
| Generic name of medication | **AMOXICILLIN 500 MG** |

| | |
|---|---|
| Quantity and form of medication dispensed | **30 CAPSULES** |
| Expiry date | **USE BEFORE: 15-MAY-2021** |
| Abbreviation for manufacturer of medication | **ABC** |
| Drug Identification Number (DIN) | **0123456** |
| Reason the drug is prescribed | **REASON TO USE** |

# Appendix I Design Workshop Questions

*Thank you all for joining us today in this co-design workshop. As a reminder, today we will be designing prescription labels with the addition on reason for use information. The term reason for use it is used to convey why, specifically, the medication it is prescribed. This information is important to have as many medications have multiple reasons for use which affect the dose, route, duration, frequency of use, or monitoring needs. Without an understanding of the reason a medication is prescribed, individuals are not able to assess if a prescription is appropriate or safe. Today we will be focusing on how that information should look and where that information should be placed on the label.*

*First, we are going to ask you a few questions about yourself.*

**Demographic questions***:*

1. What is your age?

2. What is your gender?
    a. Man
    b. Woman
    c. Non-binary

**Questions related to your medication history**:

1. How many medications do you take regularly?

2. In the last month, can you tell me what medications you took and why you took each of your medications?
3. Do you keep any lists of these medications (in a file, on a computer, etc.)?

4. Would you be comfortable with us taking a picture of these records? We will ensure that all identifying information is kept confidential and protected.

(Hand participant example prescription label template and example prescription label template)

*Please place an 'X' where you would want to see "reason to use" information.*

1. Why did you choose this location?

2. How much detail would you expect the RFU information to be? (Potential probes: Short-hand? Long-hand?)

*If you could add, remove, or rearrange the information on this prescription label, would you?*

If yes: *please show us what you'd like to see differently.*

(Hand participant blank prescription label template, corresponding prescription label information, scissors, and tape)

1. Why did you choose the layout you did?

(Walk through patient's design choices and probe to understand their design-decision making process)

*Now we are going to talk a little more about adding RFU onto prescription labels,*

**Follow-up Questions:**

1. Do you have any concerns regarding the sharing of reason for use information with the pharmacist or on your prescription labels? If so, what?

2. On what occasion(s) would you like this information on your prescription label?

3. On what occasion(s) would you not like this information on your prescription label?
    a. (if they acknowledge privacy concern) How you suggest affording privacy concerns?

4. Do you prefer the phrase 'reason to use' or 'reason for use'?

5. Who do you think would benefit from this new design?

6. Do you have any final thoughts, comments, or concerns?

# Appendix J Participant Feedback Form

Dear Participant,

Thank you for your participation in our research study entitled, “Exploring how ‘reason to use’ information can be shared between pharmacists, physicians, and patients.” As a reminder, the purpose of this study is to understand how “reason to use” information can be shared to improve decision making among pharmacist, physician, and patients.

The information collected during interviews will lead us to a better understanding of how the "reason to use" information can improve shared decision-making process between physicians and pharmacist. This information will be especially useful in situations where physician and pharmacist are working with patients who are taking multiple medications.

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee (ORE# 22713). If you have questions for the Committee, contact the Office of Research Ethics by phone at 1-519-888-4567 ext. 36005 or by email at ore-ceo@uwaterloo.ca.

For all other questions contact Catherine Burns, Executive Director, Centre for Bioengineering and Biotechnology, by phone at 519-888-4567 Ext. 33903 or email at catherine.burns@uwaterloo.ca.

As a reminder, any data pertaining to you as an individual participant will be kept confidential. Please be advised, however, that confidentiality will be in accordance to

Article 5.1 of the of the Tri-Council Policy Statement. Confidentiality will be balanced against competing ethical considerations or legal or professional requirements that call for disclosure of information obtained or created in this research context. Once all the data collected from this project has been analyzed thoroughly, I plan on sharing the results with the research community through seminars, conferences, presentations, and journal articles.

If you are interested in receiving more information regarding the results of this study, or would like a summary of the results, please provide your email address for us to forward the results to. In the meantime, if you have any questions about the study, please do not hesitate to contact me at the email provided below.

Yours sincerely,

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