

SIDE EFFECT INFORMATION AND THE INFLUENCE ON PATIENT
MEDICINE-TAKING BEHAVIOUR

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By

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ABSTRACT

Lack of patient adherence with medication results in health care costs and adverse clinical outcomes. Although fear of side effects can contribute to non-adherence, being informed about them can actually improve matters. Nonetheless, questions persist as to the most efficient way to convey that type of information to patients for a given medication. Information on side effects is largely limited to a simple list in medication leaflets, often without frequency data (that is, lacking detail as to how often they might occur). The decision-making literature suggests that the interpretation of information varies depending on the presentation format or the *frame* used.

This study examined the impact of providing numerical information for side effect frequency, levels of illness severity, and side effect framing on the likelihood of taking an OTC medicine.

Participants received a headache scenario with three drug options (X, Y and Z) to consider for use. These painkillers had three levels of potency (defined as 50, 75, and 100% effective) and were accompanied with three levels of side effects (two, four, and six items). When considering their drug choice for the headaches, participants received drug information written *without* side effect frequency data, then again *with* side effect frequency data. Subjects rated their likelihood of taking Drug X, Y and Z on a scale of 1 (*very unlikely*) to 100 (*very likely*). Participants were also asked to show their likelihood of taking

a different set of two medications for headaches (coined Drug N and P) based on positively-slanted or negatively-slanted wording in relation to chances of experiencing a side effect (heartburn).

Thirty subjects from Saskatoon over 50 years of age participated. The average age was 66.6 years and 63.3 percent of participants were female. Less than half of participants (n=11) had previous experience with side effects. Most participants were using at least one medicine (whether OTC or prescribed) and described themselves as *knowledgeable* or *somewhat knowledgeable*.

Participants were more likely to take the hypothetical drugs in the situations described when they received frequency data for side effects ($p<0.05$). Also, there was a significant higher mean likelihood of use when the drug was framed positively ($p<0.01$).

When considering decisions involving drug effectiveness and their side effects, the provision of frequency data increased patient likelihood of use. Framing the context in positive format also increased patient likelihood to use a medicine. This information could be important for pharmacists counselling on medication side effects, especially for those patients with medication adherence problems.

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LIST OF ABBREVIATIONS

<u>Abbreviation</u>	<u>page</u>
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CHAPTER 1 INTRODUCTION

Over the past 30 years or so, there has been a growing awareness of the need to provide people with information about their illnesses and associated treatments. The process of successful medicine-taking is likely based on a partnership between patients and health care professionals. It is necessary that patients and their caregivers have two-way exchange of information and views about medicines.¹ In line with this, a number of studies have reported beneficial effects of giving people health-related information.^{2,3}

Pharmacists often convey drug-related information to patients through the use of computer-generated leaflets, but the value of such documents has been questioned, due in large part to the extensive lists of side effects within them. It has been suggested that such a comprehensive style may in fact scare patients into states of non-adherence. Yet, researchers have found patients who received such leaflets knew more about their medicines (especially the side effects) and were significantly more satisfied.⁴⁻⁸ Others support the value of written information for increasing patients' knowledge and adherence with treatment.^{2,3}

In addition to written information, pharmacists convey information verbally. Evidence suggests pharmacists display a broad range of approaches when counselling patients about their medicines – some provide extensive information while others are more selective. In a small Canadian study, Dyck et

al. found that pharmacists discussed side effect information with all patients, but only half of patients received information on the drug's benefits.⁷ Side effects that were raised were often described with respect to occurrence using terms and phrases such as "might happen", "rarely", and "not that common".

One type of information noted to cause particular difficulties in terms of patient and health professional understanding is the presentation of risk information.⁹ Patients want and need understandable information about the risks of medicines. The best predictors of adherence are patient attitudes, beliefs, and perceptions about their illness and treatment.¹⁰ These include whether patients perceive a medicine as necessary for maintaining health, as well as concerns about possible adverse consequences such as unpleasant side effects, dependency, or long term harm. This is essential if they are to become partners in medicine-taking.

The use of verbal descriptors to convey information about side effect risk may lead to over-estimation of the level of harm and may lead patients to make inappropriate decisions about whether or not they take a medicine.¹¹ It appears that patients may prefer numerical (e.g. 4 percent or 4 out of 100) rather than verbal descriptors (*rare, infrequent, common, etc*) and are able to use that format to make more accurate predictions of their personal likelihood of experiencing a particular reaction.^{2,7,9,12,13} Also, studies show patients who were informed in terms of natural frequencies were less anxious about taking their drugs.^{9,14-17} A study by Timmermans showed that risks presented as population figures were perceived as having the greater chance of occurring compared

with percentages and frequency formats.¹⁸ However, Hawley et al. evaluated the ability of six graph formats to impart knowledge about treatment risks/benefits to individuals with low and high numeracy ability. They found communicating probabilities with pictographs would be particularly useful among lower numeracy individuals.¹⁹ Careful attention to information presentation allows the less numerate to understand and use numbers more effectively, especially in risky decisions. It is important that a physician or pharmacist be aware of the meaning patients may attach to a probability expression during a consultation.^{20,21} Where individual differences exist, a health care provider should consider presenting probability information in more than one format to make sure a message has been delivered properly.

While many reports suggest that the public wants more information about their drug therapy,^{5,11,22-35} simply providing *more volume* may be less desirable than striving for *more effectiveness*. There is a need to synthesize the current evidence on patient preferences for different information formats and assess the effects of various forms of delivery.^{2,36} For instance, little is known about how many adverse effects should be mentioned for a given drug before the informational load becomes unmanageable.

The content of counselling will vary depending on whether a prescription (Rx) or an over-the-counter (OTC) drug is involved. When considering patient counselling workload, pharmacist priority will also be different regarding the formulation of drug (e.g. inhalation or injection) and the seriousness of the condition. Where a drug is known for a high risk of interactions or adverse

effects, this information would likely be more emphasized by pharmacists.

Overall, the length of counselling a patient receives will be influenced by other factors such as lack of privacy, knowledge about drugs and conditions, communication skills, and time.

There is even less research on agents available without a prescription (over-the-counter or OTC). Standard OTC counselling textbooks encourage pharmacists to approach patients and offer them information about OTC drugs, to make sure the benefits and risks have been explained.²³ Yet, according to a 2003 US national survey, only 43 percent of people consult a pharmacist when buying an OTC drug.²³ Patients often do not ask the pharmacist for advice because they believe they know all that is necessary or because they are unaware of potential problems.

OTC medicines are commonly used to treat minor illnesses. Though most Canadians believe that such medicines are safe and effective, they can have adverse effects and interactions with other agents.^{35,37,38} People in Canada can purchase OTC medicines from pharmacies, or for select agents, in non-pharmacy outlets such as convenience stores. Given that people are being encouraged to be more active in their care and to select their own medicines, they must have clear information to choose and use them effectively.

Bissell found consumers emphasize the benefits and effectiveness of OTC medicines rather than their risk.³⁸ In this study, the researchers chose an OTC hay fever medicine (terfenadine) that has known potential for interactions with a number of antibiotics and anti-fungal agents. These interactions were

purported to have caused 33 cases of serious cardiac arrhythmia at the time, of which 14 were fatal. As a result, terfenadine was re-classified from OTC to prescription-only status. After release of this news, in interviews with 94 consumers purchasing OTC medicines, they found consumers were far more likely to talk about the benefits of such medicines, and rarely referred to the risks or dangers of medication unless prompted by the researcher. The majority of consumers' views regarding OTC medicines were that those available in a pharmacy must be safe and less dangerous than prescription medicines. Another study regarding the use of non-steroidal anti-inflammatory drugs, which are available OTC at pharmacies, found that patients were more likely to overuse OTC drugs than prescribed drugs.³⁹ There is more to be learned about how consumers of OTC medicines process product-related information.

In summary, valuable information is accruing on the extent to which patients consider the use of prescribed medicines in relation to side effects. Far less is known as to how this relates to the use of OTC medicines. When a pharmacist counsels a patient on the use of such a medicine, s/he will have to consider how best to convey the benefits and risks of use. However, many purchase decisions in pharmacies regarding OTCs take place without pharmacist involvement. In these situations, it is the written information on the box or product insert that must convey the information. Current medication packaging and inserts usually provide lists of adverse effects with no indication for frequency of occurrence. Such information may be useful in helping a patient estimate the degree of risk to which s/he will be exposed, in relation to

any expected relief of symptoms. Because of this lack of knowledge, this study will examine aspects of how OTC medicine users process side effect information when considering product use.

1.1. Objective

During the process of informing patients about a medicine, including the potential for side effects to occur, variations in approaches might affect patient likelihood of taking that medicine. This study examines provision of numerical data for side effects and the effect of this information on patient medicine-taking behaviour. A secondary focus will investigate the impact of numerical information formatted in negatively-slanted or positively-slanted phrasing.

The objective of this study was to determine how citizens of Saskatoon are influenced when given numerical risk estimates of side effects and differing phrasing formats.

1.2. Research Questions

- 1) What is the impact of varying levels of side effect potential and drug effectiveness, when considered concurrently, on perceived likelihood of taking a medicine?
- 2) What is the impact of providing percentages and frequency occurrences of side effects on the likelihood of taking a medicine?
- 3) What is the impact of illness severity on the likelihood of taking a medicine?

- 4) What is the impact of presenting side effect information within a negatively- or positively-slanted context on perceived likelihood of taking a medicine?

1.3. Null Hypothesis

- 1) There is no difference on perceived likelihood of taking three hypothetical drugs when varying levels of side effect potential and drug effectiveness are considered concurrently.
- 2) There is no difference on perceived likelihood of taking three hypothetical drugs when providing the public with natural frequency and percentages of side effect occurrences.
- 3) There is no difference on perceived likelihood of taking three hypothetical drugs across two levels of illness severity.
- 4) There is no difference on perceived likelihood of taking a drug when presenting side effect information within a negatively- or positively-slanted context.

CHAPTER 2 LITRATURE REVIEW

Hundreds of thousands of people a year visit physicians for a multitude of ailments. For many, a medicine is prescribed, with intent to promote a higher state of health. *Compliance* is the extent to which a patient's behaviour coincides with health care provider advice.⁴⁰ Although the term compliance is widespread and is still in use, the World Health Organization (WHO) formulated a definition of compliance and renamed it *adherence*. The WHO definition for adherence is: "the extent to which a person's behaviour (taking medication, following diet, and/or executing lifestyle changes) corresponds with agreed recommendations from a health care provider".⁴¹ The main difference between *compliance* and *adherence* is that adherence requires the patient's agreement on the recommendation. The term *adherence* is intended to be non-judgmental; it is an observation of a fact and not intended to blame the patient.

A patient is more likely to follow a regimen when there is agreement between physician and patient, and the patient has confidence in the medical diagnosis and prognosis. The process is complicated by uncertainty about the nature of an illness and the effects of treatments, particularly medications.⁴⁰ The prevalence of low adherence to medication regimens is of concern for the health care system and society because waste is incurred if suboptimal therapeutic outcomes are returned for the resources invested to provide drug therapy. The following facts reflect the nature of the problem:

- It is estimated that approximately 30 to 50% of prescribed medication is not taken as directed,⁴²⁻⁴⁴
- One in five patients will not comply with their medications,⁴⁵ even after receiving mail and telephone reminders;^{45,46}
- In Canada, the cost of non-adherence is approximately \$7 to \$9 billion annually;⁴⁵
- 125,000 patients die in the United State every year because of non-adherence;²²
- 10 percent of hospital visits are due to non-adherence;^{22,45}
- 28 percent of hospital visits for the elderly are due to non-adherence.⁴⁵

Various patient and health professional factors have been considered for their effects on adherence, including specific barriers (e.g. cost and access) and communication failure.^{23,44} The latter involves situations where the patient does not know, understand, or remember what has been prescribed.^{23,24,44} Yet, even when there are no obvious barriers and when patients are well informed about their treatment, they still may not comply with it. This is deemed to be intentional non-adherence.⁴³ Here, patient beliefs are usually the key determinants. Patients may have negative beliefs about medicines in general; they may be seen as unnatural, harmful or over-prescribed by doctors or as having negative outcomes such as adverse effects or dependence.⁴⁴

Some authorities have presumed that discussing adverse effects with patients would increase non-adherence due to fear,^{11,23-27} but this does not appear to be the case in all instances. Fear of adverse effects can contribute to

non-adherence, but being informed about side effects can resolve fears.^{11,23-27}

In a survey about the risks of drugs, 90 percent of patients reported that precaution and warning information would encourage them to take the drug exactly as prescribed.⁴⁷

Communicating medication information effectively should help patients make personal decisions about treatments and find ways to integrate medication-taking into their daily activities. To be effective, health professional interaction with patients should involve strategies that modify the patient's health beliefs and attitudes.²³

To understand a message about adverse effect risk, readers need to know the population at risk and how this risk compares to other risk. Improving public understanding of risk is a problem (but also an opportunity) that involves multiple players, including those in traditional print and broadcasting news, entertainment, advertising, public health, health communication, clinical medicine, scientific research, government at all levels, and professional and lay advocacy groups.⁴⁸ The target is the public; but there is no single "public". There are publics not only in terms of sex, age, and geography, but also in terms of individual risk susceptibility, exposure, and risk literacy. *Risk literacy*, in essence, is defined as the acquisition and application of a body of knowledge about risk. This includes a familiarity with the nature of risk and risk-taking, an ability to specify and use suitable risk assessment approaches, and an ability to deal appropriately with risk issues that have been identified.⁴⁹ It also could be defined as a basic grasp of statistics and probability that is critical to making

choices about health, money and even education, yet it is largely ignored by the national curriculum. Often, those at greatest potential risk are less likely to be informed about the risks they face or able to understand the complex, changing data involving health hazards.⁴⁸ Conversely, many of the most voracious consumers of health information are a more capable, literate audience. They may be better informed, but also at lower risk, because they are already taking good care of their health and have greater access to the health care system. To make inroads into the difficult task of improving health risk understanding across the board, one must address diversity of health care consumers in the real world.⁴⁸ Past research suggests that among seniors whose health is at high risk, literacy levels may be very low.

Literacy skills can have a direct effect on a person's health in the use of prescription drugs. The potential for medication errors is enormous among those unable to understand written directions properly, or among those who are unable to decipher the written text. Elderly patients will experience this problem to a much greater degree since they are more likely to use medication and take several drugs simultaneously. The International Adult Literacy and Skills Survey tested more than 23,000 Canadians aged 16 years or more in 2003 on their skills proficiency in four domains: prose, document, numeracy and problem-solving.⁵⁰ Skills were rated on the basis of levels one to five (lowest to highest). About 42 percent of adults between the ages of 16 and 65 scored below level three on the prose literacy scale and when those aged 66 and over were also included, the proportion scoring below level three in prose literacy increased to

nearly one-half (48 percent). At 55 percent, the proportion of the population aged 16 and over with numeracy scores below level three was even more pronounced. Levels below three are considered to indicate limited proficiency, while levels about three indicate high proficiency. Even in the top performing jurisdictions at least three out of ten adults aged 16 and over performed at the lowest levels in prose and document literacy and at least four out of ten adults performed below level three in numeracy. These individuals are likely to have difficulties coping with increasing literacy- and numeracy-related demands common in everyday life.⁵⁰

2.1. Decision-making in Today's World

In general terms, a decision is the selection of an action among alternatives. Alternatives must be available and in most markets, contemporary consumers are usually offered a wide range of product choices.⁵¹

Decision-making involves evaluating information and making a choice among several possible alternatives which have different costs, benefits, and consequences. Decisions might involve uncertainty or risk.⁵² Unfortunately, in facing uncertainty, people might not consider each of the relevant branches of a decision tree.⁵³ Decision-making situations may also require a degree of knowledge or computational skill that is beyond what humans can do. Further, when making decisions, a person can stray beyond factual information into uncertain territory.⁵²

Expected utility theory states that when faced with uncertainty in choice, people make decisions based on two factors – the expected utility (i.e. the attractiveness of consequences) and the respective probability of the outcomes.⁵² Utility refers to the outcome a person would like to achieve, such as health, wealth or happiness. In other words, utility refers to the perceived value derived from a decision. So basically, people weigh the good that might come out of each alternative against the costs of that alternative. Decision-makers also assess the probability of alternative outcomes to inform their decisions.

Choices should not vary with how options are presented. However, *preference reversals* indicate they do.⁵² Preference reversal means switching preferences for one outcome over another based only on how these outcomes are presented. The expected utility model does not fully explain how people make choices in many circumstances because it assumes too much; humans rarely, if ever, have all of the information necessary to make a decision. Even if they did, they may lack the ability to combine and comprehensively weigh the information logically. Expected utility proposes that people base their decisions on expected consequences, but there is no real way to foresee consequences with certainty.⁵²

Prospect theory, as developed by Kahneman and Tversky, is concerned with behaviour of decision-makers who face a choice between two alternatives.^{52,54} Decisions between alternative actions are associated with probabilities (prospects) or gambles. Prospect theory assumes that people

make decisions based on what they have right now and how they interpret gains and losses on different scales, with losses being more psychologically powerful than gains.⁵²⁻⁵⁵ This theory predicts the *framing effect*, whereby people are risk-averse when faced with certain gains and risk-prone when faced with certain losses.⁵² The researchers found that people underweigh outcomes that are merely probable (in comparison with outcomes that are obtained with certainty) and also that people generally discard components that are shared by all prospects under consideration.⁵⁴ In addition, some studies noted people lend too much weight to small probabilities and too little weight to larger probabilities.^{22,56}

The research on framing indicates that people make different choices depending on how the alternatives are framed. According to the *psychological accounting principle*, people make different decisions depending on how each outcome is perceived.⁵² Consider the following scenarios:

1. Imagine that you have decided to see a play where admission is \$10 a ticket. As you enter the theatre, you discover that you have lost a \$10 bill. Would you still pay \$10 for a ticket to the play?
2. Imagine that you have decided to see a play where admission is \$10 a ticket. As you enter the theatre, you discover that you have lost the ticket. The seat was not marked, and the ticket cannot be recovered. Would you pay \$10 for a ticket to the play?

In these scenarios, what is being manipulated is not the cost or benefit, but the way that participants are likely to think about the extra \$10 that needs to be spent. Results showed that participants were less willing to purchase a ticket in

scenario 2. Why should this be? In this scenario, \$10 has already been invested for the play, so spending another \$10 seems an unattractive alternative. In scenario 1, people think they simply lost \$10, money that could have been spent for anything. So it seems that participants were less averse to losing money from their general “psychological account” than they were from their “play account”, which already had been tapped for the \$10 play ticket. In both scenarios, we are out \$20, and we get to see a play, so there should be no difference in our willingness to spend 10 more dollars.⁵²

Another variation on the notion of psychological accounting relates to what has been termed the *sunk-cost effect*. The sunk-cost effect is the tendency to continue investing, even in the face of loss. The sunk-cost effect states that people attribute too much weight to the resources already invested in a particular course of action as a decision criterion.⁵²

Another study of the framing effect in decision-making found that a preferred option and a less preferred option may differ in magnitudes. Such discrepancies are called *valence effects*. Yamagishi and Miyamoto observed *systematic positive valence effects* (“better” exceeding “worse”) in the domain of gains and *systematic negative valence effects* (“worse” exceeding “better”) in the domain of losses.⁵⁷ Preferences under the framing effect switch from certain options in the domain of gains to uncertain options in the domain of losses.

How do people make decisions in risky choice situations? When people have access to information sources such as newspaper weather forecasts, drug-package inserts, and mutual-fund brochures, all of which provide

convenient descriptions of risky prospects, they are making decisions from *description*. When people must decide whether to back up their computer's hard drive, cross a busy street, or go out on a date, however, they typically do not have any summary descriptions of the possible outcomes or their likelihoods. For such decisions, people rely on *experience*. Decisions from *experience* and decisions from *description* can lead to dramatically different choices.⁵⁸

Description-based decisions tend to overweigh the probability of rare events, as described by prospect theory. Hertwig et al. found that experience-based decisions tend to underweigh the probability of rare events.⁵⁸ They proposed two different theories of risky choice: 1) in decisions from *experience*, rare events had *less* impact than they deserved; 2) in decisions from *description*, rare events had *more* impact than they deserved.⁵⁸ But how does direct experience lead to underweighing? Decisions from experience depend on the sampled information, so any account of how such decisions are made ought to consider how people search for information and how the results of the search affect subsequent decisions.

2.2. Decision-making Involving Drug Therapy

Times have changed regarding the nature of decisions involving use of a drug. Patients of previous generations merely needed to decide whether to seek medical attention; it was generally not their place to question the advice given. Physicians tended to fill a paternalistic role, maintaining exclusive purview over medical knowledge. The expectation of both providers and

consumers of health care was that the physician knew what was best. Today, roles and expectations for information have shifted, giving way to the newer model of informed choice and active patient participation in health care.⁵⁹ However, while improvements have been made, imbalances in relationship power most likely still exist.

Patients must be adequately informed about treatment alternatives and outcomes before they can participate in the decision-making process. Given that the manner of presentation of such outcomes can influence such decisions, greater use of written and electronic tools might serve to clarify choices for patients. However, decision aids alone are not likely to replace the human element in facilitating informed choice. In theory, it might be better to couple descriptive or quantitative information with high-quality decision counselling (e.g. use of pictographs) to help patients understand the potential risks, benefits, and uncertainties of clinical options that best accommodate their personal preferences.⁵⁹ When treatment effects are described to patients, a balanced presentation of the information should enable patients to make informed decisions.⁶⁰

2.3. Challenges to Informed Patient Decision-making

In general, there are three main goals of treating a patient: 1) to make the patient feel better; 2) to reduce the risk of future disease complications; and 3) to improve survival. There are those who include a fourth goal – economic benefit – both to the patient and to society, but Furberg notes that economic

benefit represents a natural consequence of reaching one or more of the three main goals.⁶¹

Providing the data needed to make informed medical decisions is a challenging task.^{28,62} People deciding whether to use a medication need reliable evidence on the benefits and harms. Unfortunately, reliable evidence of harm is often lacking, in part because reporting of harmful effects is incomplete.⁶³ Emotional and psychological barriers are also involved in the reporting of harm. There are many issues that may need to be clarified before a health care provider can confidently counsel a patient, but the main three are: 1) the goals of treatment; 2) the intended benefit of a treatment; and 3) the potential harms of a treatment. Regarding that potential harm, clinicians should address the issue at an appropriate depth and breadth of patient understanding to support informed choice about potential side effects of drug treatment, thereby covering: 1) the nature of an adverse effect of the medication; 2) the seriousness of the adverse effect; 3) the likelihood and uncertainty of experiencing the adverse effect; and 4) whether there are therapeutic options to reduce the potential for adverse effects.

A common complaint of patients is that a prescribed medication makes him/her feel worse. The problem can range from something simple such as dryness of the mouth to serious adverse events that may require the treatment to be stopped. Even simple adverse effects can be very distressing to the patient, thereby reducing adherence. Adverse effects with a gradual onset are

the most difficult to detect because the patient may not attribute them immediately to the treatment.

Occasionally, drugs may have serious adverse effects such as allergic reactions, hepatitis, cardiac arrhythmias or gastric ulcer. Despite this, attributing an adverse event to a specific treatment can sometimes be difficult, particularly when the event is rare, unexpected, or appears a long time after the start of treatment. It can also be difficult to recognize an adverse effect when it occurs as part of the natural history of the underlying condition.

Direct-to-consumer advertising of drug products often neglects to mention all known side effects and provide incomplete risk information to consumers. Davis provided an example which emphasizes the issue: ⁶⁴

Imagine two drugs that work identically and that have the same set of side effects. One drug is advertised with an incomplete risk statement and the second is advertised with a complete risk statement. Harm (through loss of sales) is done to the second drug's advertiser if consumers prefer the first drug over the second because of the difference in the number and types of side effects reported in each drug's risk statement. Psychological and physical harm also can be done to consumers should they request the first advertised drug over the second, thinking that they can avoid some of the side effects associated with the second drug, but then experience some of side effects not noted in the first drug's incomplete risk statement.

The researcher explored the relationship between the completeness of the risk statement describing drug-associated side effects (the risk statement) and consumers' perceptions of a drug's safety and appeal.⁶⁴ The study design manipulated risk statement completeness with regard to the incidence of side effects mentioned and the presence or absence of a numeric indicator of side

effect incidence. Results strongly suggested a direct relationship between risk statement completeness and consumer perceptions of drug safety and appeal. Consumers rated the safety and appeal of drugs described with an incomplete risk statement significantly more positively than comparable drugs described with a more complete risk statement.

The Food and Drug Administration (FDA) called for comments regarding advertising of prescription drug products directly to consumers. Smith stated that, more than ever, consumers want the facts, and in no place is that more apparent than in direct-to-consumer advertising. Meeting the FDA's fair balance mandate provides an accurate and fair assessment of the risks as well as the benefits, but what is missing is the concept of trust.⁶⁵ Another response by the staff of the Bureau of Consumer Protection also noted.⁶⁶

The FDA should make clear that the fair balance requirement for direct-to-consumer ads prohibits only ads that convey a deceptive impression of the risk and benefits from the overall presentation of information, rather than those that fail to achieve a mechanistic balance between risks and benefit information because they do not present such information with identical emphasis.

Pharmaceutical companies now must move beyond simply meeting fair balance requirements and seek the trust of consumers reading their ads. Only then will consumers be willing to take the next step: deciding that the benefits of taking a medication outweigh the risks.

People and organisations may have competing interests, or come under pressure to take a lenient approach, for reporting harm. Little gratitude is to be expected by a health care provider or an institution reporting that the

interventions they offered were harmful.^{61,63} The federal government has suggested that physicians should be required to report drug-related side effects that occur in their patients. At the moment, reporting is voluntary for physicians, as it is for pharmacists.

Informational needs, decision-making styles, and ability to use data vary widely among patients. Everyone who has to explain risk should also understand the instinctive bias that the public typically brings to their judgments. Effective communication has to take into account the realities of how people reason.⁶⁷ Studies show that framing medical information has an effect on patients' decision-making on whether or not to follow treatment.^{68,69} There is always the possibility of misunderstanding, even when patients and doctors use identical words. Paling states that "it is pretty obvious that, if the patient doesn't have the health care provider's knowledge and context, all such descriptive words are likely to mean widely different things to different patients."⁶⁷ As an example, a group of researchers investigated how readers interpreted the level of likelihood intended by "a low risk". They found that some individuals interpreted it as meaning odds as high as one in five, while others said they would expect the term to be used for odds of one in 10,000; it depended on people's knowledge or expectations of the context.⁶⁷

When a decision involves a drug, a physician and/or pharmacist is (for the most part) charged with the task of communicating information to the user. Effective communication is associated with improved patient satisfaction, better adherence, improved health outcomes, more informed medical decisions,

reduced malpractice suits, and likely contributes to reduced costs of care.⁷⁰

Many patients want and need comprehensive and accurate information about their medicines and some want full disclosure of associated risks so they can participate in decisions about their care.^{14,71} Effectively communicating even the simplest and most unthreatening of messages to a diverse audience is in itself difficult, but the reality is that the problem of communicating complex medical information and risks to patients can't be avoided.⁷¹

2.4. The Art and Science of Patient Counselling

Pharmacists have a professional and ethical responsibility to assist and instruct patients on the appropriate use of medications. The processes of informing patients about medicines are defined as *patient counselling*. When a new prescription is presented in a pharmacy, a few rudimentary questions are initially asked, and then the prescription is filled. The pharmacist will call for the patient to return to the dispensary counter and the process of counselling begins. The name, indication, route of administration of the medication, storage instructions, and refill information will be stated. Patients should also be told about the side effects that may occur and what they can do to prevent or minimize them. Generally, a pharmacist will mention certain items verbally and support the process with a more comprehensive printed version of information (the so-called medication information leaflet or handout). Time of counselling will vary depending on whether the customer is a new patient or a returning

patient. When a medicine is a refill of a chronic medicine, less information is presented on the assumption that the person was previously counselled.

The counselling protocols suggested by Rantucci note that patient needs vary and pharmacists need to recognize these situations and understand the issues involved.²³ Certain points in the counselling may need to be emphasized, and the various materials, methods, and techniques used in counselling may need to be altered. Pharmacists have reported that many factors contribute to challenges in patient counselling. These factors include characteristics of the patient, the type of drug prescribed or condition being treated, and various aspects of the situation. In addition, there are factors involving the individual pharmacist that contribute to challenges.

Patient counselling is an integral part of the pharmaceutical care model.⁷² Pharmaceutical care is defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.⁷³ In order to provide pharmaceutical care, pharmacists must accept responsibility for their patients' drug-related problems and re-design their practices in a manner that facilitates this level of care.⁷⁴

Implementation of a pharmaceutical care plan, the decisions about drug use, and monitoring of therapeutic outcomes require consultation with the patient.²³ In the community pharmacy setting, the patient is the pharmacist's main source of information.⁷² The patient can contribute to the identification of problems and should play a role in the formulation of treatment goals and regimens. Researchers have established that communication between

pharmacists and patients is important for improving appropriate medication use and achieving desired outcomes.⁷⁵ Pharmacist counselling can improve patient adherence, therapeutic outcomes, and quality of life. Also, it can decrease adverse drug reactions, the number and cost of medications, emergency room visits, hospitalizations, length of stay in hospitals, and overall health care costs.⁷⁶

Counselling should consist of a two-way discussion between patient and pharmacist. But, pharmacists often view counselling as a one-way process in which they *tell* or *lecture* the patient about their medication. A two-way discussion may be more time-consuming, but has the potential to positively affect patient understanding and compliance.⁷² Two-way communication uses open-ended questioning and other methods to ensure the patient has input into the process; it means there is a balance of pharmacist and patient talk.

The pharmacist must often decide the extent of detail that is appropriate on the basis of several considerations. One consideration is that of the patient's rights to know about their drug treatments, alternative treatments, and possible risks of treatment. Another consideration is the pharmacist's perception of the patient's ability to understand the information based on the patient's educational background. The pharmacist should weigh these considerations for each individual patient and situation, but the needs of the patient identified during information gathering and care plan development phases of counselling should be the ultimate guide to the selection of information.²³

A study by Wolf et al. examined the common causes for the misunderstanding of prescription drug warning labels among adults with low literacy.⁷⁷ Patients were asked to interpret and comment on eight commonly used warning labels found on prescription medications. Patients with low literacy skills demonstrated a lower rate of correct interpretation than did those with higher literacy skills. Multiple-step instructions, reading difficulty of text, the use of icons, the use of color, and message clarity were the common causes of label misinterpretation.⁷⁷

Effective patient counselling is not simply the provision of information. Information is prerequisite to compliance, but the timing and organization of the message and involvement of the patient are also critical in determining what the patient understands and remembers. Pharmacists are experts on drug therapy, but patients contribute information about their daily routines, how they understand their illness and their treatments, and whether they anticipate any problems taking the medicine as prescribed. Each of these points needs to be assessed if counselling is to be effective.⁷⁸

Lack of communication between the patient and their care providers is a problem in medicine and pharmacy. Efforts have been made to improve communication, especially in community pharmacies.²⁸ Traditionally, patient information provided by community pharmacists has focused on technical aspects of the use of medicines and applicable reimbursement rules.⁷² Now, pharmacists are trying to move away from a drug-focused, paternalistic approach in patient information, to providing customized information according

to patient needs.^{23,72} It requires knowledge and skills beyond product knowledge about medicines.

Greater involvement of patients in decisions about their treatment is predicated on the patient having access to understandable information.¹¹ The quality of the pharmacist-patient relationship and the content and style of the communication may also be crucial to improving patient counseling.^{23,79}

During the provision of prescription drug information, individuals often do not control how much (or what) information the health care practitioner provides.⁸⁰ By extension, evidence of information overload exists in the health care literature. Labor et al. reported perhaps the obvious, that individuals who received too much written information about a medication were more likely to be confused and overwhelmed than those who received an amount that was right for them.⁴ Similarly, a study by Schommer et al. investigated individuals' processing of prescription drug information under different conditions of presentation.⁸⁰ Study materials were mailed to 624 volunteers living in the United States, of which 477 (76.4 percent) returned completed data forms. The results suggest there is a balance between the need for information at a level sufficient for individuals to make decisions and the need for information that will not overload individuals as they cognitively process it. Results indicate that study subjects who received written information reported lower levels of cognitive effort (less confusion). Understanding and remembering the information presented in the consultation may have been easier with written medication information, which they could refer to later. Study subject perception

of cognitive effort increased as both the breadth and depth of the information increased. A balance may be needed – greater depth likely requires less breadth, while more breadth of information may need less depth (information with simple wording).

Hahn et al. reported an inverted U-shaped relationship between information load and decision quality. Individuals with too little or too much information made poorer decisions compared to those with an amount of information that was of sufficient breadth and depth.⁸¹ Individuals can select the most important information from the total, but useless or less relevant information can dilute the effects of more important information on judgments.⁸⁰

2.5. Side Effects as a Component of the Counselling Process

In medicine, uncertainties are abundant.¹⁵ The benefit of using an agent and the side effects of treatment may be uncertain. In practice, clinicians frequently communicate information about uncertainty to the patients by verbal probability estimates,^{15,82} using descriptive words such as *rarely* or *uncommon*. A study of how family physicians value the use of numerical formats for talking with patients, and how confident they were with each mode of communication, showed that 189 of 300 agreed that communicating risk both qualitatively and numerically was equally important.⁸² Of the remaining 111 physicians, 94 percent endorsed the importance of communicating qualitatively more strongly than numerically. In terms of relative confidence, 104 of 300 (34.7 percent) felt equally confident in their qualitative and numerical communication skills. Of the

remaining 196, 97 percent were more confident in communicating qualitatively than numerically. However, Edwards et al. reported higher anxiety among patients receiving verbal description about risks than numerical descriptions.⁶⁹ Within this process, a health care professional may choose to use numerical probabilities expressed as either percentages or frequencies.

Communicating the risk of medication side effects to patients is often suboptimal. The side effect sections of patient information leaflets generally provide a list of all possible side effects with no indication of individual risk.^{11,17,83} Studies have shown medication guides in their current form are unlikely to be useful to patients,^{2,11,17,25-27,83,84} especially those with limited literacy skills.⁸⁴ Adverse effects listed without frequency or percentage data may make it harder to understand individual risk.^{11,26} Research suggests that such information is the highest priority for patients^{17,28,83,85-87} and that the perception of them is influential in many patients' decisions about taking a medicine.²⁷

2.5.1. Patient / Provider Perceptions of Demand for Side Effect Information

The public appears to want more information about drugs. A review by Raynor et al., with a focus on patient interest in reading prescription information leaflets (PILs), noted that 40 to 89 percent of consumers read written medication information (depending on the type of written information they received).² Airaksinen and colleagues surveyed the public and pharmacists in Finland on the aspects of drug information each felt was important to receive.²⁸ The opinions of these two groups differed remarkably on several items. For the

public, the highest perceived need was for information about adverse effects and interaction with other drugs, with 79 percent definitely wanting this information. In contrast, pharmacists thought the most important things that customers should be told about were dose instructions (78 percent) and storage information (74 percent). Information on side effects was given a lower priority by pharmacists, with only 13 percent saying it must be given.

In a study by Barnett et al., an intervention to foster patient participation in medication counselling was tested in community pharmacies.⁷² This intervention consisted of a written prompt, instructing patients who were waiting for new prescriptions to write prescription-related questions they wished to ask their pharmacist. The pharmacist then used the questions as an aid in counselling. The findings showed that 56 of 106 patients told to write a question for the pharmacist did so. All but two of these patients wrote three questions or less. The most common questions related to side effects (52 patients); whether the medicine should be taken with food (14); interactions with food or medicines (12); how to take the medicine (11); and how the medicine works (10).

Berry et al. presented participants with a brief hypothetical scenario about a visit to the doctor (which entailed being prescribed some medication) and were then asked to list the questions they would like to ask.⁸⁷ There was considerable consistency in responses, with the most frequently asked questions being about side effects, what the medication actually does, what lifestyle changes might be involved, and how to take the medication. Conversely, studies have shown that doctors hardly discuss adverse effects

with patients.¹ Smith and Henderson forwarded an interesting view of how physicians discuss adverse effects of antipsychotic medications.⁸⁸ They noted that doctors inform patients about the adverse effects of medication, but are highly selective with regard to which side effects they feel ready to discuss with patients. This might not correlate with what patients may wish to be told. This study concluded that discussing side effects with patients needs to be more comprehensive than current practice.

Physicians continually face the problem of how much detail concerning risk for adverse effects they should provide patients. Although patients have a moral right to full disclosure, patient surveys are contradictory regarding how much side effect information they want. Most people appear to want to know all potential adverse reactions, even if they are relatively rare.^{3,29-32,71} However, it has been suggested by health care workers that to explain to patients (for each medication prescribed) every possible adverse effect would clearly be a task of unacceptable time and questionable advisability.³ How then is the physician to choose what level and extent of information to give? A study by Ziegler et al. found that most individuals desire all information concerning possible adverse effects of prescribed medication and do not favour physician discretion in these decisions.³ Among 2500 adults who filled out a 12-item questionnaire, the feedback was: 76.2 percent wanted to be told of all possible adverse effects; 13.3 percent only if an adverse effect occurred one in 100,000 times; 10.2 percent only if such occurrence was one in 100 times; while 0.4 percent were not interested in any information. Elsewhere, Åström et al. found that providing

information about medicines to patients who desire it makes them more satisfied and empowered, whilst providing information to those who do not want it makes them more anxious and less empowered.³³

2.5.2. Presenting Side Effect Information to the Public

The question of whether to inform patients about possible side effects of prescribed medication has given rise to considerable debate in recent years. On one hand, several studies have shown that patients do want to be told about possible side effects. On the other hand, many doctors believe that informing patients about side effects might reduce adherence with the medication.¹⁶ Studies that have directly addressed this question have generally found that informing patients about side effects does not increase the incidence of their occurrence, nor does it have a negative effect on adherence.^{16,34} Some studies reported provision of detailed information about possible adverse consequences of treatment can improve patient understanding and satisfaction without unnecessary anxiety.^{5,32}

Howland et al. investigated whether patient education leads to drug side effects, a situation called *suggestion-induced side effects*.⁸⁹ Ninety-eight adults treated with erythromycin (for a variety of illnesses) were randomized into two groups: one group received patient education about side effects, while the other group was given no such information. Overall, 10 percent of the uninformed and eight percent of the informed group felt that the erythromycin bothered them in

some way. There were no significant differences in the occurrence of various individual side effects.

Most current mandatory medicine information lists side effects without frequency data.¹¹ In 1999, the European Union (EU) produced a guideline on the readability of leaflets, which indicated that the frequency of side effects could be denoted by the use of five verbal descriptors (*very common, common, uncommon, rare, very rare*) as an alternative to numerical incident rates (see Table 2.1). The intent was to help standardize language already in common use.

Table 2.1 European Union verbal descriptors of side effect probability and allocated frequencies

Descriptor	Probability
Very common	>10 %
Common	1-10 %
Uncommon	0.1-1 %
Rare	0.01-0.1 %
Very rare	<0.01 %

Several studies have examined how people interpret the set of verbal probability labels as proposed for use by the EU guideline. They found that both members of the general public and patients visiting a cardiac clinic consistently over-estimated the risk of side effects when presented with the recommended descriptors, and that this in turn affected their perception of risk to health and their likelihood of taking the medicine in question.^{11,14,17,26,35} Based on EU verbal descriptors, *very common* is set at more than 10 percent risk, but this was interpreted to mean 54 percent risk by readers. *Very rare* was set at less

than 0.01 percent and was understood by readers to equate to four percent risk (see Table 2.2).

Table 2.2 Comparison of EU verbal descriptors of side effect probability and allocated frequencies with level of risk understood by readers^{11,17,26,83}

EU terminology	Level of risk	Level of risk understood by reader
Very common	>10%	54-65%
Common	1-10%	34-45%
Uncommon	0.1-1%	11-18%
Rare	0.01-0.1%	8%
Very rare	<0.01%	4%

Some studies that evaluated the influence of verbal descriptors on people’s medicine-taking behaviours suggested use of numerical data when describing risk, in order to avoid confusion of estimated risk.^{11,14,17,26,35,83} Regarding this content, a study done in England looked at the 50 most prescribed medicines and found that 40 percent of medication leaflets had no information on the likelihood of adverse effects, 12 percent used EU terms, 40 percent used a wide range of other verbal descriptors and eight percent provided numerical indication of risk.⁸⁶

It has been established that people tend to attribute too much weight to lower probabilities and too little weight to higher probabilities.⁵⁶ This leads to misconceptions about the likelihood of uncommon events, which influences their behaviour in a wide array of domains. If people unreasonably over-estimate their risk for side effects, this may subsequently reduce adherence.^{22,83} Because pharmaceutical companies and pharmacists frequently present risk

information semantically, patients might perceive their risk to be much greater than clinical trial results would suggest.

The way risk information is communicated plays an important role in how people understand risk, accept or deny risk, and deal with risk information. Typically, side effect information is disclosed using ambiguous semantic descriptions, such as “some people may experience ...”, “side effects may include ...”, and “commonly reported side effects are ...”.^{11,12,22,36} These semantic descriptors do not express the exact percentage of risk and are subject to personal interpretation. Disclosing the actual percentages associated with side effects may improve the accuracy of people’s risk estimates. However, there has been little evidence-based guidance on how best to communicate that information.^{12,36}

Young and Oppenheimer proposed that informing a person of actual percentage risk of side effects might reduce fear and increase intentions for adherence.²² The aim of their studies were to investigate whether commonly used methods of conveying side effect risk might influence peoples’ perception of their risk, then whether disclosing this information as actual percentages might subsequently influence their intentions to comply with the medication.²² Results showed respondents expressed a stronger intention to comply with their prescribed treatment regimen when they received percentage information compared to those who received the semantic framing. Those in the group receiving percentages also expressed less fear of experiencing drug-related side effects than those in the semantic group.

In a review, Edwards et al. found that terms such as *probable*, *unlikely*, and *rare* convey elastic concepts.³⁶ In other words, one person's understanding of *likely* may be a chance of one in 10, whereas another may think that it means a chance of one in two. Individuals may interpret those terms differently in different contexts -- for example, a *rare* outcome is a different prospect in the context of genetic or antenatal tests than in the context of antibiotic treatment for tonsillitis.

Interpretation of numerical information can also be problematic. Yamagishi found that a death rate of 1286 out of 10000 was rated as more risky than a rate of 24.14 out of 100.⁵⁶ This study showed that perceived riskiness would increase when risks were presented as relative frequencies using larger numbers.

The psychological literature on decision-making also suggests that the interpretation of information varies depending on the presentation format or the *frame* used. For example, if a person is told of a 30 percent chance of survival (positive frame), it is obviously equivalent to a 70 percent chance of mortality (negative frame).⁶⁰ Positive framing (chance of survival) is more effective than negative framing (chance of death) in persuading people to take risky options.^{36,68} A comprehensive review has also indicated that among patients, messages framed in terms of losses may be more effective in promoting the uptake of screening than those framed in terms of gains.⁶⁹

Schwartz et al. conducted a medical data interpretation test and found 25 percent of participants who received information framed around death (nine in

1000 people die from this surgery), rated “nine in 1000 chance of death” as riskier than “991 in 1000 chance of surviving”. On the other hand, 61 percent rated both as having the same risk, while 14 percent rated the chance of the surviving frame (991 in 1000 people survive this surgery) as riskier than the chance of death.²⁰

Another study by Gurm and Litaker found that patients were more likely to opt for angioplasty treatment when told that it was 99 percent safe, compared with a one percent likelihood of a serious complication.⁶⁸ Positive framing, therefore, affects people’s treatment preferences and it has been shown to improve their understanding of the information presented.

There is indirect evidence that probability concepts are intrinsically difficult for humans.^{20,21,90-94} Hoffrage et al. offer persuasive evidence that when prevalence, sensitivity, and false positive rates were given as probabilities (e.g. 10 percent), even physicians misinterpreted the information in a way that could be potentially disastrous for the patient. But when they were presented as natural frequencies (e.g. 10 cases in 100), physician performance was dramatically better.⁹² Accordingly, studies suggest that one way to improve both communication of statistical information and medical education is to use natural frequencies rather than probabilities.^{21,90-96} Presenting information in a frequency format also has broader implications, for its application can be employed in a wide spectrum of medical decision-making.

Berry et al. found that people’s perception of risk and their stated likelihood of taking a particular medicine are substantially affected by the

adverse effect information they are given.²⁶ In one report, results showed that when negative information was given about possible side effects, people gave lower ratings, both in terms of how good they believed the explanation to be, and their perceived likelihood of taking the medication.³²

Knapp et al. found that verbal descriptors were associated with more negative perceptions of the medicine than their equivalent numerical descriptors.¹¹ Bergenstrom and Sherr found verbal expressions of probability to be vague and subject to individual interpretation.¹⁵ Therefore, in applied practice, it is important to codify the meaning of verbal probability expressions, especially as it relates to risk and health decision-making.¹⁵

2.5.3. The Importance of Inclusion of Benefit Information to the Counselling Process

A study by Bersellini and Berry examined the effectiveness of simple benefit statements on people's judgments about a medicine.⁹⁵ They found that when participants received information about benefits of medications (without side effects), it did not influence their intention to comply. The reason was that people assumed prescribed medicines had side effects, even when there was no reference to these in the scenario. In another experiment, they examined two kinds of benefit information, but included side effects for the medicine. Patients were told the medicine was associated with four side effects and found that both forms improved patient intention to comply.⁹⁵ The study provided support for the inclusion of benefit information in medicine information leaflets, particularly to balance concerns about adverse effects.

Dyck et al. studied pharmacist communication skills when counselling on medication side effects.⁷ They videotaped the patient counselling approaches of 10 pharmacists to examine how they equipped patients with knowledge about medication management and side effects. The results indicated that the pharmacists used vague terms such as *sometimes*, *might*, and *may* to describe side effects, as opposed to citing the frequency of possible occurrence from clinical studies. The pharmacists also spent less time discussing the overall benefits of the medications and focused more on medication safety issues. Further, the authors noted that a majority of the pharmacist-patient encounters did not facilitate effective two-way communication. The researchers concluded that patient satisfaction and treatment compliance may be challenged as a result of inadequate pharmacist-patient communication. The inclusion of benefit information to information leaflets has been suggested by some other studies too, as a way to balance concerns about adverse drug reactions.^{12,69,96,97}

2.6. Summary

How to convey risk information to patients is a developing science. More information is needed on how best to inform potential medicine users about side effects. This is especially true for OTC medicines. Research was therefore undertaken to address how providing risk of medication side effects in numerical format would affect patient medicine-taking behaviour. The format for presenting the numerical data was also examined (positively- versus negatively-slanted wording).

CHAPTER 3 METHOD

This study was designed to obtain data on public perceptions of various methods for conveying risk information about OTC medicines and the subsequent influence these perceptions have on the tendency to use medicine. It had three components:

- 1) Demographic and attitudinal information
- 2) Presentation of scenarios
- 3) Participant interviews

3.1. Participants

Participants were residents of Saskatoon who were 50 years of age or older. Older citizens were chosen because they are more likely to take medicines than their younger counterparts. Participants had to have English as their first language and have reached a pre-determined score on the Rapid Estimate of Adult Literacy in Medicine⁹⁸ (REALM) test (discussed below).

Subjects were recruited using posters (see Appendix A) placed in 30 randomly chosen pharmacies and recruitment brochures placed in prescription bags (subsequent to interest shown by a patient). Pharmacists were allowed to use professional discretion in determining which patients might be appropriate for this study. The researchers of this study had no contact whatsoever with a

pharmacy's clientele to this point. The letter requesting pharmacist help for recruiting is available in appendix B.

Patients who were interested in participating were asked to call the researchers to gain entry into the study. If requested, additional information was sent to potential participants or clarifications were made over the phone. Recruitment was complete when 30 patients meeting the entrance requirements had volunteered. Power considerations did not drive the sample size calculations for this study, since effect size and standard deviation values were not available at the time. Rather, past research involving patient interviews of a like-minded report guided the decision to enlist 30 subjects.³⁸ Issues such as time and budget limitations were also factors.

Before initiation of the study, participants were provided with information on study procedures and what was expected of them. Participants were divided into two groups. Odd-numbered participants (based on their order of contact with the researcher) were assigned to a *mild headache* scenario, while even-numbered participants were assigned to a *severe headache* scenario (discussed below).

Appointment times were made over the phone to accommodate the preferences and schedule of participants. It may have been difficult for older adults not familiar with the University of Saskatchewan campus to find parking, then find their way to the Thorvaldson building where the study was to be held. To counter this, participants were provided with an option of being paid for their parking meter or their bus pass to partake in the study. The researcher also

walked them from University Hospital parking to the building where the study took place and then walked them back to their cars. In some cases, the researcher met people at an off-campus site that was more convenient for them.

Participants who had REALM scores of less than 19 would have been excluded from the study because they would not be able to read the medicine-based information of the study materials. However, no participants scored less than 19.

3.2. Procedures

Those agreeing to participate were asked to come to the study site for a period of approximately one hour. An honorarium of \$30 was provided for their time plus \$3 for parking or bus pass.

Appointment times were scheduled over the course of two months. At the time of arrival and before the study commenced, participants were provided with a form (Appendix C), inviting them to provide written consent to participate in data collection and interviewing for the study. Written permission was also obtained from participants for the tape-recording of interviews (Appendix D). After consent forms had been obtained, a brief orientation to the project was undertaken. Then, subjects were given the study materials to complete. A researcher was present to answer questions, but caution was used in order to prevent over-guidance during this step.

In the first phase, participants answered questions on age, gender, education level, experience with medication side effects, and some questions regarding expectations of pharmacists and medication leaflets (see Appendix E). Questions regarding side effects and expectations from pharmacists were created by the researchers, except for question 14 in Form 1 which has been taken from another study (Ziegler et al.³). It should be noted that for this study, we replaced *physicians* with *pharmacists* in the statement (*Physicians should give as much information concerning side effects as he or she thinks best for the individual patient*).

Next, to ascertain existing attitudes towards medicines, the *Beliefs about Medicines Questionnaire*⁴³ (BMQ) was administered (see Appendix F). The BMQ is a questionnaire for assessing patients' perceptions of medicines from a health psychology perspective. Two major themes can emerge for beliefs about medicines in general: *general-harm* and *general-overuse*. The first comprises beliefs about the intrinsic nature of medicines and the degree to which they are perceived as fundamentally harmful. The second comprises beliefs about the way in which medicines are used, particularly the extent to which they are perceived to be over-prescribed by doctors. Participants were asked to indicate to what extent they agree or disagree (5=*strongly agree*, 4=*agree*, 3=*uncertain*, 2=*disagree*, and 1=*strongly disagree*) with statements about medicines in general:

- Doctors use too many medicines (*General-Overuse*)

- People who take medicines should stop their treatment for a while every now and again (*General-Harm*)
- Most medicines are addictive (*General-Harm*)
- Natural remedies are safer than medicines (*General-Overuse*)
- Medicines do more harm than good (*General-Harm*)
- All medicines are poisons (*General-Harm*)
- Doctors place too much trust on medicines (*General-Overuse*)
- If doctors had more time with patients they would prescribe fewer medicines (*General-Overuse*)

Scores could range from four to 20. Higher scores (20) on the BMQ-general would mean a strong belief that medicines are either *overused by doctors* (i.e. BMQ-overuse) or *harmful and addictive* (BMQ-harm).

To gauge existing health status, a short form health survey (*SF-8*) was used⁹⁹ (see Appendix G). Scores could range from eight to 42, where eight would mean no physical or mental health concerns and 42 would mean physical and emotional problems exist.

The REALM test was used to determine the health literacy of subjects⁹⁸ (see Appendix H).

Finally, a measure of numeracy was given using two sets of questions (condensed version) from Schwartz et al.²⁰ and Woloshin.⁶² Of a total of six questions, four questions were numerical probability problems, while two questions examined reasoning ability regarding risk probability communication (see Appendix I). The four questions pertaining to probability and frequency were posed as follows:

- 1) *Imagine that we flip a coin 1000 times. What is your best guess about how many times the coin would come up heads in 1000 flips? [500 times out of 1000 is the correct answer]*
- 2) *In the Big Bucks Lottery, the chance of winning a \$10 prize is 1%. What is your best guess about how many people would win a \$10 prize if 1000 people each buy a single ticket to Big Bucks? [10 persons out of 1000 is the correct answer]*
- 3) *In the ACME Publishing Sweepstakes, the chance of winning a car is 1 in 1000. What percent of tickets to ACME Publishing Sweepstakes win a car? [0.1 percent is the correct answer]*
- 4) *Mrs. Smith is told she has a 1 in 296 chance of dying from cancer and a 1 in 407 chance of dying from a stroke. Which is bigger, Mrs. Smith's chance of dying from a stroke or cancer? [cancer is the correct answer]*

Participant responses to these questions were assessed based on the number of correct answers.

Participant responses to positive and negative numerical presentation of a risk associated with surgery were explored in two kinds of framing: *9 in 1000 people die from this surgery versus 991 in 1000 will survive*. Participants were asked to show how risky they felt this surgery was by choosing one of four options presented (*very risky, risky, slightly risky, and not risky*). The responses were assessed to see if participants chose the same level of riskiness for both surgeries (the correct interpretation). The time required to complete phase one was approximately 15-20 minutes.

In the second phase, TWO studies were carried out back-to-back. In Study 1 (see Appendix J), a design was chosen to allow comparisons of patient choices based on:

- A. Variation in drug efficacy and side effect potential for hypothetical situations where a participant could choose one of three fictitious drugs (arbitrarily called Drugs X, Y, and Z) for symptomatic relief of a headache
- B. Variation in the severity (mild or severe) of the symptom in question (headache)
- C. Variation in the extent that information was presented (\pm probability data) with respect to side effect frequency rates

In Study 2 (see Appendix K), a design was chosen to allow comparisons of patient preference based on the use of positively- or negatively-slanted phrasing in the presentation of side effect frequency. This was done using two fictitious drugs (Drug N and P), with each associated with one side effect (heartburn). The difference between Drug P and N, therefore, was the format of numerical presentation in describing the frequencies with which heartburn would present. Drug P was presented in a positively-slanted format, while Drug N was in a negatively-slanted format. The time required to complete phase two was approximately 15-20 minutes.

During the third phase, individual interviews were carried out to garner more in-depth understanding of the decisions made during Studies 1 and 2 of phase two. Appendix L shows the steps for how the interviews were conducted. The time required to complete each interview of phase three was approximately 15-20 minutes.

3.3. Category of Medicines for Consideration

Of the vast array of medicines that could be considered, only those available OTC were chosen. One that is used for a common ailment (headache) was considered so that participants would have reasonable potential for familiarity with the symptom under consideration. Support for this was a global health survey conducted by The Nielsen Company which found headaches to be one of the most common minor ailments.¹⁰⁰ Nearly half of those polled had claimed to have suffered a headache in the last four weeks. When it comes to the treatment of this common ailment, consumers often purchase OTC products.

An actual brand name or recognizable generic name was not used. Rather, the terms *Drug X*, *Drug Y*, and *Drug Z* were the options presented to participants. It was thought this might prevent direct association to agents they may have used in real life. Precedence for this approach exists in other research. A number of studies used fictitious names such as *Epidoxin* or *Flavocin* (antibiotic) for participants responding to a scenario involving a sore throat or ear infection.^{25,27,95,101-103} Schwartz et al. assessed patient medical data interpretation skills using an imaginary drug called *Gritagrel*.²⁰ Young and Oppenheimer used *Drug X* as a hypothetical drug name for their study.²²

3.4. Side Effects Chosen for this Study

For the execution of Study 1, common side effects (and the corresponding frequencies) were chosen from product monographs of Advil[®],

Motrin[®], Tylenol[®], and Aspirin[®] (Lexi-Comp online and e-CPS circa 2007). By design, severe and very rare effects were not utilized. Table 3.1 shows some OTC and Rx medications for relief of headache and their possible side effects.¹⁰⁴ The side effects utilized in this study for Drug X, Y, and Z were therefore similar and relevant to real medication for relief of headache. Further justification for the selected side effects was provided by Young and Oppenheimer.²² They found, based on 20 randomly chosen advertisements, that the most commonly occurring side effects were diarrhoea (reported in 18 of 20 advertisements), headache (17 of 20), and nausea (17 of 20). For 11 selected advertisements, the most frequently occurring side effects were dizziness (10 of 11), diarrhoea (11 of 11), and nausea (11 of 11).

Table 3.1 Headache medicines and their possible side effects¹⁰⁴

Generic Name	Brand Name	Use	Possible Side Effects
Acetaminophen (OTC)	Tylenol	Pain relief	Few side effects if taken as directed, although they may include: changes in blood counts and liver damage
Aspirin (OTC)	Bayer, Bufferin, Ecotrin	Pain relief	Heartburn, Gastrointestinal bleeding, Bronchospasm or constriction that causes narrowing of the airways, Anaphylaxis (life-threatening allergic reaction), Ulcers
Fenoprofen (Rx)	Nalfon	Prevention of tension headaches; migraines; hormone headaches	Nausea, Diarrhoea, Indigestion, Dizziness, Drowsiness
Flurbiprofen (Rx)	Ansaid	Prevention of tension headaches; migraines Treatment of tension headache; migraines	Gastrointestinal upset, Drowsiness, Dizziness, Vision problems, Ulcers
Ibuprofen (OTC)	Advil, Motrin IB, Nuprin	Treatment of tension headache; migraines	Gastrointestinal upset, Gastrointestinal bleeding, Nausea, Vomiting, Rash, Liver damage
Ketoprofen (Rx)	Actron, Orudis KT	Prevention of tension headaches; migraines Treatment of migraines	Gastrointestinal upset, Gastrointestinal bleeding, Nausea, Vomiting, Rash, Liver damage
Nabumetone (Rx)	Relafen	Prevention of tension headaches; migraines	Constipation, Heartburn, Diarrhoea, Nausea, Vomiting
Naproxen (Rx)	Aleve	Prevention of tension headaches; hormone headaches Treatment of migraines	Gastrointestinal upset, Gastrointestinal bleeding, Nausea, Vomiting, Rash, Liver damage
Diclofenac (Rx)	Cataflam	Treatment of tension headache; migraines	Stomach upset, Bloating, Dizziness, Drowsiness, Loss of appetite
Ketorolac (Rx)	Toradol	Treatment of tension headache	Gastrointestinal upset, Drowsiness, Dizziness Vision problems, Ulcers
Meclofenate (Rx)	Meclomen	Treatment of tension headache	Nausea, Diarrhoea, Indigestion, Dizziness, Drowsiness
Carisoprodol (Rx)	Soma	Treatment of tension headache	Dizziness, Drowsiness, Nausea, Headache, Nervousness, Skin rash, Bleeding
Orphenadrine citrate (Rx)	Norflex	Treatment of tension headache	Drowsiness, Dizziness, Headache, Nervousness, Blurred vision
Cyclobenzaprine HCL (Rx)	Flexeril	Treatment of tension headache	Dry mouth, Drowsiness, Dizziness
Metaxalone (Rx)	Skelaxin	Treatment of tension headache	Drowsiness, Dizziness, Headache, Nervousness

3.5. Design

3.5.1. Study 1: Provision of Frequency Data for Side Effects

The sample of 30 participants in the study was divided into two arms. HALF of participants were given the FIRST hypothetical scenario, where the headache was described as *mild but common*:

*Whether true or not, consider for a moment that you get headaches. They tend to be **mild** and occur **6 times a year**. You need a pain killer for these headaches in order to focus better on your daily activities. You have the choice of the following 3 headache medicines for relief.*

The other HALF were given the SECOND hypothetical scenario, where the headache was *severe but rare*:

*Whether true or not, please consider for a moment that you get headaches. They tend to be **severe** and occur **twice a year**. You need a pain killer in order to get out of bed. You have a choice of the following 3 headache medicines for relief.*

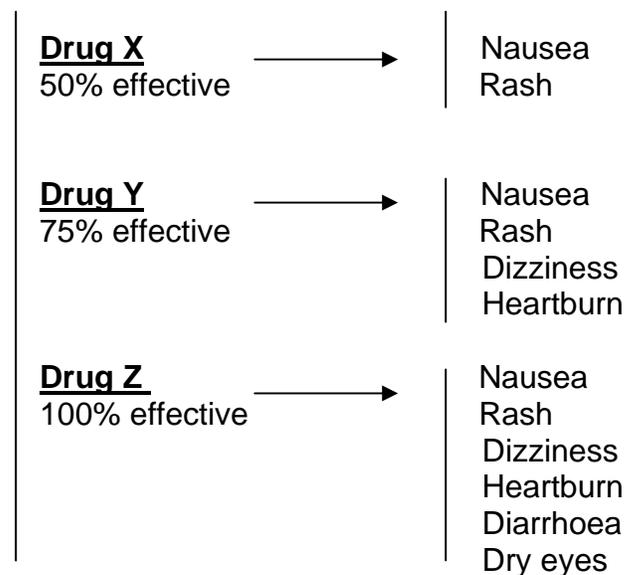
The only methodological difference between these two groupings of participants was the scenarios.

All participants, regardless of their scenarios, then received two variations in side effect presentation for the three drugs (Drug X, Y, and Z):

- 1) Side effects **without** frequency data included
- 2) Side effects **with** frequency data included

Participants were first asked to consider three medicines (Drug X, Y, Z) with no frequency data (*without*) included for the side effects. The three agents under

consideration were characterized from lower efficacy (with few potential side effects) up to high efficacy (but more potential side effects). While all three were “effective”, one was 50 percent effective and had *two* side effects, the second one was 75 percent effective and had *four* side effects, while the third was 100 percent effective and had *six* side effects. A graphical illustration of this is as follows:



Subjects were then asked consecutively: “How likely is it that you would take Drug X?”, “How likely is it that you would take Drug Y?”, and “How likely is it that you would take Drug Z?” Their answers were recorded on a Visual Analogue Scale of 100 points (from *very unlikely* to *very likely*) [see Form 6 in Appendix J]. Subjects were also asked to outright choose one of these drugs as the preferred agent.

Next, these same participants received the same list of side effects with frequency data, but added at this juncture were the *percentages* (and

frequencies) for how often side effects might occur. Subjects were still given the choice of using Drug X, Y, and Z for their headache. As before, subjects again were asked: “How likely is it that you would take Drug X?”, “How likely is it that you would take Drug Y?”, and “How likely is it that you would take Drug Z?” Their answers were again recorded on a Visual Analogue Scale of 100 points (from *very unlikely* to *very likely*) [see Form 7 in Appendix J]. As before, subjects were again asked to choose outright one of these drugs as the preferred agent after seeing the percentages and frequencies of side effects. An illustration of the inclusion of frequency data for this process is as follows:

<p><u>Drug X</u> 50% effective</p>	→	<p>Nausea 3% (3 in 100) Rash 4% (4 in 100)</p>
<p><u>Drug Y</u> 75% effective</p>	→	<p>Nausea 3% (3 in 100) Rash 4% (4 in 100) Dizziness 7% (7 in 100) Heartburn 5% (5 in 100)</p>
<p><u>Drug Z</u> 100% effective</p>	→	<p>Nausea 3% (3 in 100) Rash 4% (4 in 100) Dizziness 7% (7 in 100) Heartburn 5% (5 in 100) Diarrhoea 2% (2 in 100) Dry eyes <1% (less than 1 in 100)</p>

This design would allow a comparison in mean likelihood of taking drugs *without* percentages versus *with* percentages for side effects, given that responders would be exposed to both styles.

Participants were asked to choose one of the agents for their headache. Options were *Drug X*, *Drug Y*, *Drug Z* or *none*. In essence, the choice would involve balancing between level of efficacy desired in relation to its associated side effects. By design, all participants responded to the preference question twice, once *without* frequency data and again *with* side effect frequency data [see question 4 in *Form 6* and question 8 in *Form 7* of Appendix J]. This was undertaken to determine if their decision to use a medicine would be affected by frequency of side effect occurrence. The outcome could be either a participant staying with his/her first choice or changing his/her decision.

All participants were asked which style of presentation for side effects they would prefer – side effects with no frequency data OR side effects with frequency data.

3.5.2. Study 2: Negatively- or Positively-Slanted Presentation of Side Effects

The goal of this component was to determine if negatively- or positively-slanted information has any effect on medicine-taking behaviour and which approach people prefer (see Appendix J). For this section, subjects were given a brief explanation of OTC medicines for headache, ones which have the potential to cause a mild side effect (heartburn) when used (see Appendix K). Many of the remedies that are used to treat headaches can cause heartburn symptoms.¹⁰⁵

Hypothetical names of drugs were again used so that participants would not bring their own experiences with any previously used drugs to this study.

For this, Drug *P* stood for positively-slanted wording and Drug *N* stood for negatively-slanted wording. Two ways of expressing the *same* frequency of the side effect were presented in both forms:

- 1) 10 out of 100 people WILL experience heartburn when taking Drug N
- 2) 90 out of 100 people will NOT experience heartburn when taking Drug P

Subjects were asked how likely it would be that they would take Drug N and Drug P, recorded on a Visual Analogue Scale of 100 points (*very unlikely* to *very likely*). Then they responded to preferences for the approaches and either drug. The sequence of the phrasing was changed for half of the sample, that is, group 1 received the negatively-slanted presentation first, followed by the positively-slanted phrase, whereas group 2 received the terms in the opposite order. This change was to control for presentation order as an influence on the decision-making process.

3.6. Interviews

Individual interviews were carried out to get more in-depth understanding of the decisions made during Studies 1 and 2. See Appendix L for a guide of the interview format.

3.7. Ethics

Approval from the University of Saskatchewan Advisory Committee on Ethics in Behavioural Research was obtained on August 28, 2007. In order to protect responder confidentiality, surveys and demographics were identified only by a participant number and only aggregate data were reported.

3.8. Data Analysis

Data was analyzed using Chi-Square (gender, numeracy test result, levels of education, previous experience with side effects, choice of drugs) for comparing the equality of distributions between groups. The Independent *t*-test compared means for the two groups on age, SF-8 health scores, and BMQ harm and overuse. Doubly Multivariate Repeated Measures Designs assessed the effect of providing percentages for side effects (*without* percentages vs *with* percentages), the effect of illness severity (*mild* vs *severe* headache), and the interaction of these two factors. Multivariate design means participants are measured on two or more correlated dependent variables (DVs) (or within a regression context, two or more predictors). Doubly Multivariate (Repeated Measures) Analysis of Variance Design is a design with multiple variables measured at multiple times. Doubly Multivariate means that the usual DVs serve as one set of multiple variables, while repeated measures serve as a second set of multiple variables. In the current study, 30 participants were randomly assigned to either the mild headache scenario or the severe headache scenario, and were measured on three measures of likelihood of

taking drugs (Drug X, Y and Z) at two points (*without* percentages and *with* percentages for the various side effects).

A Paired sample *t*-test was used to compare the mean likelihood of taking Drug P and N. Two-way Repeated Measures Analysis of Variance (ANOVA) (factorial design) determined the effect of previous experience with side effects and gender on the mean likelihood of taking Drug P and Drug N.

SPSS (version 15) was used to analyse the data with significance set at 0.05.

CHAPTER 4 RESULTS

As a preliminary step toward participant recruitment in September 2007, letters were sent to 30 randomly selected pharmacies in Saskatoon. Names and addresses for these pharmacies were obtained from the Directory of Pharmacies, Saskatchewan College of Pharmacists (June 2007). Based on their assistance, recruitment of the 30 study participants occurred over a period of two months (September 26th to November 26th).

As participants entered the study, odd numbers were assigned to group 1 and even numbers to group 2. Results regarding participants' ages, gender, education level, current medication use, knowledge of medication, experience with side effects in the past six months, expectations of pharmacists (with regard to side effect information), beliefs about medication (BMQ), health status (SF-8), health literacy (REALM) and numeracy are reported in separate sections for the 30 participants, as a whole and within their group.

There was no missing data for individual participants.

4.1. Demographics

4.1.1. Age

The age range of respondents varied from 51 to 89 years, with an average of 66.6 ± 10.6 years. Independent *t*-test showed no significant difference between the groups' mean ages ($t(28) = -0.254$; $p > 0.05$) (Table 4.1).

Table 4.1 Age differences for two groups

Participants	N	Mean \pm SD	Std. Error Mean
Group 1	15	66.1 \pm 11.1	2.86
Group 2	15	67.1 \pm 10.5	2.71

4.1.2. Gender

Of the 30 participants, the majority were female (N=19; 63.3%). The first group had six males and nine females and in the second group, five and 10 respectively. Pearson Chi-Square showed no significant difference among the two groups regarding the distribution of gender ($\chi^2(1) = 0.144$; $p > 0.05$).

Mean age and standard deviation of females and males were 65.6 ± 10.1 (N=19) and 68.2 ± 11.7 (N=11) years, respectively.

4.1.3. Education Level

Participants were asked about the education level they had completed. Of the 30 participants, five (16.7 percent) had less than grade twelve, four (13.3 percent) had a high school diploma or equivalent, six (20.0 percent) had some university or technical school degree, seven (23.3 percent) had a bachelor's degree, and eight (26.7 percent) held higher degrees (Master's degree or PhD). Table 4.2 shows the distribution of participants between the two groups. Pearson Chi-Square test identified a significant difference among the groups regarding their level of education ($\chi^2(4) = 9.952$; $p < 0.05$), with group 2 being more educated.

Table 4.2 Participant level of education

Education level for two groups	Groups		Total
	Group 1	Group 2	
Less than grade 12	5	0	5
High school diploma	1	3	4
Some university or technical school education	2	4	6
Technical school diploma or Bachelors degree	5	2	7
Masters degree or PhD	2	6	8
Total	15	15	30

4.2. Baseline Inquiry Questions

4.2.1. Current Medication Use

Regarding the current use of Rx and OTC medication, 19 participants were taking both types, four were on Rx only, another four were just using OTCs, and three were not taking any medication. Overall, 23 participants (76.7 percent) were taking OTCs and 23 (76.7 percent) were taking Rx medications.

4.2.2. Knowledge of Medication

On describing their knowledge of Rx and OTC medication (with options being *very knowledgeable*, *knowledgeable*, *somewhat knowledgeable*, *not very knowledgeable*, or *does not apply to me – I rarely use medicine*), 76.6 and 70.0 percent considered themselves *knowledgeable* or *somewhat knowledgeable* for OTC and Rx medicines, respectively. On the other hand, 16.6 percent of participants described themselves as *not very knowledgeable* of OTC and Rx medicine (Table 4.3).

Table 4.3 Participant knowledge of medication

Knowledge of medication	Over The Counter		Total	Prescribed		Total
	Group 1	Group 2		Group 1	Group 2	
Very knowledgeable	1	0	1	1	2	3
Knowledgeable	3	7	10	2	5	7
Somewhat knowledgeable	8	5	13	9	5	14
Not very knowledgeable	3	2	5	3	2	5
N/A- I rarely use medication	0	1	1	0	1	1
Total	15	15	30	15	15	30

4.2.3. Previous Experience with Side Effects

In response to the question – *Have you had any experience with side effects of medication in the last 6 months?*, 11 (36.6 percent) reported yes, while 19 (63.3 percent) had not had any experience with any. Seven of 11 participants who had previous experience with side effects mentioned that they experienced some of the side effects listed in Study 1 (*nausea, rash, dizziness, heartburn, diarrhoea and dry eyes*), while the other four had experienced different side effects (e.g. shortness of breath, muscle pain, among others). Pearson Chi-Square showed no significant difference between the two groups regarding the distribution of people who had previous experience with side effects ($\chi^2(1) = 3.589$; $p > 0.05$). Table 4.4 shows the distribution of participants with previous experience of side effects among the two groups.

Table 4.4 Participant previous experience with side effects

Previous experience with side effects	Participants		Total
	Group 1	Group 2	
Yes	8	3	11
No	7	12	19
Total	15	15	30

4.2.4. Side Effect Information and Patient Expectations of Pharmacists

Participants were asked to indicate to what extent they agreed or disagreed with seven statements regarding side effects and how pharmacists should be involved in the process (Table 4.5). Choices were *strongly agree*, *agree*, *uncertain*, *disagree*, and *strongly disagree*.

Overall, 84.8 percent either agreed or strongly agreed with all statements, 13.8 percent disagreed, while 1.4 percent were uncertain.

Almost all participants (96.6 percent) *strongly agreed* or *agreed* that they would like to receive information about side effects, read medication leaflets or written information, and desired detailed information regarding mild and frequent side effects. However, 86.6 percent also *strongly agreed* or *agreed* that side effect information puts them in a position to think twice about taking that drug. Table 4.5 shows participants' responses to each statement. Only statement number seven – *Pharmacists should put more emphasis on the benefits of medications rather than the side effects* – varied from this typical pattern. Half of participants *agreed*, while the other half *disagreed* with this statement.

Table 4.5 Information about medication side effects

Statements	SA	A	U	D	SD
I like to receive information about my medication's side effects.	23	6	0	0	1
I read medication leaflets or written information provided by pharmacists.	21	8	0	1	0
Side effect information provided to me puts me in a position to think twice about taking that drug.	13	13	0	4	0
Pharmacists should give detailed information to all individuals regarding <u>mild and frequent</u> side effects.	19	10	0	1	0
Pharmacists should give detailed information to all individuals regarding <u>mild and rare</u> side effects.	17	11	0	2	0
Pharmacists should give as much information concerning side effects as he or she thinks best for the individual patient.	16	7	1	6	0
Pharmacists should put more emphasis on the <u>benefits</u> of medications rather than the <u>side effects</u> .	2	12	2	13	1

Legend: SA = strongly agree; A = agree; U = uncertain, D = disagree; SD = strongly disagree.

4.3. Health Survey (SF-8)

The study used the Short-Form Health Survey (SF-8) for assessing overall health of participants.⁹⁹ Scores could range from eight to 42, where eight means no physical or mental health concerns and 42 means physical and emotional problems exist. The overall mean score for all 30 participants was 32.4 ± 5.7 and ranged from 22 to 42. This result shows there were some concerns about participants' health. The first group had an average of 32.3 ± 5.4 , with the second group scoring 32.5 ± 6.2 . They did not differ significantly according to Independent *t*-test ($t(28) = -0.094$; $p > 0.05$).

4.4. Beliefs about Medicines Questionnaire (BMQ)

Participants were asked to indicate to what extent they agreed or disagreed with statements about medicines in general (see appendix F). Higher scores (20) for the BMQ-general means a strong belief that medicines are either *overused by doctors* (BMQ-overuse) or *harmful and addictive* (BMQ-harm). Scores could range from four to 20. Participants' responses were between four and 18 on this measure. Overall mean and standard deviation for BMQ-overuse was 12.8 ± 2.8 and for BMQ-harm was 8.4 ± 2.9 (see Table 4.6). Participants were somewhat uncertain about physician overuse of medication, but disagreed with the harmfulness of medication.

Table 4.6 Belief of medication in general (BMQ-general)

BMQ General	Participants	N	Mean* \pm SD
Belief of medication overuse	Group 1	15	13.7 ± 2.9
	Group 2	15	11.9 ± 2.6
	Total	30	12.8 ± 2.8
Belief of medication harm	Group 1	15	9.5 ± 2.8
	Group 2	15	7.4 ± 2.6
	Total	30	8.4 ± 2.9

* Scores could range from 4 to 20

Independent *t*-test compared the two groups for mean scores. There was no significant difference regarding the *BMQ-overuse* ($t(28) = 1.792$; $p > 0.05$), but there was a significant difference for *BMQ-harm* ($t(28) = 2.090$; $p < 0.05$), where group 1 had stronger beliefs about the harmfulness of medications.

4.5. Rapid Estimate of Adult Literacy in Medicine (REALM)

The range possible for the *REALM* test is from 0 to 66 (Appendix H). A score above 61 equates to a high school education. Mean score for participants in this study was 64.6 ± 3.02 , ranging from 50 to 66. This indicates that our participants had the ability to read most patient education materials.

Independent *t*-test showed no significant difference between the two groups for mean scores ($t(28) = -1.412$; $p > 0.05$) (see Table 4.7).

Table 4.7 Participant REALM scores

Participants	N	Mean* \pm SD	Std. Error Mean
Group 1	15	63.8 \pm 4.02	1.038
Group 2	15	65.3 \pm 1.23	.319

* Scores could range from 0 to 66

4.6. Numeracy Test

The public's ability to understand drug information involves digesting numerical data. For this reason, an examination of the ability of participants to use numerical data (in probabilities and percentages) when interpreting risk information in different formats was needed.

4.6.1. Estimate of Numerical Ability to Understand Probabilities

Four questions related to probability and frequency were posed (see appendix I):

- 1) *Imagine that we flip a coin 1000 times. What is your best guess about how many times the coin would come up heads in 1000 flips? [500 times out of 1000 is the correct answer]*

- 2) *In the Big Bucks Lottery, the chance of winning a \$10 prize is 1%. What is your best guess about how many people would win a \$10 prize if 1000 people each buy a single ticket to Big Bucks? [10 persons out of 1000 is the correct answer]*
- 3) *In the ACME Publishing Sweepstakes, the chance of winning a car is 1 in 1000. What percent of tickets to ACME Publishing Sweepstakes win a car? [0.1 percent is the correct answer]*
- 4) *Mrs. Smith is told she has a 1 in 296 chance of dying from cancer and a 1 in 407 chance of dying from a stroke. Which is bigger, Mrs. Smith's chance of dying from a stroke or cancer? [cancer is the correct answer]*

Participant responses to these questions were tallied according to the number of correct answers. The data indicates 26.7 percent (N=8) of participants answered all four questions correctly, 13.3 percent (N=4) had three correct responses, while 36.7 percent (N=11) answered two correctly (see Table 4.8). This means 40 percent of participants have the ability to interpret information involving numerical data. However, 23.3 percent would need “more explanation” to comprehend numerical data. Pearson Chi-Square showed no significant differences between the two groups regarding the distribution of correct responds to the questions ($\chi^2(4) = 8.591; p>0.05$).

Table 4.8 Participant ability on the numeracy test

Number of correct answers	Participants		Total	Percent
	Group 1	Group 2		
None	3	0	3	10.0
One	0	4	4	13.3
Two	6	5	11	36.7
Three	1	3	4	13.3
Four	5	3	8	26.7
Total	15	15	30	100

4.6.2. Risk Information and Interpretation of Numerical Data

Participants were asked to show how risky they felt surgery scenarios were by choosing one of four options presented (*very risky, risky, slightly risky, not risky*). Results demonstrated that 40 percent (N=12) rated *9 in 1000 will die* as riskier than *991 in 1000 will survive*, while 16.7 percent (N=5) rated *991 in 1000 will survive* to be riskier. Only 43.3 percent (N=13) rated the same level of risk for both presentations, the correct interpretation. Table 4.9 shows the number of people who responded to each statement in each of the two groups. Pearson Chi-Square showed no significant difference between the two groups ($\chi^2(2) = 4.056; p>0.05$).

Table 4.9 Level of riskiness reported by participants

Level of riskiness	Participants		Total
	Group 1	Group 2	
Equal	4	9	13
<i>9 in 1000 will die</i> is riskier	7	5	12
<i>991 in 1000 will survive</i> is riskier	4	1	5
Total	15	15	30

4.7. Study 1: Effect of Numerical Data on Participant Medicine-Taking Behaviour

Study 1 examined three research questions: 1) the effect of providing numerical side effect data on the likelihood of taking medications; 2) effect of illness severity on choice of drug; and 3) effect of providing numerical side effect data on their choice of drugs when considering drugs effectiveness and number of side effects concurrently.

4.7.1. Effect of Providing Side Effect Percentages and Frequency Data

Participants were given a hypothetical scenario for a headache and then were asked to express their likelihood of taking three hypothetical drugs to treat it. As before, the visual analog scale used was from 1 (*very unlikely*) to 100 (*very likely*) for likelihood of using it. Half of participants were assigned to the mild headache scenario and the other half were assigned to the severe headache scenario.

Three hypothetical drugs – Drug X (50 percent effective with two side effects), Drug Y (75 percent effective with four side effects), and Drug Z (100 percent effective with six side effects) – were options for both groups to treat each headache type. The three drugs (Drug X, Y, Z) and the two groups (mild and severe headache scenarios) were the independent variables (IVs) in this study.

Participants received two sets of presentations pertaining to the side effects. The first presentation only provided a written list of side effects (referred to as “before seeing percentages” or “without percentages”), whereas the second presentation had a list of side effects with their probability of occurrence included (deemed “after seeing percentages” or “with percentages”). The likelihood of taking drugs *without* and *with* provision of percentages is the DV. Table 4.10 shows the mean likelihood to take each type of drug *with side effects percentages* and *without side effect percentages* per headache scenarios (mild and severe).

Table 4.10 Mean likelihood of taking Drug X, Y, and Z *with* and *without* side effect percentages per headache scenario

Drug	Presentation of Side Effects	Headache Scenario		Total N=30
		Mild (N=15)	Severe (N=15)	
		Mean* ± SD	Mean* ± SD	
Drug X	Without percentages	50.2 ± 28.9	39.8 ± 26.4	45.0 ± 27.7
	With percentages	62.6 ± 29.3	39.0 ± 21.3	50.8 ± 27.9
Drug Y	Without percentages	38.1 ± 30.7	50.1 ± 27.8	44.1 ± 29.4
	With percentages	33.1 ± 28.5	47.1 ± 29.9	40.1 ± 29.6
Drug Z	Without percentages	37.1 ± 38.1	41.3 ± 32.0	39.2 ± 34.6
	With percentages	35.2 ± 40.4	64.7 ± 30.9	50.0 ± 38.4

* Likelihood of taking drugs on a 1-100 scale

The results of the multivariate test of main effects (see Table 4.11) showed no significant difference between mild and severe headache groups ($F(3, 26) = 1.814$; $p > 0.05$) according to the mean likelihood of taking Drug X, Y, or Z.

Figure 4.1 shows the mean likelihood of taking Drug X, Y and Z in the mild and severe headache groups.

Table 4.11 Doubly multivariate analysis of repeated measure (main effects)

Effect		F	df	Error df	Sig
Between-Subjects	Mild vs Severe	1.814	3	26	.169
Within-Subjects	Without vs With Percentages	3.340	3	26	.035*
Within-Between	Without vs With by Mild vs Severe	.802	3	26	.504

*Sig $p < 0.05$

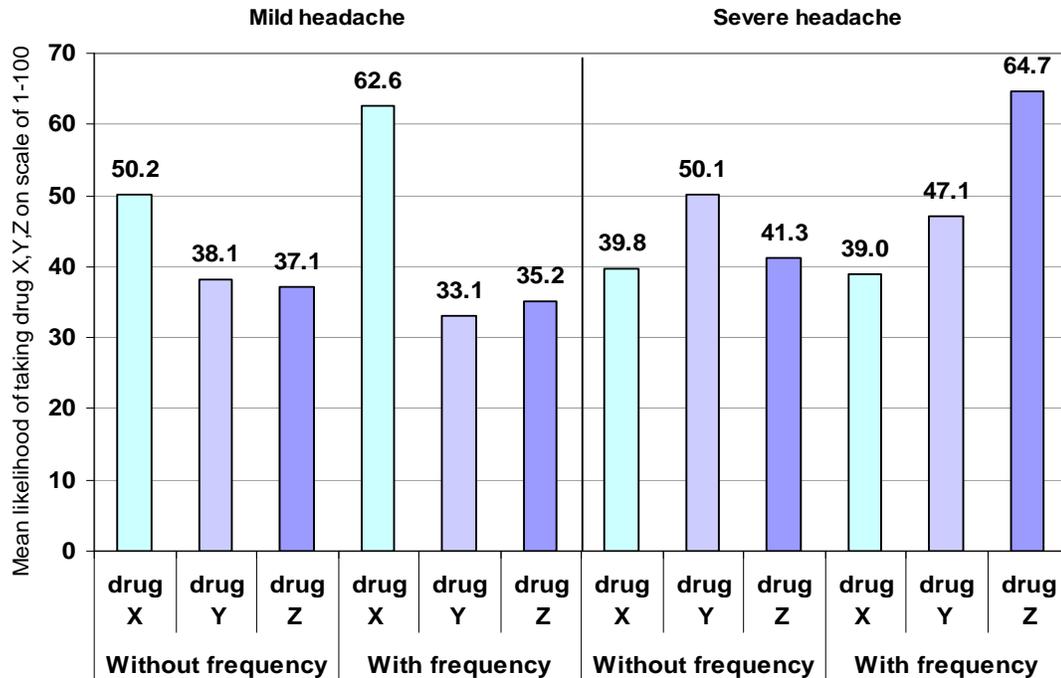


Figure 4.1 Mean likelihood of taking Drug X, Y, and Z *with* and *without* percentages for side effects per headache scenario

There was a significant within-subject difference when comparing mean likelihood of taking the three drugs *without* side effect percentages to the mean likelihood of taking the three drugs *with* side effect percentages ($F(3, 26) = 3.340; p < 0.05$). Figure 4.2 shows the mean likelihood of taking Drug X, Y and Z *with* and *without* side effect percentages, regardless of group factor (mild vs severe).

There was no significant interaction of the mean likelihood of taking all three drugs *without* versus *with* providing percentages by the two groups (mild vs severe headache) ($F(3, 26) = 0.802; p > 0.05$) (see Table 4.11).

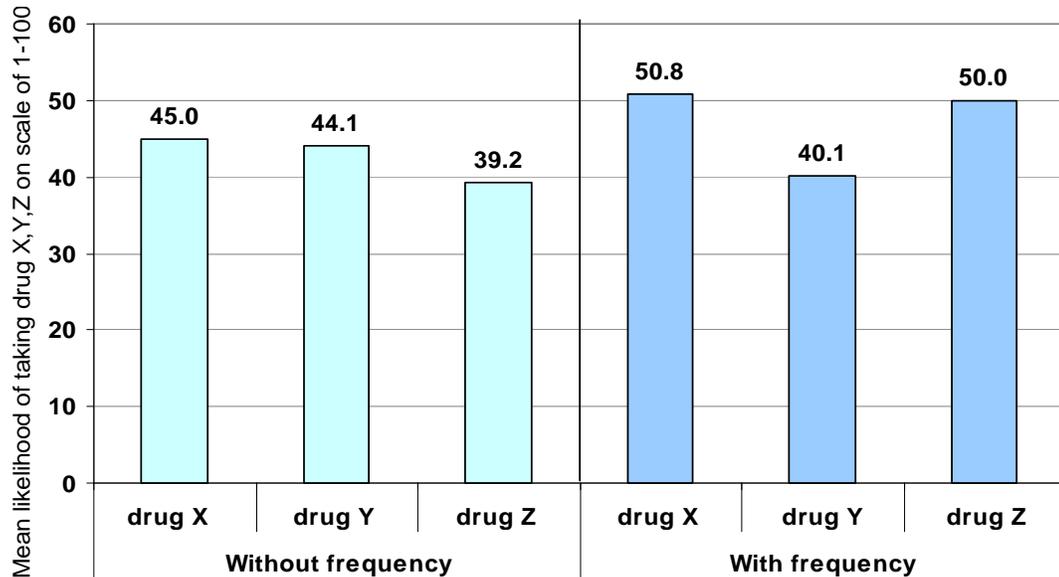


Figure 4.2 Mean likelihood of taking Drug X, Y, and Z *with* and *without* percentages for side effects

The univariate test (see Table 4.12) compares the mean likelihood of taking (*with* and *without* side effect percentages) Drug X ($F(1, 28) = 1.219$; $p > 0.05$), Drug Y ($F(1, 28) = 0.696$; $p > 0.05$), and Drug Z ($F(1, 28) = 1.767$; $p > 0.05$) separately. The mean likelihood of taking Drug X and Z increased upon seeing the percentages, from 45.0 to 50.8 and 39.2 to 50.0, respectively. However, there were no significant differences when comparing the mean likelihood of each drug separately while considering the *with* and *without* side effect percentages factor (regardless of group). There was also no significant interaction of groups (mild vs severe) when providing the percentages factor for Drug X ($F(1, 28) = 1.578$; $p > 0.05$), Drug Y ($F(1, 28) = 0.046$; $p > 0.05$), and Drug Z ($F(1, 28) = 2.458$; $p > 0.05$) separately (see Table 4.12).

Table 4.12 Univariate tests for simple effect of providing percentages for each drug and interaction by mild versus severe group

Source	Measure	df	Error df	F	Sig.
<i>Without</i> vs <i>With</i> side effect frequencies	Drug X	1	28	1.219	.279
	Drug Y	1	28	.696	.411
	Drug Z	1	28	1.767	.195
<i>Without</i> vs <i>With</i> by headache severity (Mild vs Severe)	Drug X	1	28	1.578	.219
	Drug Y	1	28	.046	.832
	Drug Z	1	28	2.458	.128

4.7.2. Effect of Illness Severity on Likelihood of Taking Each Drug

Further investigation of between-subject effects (mild vs severe headache scenarios) demonstrated that the only significant difference was to the mean likelihood of taking Drug X (overall mean likelihood of *with* vs *without* percentages) when comparing the two groups (see Table 4.13).

Table 4.13 Effect of headache scenarios on mean likelihood of taking Drug X, Y and Z

Measure	Severity of headache	N	Mean* ± SD	Std. Error
Drug X	Mild headache scenario	15	56.4 ± 29.2	5.8
	Severe headache scenario	15	39.4 ± 23.6	5.8
Drug Y	Mild headache scenario	15	35.6 ± 29.2	6.7
	Severe headache scenario	15	48.6 ± 28.4	6.7
Drug Z	Mild headache scenario	15	36.2 ± 38.6	7.2
	Severe headache scenario	15	53.0 ± 33.1	7.2

* Likelihood of taking drugs on a 1-100 scale

Participants in the mild headache group reported a higher mean likelihood of taking Drug X (56.4 on the scale of 1-100) compared to the mean likelihood of taking Drug X (39.4) in the severe headache group ($F(1, 28) = 4.312; p < 0.05$).

Table 4.14 presents test statistic information for effect of groups (mild vs severe) by drugs. There were no significant differences between the mean likelihood of taking Drug Y in the mild headache group and the mean likelihood of taking Drug Y in the severe headache group ($F(1, 28) = 1.876; p > 0.05$). There were also no significant differences between mean likelihood of taking Drug Z in the mild headache group and the mean likelihood of taking Drug Z in the severe headache group ($F(1, 28) = 2.752; p > 0.05$).

Table 4.14 Tests of between-subjects effects of mild versus severe headache variables on Drug X, Y, and Z

Source	Measure	df	Error df	F	Sig.
Mild vs Severe headache scenario	Drug X	1	28	4.312	.047*
	Drug Y	1	28	1.876	.182
	Drug Z	1	28	2.752	.108

*Sig $p < 0.05$

4.7.3. Impact of Varying Levels of Side Effects and Effectiveness of Drug X, Y, and Z on Participant Decision to Use a Drug

To determine the effect of providing percentages for side effects on participant decisions to use a medicine (options were Drug X, Y, Z or no drug at all), two answers were compared regarding which drug the participants would choose if they were experiencing a headache. This was done first *without* the frequency data for side effects and then *with* the frequency data for side effects. Of the 30 subjects, 17 (56.6 percent) kept the same drug, nine (30.0 percent) changed to a more effective drug, and four (13.3 percent) participants changed to a less effective drug (which also carries less side effects) (see Table 4.15).

Table 4.15 Effect of providing percentages for side effects on participant decision to take a drug

Change in drug choices	Percent	N
Switched to less effective drug with less side effects	13.3	4
Switched to more effective drug with more side effects	30.0	9
Did not change their choices of drugs	56.7	17
Total	100	30

4.7.4. Impact of Illness Severity on Drug Choice

Participant choices of drugs also differed in relation to the mild versus severe headache scenarios. Pearson Chi-Square showed a significant difference between drug categories and illness severity for both methods of presenting side effects, that is, *without* and *with* percentages ($\chi^2(3) = 11.083$; $p < 0.05$ and $\chi^2(3) = 10.597$; $p < 0.05$), respectively. Table 4.16 shows the frequency of participants in the two groups who preferred Drug X, Y, or Z *without* provision of percentages for side effects and *with* provision of percentages.

Table 4.16 Chosen drug for mild and severe headache scenario groups

	Preferred drug	Severity of headache scenarios		Total
		Mild headache	Severe headache	
Without percentages	None	1	3	4
	Drug X	9	1	10
	Drug Y	1	6	7
	Drug Z	4	5	9
	Total	15	15	30
With percentages	None	1	0	1
	Drug X	9	2	11
	Drug Y	0	4	4
	Drug Z	5	9	14
	Total	15	15	30

4.7.5. Preferred Presentation Style

All participants during baseline questioning (Form 1, question 16, Appendix E) responded to the question:

Side effects can be communicated to patients by listing them, with the option of adding numbers that represent the percentage of people who experience a particular side effect. For example, a pharmacist or doctor could say: “*The most common side effects are stomach ache, back ache, and drowsiness.*” Or they could say: “*The most common side effects are stomach ache (12%), back ache (6%), and drowsiness (2%).*” Which approach, if any, do you prefer?

They had three options: 1) *just the side effects*, 2) *the side effects and the percentages*, or 3) *no preference*. Nineteen (63.3 percent) were interested in seeing the percentages for side effects, whereas 10 participants (33.3 percent) were interested just in the name of side effects. One participant did not have any preference (3.3 percent) (see Table 4.17).

Table 4.17 Preferred presentation of side effects before Study 1

Preferred presentation	Frequency	Percent
Side effects only	10	33.3
Side effects plus percentages	19	63.3
No preference	1	3.3
Total	30	100

Later in Study 1, participants responded to a question (Form 8 of Appendix J) which asked them about those same preferences for presentation of side effects:

From what you read [i.e. side effects *with* and *without* percentages], which explanation would YOU prefer to be given on medication side effects? Check ONE of the following options: The first version (*a list of possible side effects*), the second version (*a list of possible side effects plus the percentages that they may occur*), or *No preference*

Their choices indicate that 83.3 percent (N=25) preferred side effects with percentages and their frequency of occurrences, whereas 16.7 percent (N=5) of participants still preferred to see the list of side effects only (see Table 4.18).

Table 4.18 Preferred presentation of side effects after Study 1

Preferred Presentation	Frequency	Percent
Side effects only	5	16.7
Side effects plus percentages	25	83.3
No preference	0	0
Total	30	100

Figure 4.3 compares participant preference for side effect presentation style at baseline with their preferences after Study 1. Six participants preferred to receive numerical data after doing Study 1, a 20.0 percent increase.

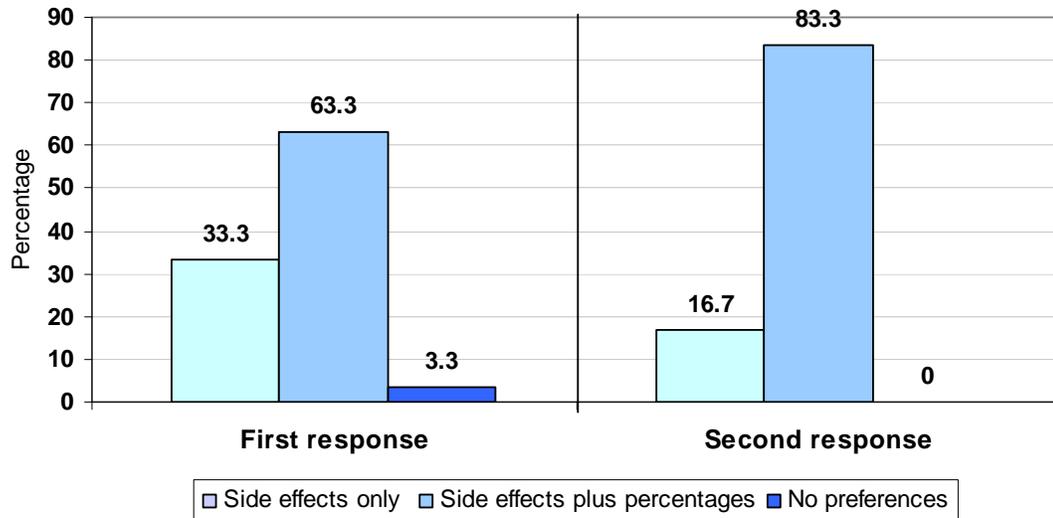


Figure 4.3 Participant responses to presentation styles at baseline and after Study 1

4.7.6. Effect of Gender on the Likelihood of Taking Drug X, Y, and Z

The effect of gender was analyzed using Doubly MANOVA to investigate whether a main effect of gender, disregarding the headache scenarios, existed for the likelihood of taking the three hypothetical drugs *with* and *without* providing percentages for side effects. If this data were analyzed within the two headache scenarios – in which gender would be a third IV to be included in the MANOVA – there would be greater need for more participants to give the test enough power to find significance without committing type I or II errors.

Therefore, a safe conclusion could not be drawn on whether gender was a main effect when comparing it within the headache scenario simultaneously. The severity of headache factor was therefore eliminated in order to achieve enough stochastic power to test for a gender effect. Table 4.19 shows the means for the

likelihood of taking the three drugs *with* and *without* percentages for side effects for female and male participants.

Table 4.19 Effect of gender on mean likelihood of taking Drug X, Y, and Z *with* and *without* side effect percentages

Drug	Presentation of Side Effects	Gender		Total N=30
		Male (N=11)	Female (N=19)	
		Mean* \pm SD	Mean* \pm SD	
Drug X	Without percentages	30.3 \pm 16.5	53.5 \pm 29.6	45.0 \pm 27.7
	With percentages	41.0 \pm 28.4	56.5 \pm 26.6	50.8 \pm 27.9
Drug Y	Without percentages	53.4 \pm 26.1	38.7 \pm 30.5	44.1 \pm 29.4
	With percentages	39.9 \pm 19.5	40.2 \pm 34.6	40.1 \pm 29.6
Drug Z	Without percentages	47.1 \pm 34.2	34.6 \pm 35.0	39.2 \pm 34.6
	With percentages	52.9 \pm 36.6	48.3 \pm 40.2	50.0 \pm 38.4

*Likelihood of taking drugs on a 1-100 scale

Figure 4.4 graphically compares female and male participant mean likelihood of taking drugs *with* and *without* percentages. After receiving numerical data for side effects, females showed an increase in mean likelihood of taking all three drugs, but Drug X had the highest mean likelihood (56.5). Male participant mean likelihood of taking Drug X and Z increased after receiving numerical data. However, there was a decrease in likelihood of taking Drug Y for male participants. Data shows that Drug Y had the highest mean likelihood (53.4) when side effects were presented *without* percentages, while Drug Z had the highest mean (52.9) when side effects were presented *with* percentages. This could mean males switched their preferences to a more effective drug (which carries more side effects) after receiving frequency data.

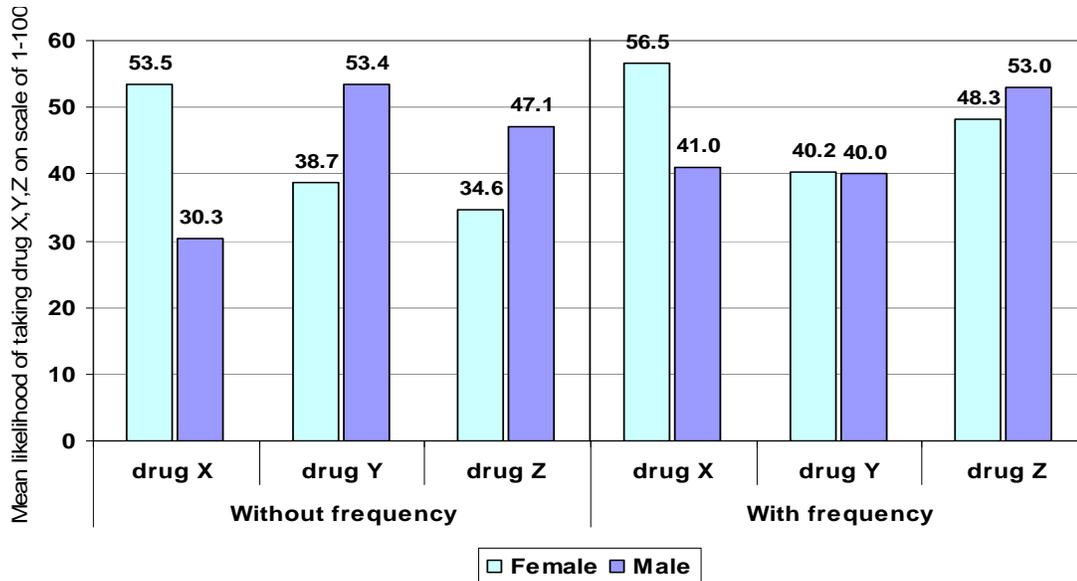


Figure 4.4 Effect of gender on mean likelihood of taking Drug X, Y and Z *with* and *without* percentages for side effects

After eliminating the headache severity grouping factor (mild versus severe), some data did not meet the assumptions of MANOVA. For example, unequal covariance matrices across the groups (gender) (Table 4.20) and unequal error of variance (Levene's test) existed in some data (Table 4.22). Although these assumptions were not met by some of the data, MANOVA is a robust test against violations of the homogeneity assumption¹⁰⁶ and, therefore, was still employed to determine if there were any main effect of gender and any significant interaction between the provision of percentages and gender (Table 4.21). Results of the Doubly MANOVA test showed no significant differences with regard to the gender factor ($F(3, 26) = 1.917; p > 0.05$). There was also no significant interaction of gender by provision of the side effects percentages factor ($F(3, 26) = 1.073; p > 0.05$). However, Table 4.21 also showed there was

a significant difference for mean likelihood of taking Drug X, Y, and Z when side effects were presented *without* and *with* percentages ($F(3, 26) = 3.854$; $p < 0.05$), which was also reported in Table 4.11.

Table 4.20 Box's test of equality of covariance matrices considering gender

Box's M	47.026
F	1.642
df1	21
df2	1614.135
Sig.	.034

Tests the null hypothesis that the observed covariance matrices of the dependent variables are equal across groups

Table 4.21 Multivariate test of variances for effect of gender and provision of side effect percentages

Effect		F	df	Error df	Sig.
Between-Subjects	Gender	1.917	3	26	.152
Within-Subjects	Without vs With percentages	3.854	3	26	.021*
Within-Between	Without vs With by gender	1.073	3	26	.378

*Sig $p < 0.05$

Table 4.22 Levene's test of equality of error variances considering gender

	F	df1	df2	Sig.
Drug X without percentages	4.425	1	28	.045
Drug X with percentages	.025	1	28	.874
Drug Y without percentages	.980	1	28	.331
Drug Y with percentages	21.801	1	28	.000
Drug Z without percentages	.086	1	28	.771
Drug Z with percentages	.677	1	28	.418

Tests the null hypothesis that the error variance of the dependent variable is equal across groups

The test of between-subject effects (Table 4.23) showed there was a significant difference between the mean likelihood of taking Drug X when comparing males with females ($F(1, 28) = 5.366; p < 0.05$), but there was no significant differences between females and males regarding their mean likelihood of taking Drug Y ($F(1, 28) = 0.509; p > 0.05$) or Drug Z ($F(1, 28) = 0.614; p > 0.05$). This means female participants were more likely to use Drug X.

Table 4.23 Tests of between-subjects effects of gender variable on Drug X, Y, and Z

Source	Measure	df	Error df	F	Sig.
Gender	Drug X	1	28	5.366	.028*
	Drug Y	1	28	.509	.482
	Drug Z	1	28	.614	.440

*Sig $p < 0.05$

4.7.7. Effect of Previous Experience with Side Effects on the Likelihood of Taking Drug X, Y, and Z

The effect of previous experience with side effects was examined on the likelihood of taking the three hypothetical drugs *with* and *without* providing percentages for side effects using Doubly MANOVA. In order to detect a main effect of previous experience, it was necessary to disregard the headache scenario factor for the same reason as mentioned in section 4.7.6. After eliminating this grouping factor, and looking at previous experience with the side effects factor, the data met all assumptions for Doubly MANOVA.

Table 4.24 shows the mean likelihood of taking Drug X, Y and Z *with* and *without* providing percentages for side effects for the two groups of participants

who previously experienced any side effects (defined by *Yes = had experienced* and *No = had not experienced*).

Table 4.24 Effect of previous experience with side effects on mean likelihood of taking Drug X, Y, and Z *with* and *without* side effect percentages

Drug	Presentation of Side Effects	Previous Experience with Side Effects		Total N=30
		Yes (N=11)	No (N=19)	
		Mean* ± SD	Mean* ± SD	
Drug X	Without percentages	47.5 ± 29.5	43.5 ± 27.3	45.0 ± 27.7
	With percentages	53.8 ± 30.4	49.0 ± 27.0	50.8 ± 27.9
Drug Y	Without percentages	35.5 ± 35.0	49.1 ± 25.3	44.1 ± 29.4
	With percentages	25.6 ± 30.0	48.5 ± 26.6	40.1 ± 29.6
Drug Z	Without percentages	28.2 ± 31.4	45.6 ± 35.6	39.2 ± 34.6
	With percentages	38.9 ± 42.3	56.4 ± 35.5	50.0 ± 38.4

* Likelihood of taking drugs on a 1-100 scale

The result showed no significant difference between groups who had experienced side effects in the past and those who hadn't ($F(3, 26) = 1.342$; $p > 0.05$). There was also no significant interaction between *with* versus *without* percentages by previous experience with side effects ($F(3, 26) = 0.298$; $p > 0.05$). Test of the within-subject factor (as reported in previous sections) showed a significant difference ($F(3, 26) = 3.408$; $p < 0.05$) in comparing the *with* versus *without* side effect percentages factor on the mean likelihood of taking Drug X, Y and Z (see Table 4.25).

Table 4.25 Multivariate test of variances examining participants previous experience with side effects, provision of side effect percentages

Effect		F	df	Error df	Sig.
Between-Subjects	Previous experience with side effect	1.342	3	26	.282
Within-Subjects	Without vs With percentages	3.408	3	26	.032*
Within-Between	Without vs With by previous side effect experience	.298	3	26	.826

*Sig $p < 0.05$

There were no significant differences in mean likelihood of taking Drug X ($F(1, 28) = 0.234$; $p > 0.05$), Drug Y ($F(1, 28) = 3.598$; $p > 0.05$), or Drug Z ($F(1, 28) = 2.739$; $p > 0.05$) for the two groups of participants who had or hadn't experienced any side effects. Table 4.26 shows the test of between-subjects effect of previous experience with side effects on each drug.

Table 4.26 Tests of between-subjects effect of previous experience with side effect variables on Drug X, Y, and Z

Source	Measure	df	Error df	F	Sig.
Previous experience with side effects	Drug X	1	28	.234	.633
	Drug Y	1	28	3.593	.068
	Drug Z	1	28	2.739	.109

4.7.8. Effect of Gender on Preferred Drugs

Pearson Chi-Square tests were used in order to determine if participant choices of drugs were different between females and males (for the two presentation styles of *with* and *without* percentages). Pearson Chi-Square showed no significant differences among females and males on their choices to take a drug across both presentation styles (*without* and *with* percentages for

side effects ($\chi^2 (3) = 2.929; p>0.05$) and ($\chi^2 (3) = 5.533; p>0.05$), respectively) (see Table 4.27).

Table 4.27 Effect of gender on drug choices

	Preferred drug	Gender		Total
		Male	Female	
Without percentages	Drug X	2	8	10
	Drug Y	4	3	7
	Drug Z	4	5	9
	None	1	3	4
	Total	11	19	30
With percentages	Drug X	3	8	11
	Drug Y	0	4	4
	Drug Z	7	7	14
	None	1	0	1
	Total	11	19	30

4.8. Study 2: Effect of Negatively- or Positively-Slanted Presentation of Side Effects

In the second study, the mean likelihood of taking two hypothetical drugs (Drug P and N) were compared to investigate whether or not presenting side effects in positively- or negatively-slanted wording would have an effect on their likelihood of taking those medicines. All 30 participants considered both Drugs P (standing for *Positively-slanted*) and Drug N (standing for *Negatively-slanted*) and were asked to express their likelihood of taking them on a scale of 1 (*very unlikely*) to 100 (*very likely*). To control for the effect of presentation order, half of participants received Drug P first and the other half received Drug N first. Table 4.28 shows the mean likelihood of taking Drugs P and N.

Table 4.28 Likelihood of taking Drug P and N

Drug	Drug order	N	Mean* \pm SD	Std. Error
Drug N	Drug N first, Drug P second	15	53.1 \pm 26.3	6.78
	Drug P first, Drug N second	15	67.1 \pm 23.3	6.02
	Total	30	60.1 \pm 25.4	4.64
Drug P	Drug N first, Drug P second	15	70.5 \pm 21.4	5.52
	Drug P first, Drug N second	15	79.9 \pm 15.0	3.88
	Total	30	75.2 \pm 18.8	3.43

* Likelihood of taking drugs on a 1-100 scale

Independent sample *t*-test showed no difference between the mean likelihood of taking Drug P ($t(28) = 1.393$; $p > 0.05$) and Drug N ($t(28) = 1.551$; $p > 0.05$) for participants receiving the drugs in the different order. Therefore, the presentation order did not significantly affect the measure of likelihood.

After discounting the possible influence of the order of presentation, a Paired sample *t*-test was carried out to compare the mean likelihood of taking Drug P (with the side effect expressed as 90% *will not* experience heartburn) with Drug N (with the side effect expressed as 10% *will* experience heartburn). Results of the *t*-test (see Table 4.29) showed that the likelihood of taking Drug P (positive-slant) was significantly greater than the likelihood of taking Drug N (negative-slant) ($t(29) = 3.558$; $p < 0.05$) (see Figure 4.5)

Table 4.29 Paired sample *t*-test comparing mean likelihood of taking Drug P and N

	Paired Differences		<i>t</i>	<i>df</i>	Sig.
	Mean \pm SD	Std. Error			
Drug P vs Drug N	15.1 \pm 23.3	4.253	3.558	29	.001*

*Sig $p < 0.05$

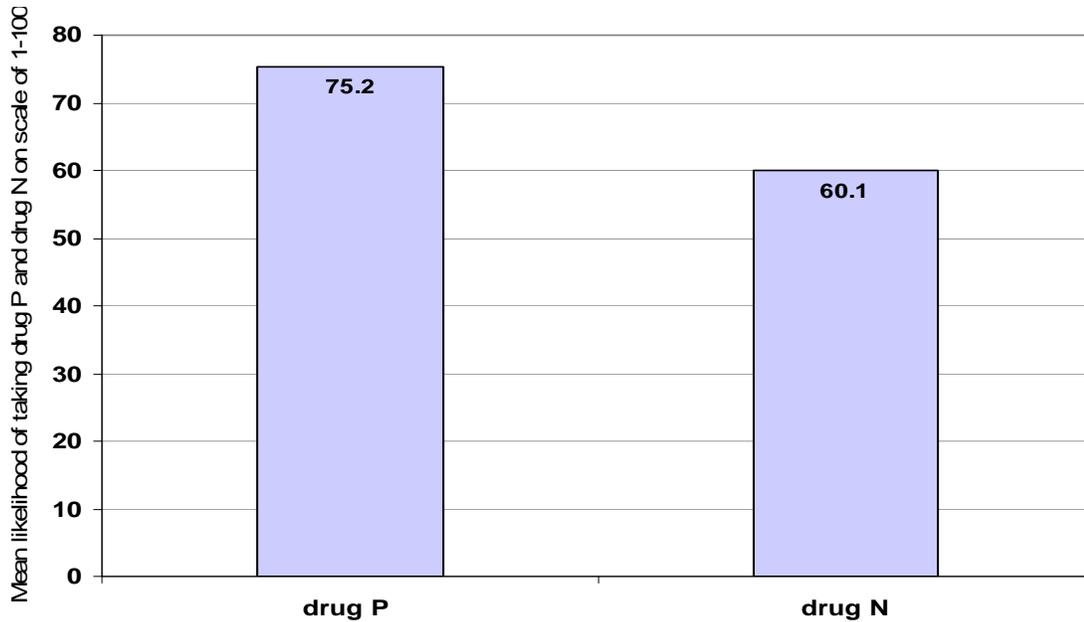


Figure 4.5 Likelihood of taking Drug P and N

Participants were asked which they would prefer to use if they had a headache; the choices were *Drug P*, *Drug N*, *Equally*, or *Neither Agent*. Sixty percent (N=18) of the participants agreed with the statement – *I would prefer the two agents equally* – whereas 30 percent (N=9) preferred Drug P, 10 percent (N=3) were not interested in any drug, and no one chose Drug N.

When asked to choose which presentation style for side effects they preferred, participants slightly preferred the statement – *90% will not get heartburn* – (56.7 percent) compared to the statement – *10% will get heartburn* – (chosen by 43.3 percent).

4.8.1. Effect of Gender on the Likelihood of Taking Drug P and N

Factorial ANOVA (two-way ANOVA) was run to compare the likelihood of taking Drug P and N for females versus males. Table 4.30 shows the overall mean likelihood for Drug P and N considering the gender factor. The data, divided by the gender factor, did not meet the assumption of homogeneity of variance for the ANOVA test (Table 4.31), but the test is robust against violations of the homogeneity assumption. Therefore, it was used to examine if there was any significant effect of gender.

Table 4.30 Mean likelihood of taking Drug P and N based on gender

Gender	Drug	N	Mean* ± SD	Std. Error
Drug P	Male	11	70.6 ± 13.6	4.1
	Female	19	77.9 ± 21.1	4.8
	Total	30	75.2 ± 18.8	3.4
Drug N	Male	11	62.9 ± 19.9	5.9
	Female	19	58.5 ± 28.6	6.5
	Total	30	60.1 ± 25.4	4.6

* Likelihood of taking drugs on a 1-100 scale

Table 4.31 Levene's test of equality of error variances considering gender

Drug	F	df1	df2	Sig.
Drug P	2.876	1	28	.101
Drug N	5.894	1	28	.022

Results showed there was no significant difference between females and males regarding their mean likelihood of taking either Drug P or Drug N ($F(1, 28) = 0.037$; $p > 0.05$). There was also no interaction of gender by mean likelihood of taking Drug P and Drug N ($F(1, 28) = 1.804$; $p > 0.05$) (see Table

4.32). However, the within-subject test comparing the mean likelihood of taking Drug P and Drug N showed a significant difference ($F(1, 28) = 9.726; p < 0.05$), even after adding the gender factor to the data (see Table 4.32).

Table 4.32 Effect of gender on Drug P and N

Tests	Effect	F	df	Error df	Sig.
Between-Subject	Gender	0.037	1	28	.849
Within-Subject	Drug P vs Drug N	9.726	1	28	.004*
Between-Within	Drugs by Gender	1.804	1	28	.190

*Sig $p < 0.05$

4.8.2. Effect of Previous Experience with Side Effects on the Likelihood of Taking Drug P and N

Factorial ANOVA (two-way ANOVA) was used to determine the effect of previous experience with side effects on the mean likelihood of taking Drug P and Drug N. Table 4.33 shows the mean likelihood of taking Drug P and N between the two groups of participants in relation to previous experience with a side effect (defined by *Yes = had experienced* and *No = had not experienced*).

Table 4.33 Mean likelihood of taking Drug P and N considering previous experience with side effects

Drugs	Previous experience	N	Mean* \pm SD	Std. Error
Drug P	Yes	11	74.3 \pm 18.1	5.5
	No	19	75.8 \pm 19.6	4.5
	Total	30	75.2 \pm 18.8	3.4
Drug N	Yes	11	52.6 \pm 24.6	7.4
	No	19	64.4 \pm 25.5	5.8
	Total	30	60.1 \pm 25.4	4.6

* Likelihood of taking drugs on a 1-100 scale

Two-way ANOVA showed no significant differences between the two groups (Yes and No) regarding to their likelihood of taking Drug P and N ($F(1, 28) = 0.841$; $p > 0.05$). There was also no significant interaction of the mean likelihood of taking Drug P and N with previous experience with the side effects factor ($F(1, 28) = 1.371$; $p > 0.05$). However, the within-subject test comparing the mean likelihood of taking Drug P and Drug N showed a significant difference ($F(1, 28) = 14.165$; $p < 0.01$), even after adding the previous experience with side effect factor to the data (see Table 4.34).

Table 4.34 Effect of previous experience with side effects on mean likelihood of taking Drug P and N

Tests	Effect	F	df	Error df	Sig.
Between-Subject	Previous experience with side effects	.841	1	28	.367
Within-Subject	Drug P vs Drug N	14.165	1	28	.001*
Between-Within	Drugs by previous experience with side effects	1.371	1	28	.252

*Sig $p < 0.05$

4.9. Interview Highlights

While the interviews represent qualitative data, the approach to analysis was not to undertake numerous iterations to uncover exacting themes as is typical for qualitative research. Rather, these interviews were done to provide greater depth in how respondents approached their decision-making. To attain this goal, the researcher asked for their thoughts in relation to the position they took using the research questions as a guide. In the pharmacy literature, this

does not appear to be common practice. Instead, methodologies tend to follow one (survey) or the other (interview) approaches.

4.9.1. Personal Experience with Side Effects

Participant past experience with medicine side effects could impact decisions on using another medication in the future. Of note is that few participants described having previous experience with any of the side effects listed for drugs of the study. Some had encountered other effects not listed. The nature of that side effect history had little effect on the propensity to take any of the drugs presented. However, the interviews uncovered some concern that for some, affected their decision-making process:

And this one here causes nausea, rash, dizziness, heartburn, diarrhoea, dry eyes – I mean like why would I want to take this one [pointing to Drug Z]? I wouldn't if they have all that. I can handle a little nausea ... diarrhoea I can't because I suffer from colitis and I get it enough anyway, so I don't want to take a pill that's going to give it to me more. Many years ago, I have taken pills that gave me every one of these ... well not about heartburn ... everything else – I get dry eyes. Some places neglect to put on dry mouth because that generally happens more than dry eyes. [Interview 7]

I took the one pill I had – you couldn't believe the side effects on it. It was for an arthritis pill – Methotrexate. I mean, I'm lucky my hair is even here – my hair would come out, just fell out. And yet, it was a very low percentage of hair loss but that affected me worse than anything ... when my hair started falling out in globs. I went back and I said you know what I'd rather be in pain than be bald. [Interview 7]

It kind of depends on what the side effects are. I mean dizziness, nausea, that's prevents you from doing your job as much as the headache – it's a headache type thing – so I would say it kind of depends on what the of side effects are. If it's a dry cough, every so often, that doesn't stop you from doing your job – or if it's – whatever some of the other side effects may be, like a rash, that could be treated

with something else. But I like the drugs to be effective and stop the pain, for example, if it's pain medication. But you don't want some bizarre side effects though either. [Interview 29]

4.9.2. Impressions of Taking Too Many Medications

Much like having to deal with side effects in the past, some participants' current use of medications probably affected their decision to use another medication for a headache. It would surely be the rare person who would enjoy adding another agent to their day. As such, such hesitancy would come into play in their real worlds, as it could during this study:

With the medication I'm taking, there is very little that I can take for pain, except for Tylenol. So I guess I kind of put my own experience in there. [Interview 4]

I take a lot of drugs – and I will only take – if it bothers me. I mean it drives my doctor crazy sometimes but I'm just not taking it. There must be something better out there and if you keep on, they will find you something better. They might get annoyed at you, but they will find something better. I go to an arthritis specialist because I have arthritis and I have to go back over and over. [Interview 7]

The side effect information was processed quite methodically by one participant who had to deal with a few medications in his own life. The following is his reasoning for choosing Drug Z:

I tend to be lucky with those things and not fall into the category that gets hammered by side effects. Usually I have a very solid stomach so nausea is something that rarely ever occurs in me. Then I look at rash – I have rash all the time so ... because of other medications I take. So that wouldn't affect me or that wouldn't affect my decision. And then dizziness – I rarely ever get dizzy. I used to when my diabetes wasn't in control but that's over. So then heartburn – I very rarely have that. I have high acidity, but I have drugs to deal with that. Diarrhoea occurs only with one

medication that I take in combination with certain foods, so I have that in control. All those side effects that you mentioned are in control with me and the likelihood that they would occur with this sample drug would be low. [Interview 23]

4.9.3. Role of Numerical Data and Its Effect

The impact of presenting side effect frequency in numerical form was explored in the interviews. Participant likelihood of taking the medications increased subsequent to the numerical information they received. Some examples of how participants processed the information before (and after) seeing the percentages are included in this section:

I think probably because of some of the side effects – when I first looked at it, I was a little concerned about what my activities might be after I took Drug Z and I didn't want to, say, be caught in a bad position if I did develop diarrhoea ... that I wanted to be somewhere close to a bathroom or something like ... I didn't want to be driving a car down the highway or something like that. That was kind of my main concern with picking Drug Y over Drug Z ... is the possible side effects when I'm doing some other activities. [Interview 6]

With numerical data appearing, participant likelihood to take an agent generally increased. For some, it persuaded them to switch to a more effective drug (accompanied by more side effects):

As I said before, I was concerned about the diarrhoea but when I see it ... the diarrhoea is only a 2% chance of developing it. That's a pretty good risk to take and you are not going to get it. [Interview 6]

Because I looked at the percentages and some of them are very low for ... for some of the side effects ... more debilitating perhaps. This just lists the consequences or the possible side effects. And this one [Form 7] shows the approximate percentages, which are not that high for the

diarrhoea and dry eyes, which are the ones that are added from the others. And it was faster and more effective. [Interview 8]

The second one gives the percentages and I think the first one seemed simpler in a way. It didn't require thinking about percentages and I thought Drug Y – I guess it was, yeah, 75% effective. I choose it because there was no mention of diarrhoea and I thought Drug Z with diarrhoea would be, could be anyway, fairly severe. So that was my reasoning there. Then looking at the percentages in form seven, they are quite low anyway, so that's why I moved up to Drug Z to the one actually I prefer because the percentages of rash or diarrhoea is less than 1% and so on. So it seemed very minimal, so it was worth the risk. [Interview 10]

So my main objective was to do whatever would be most likely to help me feel better, so I could do what I have to do. That's why I went for the one that was the least likely to have the side effects. It would depend on how crucial the deadline is because if it was really really crucial, I might have thought of taking the 100% one and risk the side effects. But if it's not so crucial, then I'm not willing to risk those side effects. It turned around here [After numerical data] because I was given the percentages, I could see they were very low. And the first one, I wasn't given the percentages to tell me how likely those side effects were. And when I saw they were very low, I thought well then, I'll take the one that's most likely to be effective because that's very low percent of chance that I'll get those side effects. [Interview 5]

The side effects do not look that high. The highest side effect was 7% and I guess I would be watching to see if I experience some dizziness or some heartburn ... or I guess any of these side effects. But the two [critical one] I'd be looking at mostly is the dizziness and the heartburn. [Interview 22]

One participant thought the numerical data added unnecessary clutter to the reading materials:

I had originally said that I thought the percentages would ... What I saw when I read it was it somehow made the information more ... and made me less likely to read it because it was more so ... I think that's why it actually didn't change. But in both cases, I felt that two side effects is far better than three or four or five and that's why I stayed with X on both of them. And it is because it [Drug X] had less potential side effects. I think in a way it was feeling like ... because I know that I'm a healthy person and I don't usually get side effects. Seeing two side effects, you are

feeling very confident with that. When I go down to Z, for example, I think there's five of them here, you begin to think though, the law of average says I'm going to get one of them. [Interview 9]

4.9.4. Illness Severity and Importance of Drug Effectiveness

Participant choice for a drug depended on which headache scenario they received. Here are two participant statements on how they decided to use a medicine:

Mild headache scenario – My feeling was that even though Drug X was the least effective, it also had the least side effects. So I was prepared to wait a little longer or have even just a little reduction in pain as opposed to ... maybe if I was somebody who actually suffered from migraines, I might have felt differently. [Interview 9]

Severe headache scenario – Well, because it [Drug Z] was 100% effective. I know it has a lot of side effects, but it probably doesn't affect everyone that way. So that's why I picked that one. [Interview 2]

4.9.5. Side Effects versus Effectiveness

Participant decisions toward selecting a medicine evoked different takes on attributes. For some, effectiveness was more of a concern while for others, it was side effects. The majority, however, felt their decisions were influenced by both. The following examples reveal how people might weigh a drug's benefits versus its' risks:

The side effect information was more influential in choosing Drug X because it has a lower ... 3% ... 4% ... and well, nausea, rash not that bad – it's a headache – dizziness at 7% – when you are taking a medication to get rid of headaches. But it's still going to cause dizziness so therefore, you know, 7% ... I rounded it up to 10 again, and that's

pretty major. So that it was definitely the percentages of the side effects that caused me to choose Drug X. [Interview 29]

I think it would be side effects ...in the first form [Form 6] ... because it says it may cause nausea or rash. But no mention of how lightly – whereas form seven says how lightly and it seemed like a small ... like the odds are small. So I'd rather have the 100% effective ... given the small odds of the side effects. [Interview 10]

So that's why I picked it here [Drug Z in Form 7] and changed [my choice] from 75% [effectiveness] because this one here says – it gives you the same. This one gives you nausea, rash, dizziness and heartburn and no diarrhoea or dry eyes – I never have problems with that. So I simply decided from the point of view of mathematical probability – I won't probably be one of those affected. And I would take it. But I'm always thinking that when I give you an answer like that, that I have a choice to go back to Y or X. After this goes on ... won't kill me. You don't say as a side effect as killing. You have no idea how many times I read about drugs which have sudden death as a side effect, so if that's not in there, then I'm fine. [Interview 23]

4.9.6. Effect of Negatively- versus Positively-Slanted Wording

Probing was undertaken for participants who showed more than 10 points (on the scale) in favour of using Drug P over Drug N. Some explanation for this finding is as follows:

I think it's in the way it was phrased – one is I have a 10% chance of getting it ... sounds so much more than when you say 90% of people don't. I can easily ... for some reason ... it sounds ... but maybe I just like things phrased positively. But yeah, I felt that even though I know it's the very same thing, that 90% not getting it sounds somehow less scary than 10% getting it. [Interview 9]

Yeah, I started out with – 90% will not experience heartburn, I think it's a psychological difference. I'm assuming I would be among the 90, I think, that would not experience heartburn, so I feel comfortable with that. Drug N, on the other hand, says 10 out of 100 'will' experience heartburn, which seems like a very positive ... like it's very ... if the word was 'might' experience heartburn, I would feel more comfortable with that drug. But it says 10 out of 100 will experience heartburn, so that moves it

down in my preference list. See this one ... on the flip side ... will not experience ... it doesn't say that the other *ten* ... they may be in that group as well. Now, if it went on to say – will not experience heartburn, however ten will, then I would put them on an equal playing. [Interview 10]

Well, I suffer from heartburn, so I thought if this one ... it says will not experience heartburn and this one will experience heartburn, so that's why I went with this one instead of that one, because I hate heartburn. [Interview 2]

4.10. Summary of Interviews

Interview data support the finding of the main results. Participants were more likely to use their medicine with inclusion of numerical data to the medication side effects. This was the first finding of the study and participant opinions during the interviews reveal a similar pattern. Regarding the importance of illness severity in choice of medication, as headache severity rises, people chose more effective remedies in spite of side effect potential. Participant interviews confirmed that seeking a more effective drug would be considered when experiencing a severe headache. The interviews revealed both side effects and effectiveness of a medicine play an important role, but severity and risks were of equal importance in their decision; all these influences affected their decision. Some articulated that the probability of experiencing any of the side effects was acceptable, further enhanced by the fact they were not perceived as all that severe. On the issue of positively- and negatively-slanted framing, interviews of just those who felt Drugs N and P presented different risk confirmed that experiencing heartburn was less likely to happen when they received positive framing.

CHAPTER 5 DISCUSSION

Patients increasingly face a bewildering array of health risks. Deciding which risks are important for patients to attend to is difficult – but it matters. Inaccurate risk perceptions have important consequences. If people at high risk for diseases are unaware of their elevated risk, they may fail to appropriately consider interventions that might be beneficial. If those at low risk for diseases have a falsely heightened sense of risk, they may experience undue anxiety and may pursue interventions that offer them more harm than benefit. Understanding the magnitude of a health risk is fundamental to deciding whether the risk is acceptable and, if so, whether to consider taking some action to reduce the risk.

In the field of pharmaceutical care, drug information on labels and inserts is a major source of knowledge for patients as they attempt to balance the risks and benefits of drugs and administer them safely. However, this information is often inconsistent, incomplete, and difficult for patients to read and understand. The fact is it is not easy to present a single best approach for conveying a medication's adverse effects to individuals. This is true for all medication, but may especially be true for medicines available without prescription. For this reason, this study was undertaken.

Thirty subjects 50 years of age and up from Saskatoon participated, with an average age of approximately 67 years. Of those, 63.3 percent were female

which, for comparison purposes, appears to be slightly (8.2 percent) more than the city population (based on Community Profiles from the 2006 Statistics Canada Census¹⁰⁷). Less than half of participants (n=11) had previous experience with side effects. Most participants (90 percent) were using at least one medicine (be it OTC or Rx or both) and described their knowledge as *knowledgeable* or *somewhat knowledgeable*. On the BMQ, subjects tended not to perceive medicines as harmful, but showed some uncertainty as to whether physicians overused them.

To gauge how well people in this study understood medical information, a measure was used to quantify their numerical skill.^{20,62} Six questions which were most relevant to this study were chosen (four questions related to Study 1 and two related to Study 2). Forty percent of participants answered three to four questions correctly, 50 percent answered one to two, and 10 percent failed to provide a correct answer to any question. This shows that almost 60 percent of our participants struggled to solve basic numerical questions, despite the fact that about 50 percent of the participants had a university degree and 33.3 percent had a high school or technical diploma.

Headaches are a very common complaint for consumers¹⁰⁰ and this helps explain why analgesics are a large category in the OTC market. The study created hypothetical scenarios in which a person was asked to decide on a painkiller for relieving headache. Differing levels of headache severity were utilized because illness severity may be an issue in participant choice. This set in motion a situation requiring the balancing of risk-benefit information during a

decision-making process where different choices were available. More importantly, assessing the impact of providing numerical data for side effect occurrence was possible. In other words, would the propensity to take Drug X (just by way of example) change with the provision of numerical side effect data? Would subjects be more or less willing to take it (or any of the others) upon seeing the numerical data? Then, might subjects change their overall decision, perhaps from a drug of low efficacy and minimal side effects, to one of higher efficacy and more side effects, if provided that same numerical side effect data?

Thirty participants were given the option of three hypothetical OTC medicines, all of which had differing efficacy and differing numbers of side effects. The three drugs available for selection were fictitious (Drug X, Y and Z) and were described as 50, 75, and 100 percent effective, while exhibiting two, four, and six side effects, respectively. While side effects were the focus of the study, a measure of effectiveness was needed in the design. The reason for this is that increasing the number of side effects attributed to the three drugs had to be offset by how well the agent might treat a headache (aka "effectiveness"). Otherwise, subjects would have balked at selecting a drug with more side effects if it possessed the same potential for relief. Another methodological issue was drug nomenclature. Choosing agents that did not exist in the market place removed the direct effect of personal experience from the decision-making process. Because side effects were presented, first without percentages and then with percentages, instant feedback could be obtained

with minimal influence from external factors. This simultaneity allowed a better determination of patient preference of a drug (or the likelihood of taking a certain medicine) when the provision of frequency of side effects was the only factor.

The results (Table 4.10) show the mean likelihood (scale 1 to 100) of taking Drug X was 50.2 *before* seeing side effect frequencies, then moved to 62.6 (on the same scale) *after* seeing the numerical side effect data. This applied to the *mild* headache scenario. For the *severe* headache scenario, for Drug Z, the mean likelihood value went from 41.3 *before* seeing the percentages to 64.7 *after* seeing the percentages. However, only the change seen for Drug Z was significant. The values for Drug Y showed the opposite trend. This shows that when the headache was severe, the effectiveness of medication becomes more important to participants than side effects. But providing numerical data for side effects also increased participant likelihood of using Drug Z and since some participants switched their choice from Drug Y to Drug Z (in the severe headache group), their mean likelihood of taking the chosen drugs went up for Drug Z and down for Drug Y. This was seen as a reason why there was a decrease in the mean likelihood of choosing Drug Y. It was also possible that the low percentages of alarming side effects (diarrhoea and dry eyes) were a reason to make participants comfortable in switching to a more effective drug.

Given the fact there were two headache scenarios, limited sample size, and a need to consider changes across all three drug choices simultaneously,

more complex analyses were required. Doubly Multivariate ANOVA allowed a comparison of two headache groups (*mild* and *severe*) and side effect frequency data (*with* and *without* percentages) at the same time. When taken as a whole, the results showed a significant increase in the mean likelihood of taking all three agents (Drug X, Y and Z) subsequent to receiving numerical data. This suggests that providing numerical data instilled some sense of relief, to be confident in choosing a medicine that works and not be alarmed by the level of risk (once perspectives on occurrence were added).

When looking at the mean likelihoods (*with* and *without* percentages together) for the three medicines, there was no difference between the mild versus severe headache group. In the *severe* headache scenario, it appeared that respondents were not interested in Drug X because at only 50% effective, it would not be strong enough for severe headaches. People wanted relief, so the choices largely came down to either Drug Y or Z. Their first choice for severe headaches was in fact Drug Y *before* seeing side effect percentages. *After* seeing the numerical data, most changed their selection to Drug Z. Before percentages, what seemed to be the issue between Drug Y and Drug Z was that the new side effects – diarrhoea and dry eyes – may have scared people away from Drug Z. It appeared that after they saw the percentages, the frequency values attached to those problematic side effects led to less alarm, thus allowing a switch to Drug Z with more confidence. This was articulated by the following participants:

When I first looked at it, I was a little concerned about what my activities might be after I took Drug Z and I didn't want to say be caught in a bad position if I did develop diarrhoea ... that I wanted to be somewhere close to a bathroom or something like – that was kind of my main concern with picking Drug Y over Drug Z ... I was concerned about the diarrhoea. But when I see it [Form 7], the diarrhoea is only a 2% chance of developing it, that's a pretty good risk to take and you are not going to get it. [Interview 6]

I thought Drug Y ... I guess it was, yeah, 75% effective. I choose it because there was no mention of diarrhoea and I thought Drug Z with diarrhoea would be, could be anyway, fairly severe. Then looking at the percentages in Form 7, they are quite low anyway, so that's why I moved up to Drug Z to the one actually I prefer ... because the percentages of rash or diarrhoea is less than 1%. It seemed very minimal, so it was worth the risk. [Interview 10]

In the *mild* headache scenario, Drug Y was rarely considered; Drug X was largely perceived as the better option. People were very pragmatic – it was still considered somewhat effective, but if it did not work for them (in real life), they could easily move on to a stronger agent in a day or so. For that level of headache, though, there seemed to be low tolerance for side effects, thus they chose the agent with the least risk. Therefore, numerical frequency data for side effects at this juncture had the following effect – to further justify their choice in selecting Drug X.

The percentage figures utilized for the side effects were very close to those values seen for actual agents such as acetaminophen and ibuprofen. They were selected from product monographs of Advil[®], Motrin[®], Tylenol[®], and Aspirin[®] via Lexi-Comp online and e-CPS (circa 2007). However, participant decisions might have been different if higher percentages were attached to the given side effects. For example, if the possibility of experiencing dizziness was

17 percent instead of seven, participants may not have considered it at all. The choices of side effects selected were also a factor which might have influenced decisions on using a medicine. Therefore, if a participant actually suffered from dry eyes, even a small chance of getting it might be considered an unacceptable risk. By extension, a choice of side effects considered more severe (e.g. kidney problems, troubled breathing) by the public would also create stronger hesitation towards use.

Each person was asked to select which style of presentation (*with* and *without* percentage data) they would prefer. This was in fact done twice. The first time was done at the very beginning of the study. The second time occurred at a later juncture. This approach was taken to allow participant perspectives before exposure to the technical aspects found within this study. Thus, preferences would be seen for so-called naïve participants in the beginning of the survey, then again later after seeing numerical percentage data by the end of the survey. It turned out that most people did not change their answers, but six did move from preferring just a list of side effects to then welcoming inclusion of frequency data. So, for some, exposure to the study process may have increased their interest in numerical data to help with future decision-making involving medicines. Of significant interest, though, is that 19 of 30 wanted this level of information upon arrival at this study. If creators of medicine information leaflets are hesitant to include frequency data – out of fear for scaring off users, creating information overload, or causing leaflet clutter – this may not be the case.

While participants responded to Drug X, Y, and Z on likelihood of use and how it might change *before* and *after* frequency data, participants were also asked to select which of the three they would overall prefer to use (if in real life). This was asked twice as well (*before* and *after* frequency data). The reason for taking this step was because likelihood scales just showed how use might change on an individual drug basis, disregarding the other two agents at that time. Asking for overall preference forced respondents to outright identify which, of the three agents available to them considered concurrently, was most desirable. While there was a tendency to use Drug Y (in the severe headache scenario), amongst the three drugs *before* exposure to frequency data (Table 4.16), seeing the numerical data moved choices more to Drug Z. In the mild headache scenario group, Drug X remained the desirable drug *before* and *after* frequency data were added. This was mainly influenced by illness severity; people opted for more effectiveness at a cost of a greater side effect profile when the headache was severe. In looking at the data in more detail, of the 30 decisions made initially, and then made again *after* the frequency data, 17 did not change their drug choice, while nine did (moving to a more effective agent). What this suggests is that inclusion of the numerical data did not appear to “scare away” potential users. This data also reflects what was seen for the mean likelihood data for the individual drugs. Interviews provided some depth into how subjects reacted to numerical frequency data:

Because I looked at the percentages and some of them are very low for – for some of the side effects more debilitating perhaps – this just lists

the consequences or the possible side effects. And this one [Form 7] shows the approximate percentages which are not that high for the diarrhoea and dry eyes, which are the ones that are added from the others. And it was faster and more effective. [Interview 8]

First I thought I'd take the one most likely to be effective, but then I thought, no, because if there is more chance of side effects, then it wouldn't be helpful to get things done. So my main objective was to do whatever would be most likely to help me feel better, so I could do what I have to do. That's why I went for the one ... that was the least likely to have the side effects. It would depend on how crucial the deadline is because if it was really really crucial, I might have thought of taking the 100% one and risk the side effects. But if it's not so crucial, then I'm not willing to risk those side effects. It turned around here [after numerical data], because I was given the percentages ... I could see they were very low. And the first one ... I wasn't given the percentages to tell me how likely those side effects were. And when I saw they were very low, I thought, well then, I'll take the one that's most likely to be effective because that's very low percent of chance that I'll get those side effects. [Interview 5]

Regarding personal experience with side effects, there was no significant effect on participant mean likelihood of selecting the three drugs when considering previous experience. This could be due to the small number of participants with previous side effects experience. However, six out of 11 participants (who experienced a side effect before) preferred Drug X to use as a painkiller and two decided to take no medicine. This suggests that such experience may have made subjects choose Drug X which had the least number of side effects. Some issues did arise during the interviews to reflect the existence of this factor in the participant's mindset:

And this one here causes nausea, rash, dizziness, heartburn, diarrhoea, dry eyes. I mean, like why would I want to take this one [pointing to drug Z]? I wouldn't because if they have all that ... I can handle a little nausea

... diarrhoea I can't because I suffer from colitis and I get it enough anyway. So I don't want to take a pill that's going to give it to me more. Many years ago, I have taken pills that gave me every one of these ... well, not about heartburn ... everything else – I get dry eyes. Some places neglect to put on dry mouth because that generally happens more than dry eyes. I took the one pill I had ... you couldn't believe the side effects on it – it was for an arthritis pill – Methotrexate – I mean, I'm lucky my hair is even here. My hair would come out, just fell out. And yet, it was a very low percentage of hair loss, but that affected me worse than anything. When my hair started falling out in globs, I went back and I said you know what, I'd rather be in pain than be bald. [Interview 7]

In the above example, suffering from colitis was something that eliminated the thought of using Drug Z for this participant. Experiencing all the side effects listed for these three drugs made her nervous about getting them again. She chose Drug X before and after the provision of numerical data. Of course, not all participants fell into this situation. For most participants in this study, effectiveness and side effects were the concern before receiving the percentages, while effectiveness became more important when the frequency data gave them a sense of relief.

In spite of any significance identified, or even trends in a positive direction favouring the inclusion of numerical frequency data, one should be cautious about concluding that pharmacists should include frequency data with side effect data in practice. More needs to be done for different illnesses and for different drugs, and with more severe types of side effects.

Further support for a cautious approach is the fact that contradictions were seen even within data of the current study on how to approach side effect information at a broader level. Almost 97 percent of participants *strongly agreed*

/ agreed that they would like to receive information about side effects and that they read written information provided by pharmacists. Then, 93.3 percent *strongly agreed / agreed* that pharmacists should give detailed information to all individuals regarding mild and rare side effects. However, 86.6 percent then *strongly agreed / agreed* that “side effect information provided to me puts me in a position to think twice about taking that drug”. This is sending a mixed message on how to approach side effect information. On one hand, it seems that a lot of detail is desired, on the other, it could scare the subject into avoiding the drug. Yet, the concern may be warranted and may even be a motivating factor in making an informed choice. In addition, other aspects of the data are open to speculation on how to convey side effects to patients. For a statement that asked participants – *If pharmacists should put more emphasis on the benefits of medications rather than the side effects* – 14 *agreed*, 14 *disagreed*, and two were uncertain. A few explained why they disagreed with it. How the statement was phrased was a concern for some. Many did not want to see benefits stated to the detriment of the risks. Equal emphasis on benefit-risk was suggested by some. Others felt it was a physician’s obligation to explain any benefits, but the pharmacists’ to cover the side effects. This latter suggestion appears to be what occurs during the current practise of pharmacists, as mentioned by Dyck et al.⁷ In that report, pharmacists spent less time discussing the overall benefits of medications, instead focusing on side effects and safety issues.

Research in the field of risk communication finds that patient education about potential adverse effects may be more likely to improve compliance than result in the refusal to take the drug.^{5,11,16,25-27,32,34,88} Pharmacists generally counsel individuals about side effects using vague verbal explanation and spend less time discussing the benefits of medication.⁷ Physicians, on the other hand, rarely comment on side effects.⁸⁸ When initiating treatment, it has been shown that only one-quarter of physicians discuss potential side effects with patients.¹⁰⁸ Many appear to be concerned that the power of suggestion might lead some patients to experience an increase in side effects if they are fully informed about them.

A few studies have shown that when professionals talk about adverse effects of medications using verbal descriptors (i.e. *common, rare, may occur*), most people overestimate their risk.^{11,12,17,22-27,35, 85,86,103} Berry et al. compared the effect of verbal and numerical descriptors of the medication side effects on the public's risk interpretation.¹⁰³ The verbal descriptors were selected from those recommended for use by the European Union (*very common, common, uncommon, rare, very rare*). Five hundred members of the general population were presented with a fictitious scenario about visiting the doctor and being prescribed medication participated. Information about the medicine's side effects (with probability of getting them) was provided. They found that in all age groups tested, participants given a verbal descriptor estimated side effect risk to be considerably higher than those given a comparable numerical description. The differences in interpretation were reflected in their judgments of side effect

severity, risk to health, and intention to comply. They also confirmed these findings using two different verbal descriptors (*common* and *rare*) and in scenarios which described either relatively severe or relatively mild side effects. Only seven out of 180 participants gave a probability estimate which fell within the EU assigned numerical range. Researchers concluded large scale use of the descriptors could have serious negative consequences for individuals and public health.

An essential component to assist patients in decision-making is the presentation of tailored, numeric outcome information associated with various medical options. Providing the numerical data (in percentage or frequency) for side effects has been suggested by a few studies so that the public could be informed about the possible adverse effects and have a better understanding of their risk when using it.^{11,16,17,21,22,25-26,86,103} A frequency format presents the chance of occurrence as a proportion of discrete cases over those at risk for an occurrence, whereas a probability format typically presents the chance of occurrence as a percentage. Several studies have reported advantages in using frequencies (e.g. 9 in 100) rather than percentages (e.g. 9 percent),^{21,90-93} but Berry et al. have found no difference between people's interpretations of the descriptors using the two different response formats.²⁶

Another study by Schapira et al. noted the advantages of each format – frequency formats provide ease of interpretation and simplicity, while probability or percentage formats provide an association with personal risk estimation and a mathematical quality.¹⁰⁹ Probability judgment problems are thought to be

solved by people using a combination of quantitative reasoning and intuitive estimation. It has been noted that subjects can easily visualize 10 or 100 persons and have an intuitive understanding of the magnitude of risk conveyed with a frequency format using both denominators.¹⁰⁹ Another study by Evans et al. found frequency formats were not generally associated with better performance than probability formats.¹¹⁰ However, the optimal format to assist human judgments is not clear yet.

For these Saskatoon residents, the study design encompassed both frequency and percentage formats concurrently in providing the numerical data. Since a clear picture was not evident *a priori* for the best approach, the decision to use both formats was made. There was also a concern that just one format may not sufficiently present the information required. It is therefore impossible to know which aspect of the two was more pertinent on an individual patient basis. Future researchers will need to continue to compare each format separately, hopefully on a variety of patients, with different numeracy skill levels.

Adding the numerical data meant subjects had to process more information. Regarding the usefulness of increasing the amount of information a person may be accustomed to, Schommer et al. suggest there is a balance between the need for information at a level sufficient for individuals to make decisions and the need not to overload individuals as they cognitively process it.⁸⁰ In the current study, even presenting the two aspects of benefit and harm in

numerical format was found by some to be a lot to process and read. The following thought from an interview reflects this issue:

I had originally said that I thought the percentages would be better option [in Form 8]. What I saw ... when I read it ... it somehow made the information more and made me less likely to read it, because it was more. [Interview 9]

This point to an obvious notion that adding information could be a burden for a group of people who are not interested in receiving it.

There is debate on whether to present numerical data in a positively- or negatively-slanted format. Little empirically derived guidance exists with regard to what format to use in presenting numeric risk information.^{111,112} What is known is that bias can occur when risk is presented with a positive versus negative frame⁶⁸ or with gain versus loss.^{113,114} A second key aspect under study for the Saskatoon group was whether a negative- or positive-slant to side effect information impacts on potential medicine use. Participants were asked to show their likelihood of taking two medications for headache on a scale of 1 (*very unlikely*) to 100 (*very likely*). Both medications carried one side effect (heartburn). The information provided for Drug P (which stood for positively-slanted wording) stated that 90 out of 100 *will not* experience heartburn, while Drug N (negatively-slanted wording) stated 10 out of 100 *will* experience heartburn. Participants showed a higher mean likelihood of taking a medicine (Drug P) when side effects were framed positively. It must be noted that the provision of positively- and negatively-slanted information, provided back to

back, allowed patients to consider both angles simultaneously. In real-world setting, patients would not be given both. When asked to select an overall preferred agent, nine people considered Drug P, while no one chose Drug N. Eighteen people preferred Drug N and P equally. The latter group reflected the correct interpretation of the information – in spite of the negatively- or positively-slanted format, the potential to get the side effect was equivalent. However, those 18 participants – regardless of correctly preferring the two agents equally – did not choose relatively similar locations on the likelihood scales. Even with this group, then, the results suggest that not all participants had an intuitive understanding of the magnitude of risk conveyed, even comparing two formats back to back. Of the people who preferred Drug P, either via differentiation on the scale or through outright drug selection, some of the thinking for their decision was as follows:

I think N would give you more of a risk of having heartburn than P.
[Interview 4]

Well I suffer from heartburn, so I thought if this one [Drug P]. It says ... will not experience heartburn and this one [Drug N] ... will experience heartburn. So that's why I went with this one [Drug P] instead of that one, because I hate heartburn. [Interview 2]

Only one subject showed higher likelihood of taking Drug N compared to Drug P. This is how he explained his thinking:

Oh, because when given side effects, I preferred the way it was expressed – with 10% people would be likely to experience this side effect rather than the reverse. I think which could be a little misleading for some people, for some patients, that 90 out of 100 *will not* experience

this. See the *not* bothers me – I can see them easily being confused, thinking that 90 out of 100 will. [Interview 22]

There is some cause for concern here. About half of the subjects incorrectly felt Drug P was less likely to cause heartburn. Numeracy skill (or lack thereof) is likely an influence here. Information in Table 4.9 draws attention to this within our sample, where only 13 of 30 were correct in their interpretation of the situation provided within a numeracy test. For others, it appeared that when reading the material along a straight line of text, when coming to the word “will” (as in, *will* cause heartburn), this seemed to draw most of their attention and in so doing, perhaps led to ignoring any numbers that followed. Finally, the power implied by the words *will* and *will not* could be factors, as suggested in the following interview:

Yeah, I started out with – 90% will not experience heartburn. I think it’s a psychological difference – I’m assuming I would be among the 90, I think, that would not experience heartburn, so I feel comfortable with that. Drug N, on the other hand, says 10 out of 100 will experience heartburn which seems like a very positive ... like it’s very ... if the word was *might* experience heartburn, I would feel more comfortable with that drug. But it says 10 out of 100 will experience heartburn, so that moves it down in my preference list. See this one, on the flip side, will not experience ... it doesn’t say that the other ten, they may be in that group as well. Now, if it went on to say – will not experience heartburn, however 10 *will*, then I would put them on an equal playing. [Interview 10]

Regarding a positively- or negatively-slanted format, other issues arose during the interviews. A group of participants did realize the risk of getting

heartburn would be equal in both drugs, but felt the manner of phrasing might be potentially confusing to some:

I preferred that one than against Drug P because from all the experience I ever had, very seldom do I ever remember a doctor telling me that 90% of the people will not get these symptoms or side effects from this drug. Generally it's not *very many* or 10%, let's say. It's not something I think you hear. I think you're more often to get the 10% thrown at you rather the 90 who will not. [Interview 11]

I thought that the way information is usually presented is in the possibility of getting it. So I just felt that there was a chance to misread the second one and think that 90% will. So I thought that just to stay consistent, that I actually would prefer this one. So even though I like this better, I liked P better. I felt that just kind of my sense of consistency in the way information is delivered was important to me, so if some people tell me *will* and some people tell me *will not*, that just kind of, and maybe because I read quickly ... not necessarily every word on the piece of medication. So I think I just want consistency in how information is delivered. So even though I prefer this better, you know how we all like to phrase things positively, right? But I did feel that this one [90 will not get] is most likely to be misunderstood. [Interview 9]

Interestingly, participants of this study, of whom more than two-thirds held a diploma or degree, were influenced by the positive versus negative framing of side effects. Numeracy skills were not the only factor to determine participant mindset when deciding which drug they would like better. The preference for the kind of format, the interpretation of each format, and inattention to key words, were some of the factors cited by participants to explain or justify their decision. The findings support the *preference reversals* theory, that people switch preferences for one outcome over another based solely on how outcomes are presented, even though their losses and gains are

the same. It is still unknown how and why given elements of risk format influence patient risk perceptions and reasoning.

Looking at other literature on the framing effect, one review of 40 studies examined the effect of framing on treatment, immunization, or health behaviour scenarios.⁶⁰ Active treatments like surgery was preferred to other treatments when treatment efficacy was presented in a positive frame (survival) rather than a negative frame (mortality). Framing affects were less obvious for immunization and health behaviour scenarios. However, those with little interest in the behaviour at baseline were influenced by framing, particularly when information was presented as gains. Framing effects varied with the type of scenario, responder characteristics, scenario manipulations, and study quality. This is in line with Study 2 findings and results of the numeracy test (see Table 4.9). Using an OTC drug for a headache is of far less importance compared to undergoing surgery, but the results showed participant responses were affected by positive or negative framing.

Moxey concluded that when describing treatment effects to patients, expressing the information in more than one way may present a balanced view to patients and enable them to make informed decisions.⁶⁰ When designing side effect sections of medication leaflets, positive framing could be used in styles that draw patient attention to the numerical data. Presenting numerical data positively may also need the right emphases on numbers and words (e.g. 99 out of 100 did *not*) to make sure patients see the key content.

5.1. Limitations

Volunteering for the study may potentially bias the sample. Volunteers can have certain characteristics that differentiate them from the population of patients as a whole.

The high literacy level of our participants – a third had an education level higher than a bachelor's degree – may be another limitation in generalizing our sample to the population of people 50 years and older. However, a comparison of the data from the 2006 Saskatoon Census for adults (35-64 years) showed that the education level of the study sample was only seven percent higher than the general population.¹⁰⁷ There was no data specific to the 50-plus population.

The SF-8 health survey was undertaken to determine whether the subjects were sicker or healthier than the average person of similar ages in society. However, there was no data available for overall health status of Saskatoon adults for comparison. In other reports, most SF-8 data allowed for comparing data before and after a suggested treatment in order to control for quality of life.^{99,115} The overall mean score for all 30 participants was 32.4 ± 5.7 , with a score that could range from eight to 42 (42 would represent major physical and mental concern). This result shows that there were some concerns for participant health. This issue was seen during the interview as well. For a group of participants who were using many medications already, adding another OTC drug raised anxiety and probably affected their decision to use a medicine for headaches.

Use of scales to quantify the behaviour of participants is another limitation of the study.

The choice of side effects (diarrhoea, dry eyes, etc) did have an effect on participant likelihood to take a medicine. There may have been different results for this study if the chosen side effects were milder or more severe. While the percentages chosen were reflective of rates seen for actual agents, different reactions by participants could have occurred if frequencies were higher than 10 percent, for example (a level that could be defined as *very common*).

Including both the percentages and frequency data was a limitation in some respects, in that it did not allow for an assessment of which of the two formats was most influential to any person. For some, the two could have been helpful. For others, it could have been perceived as an extra bit of material to process. Future research may be able to assess the effect of each separately on people's decision to use a medicine.

CHAPTER 6 CONCLUSION AND RECOMMENDATIONS

People are being encouraged to monitor their own illnesses, undertake lifestyle changes to prevent diseases and maintain their health. They are also being encouraged to self-treat minor illnesses such as colds, headaches, and heartburn. Most patients want to be involved in decisions relating to their health. Decisions such as whether to undertake a course of treatment, and which treatment to choose, can only be truly shared if the patient has a similar understanding of the possible advantages and disadvantages of each option as the clinician. Accurate and effective risk communication is therefore of great importance in establishing trust, reaching shared agreements and developing concordant clinical management plans.

Regarding fictitious OTC agents and hypothetical illness scenarios, participant preference revealed medication information leaflets may benefit by including frequency data for side effects. It appeared that seeing the frequency data did lessen fears or concerns for that chosen agent. Adding it to written information leaflets or to verbal content could decrease fears and improve patient intention to take their medicine. But in spite of this evidence, one should be wary about concluding that such leaflets (or pharmacists) should include frequency data with side effect information in practice. More research needs to be done on this issue with larger samples, across all adult age groups, and for a variety of acute and chronic illnesses.

When numerical data for side effects is phrased positively, participants showed higher likelihood of taking a medicine. Giving estimations for the side effects listed on medication leaflets could be helpful for patients with greater informational needs, and framing it in a positive format may impact on use. However, this approach may conflict with the tenets of informed choice and could reflect a paternalistic view. A minimum condition for the achievement of informed choice is for the care giver to inform the patient of all the necessary information that is relevant to making the decision, in a clear and concise manner. Further research in the clinical setting is needed to provide justification for the format used when presenting risk information to patients. Studies also should focus on optimizing these interventions, identifying tools that a patient is most likely to benefit from, and improving cost-effectiveness. This insight could then be the platform for informed discussion about the significance and burden of risks and the implications for the individual or family concerned. It may make the explanation of diseases and their treatment easier. Instruction in the efficient communication of statistical information should be part (or continue to be part) of health care curricula and continuing education for health care providers.

LIST OF REFERENCES

References

1. Cox K, Stevenson F, Britten N, et al. A systematic review of communication between patients and health care professionals about medicine-taking and prescribing. London (UK): Medicines partnership; 2004.
2. Raynor DK, Blenkinsopp A, Knapp P, et al. A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines. *Health Technol Assess* 2007; 11: iii.
3. Ziegler DK, Moiser MC, Buenaver M, et al. How much information about adverse effects of medication do patients want from physicians? *Arch Intern Med* 2001; 161: 706–13.
4. Labor S, Schommer J, Pathak D. Information overload with written prescription drug information. *Drug Info J* 1995; 29: 1317–28.
5. Garrud P, Wood M, Stainsby L. Impact of risk information in patient education leaflet. *Patient Educ Counsel* 2001; 43: 301–4.
6. Gibbs S, Waters WE, George CF. Prescription information leaflets: A national survey. *J Roy Soc Med* 1990; 83: 292–7.
7. Dyck A, Deschamps M, Taylor J. Pharmacists' discussions of medication side effects: A descriptive study. *Patient Educ Counsel* 2005; 56: 21–7.
8. Chaplin R. Informing patients about tardive dyskinesia: Controlled trial of patient education. *Br J Psychiatr* 1998; 172: 78–81.
9. Berry DC, Knapp P, Raynor T. Expressing medicine side effects: Assessing the effectiveness of absolute risk, relative risk, and number needed to harm, and the provision of baseline risk information. *Patient Educ Counsel* 2006; 63: 89–96.
10. Horne R and Weinman J. Patients' beliefs about prescribed medicines and their role in adherence to treatment in chronic physical illness. *J Psychosomatic Res* 1999; 47: 555–67.

11. Knapp P, Raynor DK, Berry DC. Comparison of two methods of presenting risk information to patients about the side effects of medicines. *Qual Saf Health Care* 2004; 13: 176–80.
12. Berry DC. Informing people about the risks and benefits of medicines: Implications for the safe and effective use of medicinal products. *Curr Drug Saf* 2006; 1: 121–6.
13. Franic DM and Pathak DS. Communicating the frequency of adverse drug reactions to female patients. *Drug Info J* 2000; 34: 251–72.
14. Berry DC, Raynor DK, Knapp P, et al. Patients understanding of risk associated with medication use: impact of European Commission guidelines and other risk scales. *Drug Saf* 2003; 26: 1–11.
15. Bergenstrom A and Sherr L. The effect of order of presentation of verbal probability expressions on numerical estimates in a medical context. *Psychol Health Med* 2003; 8: 391–8.
16. Berry DC, Michas IC, De Rosis F. Evaluating explanations about drug prescriptions: Effects of varying the nature of information about side effects and its relative position in explanations. *Psychol Health* 1998; 13: 767–84.
17. Berry DC, Knapp P, Raynor DK. Provision of information about drug side effects to patients. *Lancet* 2002; 359: 853–4.
18. Timmermans DRM, Ockhuysen-Vermeij CF, Henneman L. Presenting health risk information in different formats: The effect on participants' cognitive and emotional evaluation and decisions. *Patient Educ Counsel* 2008; 73: 443–7.
19. Hawley ST, Zikmund-Fisher B, Ubel P, et al. The impact of the format of graphical presentation on health-related knowledge and treatment choices. *Patient Educ Counsel* 2008; 73: 448–55.
20. Schwartz LM, Woloshin S, Welch HG. Can patients interpret health information? An assessment of the medical data interpretation test. *Med Decis Making* 2005; 25: 290–300.
21. Gigerenzer G and Edwards A. Simple tools for understanding risks: From innumeracy to insight. *BMJ* 2003; 327: 741–4.
22. Young SD and Oppenheimer DM. Different methods of presenting risk information and their influence on medication compliance intentions: Results of three studies. *J Clinthera* 2006; 28: 129–39.

23. Rantucci MJ. Pharmacists talking with patients: A guide to patient counselling. Baltimore (MD): Williams and Wilkins; 2006.
24. Davis TC. Literacy and misunderstanding prescription drug labels. *Ann Intern Med* 2006; 145: 887–95.
25. Berry DC, Michas IC, Gillie T, et al. What do patients want to know about their medicines and what do doctors want to tell them? A comparative study. *Psychol Health* 1997; 12: 467–80.
26. Berry DC, Knapp P, Raynor DK. Is 15 percent very common? Informing people about the risks of medication side effect. *Int J Pharm Pract* 2002; 10: 144–51.
27. Berry DC, Michas IC, Bersellini E. Communicating information about medication side effects: Effects on satisfaction, perceived risk to health and intention to comply. *Psychol Health* 2002; 17: 247–67.
28. Airaksinen M. Do the public and pharmacists share opinions about drug information? *Int Pharm J* 1994; 8: 168–71.
29. Howard J, Wildman K, Blain J, et al. The importance of drug information from a patient perspective. *J Soc Admin Pharm* 1999; 16: 115–26.
30. Nair K, Dolovich L, Cassels A, et al. What patients want to know about their medications? *Can Fam Physician* 2002; 48: 104–10.
31. Keown C, Slovic P, Lichtenstein S. Attitudes of physicians, pharmacists, and laypersons toward seriousness and need for disclosure of prescription drug side effects. *Health Psychol* 1984; 3: 1–11.
32. Ley P. *Communicating with patients: Improving communication, satisfaction and compliance*. London (UK): Chapman and Hall; 1988.
33. Åström K, Carlsson J, Bates I, et al. Desire for information about drugs: A multi-method study in general medical inpatients. *Pharm World Sci* 2000; 22: 159–64.
34. Quaid KA, Faden RR, Vining EP, et al. Informed consent for a prescription drug: Impact of disclosed information on patient understanding and medical outcomes. *Patient Educ Counsel* 1990; 15: 249–59.
35. Berry DC, Raynor T, Knapp P, et al. Over the counter medicines and the need for immediate action: A further evaluation of European Commission recommended wordings for communicating risk. *Patient Educ Counsel* 2004; 53: 129–34.

36. Edwards A and Elwyn GJ. Explaining risks: Turning numerical data into meaningful pictures. *BMJ* 2002; 324: 827–30.
37. Taylor J, Lo Y, Dobson R, et al. Consumer expectations of nonprescription medications according to location of sale. *J Am Pharm Assoc* 2007; 47: 729–36.
38. Bissell P, Ward PR, Noyce PR. The dependent consumer: Reflection on accounts of the risks of non-prescription medicines. *Health* 2001; 5: 5–30.
39. Ornbjerg LM, Andersen HB, Kryger P, et al. What do patients in rheumatologic care know about the risks of NSAIDs? *J Clin Rheumatol* 2008; 14: 69–73.
40. Bebbington PE. The contend and context of compliance. *Int Clin Psychopharmacol* 1995; 9: 41–50. Available at: <http://www.minddisorders.com>. Accessed May 2007.
41. Sabate E. Adherence to long-term therapies: Evidence for action. Geneva (Switzerland): World Health Organisation; 2003.
42. Shaw JM. Information for patients on medicines: Should be much more accessible and patient centred. *BMJ* 2005; 331: 1034–5.
43. Horne R, Weinman J, Hankins M. The beliefs about medicines questionnaire: The development and evaluation of a new method for assessing the cognitive representation of medication. *Psychol Health* 1999; 14: 1–24.
44. Anderson L. Adherence/non-Adherence to medical advice and treatment. London (UK): Institute of Psychiatry, King's College. Available at: <http://www.iop.kcl.ac.uk>. Accessed August 2006.
45. Cost of non-compliances. Selective Laser Trabeculoplasty (SLT) website. Available at: <http://www.slt-therapy.net>. Accessed August 2006.
46. Guthrie RM. The effects of postal and telephone reminders on compliance with pravastatin therapy in a national registry: Results of the first myocardial infarction risk reduction program. *Clin Therapeut* 2001; 23: 970–80.
47. Slovic P, Kraus N, Lappe H, et al. Risk perception of prescription drugs: Report on a survey in Canada. *Pharm Pract* 1992; 8: 30–7.
48. Russell C. Implications for improving risk communication through various channels: A discussion. *J Natl Canc Inst Monogr* 1999; 25: 177–81.

49. Abrahams D. Brand risk: Adding Risk Literacy to Brand Management. Aldershot, Hampshire (UK): Gower Publishing Ltd; 2008.
50. Learning a Living: First Results of the Adult Literacy and Life Skills Survey. Statistics Canada Catalogue number 89-603-XWE. Ottawa: Statistics Canada and the Organisation for Economic Co-operation and Development; 2005. Available at: <http://www.statcan.ca>.
51. Schiffman LG and Kanuk LL. Consumer decision-making. In: Schiffman LG and Kanuk LL (Eds). Consumer behaviour. Englewood Cliffs (NJ): Prentice Hall; 1994.
52. Robinson- Riegler G and Robinson- Riegler B. Reasoning, judgment and decision-making. In: Cognitive psychology: Applying the science of the mind. Boston (MA): Allyn and Bacon; 2004.
53. Shafir E and Tversky A. Thinking through uncertainty: Non-consequential reasoning and choice. *Cognit Psychol* 1992; 24: 449–74.
54. Kahneman D and Tversky A. Prospect theory: An analysis of decision under risk. *Econometrica* 1979; 47: 263–91.
55. Redelmeier DA, Rozin P, Kahneman D. Understanding patient's decisions: Cognitive and emotional perspectives. *JAMA* 1993; 270: 72–6.
56. Yamagishi K. When a 12.86 percent mortality is more dangerous than 24.14 percent: Implications for risk communication. *Appl Cognit Psychol* 1997; 11: 495–506.
57. Yamagishi K. Effects of valence and framing in decision-making: Assessing decision makers' interpretations of choice. In: Shohov SP (Ed). *Advances in Psychology Research*. Hauppauge (NY): Nova Science Publishers 2004; 30: 21–33.
58. Hertwig R, Barron G; Weber EU, et al. Decisions from experience and the effect of rare events in risky choice. *Psychol Sci* 2004; 15: 534–9.
59. Woolf SH. Promoting informed choice: Transforming health care to dispense knowledge for decision-making. *Ann Intern Med* 2005; 143: 293–300.
60. Moxey A. Describing treatment effects to patients: How they are expressed makes a difference. *J Gen Intern Med* 2003; 18: 948–59.
61. Furberg BD and Furberg CD. *Evaluating clinical research: All that glitters is not gold*. Secaucus (NJ): Springer science and business media; 2007.

62. Woloshin S and Schwartz LM. How can we help people make sense of medical data? *Effect Clin Pract* 1999; 2: 176–83.
63. Cuervo LG and Clarke M. Balancing benefits and harms in health care. *BMJ* 2003; 327: 65–6.
64. Davis JJ. Riskier than we think? The relationship between risk statement completeness and perceptions of direct to consumer advertised prescription drugs. *J Health Comm* 2000; 5: 349–69.
65. Smith DL. Consumer trust takes more than fair balance. *Pharmaceut Exec* 1999; 19: S18–9.
66. The staff of the bureau of consumer protection, the bureau of economics, and the office of policy planning of the federal trade commission. Before the department of health and human services food and drug administration: In the matter of request for comments on consumer-directed promotion; 2003. Available at: <http://www.ftc.gov>.
67. Paling J. Bad points about current practices. In: Paling J. (Ed) *Helping patients understand risks: Seven simple strategies for successful communication*. Gainesville (FL): The risk communication institute; 2006.
68. Gurm HS and Litaker DG. Framing procedural risks to patients: Is 99% safe the same as a risk of 1 in 100? *Acad Med* 2000; 75: 840–2.
69. Edwards A, Elwyn G, Covey J, et al. Presenting risk information a review of the effects of framing and other manipulations on patient outcomes. *J Health Comm* 2001; 6: 61–82.
70. Frymoyer JW and Frymoyer NP. Physician-patient communication: A lost art? *J Am Acad Orthop Surg* 2002; 10: 95–105.
71. Jungermann H, Schütz H, Thüring M. Mental models in risk assessment: Informing people about drugs. *Risk Anal* 1988; 8: 147–55.
72. Barnett CW, Nykamp D, Ellington AM. Patient-guided counselling in the community pharmacy setting. *J Am Pharm Assoc* 2000; 40: 765–72.
73. Worley M and Schommer JC. Pharmacist-patient relationships: Factors influencing quality and commitment. *J Soc Admin Pharm* 1999; 16: 157–73.
74. Larson RA. Patients' willingness to pay for pharmaceutical care. *J Am Pharm Assoc* 2000; 40: 618–24.

75. Schommer JC. Pharmacists' new communicative role: Explaining illness and medicine to patients. In: Whaley B (Ed). Explaining illness: Research, theory and strategies. Mahwah (NJ): Lawrence Erlbaum Associates; 2000.
76. Schommer JC. Effect of interrole congruence on pharmacist-patient communication. *Health Comm* 1994; 6: 297–309.
77. Wolf MS, Davis TC, Tilson HH, et al. Misunderstanding of prescription drug warning labels among patients with low literacy. *Am J Health-Syst Pharm* 2006; 63: 1048–55.
78. Berger BA. Communication skills for pharmacists: Building relationship, improving patient care. Washington (DC): American Pharmaceutical Association, Jobson Publishing; 2002.
79. Deschamps M, Dyck A, Taylor J. What are we saying? Content and organization of patient counselling by community pharmacists. *Can Pharmaceut J* 2003; 136: 42–7.
80. Schommer JC, Doucette WR, Worley MM. Processing prescription drug information under different conditions of presentation. *Patient Educ Counsel* 2001; 43: 49–59.
81. Hahn M, Lawson R, Young GL. The effects of time pressure and information load on decision quality. *Psychol Market* 1992; 9: 365–78.
82. Gramling R, Irvin JE, Nash J, et al. Numeracy and medicine: Key family physician attitudes about communicating probability with patients. *J Am Board Fam Pract* 2004; 17: 473.
83. Clark C. Improvements needed in risk communication. *Hospital Pharmacist* 2004; 11: 426.
84. Wolf M, Davis TC, Shrank WH, et al. A critical review of FDA-approved medication guides. *Patient Educ Counsel* 2006; 62: 316–22.
85. Raynor DK, Silcock J, Knapp P, et al. How do patients use medicine information leaflets in the UK? *Int J Pharm Pract* 2007; 15: 209–18.
86. Knapp P, Raynor DK, Carrigan N. Do patient information leaflets meet patients' needs for describing the likelihood of side effects? *Int J Pharm Pract* 2007; (Suppl 1): A26–7.
87. Berry DC, Gillie T, Banbury S. What do patients want to know: An empirical approach to explanation generation and validation? *Expet Syst Appl* 1995; 8: 419–29.

88. Smith S and Henderson M. What you don't know won't hurt you: Information given to patients about side effects of antipsychotic drugs. *Psychiatr Bull* 2000; 24: 172–4.
89. Howland JS, Baker MG, Poe T. Does patient education cause side effects? A controlled trial. *J Fam Pract* 1990; 3: 62–4.
90. Butterworth B. Statistics: What seems natural? *Science* 2001; 292: 853–5.
91. Eddy DM. Probabilistic reasoning in clinical medicine: Problems and opportunities. In: Kahneman D, Slovic P, Tversky A (Eds). *Judgment under uncertainty: Heuristic and biases*. Cambridge (UK): Cambridge University Press 1982; 249–67.
92. Hoffrage U, Lindsey S, Hertwig, R, et al. Communicating statistical information. *Science* 2000; 290: 2261–2.
93. Hanoch Y. Natural frequencies and the representation of risk. *Int J Qual Health Care* 2002; 14: 337.
94. Gigerenzer G and Hoffrage U. Overcoming difficulties in Bayesian reasoning: A Reply to Lewis and Keren (1999) and Mellers and McGraw (1999). *Psychol Rev* 1999; 106: 425.
95. Bersellini E and Berry DC. The benefit of providing benefit information: Examining the effectiveness of provision of simple benefit statements on people's judgments about a medicine. *Psychol Health* 2007; 22: 61–82.
96. Edwards A. Flexible rather than standardised approaches to communicating risks in health care. *Qual Saf Health Care* 2004; 13: 169–70.
97. Vander Stichele RH, Van Dierendonck A, De Vooght G, et al. Impact of benefit message in patient package inserts on subjective drug perception. *Drug Info J* 2002; 36: 201–8.
98. Davis TC, Long SW, Jackson RH, et al. Rapid estimate of adult literacy in medicine: A shortened screening instrument. *Fam Med* 1993; 25: 391–5.
99. Turner-Bowker DM, Bayliss MS, Ware JE, et al. Usefulness of the SF-8 health survey for comparing the impact of migraine and conditions. *Quality of Life Research* 2003; 12: 1003–12.
100. Mitchell S. Headaches, Colds and Backache -most common health complaints: Nielsen Global Survey. Available at: <http://nz.acnielsen.com>. Accessed August 2007.

101. Natter H and Berry DC. Effects of active information processing on the understanding of risk information. *Appl Cognit Psychol* 2004; 19: 123–35.
102. Berry DC. Interpreting information about medication side effects: Differences in risk perception and intention to comply when medicines are prescribed for adults or young children. *Psychol Health Med* 2004; 9: 227–34.
103. Berry DC, Raynor D K, Knapp P. Communicating risk of medication side effects: An empirical evaluation of EU recommended terminology. *Psychol Health Med* 2003; 8: 251–63.
104. Drugs for Migraine and Headache Pain. Migraines and Headaches Health Center, WebMD Medical Reference provided in collaboration with the Cleveland Clinic Neuroscience Center; 2000–2004. Atlanta (GA): WebMD. Available at: <http://www.webmd.com>. Accessed November 2006.
105. Headache and Heartburn: What is the Relationship? Available at: <http://www.diet-result.com>. Accessed November 2007.
106. Vincent WJ. Multiple analysis of variance (Repeated measure designs). In: Vincent WJ. (Ed) *Statistics in Kinesiology*. Champaign: Human Kinetics; 2005.
107. Community Profiles for "Saskatoon". Statistic Canada; 2006. Available at: <http://www12.statcan.ca/census-recensement/2006>. Accessed August 2008.
108. Lamb GC, Green SS, Heron J. Can physicians warn patients of potential side effects without fear of causing those side effects? *Arch Intern Med* 1994; 154: 2753–6.
109. Schapira MM, Nattinger AB, McHorney CA. Frequency or probability? A qualitative study of risk communication formats used in health care. *Med Decis Making* 2001; 21: 459–67.
110. Evans JB, Handley SJ, Perham N, et al. Frequency versus probability formats in statistical word problems. *Cognition* 2000; 77: 197–213.
111. Fischhoff B, Bostrom A, Quadrel MJ. Risk perception and communication. *Annu Rev Public Health* 1993; 14: 183–203.
112. Weinstein ND. What does it mean to understand risk? Evaluating risk comprehension. *JNCI Monogr* 1999; 25: 15–20.

113. Kahneman D and Tversky A. Choices, values, and frames. *Am Psychol* 1984; 39: 341–50.
114. Banks SM, Salovey P, Greener S, et al. The effects of message framing on mammography utilization. *Health Psychol* 1995; 14: 178–84.
115. Lefante JJ, Harmon GN, Ashby KM, et al. Use of the SF-8 to assess health-related quality of life for a chronically ill, low-income population participating in the Central Louisiana Medication Access Program (CMAP). *Qual Life Res* 2005; 14: 665–73.

APPENDICES

APPENDIX A
IN-PHARMACY RECRUITMENT POSTER (11" X 17")

Talking About the Side Effects of Medicines



We could use your help

The Pharmacy program at University of Saskatchewan is looking for ways to improve how pharmacists tell patients about side effects. We have asked this pharmacy to help identify people who might want to help us try to do this.

What is required of you?

Not a lot! About one hour of your time. You fill out a few forms. We then would like to hear about your preferences regarding information styles.



It's easy; we just need your opinions!

No qualifications are really needed, other than being 50 or older and the ability to read and write (and living in Saskatoon).

Your feedback is valuable, but so is your time...
That's why we want to provide **\$30** for your time.

Interested? You can contact:



**UNIVERSITY OF
SASKATCHEWAN**

College of Pharmacy and Nutrition

Mahsa Hosseini, B.Ed
966-6346

APPENDIX B
LETTER TO PHARMACISTS REQUESTING THEIR ASSISTANCE IN
PATIENT ACCRUAL

[Pharmacist Name]
[Pharmacy Name & address]
Saskatoon, SK [postal code]

September, 2007

RE: Recruiting patient volunteers from your pharmacy for a study on side effect information

Dear []:

The *EduLab* Program at the College of Pharmacy and Nutrition was created to examine how pharmacists interact with patients concerning health-related matters (focusing on drug therapy). Since, it has been involved with:

- ✓ the Pharmacist Intervention in Risk Reduction (PIRR) study, where almost 200 high-risk cardiac patients have been helped by community pharmacists;
- ✓ a project in one Saskatoon pharmacy to determine whether 'coaching' can entice the public to ask more questions about drug therapy;
- ✓ a study with local volunteer pharmacists to examine the order in which community pharmacists present information to patients;
- ✓ a study with local volunteer pharmacists to examine whether visuals during patient counselling leads to more satisfaction when compared to our typical drug information leaflets.

For our next project, we would like to know more about patient preferences for presenting side effect information numerically (e.g. "*There is a 1% chance of getting a rash with this drug ...*") versus using a verbal descriptor (e.g. "*There is a small chance of getting a rash with this drug...*"). We also plan to look into preferences for a positive format (e.g. "*Most won't get this side effect ...*") versus a negative format (e.g. "*A few will get this side effect ...*") on how information might be conveyed.

Why have we contacted you?

We could use some help in finding volunteers for this project. We are looking for people aged 50 years and over who are reasonably fluent in English. For this, 30 pharmacies have been contacted in the hopes of finding 40 volunteers. You

would be asked to consider placing an 8 1/2 inch by 11 inch laminated sign (for two weeks) near your dispensary to advertise the project. We also have prescription bag stuffers for those you feel might be interested.

If you can help out, thank you. Or, if you want more information, please contact Dr. Jeff Taylor at 966-5328 or Mahsa Seyed-Hosseini at 477-2792.

Sincerely,

Jeff Taylor, *EduLab* Director
student

Mahsa Seyed-Hosseini, Graduate

APPENDIX C
CONSENT FORM

Presenting Side Effect Information and the Influence on Patient Medicine-Taking Behaviour

Thank you for considering to be a participant in this study. The purpose is to explore different ways to discuss medicine side effects with the people who take them.

In order to protect the interests of the participants, what will be required of you is as follows:

- 1.** You will be asked some personal questions, respond to several situations involving the use of medicines and the side effects they may cause, then participate in an interview about your choices. The personal information and the situations involving medicines are contained in a booklet. It will take about 35 minutes to complete this section. For questions about medicines and side effects, there are no right or wrong answers; we just want your opinions. The researcher during one single interview will discuss your thoughts about side effect presentations. This conversation will be tape-recorded and you can request to have the recorder turned off at any time. The reasons for your opinions, and the barriers to understanding this information, will be considered important to us.
- 2.** The background information, the scenarios, and interview will last for about 1 to 1 ½ hour. You can withdraw at any time during the study for any reason and without consequence. If you withdraw, the data collected from your participation will not be published in our study results.
- 3.** The interview will be tape-recorded, then transcribed and analyzed to uncover any themes in what was discussed. You will be given a version of the transcripts in which false starts, repetitions, and utterances (um, eh etc) have been removed to make it more readable. You can add, delete or change information to reflect what you want to say. You will be asked to sign a *Letter of Consent for Release of Transcripts* following your satisfactory review of the transcript. You will be able to receive a summary copy of the study following its completion.

4. The data collected from you will be kept in a secure place and will be held at the University of Saskatchewan with the researcher's supervisor, Dr. Jeff Taylor, for five years according to the University of Saskatchewan guidelines.

5. The results of the study will be used for a master's thesis. The confidentiality and anonymity of the participants will be protected through the use of pseudonyms.

6. Participants of this study will receive a stipend of \$30 as our thanks for spending part of your day with us. The benefits to us as researchers will be greater understanding of how patients prefer to learn about medication side effects.

7. Your participation in this study is completely voluntary. You have the right to refuse to participate in the study and/or withdraw from study at any time, for any reason. You will receive \$30 if you even decide to leave before the study is finished.

If you have any questions about your participation or your rights as a participant in this study, you may contact the Ethics Office at the University of Saskatchewan (966-2084) or you can contact me, Mahsa Seyed-Hosseini, at 966-6346, or my supervisor, Dr. Jeff Taylor, College of Pharmacy and Nutrition, 966-5328.

I, _____, understand that this research project has been approved by the University of Saskatchewan Behavioural Research Ethics Board on August 28, 2007 and I agree to participate. I am aware of the nature of the study and understand what is expected of me and I also understand that I am free to withdraw at any time throughout the study. A copy of this form has been given to me for my records and at the end of the study I will receive a copy of the report.

Participant signature _____ Date _____

Mahsa- Seyed-Hosseini

APPENDIX D
LETTER OF CONSENT FOR RELEASE OF TRANSCRIPTS

I appreciate your participation in the research study: *Presenting Side Effect Information and the Influence on Patient Medicine-Taking Behaviour*.

Since the interview was tape-recorded, we are obliged to let you see the transcript. This requires sending you a copy of our conversation by mail. What will be required of you would be as follows:

Please read and re-check the transcripts for accuracy of information. You may add or clarify the transcripts to say what you intended to mean or include additional comments that will be your words. You may also delete any information that you may not want to be quoted in the study.

However, if you DON'T feel the need for a copy of the transcript of your taped interview, please check this box

The interpretation of this study will be used in a master's thesis. Except for the researchers in the study, your participation has remained confidential. The result of this study will be used to write an article for a pharmaceutical journal. Individual patient names will NOT be used; only anonymous pooled data is used for this purpose.

In accordance with the University of Saskatchewan Behavioural Research Ethics Board, the tape recordings, writing samples, and transcriptions made during the study will be kept with the supervisor in a locked file until the study is finished. After completion of the study, the tapes and other data will be kept for five years at the University of Saskatchewan and then destroyed.

Please check this box if you would like a copy of the study summary when available:

to be sent to: _____

I, _____ understand the guidelines above and agree to release the revised transcripts to the researcher. A copy of the transcript release form is provided for your records.

Participant's Signature _____ Date _____

Researcher's Signature _____

Mahsa Seyed-Hosseini

APPENDIX E
FORM 1

ID#: _____

Date: _____

Please check ✓one box of the following answers which best describes your situation.

1. What is your gender? Male Female

2. What year were you born? *(Please write the year in the blank area)*

19____

3. What is the highest level of education that you completed?

Less than grade 12

High school diploma or equivalent

Some university or technical school education

Technical school diploma or a university Bachelor's degree

Other _____

4. Are you currently taking any prescribed medications?

Yes No

5. Are you currently taking any medications available without a prescription, also called over-the-counter medicines (e.g. pain killers, heartburn products, herbal remedies)? Yes No

6. Given any past history with prescription medicine use, how would you describe your knowledge of prescription medicines?

- Very knowledgeable
- Knowledgeable
- Somewhat Knowledgeable
- Not very Knowledgeable
- Does not apply to me; I have rarely used prescribed medicines

7. Given any past history with over-the-counter (OTC) medicine use, how would you describe your knowledge of OTC medicines?

- Very knowledgeable
- Knowledgeable
- Somewhat Knowledgeable
- Not very Knowledgeable
- Does not apply to me; I have rarely used OTC medicines

8. Have you had any experience with a side effect (caused by a medicine) in the last 6 months?

- Yes No Unsure



If you answered yes, please indicate with a “✓” which of the following side effects you have experienced?

- Nausea Rash Dizziness
- Heartburn Diarrhoea Dry eyes

Please indicate the extent to which you agree or disagree with the following statements by ticking the appropriate box.

9. I like to receive information about my medications' side effects.

Strongly agree Agree Uncertain Disagree Strongly disagree

10. I read medication leaflets or written information provided by pharmacists.

Strongly agree Agree Uncertain Disagree Strongly disagree

11. Side effect information provided to me puts me in a position to think twice about taking that drug.

Strongly agree Agree Uncertain Disagree Strongly disagree

12. Pharmacists should give detailed information to all individuals regarding mild and frequent side effects.

Strongly agree Agree Uncertain Disagree Strongly disagree

13. Pharmacists should give detailed information to all individuals regarding mild and rare side effects.

Strongly agree Agree Uncertain Disagree Strongly disagree

14. Pharmacists should give as much information concerning side effects as he or she thinks best for the individual patient.

Strongly agree Agree Uncertain Disagree Strongly disagree

15. Pharmacists should put more emphasis on the benefits of medications rather than the side effects.

Strongly agree Agree Uncertain Disagree Strongly disagree

16. Side effects can be communicated to patients by listing them, with the option of adding numbers that represent the percentage of people who experience a particular side effect.

For example, a pharmacist or doctor could say:

1) "The most common side effects are stomach ache, back ache, and drowsiness."

Or they could say:

2) "The most common side effects are stomach ache (12%), back ache (6%), and drowsiness (2%)."

Which approach, if any, do you prefer?

- Option 1 (just the side effects)
- Option 2 (the side effects and the percentages)
- No preference

APPENDIX F
FORM 2

Belief about Medication Questionnaire (BMQ - General)®

We would like to ask you about your personal views about medicines in general.

These are statements other people have made about medicines in general.

Please indicate the extent to which you agree or disagree with them by ticking the appropriate box.

There are no right or wrong answers. We are interested in your personal views.

a) Doctors use too many medicines

Strongly agree Agree Uncertain Disagree Strongly disagree

b) People who take medicines should stop their treatment for a while every now and again

Strongly agree Agree Uncertain Disagree Strongly disagree

c) Most medicines are addictive

Strongly agree Agree Uncertain Disagree Strongly disagree

d) Natural remedies are safer than medicines

Strongly agree Agree Uncertain Disagree Strongly disagree

e) Medicines do more harm than good

Strongly agree Agree Uncertain Disagree Strongly disagree

f) All medicines are poisons

Strongly agree Agree Uncertain Disagree Strongly disagree

g) Doctors place too much trust on medicines

Strongly agree Agree Uncertain Disagree Strongly disagree

h) If doctors had more time with patients they would prescribe fewer medicines.

Strongly agree Agree Uncertain Disagree Strongly disagree

APPENDIX G
FORM 3 (SF-8)

- This survey asks for your views about your health.
- For each of the following questions, please mark an [✓] in the one box that best describes your answer.
- If you are unsure about how to answer a question, please give the best answer you can.

1) Overall, how would you rate your health during the **past 4 weeks?**

Excellent Very good Good Fair Poor Very poor

2) During the **past 4 weeks**, how much did physical health problems limit your usual physical activities (such as walking or climbing stairs)?

Not at all Very little Somewhat Quite a lot Could not do
physical activities

3) During the **past 4 weeks**, how much difficulty did you have doing your daily work, both at home and away from home, because of your physical health?

None at all A little bit Some Quite a lot Could not do
daily work

4) How much **bodily** pain have you had during the **past 4 weeks?**

None Very Mild Mild Moderate Severe Very Severe

5) During the **past 4 weeks**, how much energy did you have?

Very much Quite a lot Some A little None

6) During the **past 4 weeks**, how much did your physical health or emotional problems limit your usual social activities with family or friends?

Not at all Very little Somewhat Quite a lot Could not do
social activities

7) During the **past 4 weeks**, how much have you been bothered by **emotional problems** (such as feeling anxious, depressed or irritable)?

Not at all Slightly Moderately Quite a lot Extremely

8) During the **past 4 weeks**, how much did personal or emotional problems keep you from doing your usual work, school or other daily activities?

Not at all Very little Somewhat Quite a lot Could not do
daily activities

APPENDIX H
FORM 5 (REALM)

Rapid Estimate of Adult Literacy in Medicines (REALM)

Directions for the person giving the test to a subject

1. Give the patient a laminated copy of the REALM form and score answers on an un-laminated copy that is attached to a clipboard. Hold the clipboard at an angle so that the patient is not distracted by your scoring. Say:

"We understand that sometimes health instructions are given with very complicated words or phrases. To get an idea of how familiar you might already be with medical terms, we are going to ask you some questions about a series of words. Don't worry if you don't understand or have never heard of some of them, this is common."

"I want to hear you read as many words as you can from this list. Begin with the first word in List 1 and read aloud. When you come to a word you cannot read, do the best you can or say, 'blank' and go onto the next word."

2. If the patient takes more than five seconds on a word, say "blank" and point to the next word, if necessary, to move the patient along. If the patient begins to miss every word, have him or her pronounce only known words.

3. Count as an error any word not attempted or mispronounced. Score by marking a plus (+) after each correct word, a check (✓) after each mispronounced word, and a minus (-) after words not attempted. Count as correct any self-corrected words.

4. Count the number of correct words for each list, and record the numbers on the "Score" line. Total the numbers, and match the score with its grade equivalent in the table below.

TABLE Scores and Grade Equivalents for the REALM Questionnaire

Raw score	Grade range
0 to 18	Third grade and below; will not be able to read most low-literacy materials; will need repeated oral instructions, materials composed primarily of illustrations, or audio or video tapes
19 to 44	Fourth to sixth grade; will need low-literacy materials, may not be able to read prescription labels
45 to 60	Seventh to eighth grade; will struggle with most patient education materials; will not be offended by low-literacy materials.
61 to 66	High school; will be able to read most patient education materials.

List 1

- Fat
- Flu
- Pill
- Dose
- Eye
- Stress
- Smear
- Nerves
- Germs
- Meals
- Disease
- Cancer
- Caffeine
- Attack
- Kidney
- Hormones
- Herpes
- Seizure
- Bowel
- Asthma
- Rectal
- Incest

List 1 score _____

List 2

- Fatigue
- Pelvic
- Jaundice
- Infection
- Exercise
- Behaviour
- Prescription
- Notify
- Gallbladder
- Calories
- Depression
- Miscarriage
- Pregnancy
- Arthritis
- Nutrition
- Menopause
- Appendix
- Abnormal
- Syphilis
- Haemorrhoids
- Nausea
- Directed

List 2 score _____

List 3

- Allergic
- Menstrual
- Testicle
- Colitis
- Emergency
- Medication
- Occupation
- Sexuality
- Alcoholism
- Irritation
- Constipation
- Gonorrhoea
- Inflammatory
- Diabetes
- Hepatitis
- Antibiotics
- Diagnosis
- Potassium
- Anaemia
- Obesity
- Osteoporosis
- Impetigo

List 3 score _____

Raw score _____

APPENDIX I
FORM 6 (NUMERACY TEST)

1. Imagine that we flip a coin 1000 times. What is your best guess about how many times the coin would come up heads in 1000 flips? _____ times out of 1000

2. In the **Big Bucks Lottery**, the chance of winning a \$10 prize is 1%. What is your best guess about how many people would win a \$10 prize if 1000 people each buy a single ticket to **Big Bucks**? _____ person(s) out of 1000

3. In the **ACME Publishing Sweepstakes**, the chance of winning a car is 1 in 1000. What percent of tickets to **ACME Publishing Sweepstakes** win a car? _____ percent (%)

4. Mr. Roe needs surgery. 9 in 1000 people die from this surgery. How would you describe the surgery?

- Very risky
 - Risky
 - Slightly risky
 - Not risky
-

5. Mrs. Smith is told she has a 1 in 296 chance of dying from cancer and a 1 in 407 chance of dying from a stroke. Which is bigger, Mrs. Smith's chance of dying from a stroke or cancer?

- Stroke
 - Cancer
 - Chances are the same
-

6. Mr. Smythe needs surgery. 991 in 1000 people survive this surgery. How would you describe the surgery?

- Very risky
- Risky
- Slightly risky
- Not risky

APPENDIX J
DESIGN OF STUDY 1

First ½ of Subjects (N=15)

Mild Headache Scenario without Side Effect Frequency

Drug X

50%
effective

Nausea
Rash

Drug Y

75%
effective

Nausea
Rash
Dizziness
Heartburn

Drug Z

100%
effective

Nausea
Rash
Dizziness
Heartburn
Diarrhea
Dry eyes

Likelihood of taking each agent
Preferred drug

Mild Headache Scenario with Side Effect Frequency

Drug X

50%
effective

Nausea 3% (3 in 100)
Rash 4% (4 in 100)

Drug Y

75%
effective

Nausea 3% (3 in 100)
Rash 4% (4 in 100)
Dizziness 7% (7 in 100)
Heartburn 5% (5 in 100)

Drug Z

100%
effective

Nausea 3% (3 in 100)
Rash 4% (4 in 100)
Dizziness 7% (7 in 100)
Heartburn 5% (5 in 100)
Diarrhoea 2% (2 in 100)
Dry eyes <1% (< 1 in 100)

Likelihood of taking each agent
Preferred drug

Form 6 (Booklet 1)

Participant Instructions for Study 1 Mild Headache Scenario

Whether true or not, consider for a moment that you get headaches. They tend to be **mild** and occur **6 times a year**. You need a pain killer for these headaches in order to focus better on your daily activities. You have the choice of the following 3 headache medicines for relief:

Drug X

This drug is 50% effective (reduces pain by half within 10 minutes) for mild to moderate headaches. This drug may cause nausea and rash.

Drug Y

This drug is 75% effective (reduces pain by 75% within 10 minutes) for mild to moderate headaches. This drug may cause nausea, rash, dizziness and heartburn.

Drug Z

This drug is 100% effective (reduces all the pain within 10 minutes) for mild to moderate headaches. This drug may cause nausea, rash, dizziness, heartburn, diarrhoea and dry eyes.

Form 6 (Booklet 1)

**Participant Instructions for Study 1
Mild Headache Scenario**

Given what you just read about the 3 agents for headaches, how **likely** is it that you would take each drug? For this, please draw a line across any point on the scale that reflects your opinion.

For example:

|.....|.....|

1. How likely is it that you would take Drug X?

|.....|
Very Unlikely Very Likely

2. How likely is it that you would take Drug Y?

|.....|
Very Unlikely Very Likely

3. How likely is it that you would take Drug Z?

|.....|
Very Unlikely Very Likely

4. If you were in a position where you have to decide to use a painkiller, which one you would take?

- Drug X Drug Y Drug Z None
-

Form 7 (Booklet 1)

Participant Instructions for Study 1 Mild Headache Scenario

Again consider that you get headaches. And as before, they tend to be **mild** and occur **6 times a year**. You need a pain killer for these headaches in order to focus better on your daily activities. You have the choice of the following 3 headache medicines for relief:

Drug X

This drug is 50% effective (reduces pain by half within 10 minutes) for mild to moderate headaches. This drug may cause nausea 3% (in 3 of 100 users) and rash 4% (in 4 of 100 users).

Drug Y

This drug is 75% effective (reduces pain by 75% within 10 minutes) for mild to moderate headaches. This medicine may cause nausea 3% (in 3 of 100 users), rash 4% (in 4 of 100 users), dizziness 7% (in 7 of 100 users), and heartburn 5% (in 5 of 100 users).

Drug Z

This drug is 100% effective (reduces all the pain within 10 minutes) for mild to moderate headaches. This medicine may cause nausea 3% (in 3 of 100 users), rash 4% (in 4 of 100 users), dizziness 7% (in 7 of 100 users), heartburn 5% (in 5 of 100 users), diarrhoea 2% (in 2 of 100 users), and dry eyes <1% (in less than 1 of 100 users).

Form 7(Booklet 1)

**Participant Instructions for Study 1
Mild Headache Scenario**

Given what you just read about the 3 agents for headaches, how **likely** is it that you would take each drug? For this, please draw a line across any point on the scale that reflects your opinion.

For example:

|.....|.....|

5. How likely is it that you would take Drug X?

|.....|
Very Unlikely Very Likely

6. How likely is it that you would take Drug Y?

|.....|
Very Unlikely Very Likely

7. How likely is it that you would take Drug Z?

|.....|
Very Unlikely Very Likely

8. If you were in a position where you have to decide to use a painkiller, which one YOU would take?

- Drug X Drug Y Drug Z None
-

Form 8 (Booklet 1)

Preference question for Mild Headache Scenario

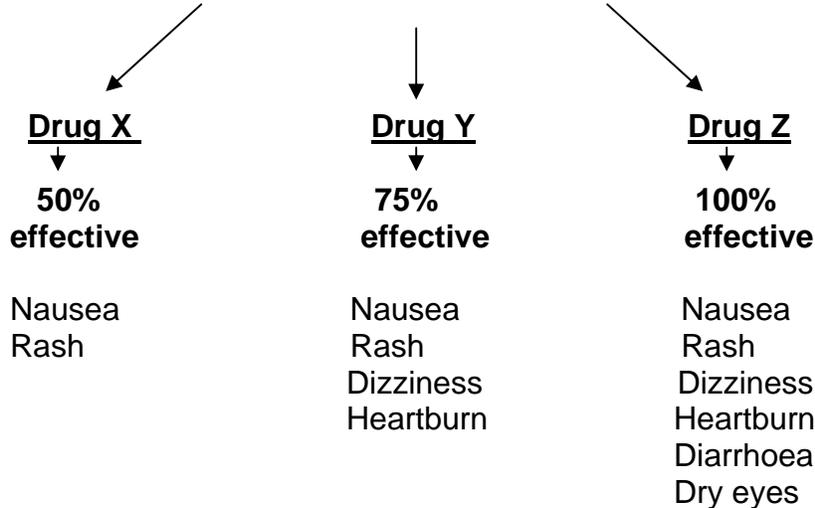
9. From what you read, which explanation would YOU prefer to be given on medication side effects? Check ONE of the following options:

- The first version (a list of possible side effects)
- The second version (a list of possible side effects plus the percentages that they may occur)

Design of Study 1

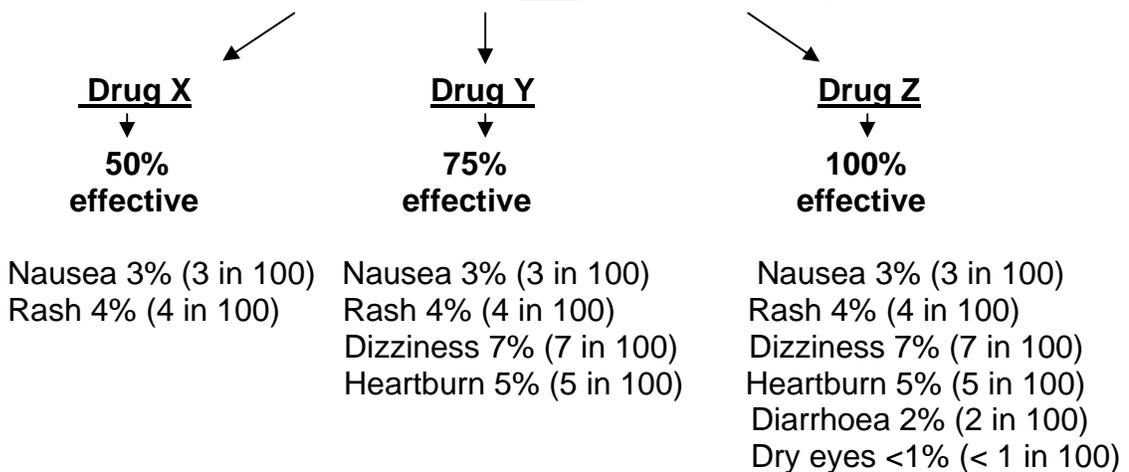
Second ½ of Subjects (n=15)

Severe Headache Scenario without Side Effect Frequency



Likelihood of taking each agent
Preferred drug

Severe Headache Scenario with Side Effect Frequency



Likelihood of taking each agent
Preferred drug

Form 6 (Booklet 2)

Participant Instructions for Study 1 Severe Headache Scenario

Whether true or not, please consider for a moment that you get headaches. They tend to be **severe** and occur **twice a year**. You need a pain killer in order to get out of the bed. You have the choice of the following 3 headache medicines for relief:

Drug X

This drug is 50% effective (reduces pain by half within 10 minutes) for mild to moderate headaches. This drug may cause nausea and rash.

Drug Y

This drug is 75% effective (reduces pain by 75% within 10 minutes) for mild to moderate headaches. This drug may cause nausea, rash, dizziness and heartburn.

Drug Z

This drug is 100% effective (reduces all the pain within 10 minutes) for mild to moderate headaches. This drug may cause nausea, rash, dizziness, heartburn, diarrhoea and dry eyes.

Form 6(Booklet 2)

**Participant Instructions for Study 1
Severe Headache Scenario**

Given what you just read about the 3 agents for headaches, how **likely** is it that you would take each drug? For this, please draw a line across any point on the scale that reflects your opinion.

For example:

|.....|.....|

1. How likely is it that you would take Drug X?

|.....|
Very Unlikely Very Likely

2. How likely is it that you would take Drug Y?

|.....|
Very Unlikely Very Likely

3. How likely is it that you would take Drug Z?

|.....|
Very Unlikely Very Likely

4. If you were in a position where you have to decide to use a painkiller, which one you would take?

- Drug X Drug Y Drug Z None

Form 7 (Booklet 2)

Participant Instructions for Study 1 Severe Headache Scenario

Again consider that you get headaches. And as before, they tend to be **severe** and occur **twice a year**. You need a pain killer in order to get out of the bed. You have the choice of the following 3 headache medicines for relief:

Drug X

This drug is 50% effective (reduces pain by half within 10 minutes) for mild to moderate headaches. This drug may cause nausea 3% (in 3 of 100 users) and rash 4% (in 4 of 100 users).

Drug Y

This drug is 75% effective (reduces pain by 75% within 10 minutes) for mild to moderate headaches. This medicine may cause nausea 3% (in 3 of 100 users), rash 4% (in 4 of 100 users), dizziness 7% (in 7 of 100 users), and heartburn 5% (in 5 of 100 users).

Drug Z

This drug is 100% effective (reduces all the pain within 10 minutes) for mild moderate headaches. This medicine may cause nausea 3% (in 3 of 100 users), rash 4% (in 4 of 100 users), dizziness 7% (in 7 of 100 users), heartburn 5% (in 5 of 100 users), diarrhoea 2% (in 2 of 100 users), and dry eyes <1% (in less than 1 of 100 users).

Form 7(Booklet 2)

**Participant Instructions for Study 1
Severe Headache Scenario**

Given what you just read about the 3 agents for headaches, how **likely** is it that you would take each drug? For this, please draw a line across any point on the scale that reflects your opinion.

For example:

|.....|.....|

5. How likely is it that you would take Drug X?

|.....|
Very Unlikely Very Likely

6. How likely is it that you would take Drug Y?

|.....|
Very Unlikely Very Likely

7. How likely is it that you would take Drug Z?

|.....|
Very Unlikely Very Likely

8. If you were in a position where you have to decide to use a painkiller, which one you would take?

- Drug X Drug Y Drug Z None

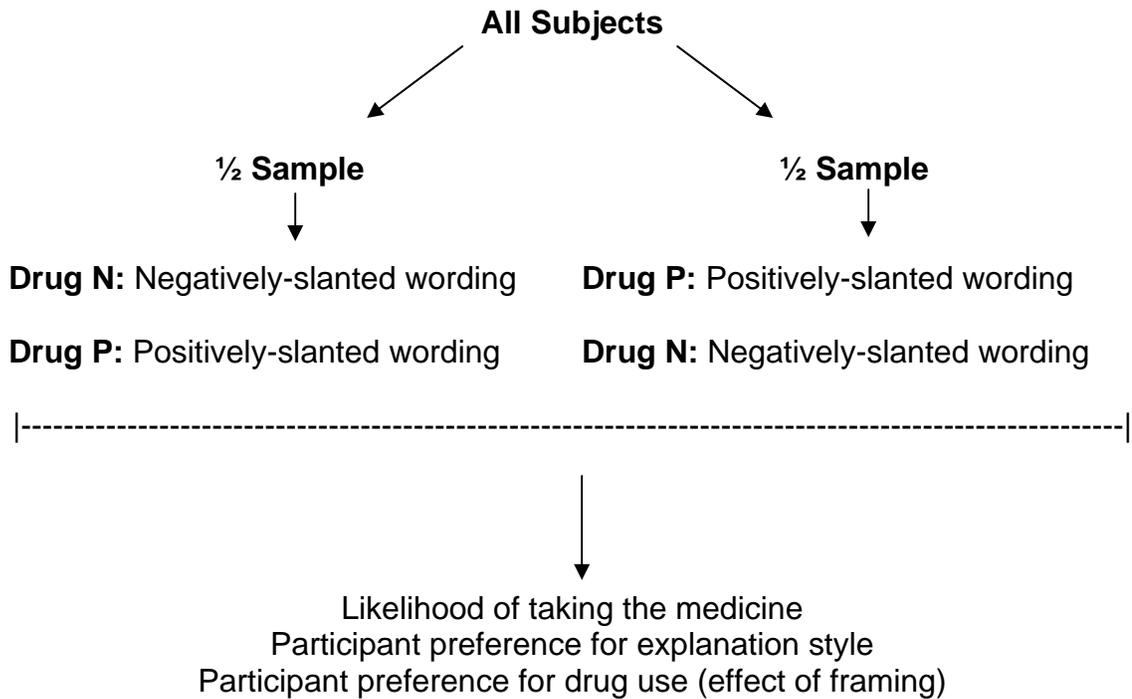
Form 8 (Booklet 2)

Preference Question for Severe Headache Scenario

9. From what you read, which explanation would YOU prefer to be given on medication side effects? Check ONE of the following options:

- The first version (a list of possible side effects)
- The second version (a list of possible side effects plus the percentages that they may occur)
- No preference

APPENDIX K
DESIGN OF STUDY 2



Form 9 (Booklet 1)

Participant Instructions for Study 2

The following information concerns 2 different medicines used for headaches. Please read the two passages and respond to the questions that follow for each.

Drug N is an effective drug for headache, but it can cause some side effects. One of those side effects is heartburn. Regarding how often this might occur, 10% (that is, 10 out of 100) of users WILL experience heartburn when taking this medicine.

1. Given what you just read, how **likely** is it that you would take this drug? For this, please draw a line across any point on the scale that reflects your opinion.

|.....|
Very Unlikely Very Likely

Drug P is an effective drug for headache, but it can cause some side effects. One of those side effects is heartburn. Regarding how often this might occur, 90% (that is, 90 out of 100) of users WILL NOT experience heartburn when taking this medicine.

2. Given what you just read, how **likely** is it that you would take this drug? For this, please draw a line across any point on the scale that reflects your opinion.

|.....|
Very Unlikely Very Likely

3. What drug would you prefer to use if you had a headache in the next few days? Check ONE of the following options:

- Drug N
- Drug P
- I would prefer the 2 agents equally
- I would prefer neither agent

4. The passages you just read mentioned a heartburn side effect and how often it might occur. From what you read, which explanation would YOU prefer to be given on its occurrence? Check ONE of the following options:

- The first version (a focus on who WILL get heartburn)
- The second version (a focus on who WILL NOT get heartburn)

Form 9 (Booklet 2)

Participant Instructions for Study 2

The following information concerns 2 different medicines used for headaches. Please read the two passages and respond to the questions that follow for each.

Drug P is an effective drug for headache, but it can cause some side effects. One of those side effects is heartburn. Regarding how often this might occur, 90% (that is, 90 out of 100) of users WILL NOT experience heartburn when taking this medicine.

1. Given what you just read, how **likely** is it that you would take this drug? For this, please draw a line across any point on the scale that reflects your opinion.

|.....|
Very Unlikely Very Likely

Drug N is an effective drug for headache, but it can cause some side effects. One of those side effects is heartburn. Regarding how often this might occur, 10% (that is, 10 out of 100) of users WILL experience heartburn when taking this medicine.

2. Given what you just read, how **likely** is it that you would take this drug? For this, please draw a line across any point on the scale that reflects your opinion.

|.....|
Very Unlikely Very Likely

3. What drug would you prefer to use if you had a headache in the next few days? Check ONE of the following options:

- Drug N
- Drug P
- I would prefer the 2 agents equally
- I would prefer neither agent

4. The passages you just read mentioned a heartburn side effect and how often it might occur. From what you read, which explanation would YOU prefer to be given on its occurrence? Check ONE of the following options:

- The first version (a focus on who WILL NOT get heartburn)
- The second version (a focus on who WILL get heartburn)

APPENDIX L
INTERVIEW GUIDE FOR INTERVIEWING RESPONDENTS

Turn the record button on then please read participants ID code aloud first,

ID# _____ Today Date....., 2007

Mr/ Mrs/ Ms _____!

Thanks for filling out the forms and sitting for this interview. All the information you provide should help us better understand how we might best discuss side effects of medicines with patients. If my questions or my pronunciation are not understandable, please stop me and ask me for clarification

What we will do now is this – I will go back to several of the choices you made in the survey you just completed. We are now interested in WHY you picked the selections you did. Again, there are no right or wrong answers; we are just interested in what may have gone through your mind as you chose. If you can give some detail on this, great. I might ask a few questions to follow-up. If you can't really give any detail, then that is okay too. We will not press you for an answer. In other words, "I don't know" or "I am not sure why I picked an answer" is fine as well.

Okay, any questions before we start? Again, this should take about ½ hour.

Question 2 and 3: Study 1, involving Forms 6, 7

**This question will only be asked if their likelihood of one drug [which is on the scale of 1-100] is more than the other two (if there was no difference between their likelihood, no question will be asked)*

2. For the FIRST version [Form 6]: Why was your likelihood of taking drug more than drug ___ and ___?

↳ If their answers to the preference question (choosing a drug to take) were different, then will be asked why that was the case:

I see your likelihood of taking drug ___ is higher than ___ and ___.
Why did you chose drug ___ (or none) if YOU needed a painkiller?

Participant Instructions for Experiment 1
First ½ of Subjects
Mild Headache Scenario without Side Effect Frequency

Given what you just read about the 3 agents for headaches, how **likely** is it that you would take each drug? For this, please draw a line across any point on the scale that reflects your opinion.

How likely is it that you would take Drug X?

.....
Very Unlikely Very Likely

How likely is it that you would take Drug Y?

.....
Very Unlikely Very Likely

How likely is it that you would take Drug Z?

.....
Very Unlikely Very Likely

If you were in a position where you have to decide to use a painkiller, which one you would take?

Drug X Drug Y Drug Z None

3. In the SECOND version [Form 7]: Why was your likelihood of taking drug more than drug ___ and ___?

↳ If their answers toward the preference question (choosing a drug to take) were different, then they will be asked why that was the case:

I see your likelihood of taking drug ___ is higher than ___ and ___.
Why did you chose drug ___ (or none) if YOU needed a painkiller.

Participant Instructions for Experiment 1
First ½ of Subjects
Mild Headache Scenario with Side Effect Frequency

Given what you just read about the 3 agents for headaches, how **likely** is it that you would take each drug? For this, please draw a line across any point on the scale that reflects your opinion.

How likely is it that you would take Drug X?

.....
Very Unlikely Very Likely

How likely is it that you would take Drug Y?

.....
Very Unlikely Very Likely

How likely is it that you would take Drug Z?

.....
Very Unlikely Very Likely

If you were in a position where you have to decide to use a painkiller, which one you would take?

Drug X Drug Y Drug Z None

Question 4 and 5: Involving Form 6&7 (Q4&8) in Study 1

Mr/Mrs. You had a mild/severe headache scenario. We just introduce 3 drugs considering the effectiveness and side effects of them, now may I ask:

4. Which aspect do you feel had more influence on your decision to choose drug __ the FIRST time (in Form 6, Q4)?

Effectiveness Side effect information you received

.....IF they choose "None", ask what was the reason?

5. Which aspect do you feel had more influence on your decision to choose drug __ the SECOND time (Form 7, Q8)?

Effectiveness Side effects information you received

.....IF they choose "None", ask what was the reason?

Question 6 and 7 involving [Form 1] (does not apply to all)

↳ *If they had any previous experience with side effects, answer this (question 8 of Form 1)*

Interviewer Instructions

- *holding Form 1, show them to the respondent one at a time as reminder, and in the sequence to the questions below*

6. As you mentioned in Form 1 (Q8), you had experienced _____. Did that fact affect your responses toward not taking any of the drug(s) with this / these side effects?

Yes No

↓
(If answered yes please continue and ask next question)...

7. If any medications – no matter how effective – had this side effect, would you still consider taking it?

Study 1
Comparing Question 9 of Form 8 and Question 16 of Form 1

<p style="text-align: center;">Form #8</p> <p style="text-align: center;">Preference Questions for First ½ of Subjects</p> <p style="text-align: center;">Mild Headache Scenario</p> <p>From what you read, which explanation would YOU prefer to be given on medication side effects? Check ONE of the following options:</p> <ul style="list-style-type: none"><input type="checkbox"/> The first version (a list of possible side effects)<input type="checkbox"/> The second version (a list of possible side effects plus the percentages that they may occur)<input type="checkbox"/> No preference	<p>16. Side effects can be communicated to patients by listing them, with the option of adding numbers that represent the percentage of people who experience a particular side effect.</p> <p>For example, a pharmacist or doctor could say:</p> <p>1) "The most common side effects are stomach ache, back ache, and drowsiness."</p> <p>Or they could say:</p> <p>2) "The most common side effects are stomach ache (12%), back ache (6%), and drowsiness (2%)."</p> <p>Which approach, if any, do you prefer?</p> <ul style="list-style-type: none"><input type="checkbox"/> Option 1 (just the side effects)<input type="checkbox"/> Option 2 (the side effects and the percentages)<input type="checkbox"/> No preference
--	---



If only the answers to the questions in these two forms differed, participants will be asked why?

The exact possible question would be one of these:

- I see in page 21 (Q9) you preferred the first version (a list of possible side effects with no frequency), then may I ask in question 16 (show them their answer) why you picked option 2 which means you liked list of side effects with the frequency of its occurrences?

OR

- I see in page 21 (Q9) you preferred the second version (a list of possible side effects with frequency), then may I ask in question 16 (show them their answer) why you picked option 1 which means you liked list of side effects with no frequency of its occurrences?

OR

I see in question 16 you picked no preference then in page 21(Q9) I asked you which version you preferred you chose version _____. Since both of these questions are quiet similar; May I ask what in this process made you realize that version _____ is a better option to be presented with?

