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Dated: July 10, 2014

**Communicating Risk of Medication Side Effects: Role of
Communication style on Risk Perception and Intention to Adhere**

By

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To my beloved

Dad, Vijay Sawant,

Mom, Shubhangi Sawant,

and

Brother, Gaurav Sawant!

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ABSTRACT

Communicating Risk of Medication Side Effects: Role of Communication Style on Risk Perception and Intention to Adhere.

Objective

The primary objective of the study was to evaluate the effects of communication style on risk perception of medication side effects. Secondary objective was to evaluate the effect of risk perception and communication style on intention to adhere to medications.

Methods

The study was an experimental cross-sectional and factorial design. Participants were exposed to information on four medications and each associated with a side effect. The description of the side effect was presented in one of eight combinations from a 2 (communication style: verbal or verbal combined with numeric) X 2 (frequency: low or high) X 2 (severity: mild or severe), factorial design. The three factors acted as independent variables. Dependent variables of perceptions of risk of experiencing side effects and intention to adhere to medication was recorded for each of the four side effects on a Visual Analogue Scale ranging from 0 to 100. Demographic information on age, gender, education, profession (healthcare/non-healthcare) and race was also recorded. Data was coded and analyzed using SAS Version 9.3 at an a priori significance level of 0.05. Multivariate analysis or covariance was performed to test the effects of communication style severity and frequency on risk perception and intention to adhere. Separate univariate analyses tests were also performed to test the effects of the three dependent variables on the two independent variables.

Results

A total of 196 completed surveys were obtained giving a response rate of 81.6%.

MANCOVA results indicated that communication style did not show any significant main effects but showed significant effects in interaction with frequency [$F(3,772) = 10.43$; $p < 0.001$]. Significant effects were also observed for frequency of side effects [$F(3,772) = 169.93$; $p < 0.001$], severity of side effects [$F(3,772) = 98.33$; $p < 0.001$] as well as their interaction [$F(3,772) = 44.30$; $p < 0.001$]. Separate univariate ANCOVAs also showed same effects for risk perception. Frequency of side effects showed the maximum effects from all the three factors. Although overall interaction of communication style, frequency and severity was not significant, least square means for risk perception showed that effects of communication style were significant only for certain combinations of severity of frequency. It was observed that for low frequency severe side effects, perceptions of risk decreased when combination of verbal and numeric descriptions were used to communicate the side effect risk as compared to only verbal communication style [Mean difference = 11.24, $p = 0.0008$]. For high frequency mild side effects, perceptions of risk increased when combined communication style was used as compared to only verbal communication style [Mean difference = 7.80, $p = 0.0203$]. Risk perception was found to be negatively associated with intention to adhere [$\beta = 0.61$, $p < 0.0001$]. There were no effects of communication style on intention to adhere. However intention to adhere was observed to decrease with increase in frequency and severity of side effects.

Conclusion

Perceptions of risk of experiencing side effects and intention to adhere are primarily affected by the frequency and severity of side effects. Communication style plays a role in

conjunction with side effect frequency in affecting perceptions of risk. Low frequency side effects are often associated with overestimation of risk when only verbal descriptions are used and hence should be carefully communicated. Overall, use of numeric descriptors along with verbal descriptors lead to better understanding of side effect frequency.

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CHAPTER ONE

BACKGROUND AND STATEMENT OF THE PROBLEM

1.1 Decision Making and Adherence

Individuals as patients are required to make decisions regarding treatment options, healthcare interventions/screenings, or taking medications/following treatment regimen as prescribed. Abiding by the instructions of the healthcare provider specifically plays an important role in terms of prescription medications, particularly those for chronic conditions. Many chronic conditions require the patients to take several medications on a daily basis, the effectiveness of which depends on the decision to adhere to treatment regimen (Bosworth et al., 2011). Adherence is defined as the extent to which patients follow instructions but involves more patient choice (Haynes et al., 2008). Consumers' decision towards a particular behavior is dependent on the risks and benefits associated with the behavior (Fagerlin, Zikmund-Fisher, & Ubel, 2011). Despite the efficacy of medications in reducing mortality and improving outcomes, patients taking chronic medication are often faced with the problem of non-adherence (Benner et al., 2002). It has been reported that patients with chronic conditions adhere to only about 50-60% of their prescribed medications (Avorn et al., 1998). Non-adherence can be unintentional (forgetting to take medications) or intentional (missing/altering doses to suit one's needs). According to Wroe, unintentional non-adherence is associated with decision balance between pros and cons of the treatment.

Also non-adherence was found to be correlated with the information provided. More the information about pros and cons, lesser the non-adherence (Wroe, 2002). Thus it is clear that in order to make appropriate decisions, patients need complete and understandable information about the medications.

1.2 Information preferences

Of all the information provided for prescription medications, it is observed that patients prefer information about side effects the most. Also they prefer simple and easier to read instructions than those provided in the pharmacies today (Knapp et al., 2009). Information on side effects however may have detrimental effects on the evaluations of medications and medication adherence (Berry, Michas, & Bersellini, 2002; Kelly, Mamon, & Scott, 1987; Mann et al., 2007; Sivell et al., 2008). A report by FDA suggests that fear of potential side effects is the single greatest deterrent from filling and taking prescription drugs ("Focus Group Report on Consumer Knowledge About Prescription Drug Risks and Benefits ", 2010). Thus it becomes imperative to provide the relevant information in a manner which leads to accurate and informed decision making. It has been observed that there are discrepancies in what and how information is provided by healthcare providers provide and what and how information is preferred by the patients. According to physicians, information on side effects is the least important (Dyck, Deschamps, & Taylor, 2005). Also, providers prefer to use terms like 'most likely', 'most common', 'rarely' to describe the frequency with which side effects occur (Erev & Cohen, 1990). Contradictorily, as mentioned earlier patients rate side effect information as the most important. Often they correlate safety of the medication to the side effects and also base their decisions to adhere depending on the side effects. Also they prefer

numbers rather than verbal terms (e.g. 'likely') while receiving information about medication side effects (Vischers et al., 2009). Thus there exists a communication paradox as to how people prefer to provide and receive information.

1.3 Study perspective

Understanding of risk associated with medications is not only dependent on the language or communication style used but also on the nature or characteristics of the risk. Medication side effects are associated with a certain specific frequency of occurrence and severity. Perceptions of risk associated with these side effects are thus also guided by the frequency and severity of the side effect along with the communication style (Weber & Hilton, 1990). In the past, research has been done to observe the effects of verbal versus numeric information on risk perception and intention to adhere and effects of frequency and severity on risk perceptions and evaluations. However it is important to understand how these factors interact to produce effects on the risk perception and intention to adhere as a consumer using a medication would be exposed to all the three factors i.e. communication style, frequency and severity of the side effect. Thus the objectives of the study were:

- 1) To assess the role of communication style, frequency and severity of side effects on risk perception of medication side effects.
- 2) To assess the role of communication style, frequency and severity of side effects on intention to adhere to medications.

CHAPTER TWO

REVIEW OF LITERATURE AND THEORY

This chapter describes concerns regarding risk communication of medication side effects, different methods of communicating medication side effects, previous studies' evaluations on risk communication, and theory used in the current study.

2.1 Risk and Risk assessment

Risk is defined as the possibility of physical, social or financial harm/detriment/loss due to a hazard (Rohrman, 2008). Perceptions of risk are primarily guided by two variables: (a) likelihood/probability/frequency of risk and (b) severity of risk (Wogalter et al., 1999). Risk cannot be defined by only likelihood or severity but is a combined effect of both. In terms of medications, perceived likelihood of side effects is suggested to influence perceptions of riskiness of a drug (Bosworth et al., 2011). Likelihood serves as a measure of magnitude of the risk. However, along with the magnitude, risk is also a function of the severity of the loss. A study conducted by Berry et al. has reported that side effect severity had the greatest impact on risk perceptions of medications (Berry et al., 2003). Likelihood and severity serve as the context in which the risk is embedded and it is upon these contextual factors that the perceptions of risk are based. With respect to medications, the risk involved is that of side effects. Patients need to know what the side effects are and how frequently do they occur. Severity is a subjective parameter and perceptions of risk associated with any event are primarily based on severity judgments (Slovic, 2000; Wogalter et al., 1999). However for events

where evaluations cannot be based purely on severity, likelihood or frequency comes into play. Most of the times, these two factors interplay to form judgments about risk.

Given the importance of likelihood of risk, it is also necessary to pay attention to the manner in which the likelihood is communicated. With respect to medications, it's the frequency of side effects. There are several ways to communicate side effect frequency i.e. use of just wordy descriptions such a 'most common', 'often', or the use of graphics or numbers. Even while using numbers, one needs to decide between percentages, relative values, absolute values etc. We will look at pros and cons associated with each in the sections ahead. Since this research pertains to communication of medication side effects, all discussions will be concerning side effects.

2.2 Why look at risk communication?

Psychological research has established that methods of communicating risk affect risk perception, decision-making, and subsequent behavioral responses. Perceptions of risk are directly associated with medication adherence. Young and Oppenheimer have demonstrated that semantic descriptors about medications side effects reduced intended medication adherence. Poor medication adherence accounts for about 33-69% of medication related hospitalizations in the United States (Osterberg & Blaschke, 2005). About 89,000 avoidable hospitalizations and about \$100 billion annual avoidable costs could be attributed to non-adherence. Research has shown that medication adherence can significantly improve health outcomes by lowering hospitalizations and emergency visits and hence strategies to improve medication adherence are warranted (Roebuck et al., 2011).

As mentioned earlier, medication adherence to an extent depends on the risk associated with the side effects. The manner in which information about medication side effects is presented affects level of fear that is cultivated in the consumer's mind. Greater the fear, lesser the intention to take medication (Young & Oppenheimer, 2009). Thus it is important to develop methods of communicating medication side effects which convey the appropriate intended message but at the same time do not stimulate unnecessary concerns and fears.

2.3 Verbal descriptions

Verbal descriptions refer to the use of plain words to describe likelihood or frequency of side effects such as 'commonly', 'rarely', 'often' and so on. Literature suggests that such descriptions are often used in practice (Erev & Cohen, 1990). Verbal descriptions seem to be advantageous because they are more natural to use and better appeal to a person's emotional interests (Lipkus, 2007). Although some literature reports that use of terms such as 'may' or 'if...' may lead to positive attitude about the appeal of medications or willingness to experiencing side effects, it may not necessarily reflect good comprehension (Davis, 2007). Verbal terms are subject to wide variability in interpretation. A term used by one individual to communicate a certain frequency may not be interpreted as the same frequency by the person on the receiving end. An attempt was made by the European Union (EU) and Medicines and Health Products Regulatory Agency (MHRA) to make recommendations for verbal descriptions and associated numeric frequencies. Following table shows the recommendations:

Table 1: EU/ MHRA recommended verbal descriptions and numeric frequencies

EU Verbal Descriptor	EU Probability of Side Effect Occurrence
Very common	>10%
Common	>1% and <10%
Uncommon	0.1% to 1%
Rare	0.01% to 0.1%
Very rare	<0.01%

However, these descriptions failed to correlate with general peoples' interpretations of the verbal descriptions used. Even patients, doctors and general public overestimated risk based on these recommendations (Knapp, Raynor, & Berry, 2004). Several other studies have pointed out that verbal descriptions are often translated to higher numeric probabilities than their intended values. The table below shows the wide variability seen in interpretation of some commonly used verbal descriptions.

Table 2: Commonly used verbal descriptions and their interpretations

Verbal descriptions	Associated Numerical Probability: Mean (SD)			
	<i>Shaw & Dear (1990)</i>	<i>Brun & Teigen (1988)</i>	<i>Kong et al. (1986)</i>	<i>O'Brien (1989)</i>
Very Likely	86% (15%)	-	85% (NS)	72% (NS)
Likely	66% (17%)	70% (15%)	63% (NS)	69% (NS)
Possibly	62% (17%)	52% (17%)	27% (NS)	30% (NS)
Rarely	20% (19%)	-	14% (NS)	19% (NS)

In spite of such uncertainty and misinterpretation, Dyck and co-workers found that pharmacists mostly use vague verbal descriptions in their counseling sessions with patients (Dyck et al., 2005).

2.4 Graphical presentation

Presenting frequency information using graphics is another way of communicating risk to patients. Graphical representations or use of pictographs have been shown to improve comprehension, better risk assessment and better knowledge (Austin et al., 1995; Garcia-Retamero & Dhimi, 2011). Graphs have also been shown to eliminate denominator negligence (a phenomenon when people focus more on the number of people who have died or experienced the adverse event rather than overall number treated). However, graphical representations may not always be superior as compared to textual information. Interpretation and understanding of pictographs and graphs are considerably dependent on education, age and socioeconomic differences and may vary significantly between lay persons and healthcare or medical professionals (Chuang, Lin, Wang, & Cham, 2010). Excess information displayed as thermometers, crowd figures/smiley faces, etc., may be unhelpful and lead to information overload for patients (Edwards et al., 2006). Complex pictographs have no advance over text and patients may require training before pictographs are very useful in helping them understand medication use, which may be a significant barrier to adoption (Katz, Kripalani, & Weiss, 2006).

2.5 Numeric Descriptions

Numeric descriptions refer to the use of numbers to express the frequency of occurrence of side effects. Naturally, numbers as compared to words communicate the frequencies more accurately and leads to better understanding on the part of both patients and physicians (Hoffrage & Gigerenzer, 1998; Gigerenzer & Edwards, 2003). Numeric risk information can be presented in a number of ways such as percentages, natural frequencies, absolute or relative risks. Depending on how numbers are represented, risks can be spun to look bigger or smaller. Therefore one needs to be careful while constructing numeric representations for risk communication.

Absolute and Relative risks: The benefits of a treatment can that reduces death rate from a 10 in 1000 (1%) to 5 in 1000 (0.5%) can be presented as an absolute risk of 5 in 1000 (0.5%) reduction or as a relative risk reduction of 50%. In these two, relative risk appears as a bigger number and draws more attention. However ratings of effectiveness and likelihood of accepting the treatment for use are more with relative risks as compared to absolute risk (Covey, 2011) (Carling et al., 2009; Sheridan, Pignone, & Lewis, 2003). However interpretation of numeric risk requires numeracy skills. Sadly, many people have poor numeracy skills as demonstrated by tests that measure individual's ability to perform on numeracy tests (Gigerenzer et al., 2007). As a result, if people are unable to accurately interpret risks and benefits associated with the treatment, chances are that the patients will make uninformed decisions (Fagerlin et al., 2007).

Frequencies: As compared to percentages, frequencies are better and easier to understand on the part of patients as well as physicians. Natural frequencies refer to providing a denominator as a reference class, for eg. 3 out of 100 instead of 30%. According to

Gigerenzer and Edwards, percentages are abstract concepts and lack a concrete reference (Gigerenzer et al., 2007; Hoffrage & Gigerenzer, 1998; Hoffrage et al., 2002). Also presenting information as natural frequencies leads to more adequate statistical reasoning and more accurate risk estimates (Visschers et al., 2009). Having said the superiority of frequencies over percentages, it is also important to choose the correct denominator. Research has reported that people have difficulties with large denominators often leading to overestimation of risk (Garcia-Retamero & Galesic, 2010). Thus it is preferable to use small denominators when natural frequencies are used.

2.6 Communication Paradox

In the sections above, we saw that numeric information is superior to verbal information in terms of understanding and accuracy. However in practice, there seems to be a communication mode paradox. A study conducted by Dyck and co-workers reflects that pharmacists prefer to use vague verbal descriptions of side effect frequencies while communicating with patients (Dyck et al., 2005). In another study regarding patient preferences for probability information, it was found that patients often prefer to receive such information numerically as compared to verbal descriptions (Erev & Cohen, 1990). Patients seem to make decisions based on numbers about half the time (Holmes-Rovner et al., 2005). Thus there seems to be disagreement between the type of information patients and provider prefer. This could be attributed to the fact that in general, people prefer to receive information numerically but prefer to express information verbally (Wogalter et al., 1999). Thus verbal information is accepted as more natural and more familiar to use than numeric information. However, in terms of medication side effects, understanding of the magnitude of the side effect frequency becomes as healthcare

providers may intend to communicate one particular value with a verbal descriptor used, however the patient may have a different numerical translation to the same verbal descriptor (Young & Oppenheimer, 2009). One way to account for advantages of both verbal and numeric descriptions is to include both. It is yet unclear whether the combination of verbal and numeric risk information is superior to either formats alone (Peter Knapp et al., 2009). Also how these formats interact at high or low severity levels and high or low frequency levels is not known.

THEORY

The concept of risk perception has been incorporated in a number of behavioral models. One such widely used model for health behaviors is the Health Belief Model (HBM). Health Belief Model was developed in the early 1950s by a group of social psychologists at the U.S. Public Health Service. The HBM attempts to predict health-related behavior in terms of certain belief patterns. It states that the perception of a personal health behavior threat is itself influenced by at least three factors: general health values, which include interest and concern about health; specific health beliefs about vulnerability to a particular health threat; and beliefs about the consequences of the health problem. Once an individual perceives a threat to his/her health and is simultaneously cued to action, and his/her perceived benefits outweighs his/her perceived benefits, then that individual is most likely to undertake the recommended preventive health action.

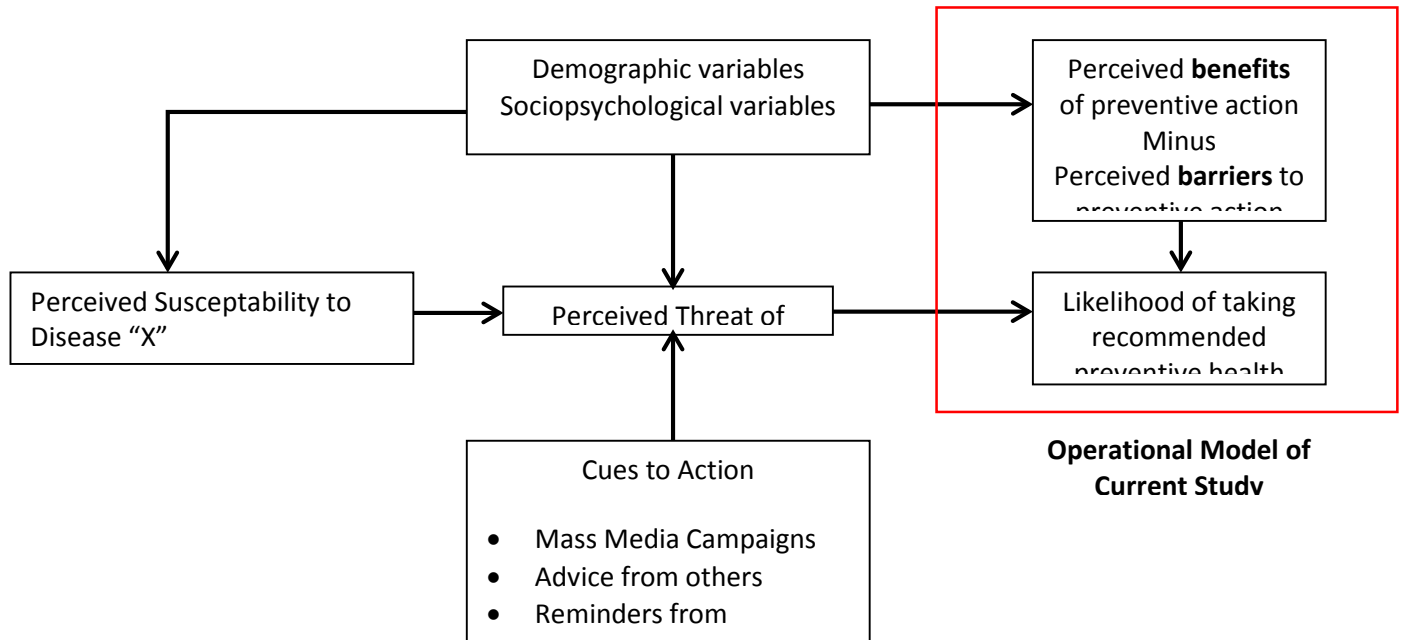


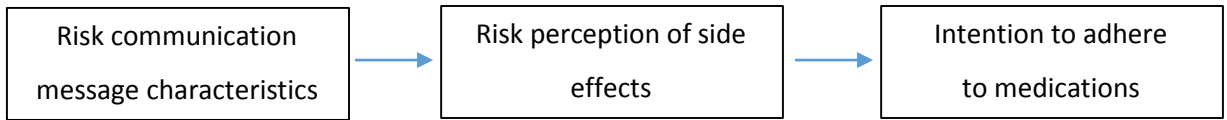
Figure 1: Health Belief Model

As shown in figure 1, the likelihood of an individual taking a recommended preventive health action is influenced by a number of factors including 1) perceived susceptibility to a specific disease, 2) perceived severity of the disease, 3) perceived threat of the disease, 4) perceived benefits of the preventive action minus the perceived barriers to the preventive action, 5) demographic and psychosocial variable and finally, 6) cues to action such as advice from friends or authority figures.

Of the factors that influence preventive health behaviors, perceived barriers consistently show the highest levels of significance in studies assessing the HBM (Janz and Becker, 1984). In a review of HBM studies, it was shown in 21 of 23 studies that barriers played a significant role in health behavior (Janz and Becker, 1984). For our study the behavior in question was intention to take medications as directed i.e. to adhere to medications. Based on review of literature, barrier to taking medications as directed is the perception of risk of experiencing side effects. We are thus going to focus only on a part of the model i.e. testing the effects of risk perception on intention to adhere.

Risk perception in turn is dependent upon several factors. We will now look at a sociopsychological model developed by Rohrmann in 1999 for analyzing risk communication process. The structural model identifies the main components of risk communication processes and specifies the factors which determine the results of risk communication efforts, referring to characteristics of the distributed messages, the conveying authority, the receiving audiences and the context in which the communication process occurs. For the purpose of our study, we are going to focus on the effect of characteristics of the risk communication message on risk appraisal/perception/evaluation of the hazard i.e. the involved risk (side effects).

This model has not been applied to healthcare behaviors and this is the first study to utilize components of the model to a study health behavior. Thus the final model used for the study is as follows:



The final conceptual framework was thus developed based on a comprehensive literature review.

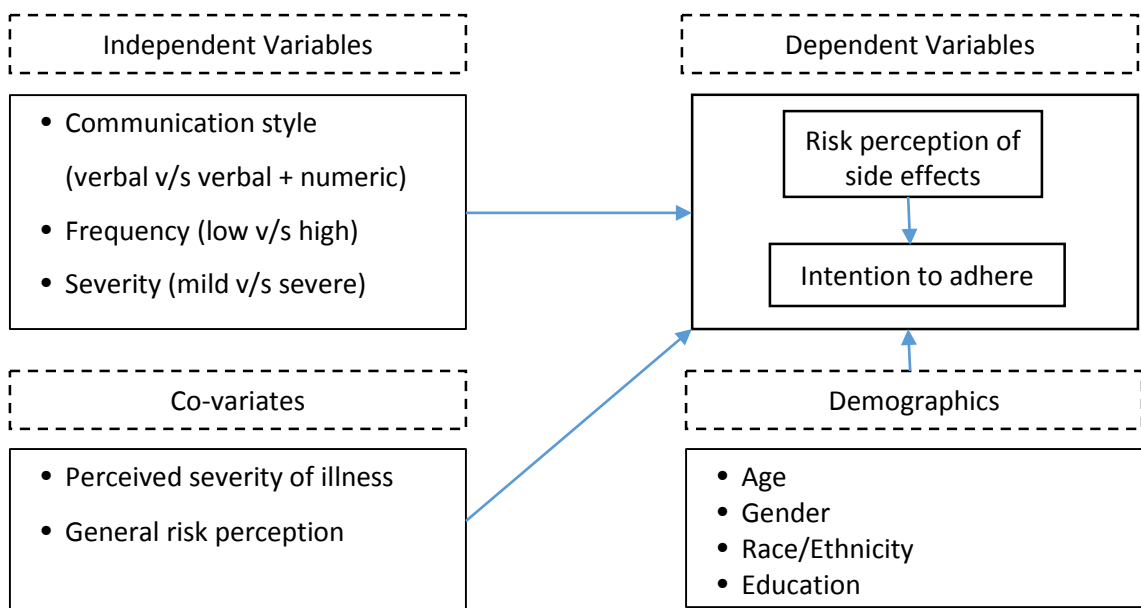


Figure 2: Conceptual framework for the study

Research Hypotheses

1. Communicating risk of medication side effects using verbal communication style combined with numeric frequencies decreases risk perception as compared to verbal only.
2. a. Decrease in risk perception of medication side effects leads to increased intention to adhere.
2. b. Communicating risk of medication side effects using verbal communication style combined with natural frequencies increases intention to adhere as compared to verbal only

CHAPTER THREE

METHODOLOGY

3.1 Design

Table 3 gives a brief summary of the research design used for the study.

Table 3: Summary of Study design

STUDY PARAMETERS	DESCRIPTION
Design	Within-between subjects (repeated) Experimental Design
Statistical Methods	Descriptive statistics Within-Between repeated measures
Outcome Measure	Objective 1: Risk perception Objective 2: Intention to take medications as directed
Population	Adults \geq 18 years
Location	Parks, places around TMC (places of public congregation)
Time-frame	May 2014 – June 2014

3.2 Study Design

The study design was an experimental within-between and factorial design. There were a total of three factors with two levels each:

Table 4: Independent variables (Factors) and their levels

FACTOR	LEVELS
1) Communication style	a) Verbal or, b) Verbal + Numeric (i.e. combined)
2) Frequency of side effect	a) Low b) High
3) Severity of side effect	a) Mild b) Severe

Thus the design was 2X2X2 factorial design with a total of 8 possible combinations of the three factors.

Table 5: List of possible combinations from the three factors (each with two levels)

COMBINATION	FACTORS		
	Communication Style	Frequency	Severity
1.	Verbal	Low	Severe
2.	Verbal	Low	Mild
3.	Verbal + Numeric	High	Severe
4.	Verbal + Numeric	High	Mild
5.	Verbal + Numeric	Low	Severe
6.	Verbal + Numeric	Low	Mild
7.	Verbal	High	Severe
8.	Verbal	High	Mild

To test the effect of all three factors on risk perception and intention to adhere, we needed to test all the eight combination. Thus to compare the response variable across the two levels of any one factor, the other two factors had to be kept constant. For e.g. if verbal communication style had to be compared to verbal + numeric communication style, one would compare the combinations 1 vs 5; 2 vs 6; 3 vs 7 and 4 vs 8. Similar comparisons would have to be done for the other two factors.

For the said comparisons, two designs could be used, a between-subjects design or a within-subjects design. In a within-subjects experimental design, each individual is exposed to more than one level of the treatment whereas in a between between-subject experimental design, each individual is exposed to only level of the treatment and different levels of the treatment are compared between different individuals (Charness, Gneezy, & Kuhn, 2012). For our study, a complete between-subjects design would require a larger sample size whereas a complete within subjects design would require each participant to respond to each one of the eight conditions and would lengthen the questionnaire. We thus chose a within-between subject design.

In the within-between study design, severity was compared within subjects whereas frequency and communication style were compared between-subjects. In order to do so, four out of the eight combinations mentioned above were clubbed together to form one group and the other four formed a second group. Thus combinations 1, 2, 3 and 4 formed one group and combinations 5, 6, 7, and 8 formed the second group.

Table 6: Combinations of factors included in Group 1

	Side effect	Frequency	Severity	Communication style
A	Stomach bleeding	Low	High	Verbal
B	Flushing	Low	Low	Verbal
C	Stomach bleeding	High	High	Combined
D	Flushing	High	Low	Combined

Table 7: Combinations of factors included in Group 2

	Side effect	Frequency	Severity	Communication style
A	Stomach bleeding	Low	High	Combined
B	Flushing	Low	Low	Combined
C	Stomach bleeding	High	High	Verbal
D	Flushing	High	Low	Verbal

3.2.1. Selection of side effects

A similar study was previously performed in Pharmacy students of University of Houston College of Pharmacy from which side effects used for the current study were adopted. The medications and side effects were chosen based on clinical expertise and knowledge about more commonly used medications. The choice of medications also depended on the characteristics of the side effects associated (severity of side effects). However the frequencies used in the current study were hypothetically assigned to fit into the study design. The verbal descriptions used for each associated frequency were taken from literature (Mosteller & Youtz, 1990).

Table 8: Study drugs and; side effects and their frequency, severity and communication style descriptions

Drug Use	Side effect	Severity	Frequency (numeric/verbal)
Prevent stroke after surgical procedures	Stomach Bleeding	High	Low (2 out of 100/ very rarely) High (70 out of 100/ likely)
Lowering cholesterol	Facial Flushing	Low	Low (10 out of 100/ rarely) High (85 out of 100/ very likely)

3.2.2 Drug Information Box

Information on side effects was presented to the participants in the form of Drug Information Box (DIB). The DIB consisted of three components, (a) Drug name/label designated as A, B, C or D in order to avoid any bias due to prior knowledge about the drug; (b) one side effect associated with the drug; and (c) description of frequency of side effect.

The following structure was used to form statements describing the side effects:

Verbal description: Drug [X] will [Y] cause [Z]

Combined description: Drug [X] will [Y] cause [Z]. Out of 100 people taking Drug [X], [W] will experience [Z].

Where,

X = Drug letter A, B, C or D

Y = Verbal description of side effect frequency

Z = Side effect

W = Numeric description of side effect

A sample DIB is as follows:

Drug A

Stomach bleeding is the side effect of drug A which is used to prevent stroke after certain surgical procedures. Drug A will very rarely cause stomach bleeding.

3.3 Questionnaire Design

The Questionnaire was designed as per the theoretical model used for the study (See Appendix Y). Some questions were adopted from a previous study which evaluated the effects of information of medication side effects on satisfaction, perceived risk and intention to comply (D. Berry et al., 2002). The survey questionnaire consisted of two sections as follows:

Section A

In section A, participants were presented with four DIBs depending on the group they were assigned to. Each DIB was followed by three questions.

Question 1: “What do you think is the risk to your health from taking Drug X, bearing in mind its side effects?” assessed the perception of risk associated with the side effect.

Question 2: “If you had been prescribed Drug X, how likely is it that you would take the medication as directed by the physician, bearing in mind the drug’s side effects?” assessed the intention of the individual to adhere to physicians instructions based on the information given about the side effects.

Question 3: “Overall how severe do you consider the illness for which Drug X is prescribed?” assessed the perception of severity of the illness/condition.

All three questions were measured on a Visual Analog Scale (VAS) ranging from 0 to 100. This scale has been previously used to measure perceptions with various behaviors such as weight and other health-related measurements (Etelson, Brand, Patrick, & Shirali, 2003). Previous studies have tested and validated the scale and have found satisfactory results. The scale has been also reported to produce more normally distributed data and greater variation in scores as compared to scales which offer discrete fixed choices (Guyatt, Townsend, Berman, & Keller, 1987; McCormack, Horne, & Sheather, 1988; McDowell, 2006).

Section B

Section B included question on general risk perception about medication side effects, “How risky do you believe it is in general to take medication for any condition?” This question was also measured using VAS from 0 to 100.

Section B also included questions on demographic characteristics of age, gender, education, race/ethnicity, and occupation (healthcare/non-healthcare).

Reliability and Validity testing

Validity Assessment: A Valid scale is one that allows accurate inferences about what is being measured (Streiner & Norman, 2008).

Content validity: Items of the questionnaire have been reviewed with utmost care and review of the literature and the content was tested for validity by using expert judgments.

Reliability Assessment: Not applicable in this study as single item measures were used.

3.4 Sample Size Estimation

Sample size estimation was done using G*Power Sample Size software (version 3.1). Based on the within-between subject design of the study and a 2X2X2 factorial design, following parameter were imputed into the software to obtain the sample size:

- a) Effect size: 0.25 (small)
- b) α -error probability: 0.05
- c) Power (1- β error): 0.95
- d) Number of groups: 8 (2x2x2)
- e) Number of measurements: 2

A sample size of 96 was found to be adequate for the study. However as we saw in the methods section, the 8 combinations (groups) were divided into two groups. As a result to obtain a sample size of 96 for the 8 groups, 96 surveys of each Group A and Group B would be required. Thus the sample size required for the study was **192**.

Table 9: Sample size for different values of effect size with alpha = 0.05 and power of 95%

Effect Size	Sample Size
0.50	32
0.45	40
0.40	48
0.35	56
0.30	72
0.25	96
0.20	144

Following is the plot between sample size and power at an effect size of 0.25. Sample size of 96 gives power of 95%.

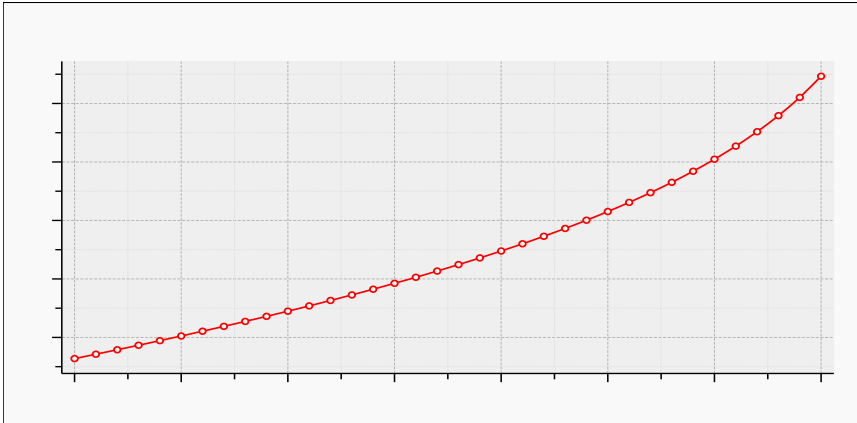


Figure 3: Plot of sample size versus power

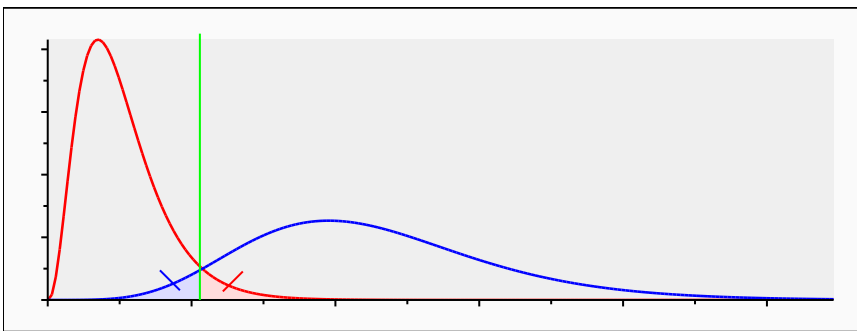


Figure 4: Distribution plot at power 95% and effect size of 0.25

3.5 Pilot Testing

Before the initiation of the actual data collection process, a pilot study was conducted with a certain number of eligible participants (n=30). Participants were asked to fill the survey and were asked if they faced any intricacies or difficulties in understanding the questions. The filled surveys were checked for any problems and the survey was revised.

3.5.1 Manipulation Check

Prior to distribution of the final surveys, a manipulation check was performed to test whether the side effects were correctly perceived as severe and mild. Participants were asked to rank the side effects from 1 (least severe) to 4 (most severe). The mean scores obtained were as follows:

Table 10: Mean rank order ratings of side effects

Severity manipulation	Side effect	Mean rank (1-4)
Mild	Drowsiness	1.24
	Facial flushing	2.33
Severe	Stomach bleeding	3.33
	Loss of immune function	3.50

3.6 Data Collection

Based upon the pilot feedback, changes were made to the questionnaire and the final instrument was used for actual data collection using the following steps:

1) Subjects at public places were approached and recited a short communique regarding the research. Willingness to participate was asked.

2) A written consent letter was given to the participants with information on the research, voluntary participation and contact information of the researcher. The participants were allowed to keep the consent letter.

3) Those willing to participate in the study were then handed over the folder with the questionnaire given instructions to answer the questions in the survey. If unwilling to participate, gender and ethnicity (judgment-based) were recorded and reason for not participating was asked. This accounted for testing of non-respondent bias.

4) Participants were then exposed to four DIBs followed by three questions for each. The next section of the questionnaire recorded demographic characteristics of the participants.

5) Participants were then thanked for their time and efforts for the survey and were asked to return the survey folders to the researcher.

3.7 Data Preparation

All data was coded and stored using Microsoft Excel 2013. All items in the questionnaire were close ended and data was coded numerically.

Responses for questions in section I were recorded on a VAS. The VAS was designed appropriate to scale using centimeters as units. The value marked by the participant was measures using a millimeter scale and recorded.

3.8 Statistical Analysis

Descriptive statistics were performed to understand the characteristics of the study population. Means of continuous variables and frequencies of categorical variables were calculated.

Differences of means of risk perception and intention to adhere across different groups were calculated using Analysis of Covariance (ANCOVA). A between-within subject design was used. This method was considered appropriate for the analysis as the design involved repeated measures of the dependent variables for two severity levels. Also there were between group comparisons for two frequency and two communication style levels.

All analysis was carried out using statistical software SAS (Version 9.3) at an apriori alpha level of 0.05

Table 11: Summary of analytical procedures

Study Objective	Variables	Measures	Statistical Procedure
Objective 1: To assess the role of communication style, frequency and severity of side effects on risk perception of medication side effects	Dependent: <ul style="list-style-type: none"> ▪ Risk perception Independent: <ul style="list-style-type: none"> ▪ Communication style ▪ Frequency ▪ Severity 	Continuous Visual Analog Scale (0 to 100)	ANCOVA, repeated between-within subjects

<p>Objective 2:</p> <p>To assess the role of communication style, frequency and severity of side effects on intention to adhere to medications.</p>	<p>a) Dependent:</p> <ul style="list-style-type: none"> ▪ Intention to adhere <p>a) Independent:</p> <ul style="list-style-type: none"> ▪ Risk perception <p>b) Dependent:</p> <ul style="list-style-type: none"> ▪ Intention to adhere <p>b) Independent</p> <ul style="list-style-type: none"> ▪ Communication style ▪ Frequency ▪ Severity ▪ Risk perception 	<p>Continuous</p> <p>Visual Analog Scale (0 to 100)</p>	<p>a) Multiple linear regression</p> <p>b) ANCOVA, repeated between-within subjects</p>
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3.9 Statistical Hypothesis

H₁: Perception of risk of experiencing medication side effects differs with difference in communication style, frequency and severity.

Difference between communication styles:

H_{1a}: There is a statistical significant difference in risk perception of medication side effects when side effects are communicated using verbal descriptions versus those communicated using verbal combined with numeric descriptions.

$$\mu_{cs1} \neq \mu_{cs2}$$

Where,

μ_{cs1} = Mean scores of risk perception with verbal communication style.

μ_{cs2} = Mean scores of for risk perception with verbal + numeric communication style.

Difference between frequency levels:

H1b: There is a statistical significant difference in risk perception of medication side effects between side effects of high frequency versus side effects of low frequency.

$$\mu_{f1} \neq \mu_{f2}$$

Where,

μ_{f1} = Mean scores for risk perception for high frequency side effects.

μ_{f2} = Mean scores for risk perception for low frequency side effects.

Difference between severity levels:

H1c: There is a statistical significant difference in risk perception of medication side effects between side effects of high severity versus side effects of low severity.

$$\mu_{cs1} \neq \mu_{cs2}$$

Where,

μ_{cs1} = Mean scores for risk perception for high severity side effects.

μ_{cs2} = Mean scores of for risk perception for low frequency side effects.

H₂: Intention to adhere to medications depends on risk perception of medication side effects and differs with difference in communication style, frequency and severity.

Intention and risk perception

H_{2a}: Intention to adhere to medications is associated with risk of experiencing side effects.

Null Hypothesis (H₀): There is no association between intention to adhere to medications and risk of experiencing side effects.

Difference between communication styles:

H_{2b}: There is a statistical significant difference in intention to adhere when side effects are communicated using verbal descriptions versus those communicated using verbal combined with numeric descriptions.

$$\mu_{cs3} \neq \mu_{cs4}$$

Where,

μ_{cs3} = Mean scores of intention to adhere with verbal communication style.

μ_{cs4} = Mean scores of for intention to adhere with verbal + numeric communication style.

Difference between frequency levels:

H_{2c}: There is a statistical significant difference in intention to adhere between side effects of high frequency versus side effects of low frequency.

$$\mu_{f3} \neq \mu_{f4}$$

Where,

μ_{f3} = Mean scores for risk perception for high frequency side effects.

μ_{f4} = Mean scores for risk perception for low frequency side effects.

Difference between severity levels:

H2d: There is a statistical significant difference in intention to adhere to medications between side effects of high severity versus side effects of low severity.

$$\mu_{cs3} \neq \mu_{cs4}$$

Where,

μ_{cs3} = Mean scores for risk perception for high severity side effects.

μ_{cs4} = Mean scores of for risk perception for low frequency side effects.

Human Subject Protection

The research was reviewed and approved by The University of Houston Institutional Review Board.

CHAPTER FOUR

RESULTS

This chapter provides description of the demographic characteristics of the respondents, results of analyses performed to test the outcomes of individual hypotheses tests.

4.1 Survey Collection, Coding and Analyses

The data collection, coding and analysis followed the following timeline:

Table 12: Time of data collection, coding and analysis

Data Collection Period	April 29 – May 18, 2014
Data Coding and Entry	Simultaneously as data was collected
Data Analysis and Interpretation	3 rd – 4 th week of May

A total of 196 completed surveys were collected. Questionnaire were coded for survey location, time and day when survey was collected and for the randomization identification number as soon as they were completed and returned by the respondents. Each questionnaire was marked with a unique identification number before entering the database into the software.

4.2 Missing Value Imputation

Cold-deck imputation method was used for imputation of missing values. The missing values for continuous variables were imputed with the respective means whereas categorical variables were imputed with the respective medians. Missing values for demographic variables such as gender as gender and ethnicity were not imputed.

4.3 Response Rate

A total of 240 individuals were approached, out of which 198 agreed to participate in the study. 2 individuals did not complete the survey due to loss of interest. Remaining 196 completed the survey giving a response rate of 81.6%.

Table 13: Non-respondent's reason to decline participation in the study

Reason	Percentage (n=42)
Not interested	17
No time/ rush	7
Language barrier	10
Other	8

4.4 Statistical analysis

All statistical analyses were performed at the set a priori alpha level of 0.05 using SAS[®] statistical package (version 9.3, SAS[®] Institute Inc. Cary, NC). Statistical analyses in this chapter are divided into three parts. First part describes the demographic characteristics of the sample. Second part presents results of the outcomes of hypotheses tests. Third part includes the summary of the results.

4.4.1 Sample Characteristics

Age: The mean age of the participants was 42.20 (± 12.14) years. Age of the participants ranged from 19 to 74 years.

Table 14: Distribution of Age in the study sample

Variable	Mean (SD)	Median	Range
Age	42.20 (± 12.14)	41	19-74

Gender: The study sample consisted of almost equal proportion of male and female respondents.

Table 15: Distribution of Gender in the study sample

Gender	Frequency (%)
Male	92 (46.94)
Female	104 (53.06)

Ethnicity: The majority of respondents were non-Hispanic Whites (57.65%), followed by African Americans (17.86%), Hispanic (16.33%), and Asian (6.63%).

Education: All the respondents in the study had at least elementary level school education. About more than half of the respondents had college level education.

Table 16: Distribution of Education in the study sample

Education	Frequency (%)
School (Elementary + High)	23 (10.71)
College	112 (57.14)
Masters	48 (24.49)
Doctoral	15 (7.65)

Profession: A majority of the respondents were in the non-healthcare profession (81.2%).

Table 17: Distribution of Profession in the study sample

Profession	Frequency (%)
Healthcare	37 (18.88)
Non-healthcare	159 (81.12)

4.4.2 Effect of extraneous variables on risk perception and intention to adhere

There was no effect of extraneous variables of age, gender, sex, education and healthcare profession ($p > 0.05$). General risk perception had a positive effect on risk perception ($p < 0.001$) i.e. perception of risk increased with increase in general perception of risk associated with medications. Race was found to be significant in the overall model. However since 57% of the study population were whites and percentage of respondents belonging to other races were very less as compared to white, we classified race into two categories i.e. Whites and non-Whites. It was found that Whites had significantly greater risk perception scores as compared to non-Whites ($p < 0.01$). However race had no significant effect on intention to adhere to medications.

4.4.3. Hypotheses testing

Before we move on to the results of the hypothesis testing, we will first take a look at the descriptive statistics for the dependent variables risk perception, intention to adhere and severity of illness.

a) Overall means of dependent variables.

Table 18: Means of Risk Perception, Intention to Adhere and Severity of Illness

Variable	N	Mean	Standard Deviation	Minimum	Maximum
Risk perception	784	39.37	30.91	0	100.00
Intention to adhere	784	65.77	31.59	0	100.00

b) Means of dependent variables across independent variables.

Table 19: Means of risk perception, intention to adhere and perceived severity of illness across different levels of communication style, frequency and severity of side effects

Comm	Freq	Sev	N	Variable	Mean	Std Dev	Min	Max
0	1	1	102	Risk	23.76	23.71	0.00	96.00
				Intent	80.44	23.55	9.50	100.00
		2	102	Risk	33.79	23.45	5.00	100.00
				Intent	71.61	30.44	0.00	100.00
				Severity	70.99	24.67	4.00	100.00
	2	1	94	Risk	31.13	26.13	0.00	95.00
				Intent	73.11	25.38	0.00	100.00
		2	94	Risk	70.81	23.87	0.00	100.00
				Intent	44.00	32.15	0.00	100.00
1	1	1	94	Risk	18.35	19.43	0.00	83.50
				Intent	79.68	22.43	15.00	100.00
		2	94	Risk	22.56	21.81	0.00	83.50
				Intent	74.62	28.31	0.00	100.00
	2	1	102	Risk	38.93	29.41	0.00	100.00
				Intent	61.50	29.81	0.00	100.00
		2	102	Risk	74.46	17.71	29.00	100.00
				Intent	41.87	32.11	0.00	100.00

Comm = Communication style (0 = verbal; 1 = verbal + natural frequency)

Freq = Frequency (1 = Low; 2 = High)

Sev = Seveirty (1 = Mild; 2 = severe)

c) Correlation between dependent variables.

Table 20: Correlation matrix for risk perception, intention to adhere and perceived severity of illness

Variables	(1)	(2)
1) Risk perception	1.000	
2) Intent	-0.574*	1.000

* Indicates a significant correlation i.e. $p < 0.05$

To test the hypotheses with the variables under consideration, two methods of n can be used:

a) ANCOVA i.e. Analysis of Co-variance: A separate univariate ANCOVA can be performed for each dependent variable. The univariate tests will not produce multivariate tests utilizing information from all variables simultaneously.

b) MANCOVA i.e. Multivariate Analysis of Co-variance: This test is performed when there is more than one continuous independent variable.

A univariate test will produce multivariate results utilizing information from all variables simultaneously. In addition, separate univariate tests are generally less powerful because they do not take into account the inter-correlation of the dependent variables. Although the correlation coefficients between the dependent variables were small, we performed a MANCOVA to test the effects of independent variables on dependent variables. Also separate univariate ANCOVAs were performed to measure the differences in least square (LS) means dependent variables across all three independent variables. The analyses were controlled for the variables general risk perception and race.

Multivariate Analysis

The MANCOVA test indicated a significant effect of frequency of side effects ($p < 0.001$) for risk perception and intention to adhere. Severity of side effects had a significant effect on risk perception, intention to adhere and perceptions of severity of illness ($p < 0.001$). Although communication style did not have significant main effects on either of the dependent variables, effects were seen in interaction with frequency of side effects for both dependent variables. Interestingly there were no significant effects of

the interaction between communication style, frequency and severity on either of the dependent variables.

In the following sections, we will see the MANCOVA estimates, interaction effects and the differences in LS means of independent variables with different combinations of communication style, frequency and severity of side effects for each dependent variable.

I. Dependent variable: Risk perception

Table 21: MANCOVA estimates for risk perception

Independent Variable	Wilk's Lambda	F (3,772)	p-value
Communication style	0.994	2.14	0.1179
Frequency	0.694	169.93	<0.001
Severity	0.797	98.33	<0.001
Severity*Frequency	0.897	44.30	<0.001
Communication style*Frequency	0.973	10.43	<0.001
Communication style*Severity	0.995	1.85	0.1586
Communication style*Severity*Frequency	0.998	0.43	0.6523

Separate univariate analysis for risk perception also indicated similar results as that of multivariate analysis (Table X). Communication style showed significant effects in interaction with frequency of side effects ($p < 0.001$). Frequency and Severity also showed individual significant effects on risk perception ($p < 0.001$).

Table 22: ANCOVA estimates for risk perception

Variable	DF	Type III SS	Mean Square	F Value	Pr > F
Communication style	1	329.70	329.70	0.64	0.4242
Frequency	1	167007.24	167007.24	323.89	<.0001
Severity	1	97844.04	97844.04	189.76	<.0001
Severity*Frequency	1	10664.18	10664.18	20.68	<.0001
Communication style*Severity	1	1219.12	1219.12	2.36	0.1245
Communication style*Frequency	1	45453.61	45453.61	88.15	<.0001
Communication style*Severity*Frequency	1	34.17	34.17	0.07	0.7969
General risk perception	1	11695.32	11695.32	22.68	<.0001
Race	1	7763.46	7763.46	15.06	0.0001
Model	9	349081.62	38786.85	75.22	<.0001
Error	774	399096.14	515.63		
Corrected Total	783	748177.76			

ANCOVA results showed that maximum effect was that of frequency of side effects followed by severity of side effects. Communication style did not show any significant effects on risk perception alone however had significant effects in interaction with frequency of side effects. Although the overall interaction effects were not significant, the LS means show significant effects for certain combinations of communication style, frequency and severity.

I. a. Two-way interaction: communication style and frequency

The LS means for communication style showed that low frequency side effects communicated in combined communication style has the least risk perception scores as compared to all other combinations of communication style and frequency. Highest risk perception scores were found for high frequency side effects with combination communication style. In general frequency played a stronger role in determining risk perception scores. Figure 5 shows the interaction plot for communication style*frequency.

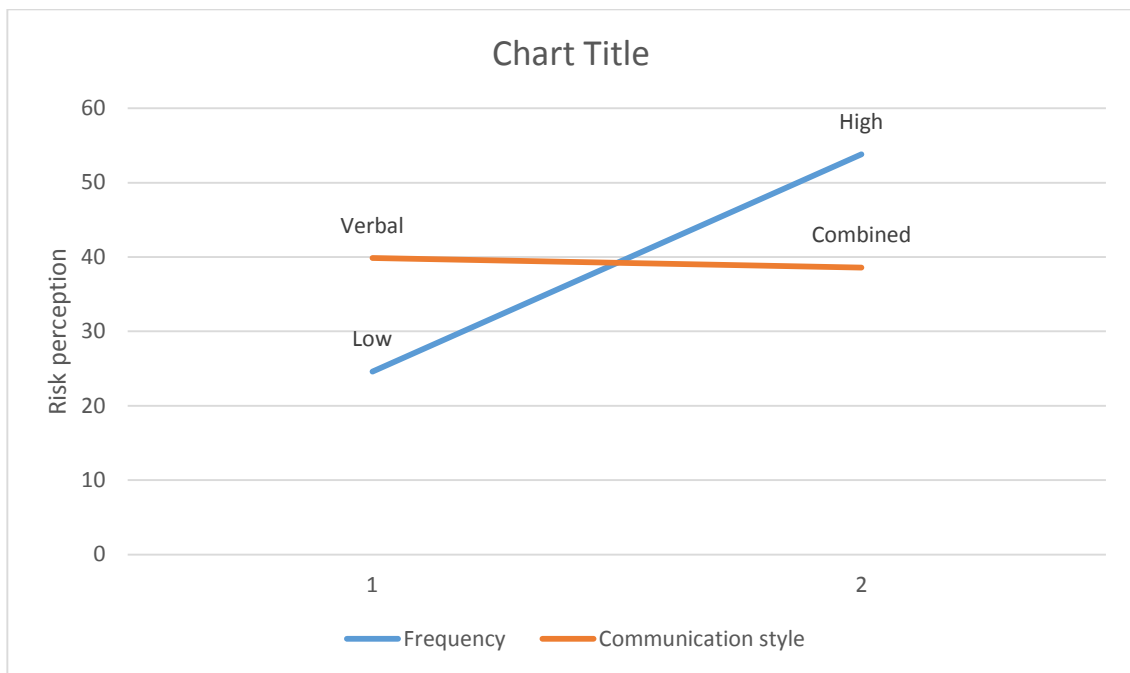


Figure 5: Interaction plot for communication style*frequency

Table 23: Least Square means of risk perception for Communication style*frequency interaction

Frequency	Communication Style	Mean (95% CI)	Difference between means (95% CI)	P-value
Low	Verbal	28.77 (25.55 – 32.00)	8.32 (3.66 – 12.97)	0.0005
	Verbal + Natural Frequency	20.46 (19.10 – 23.81)		
High	Low	50.97 (47.60 – 54.32)	5.72 (1.07 – 10.38)	0.0160
	High	56.69 (53.47 – 59.91)		

As we can see from Figure Y and Table X, there is significant interaction between communication style and frequency of side effects. Low frequency side effects have lower risk perception scores with combined communication style as compared to verbal only whereas high frequency side effects have higher risk perception scores with combined communication style as compared to verbal only.

I. b. Two-way interaction: Communication style and severity

The LS means for communication style and severity interaction showed that low severity side effects communicated in verbal communication style had the least risk perception scores as compared to all other combinations of communication style and severity. Figure 6 shows the interaction plot for communication style*severity.

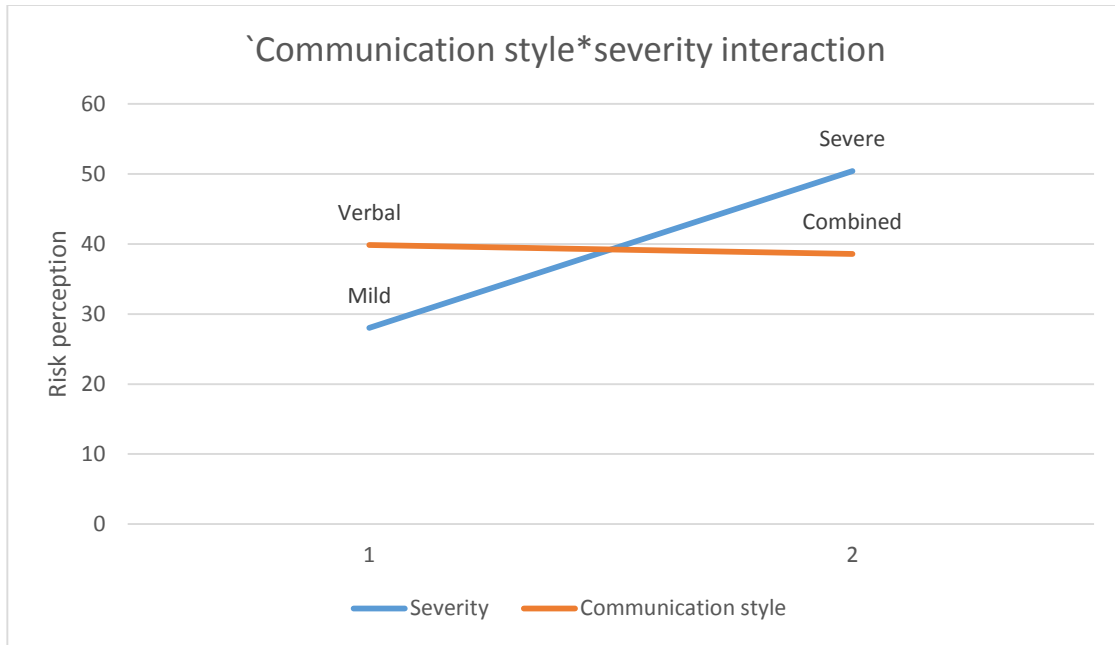


Figure 6: Interaction plot for communication style*frequency

Table 24: Least Square means of risk perception for Communication style*severity interaction

Severity	Communication Style	Mean (95% CI)	Difference between means (95% CI)	P-value
Mild	Verbal	27.44 (24.15 – 30.73)	1.19 (-5.85 – 3.46)	0.6137
	Verbal + Natural Frequency	28.64 (25.35 – 31.93)		
Severe	Verbal	52.30 (49.00 – 55.59)	3.79 (-0.86 – 8.45)	0.1101
	Verbal + Natural Frequency	48.50 (45.21 – 51.79)		

The interaction between communication style and severity was not significant. However severity alone had a significant effect on risk perception with high severity (severe) side effects having higher risk perception scores as compared to low severity (mild) side effects.

I. c. Two-way interaction: Frequency and severity

Low frequency mild side effects had the lowest risk perception scores and high frequency severe side effects had the highest risk perception scores.

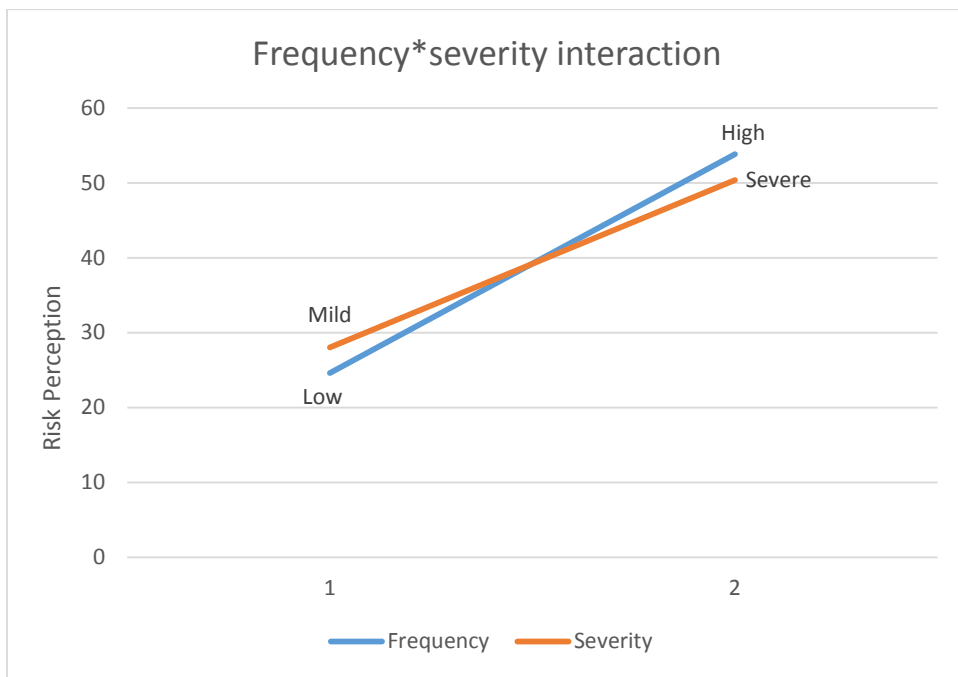


Figure 7: Interaction plot for frequency*severity

Table 25: Least Square means of risk perception for Frequency*severity interaction

Frequency	Severity	Mean (95% CI)	Difference between means (95% CI)	P-value
Low	Mild	21.05 (17.76 - 24.34)	-7.12 (-11.78 – -2.46)	0.0028
	Severe	28.18 (24.88 – 31.47)		
High	Mild	35.03 (31.73 – 38.32)	-37.60 (-42.25 – -32.95)	<0.0001
	Severe	72.63 (69.34 – 75.92)		

LS means for interaction between frequency and severity showed significant effects on risk perception. It was observed that increase in frequency lead to significant increase in risk perception scores. Similarly severe side effects had higher risk perception scores as compared to mild side effects. It was also observed that change in severity from mild to severe lead to a greater increase in risk perception when the frequency of the side effect was high (mean diff = 37.60) as compared to when the frequency of side effects was low (mean diff = 7.12). Similarly, change in frequency from low to high lead to a greater increase in risk perception scores when the severity was high (mean diff = 44.45) as compared to when the severity was low (mean diff = 13.97).

I. d. Three-way interaction: Communication style, Frequency and severity

LS means of risk perception for communication style*frequency*severity interaction showed that mild side effects of low frequency communicated using combined communication style had the lowest risk perception scores and severe side effects of high frequency communicated using combined communication style had the highest risk perception scores as compared to all combinations of communication style*frequency*severity.

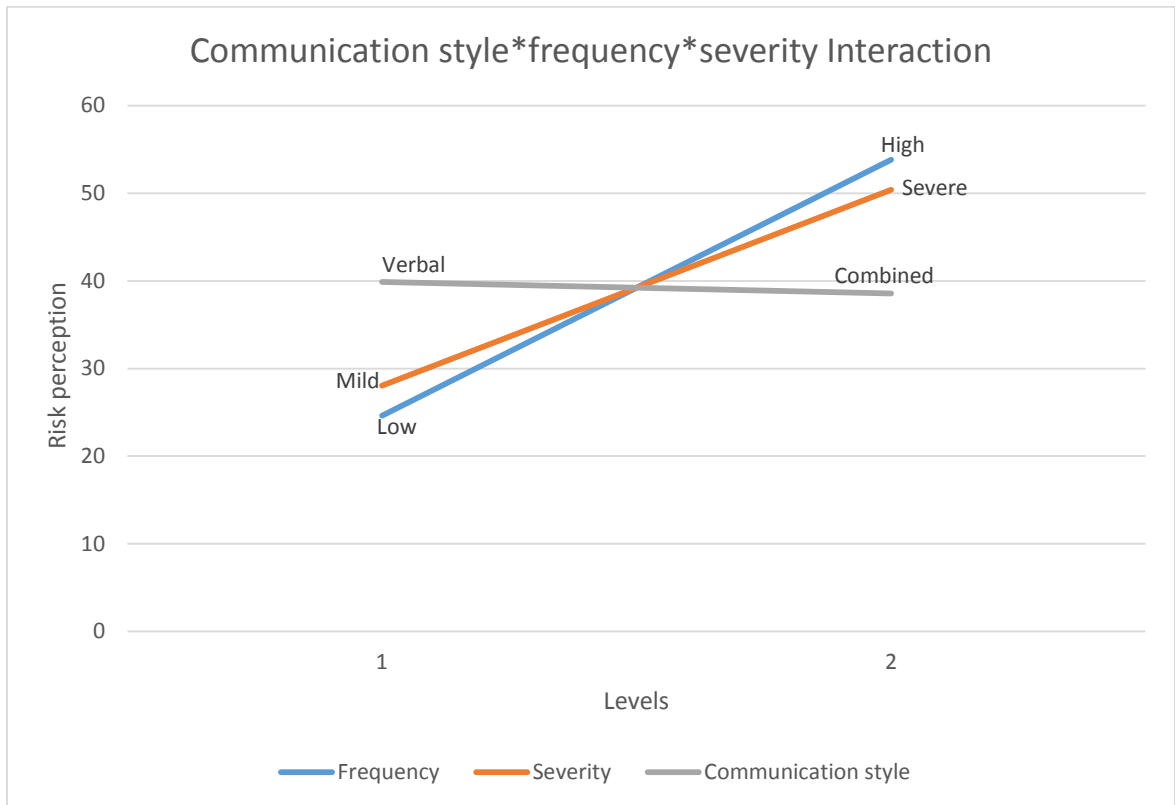


Figure 8: Interaction plot for communication style*frequency*severity

Table 26: Least Square means of risk perception for Communication style*frequency*severity interaction

Frequency	Severity	Communication style	Mean (95% CI)	Difference between (95% CI)	P-value
Low	Mild	Verbal	23.76 (19.20 – 28.32)	5.41 (-1.18 – 11.99)	0.1074
Low	Mild	Combined	18.35 (13.60 – 23.10)		
Low	Severe	Verbal	33.79 (29.23 – 38.35)	11.24 (4.6 – 17.82)	0.0008
Low	Severe	Combined	22.56 (17.81 – 27.30)		
High	Mild	Verbal	31.13 (26.38 – 35.88)	-7.80 (-14.39 - -1.21)	0.0203
High	Mild	Combined	38.93 (34.37 – 43.49)		
High	Severe	Verbal	70.81 (66.06 – 75.56)	-3.64 (-10.23 – 2.94)	0.2773
High	Severe	Combined	74.46 (69.90 – 79.01)		

The ANCOVA results indicated that there were no significant effects of interaction between communication style, frequency and severity. However, as shown in the table above, certain interactions between the three independent variables were significant. Overall, it was observed that for low frequency side effects, communicating

risk using combined communication style lead to a decrease in risk perception scores whereas use of only verbal communication style lead to an increase in risk perception scores. In case of high frequency side effects, use of combined communication style lead to an increase in risk perception scores whereas verbal communication style lead to a decrease in risk perception scores. However, significant effects of communication style were only seen for low frequency severe side effects and high frequency mild side effects. Low frequency mild side effects and high frequency severe side effects showed no significant effects of communication style.

II. Dependent variable: Intention to adhere

Before proceeding to MANCOVA and ANCOVA, a regression test was performed to test the effects of risk perception and severity of illness on intention to adhere. It was observed that risk perception was negatively associated and severity of illness was positively associated with intention to adhere. Thus both risk perception and intention to adhere were included in the final ANCOVA model as co-variates.

Table 27: Multiple Regression Analysis estimates for intention to adhere

Variable	Parameter Estimate	t-value	P-value
Risk perception	-0.61	-19.65	<0.0001

Table 28: MANCOVA estimates for Intention to adhere

Independent Variable	Wilk's Lambda	F (3,772)	p-value
Communication style	0.994	1.50	0.2134
Frequency	0.694	113.15	<0.001
Severity	0.720	99.90	<0.001
Severity*Frequency	0.897	29.70	<0.001
Communication style*Frequency	0.968	8.38	<0.001
Communication style*Severity	0.995	1.23	0.2978
Communication style*Severity*Frequency	0.998	0.33	0.8013

Separate univariate analysis for risk perception also indicated similar results as that of multivariate analysis (Table X). Communication style showed significant effects in interaction with frequency of side effects ($p < 0.001$). Frequency and Severity also showed individual significant effects on risk perception ($p < 0.001$).

Table 29: ANCOVA estimates for intention to adhere

Variable	DF	Type III SS	Mean Square	F Value	Pr > F
Communication style	1	2461.48	2461.48	3.8	0.0516
Frequency	1	7421.00	7421.00	11.45	0.0007
Severity	1	6965.46	6965.46	10.75	0.0011
Severity*Frequency	1	420.58	420.58	0.65	0.4207
Communication style*Frequency	1	294.67	294.67	0.45	0.5003
Communication style*Severity	1	841.50	841.50	1.3	0.2548

Communication style*Severity*Frequency	1	455.03	455.03	0.7	0.4023
General risk perception	1	4599.87	4599.87	7.1	0.0079
Risk perception with side effects	1	99062.81	99062.81	152.9	<.0001
Severity of illness	1	6748.93	6748.93	10.42	0.0013
Model	10	280738.21	280738.82	43.33	<.0001
Error	773	500836.44	647.91		
Corrected Total	783	781574.65			

ANCOVA results showed that maximum effect was that of frequency of side effects followed by severity of side effects. Communication style did not show any significant effects on risk perception alone as well as in interaction with frequency or severity of side effects. Only frequency and severity showed significant effects on intention to adhere. It was observed that intention to adhere was greater with low frequency side effects (Mean = 69.45; 95% CI = 66.68 – 72.23) and was lesser with high frequency side effects (Mean=62.14; 95% CI = 59.37 – 64.91). Similarly medication with mild side effects had higher intention to adhere (Mean = 69.29; 95% CI = 66.53 – 72.04) as compared to medications with severe side effects (Mean = 62.31; 95% CI = 59.56 – 65.05). Like individual effects, interaction of severity and frequency was also found to be significant.

I. a. Two-way interaction: communication style and frequency

Although frequency itself showed significant effects on risk perception, there were no significant effects of the interaction of frequency with communication style.

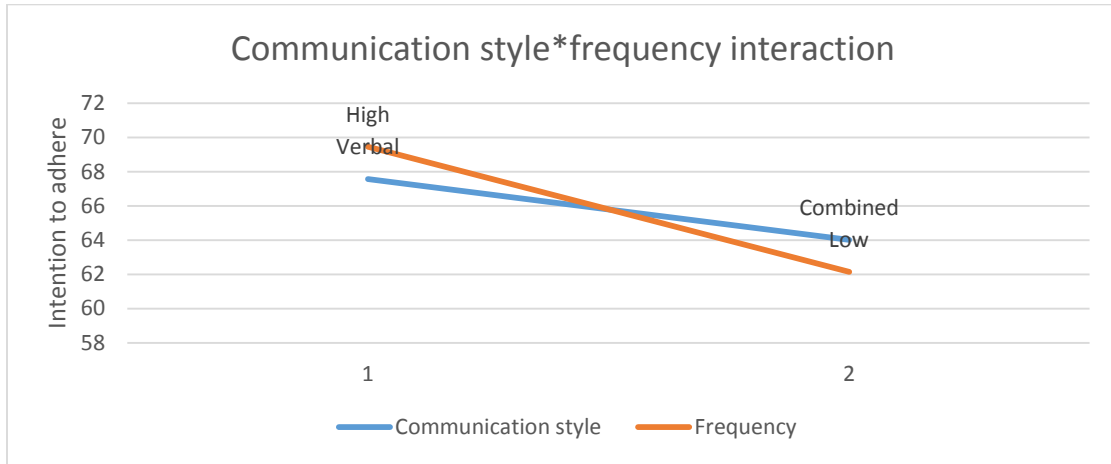


Figure 9: Interaction plot for communication style*frequency

Table 30: Least Square means of Intention to adhere for Communication style*frequency interaction

Frequency	Communication Style	Mean (95% CI)	Difference between means (95% CI)	P-value
Low	Verbal	70.60 (67.01 – 74.20)	2.30 (-2.80 – 7.41)	0.3767
	Verbal + Natural Frequency	68.30 (64.36 – 72.25)		
High	Low	64.53 (60.78 – 68.29)	4.79 (-0.29 – 9.88)	0.0645
	High	59.74 (55.98 – 63.50)		

I. b. Two-way interaction: Communication style and severity

Interaction of communication style and frequency showed that for mild side effects, use of combined communication style lead to a decrease in intention to adhere as compared to verbal communication style. However the effect of seen is partly due to the effects of frequency of side effects as communication style is associated with describing the frequency of side effects. We will discuss the interaction effects more clearly in the sections below.

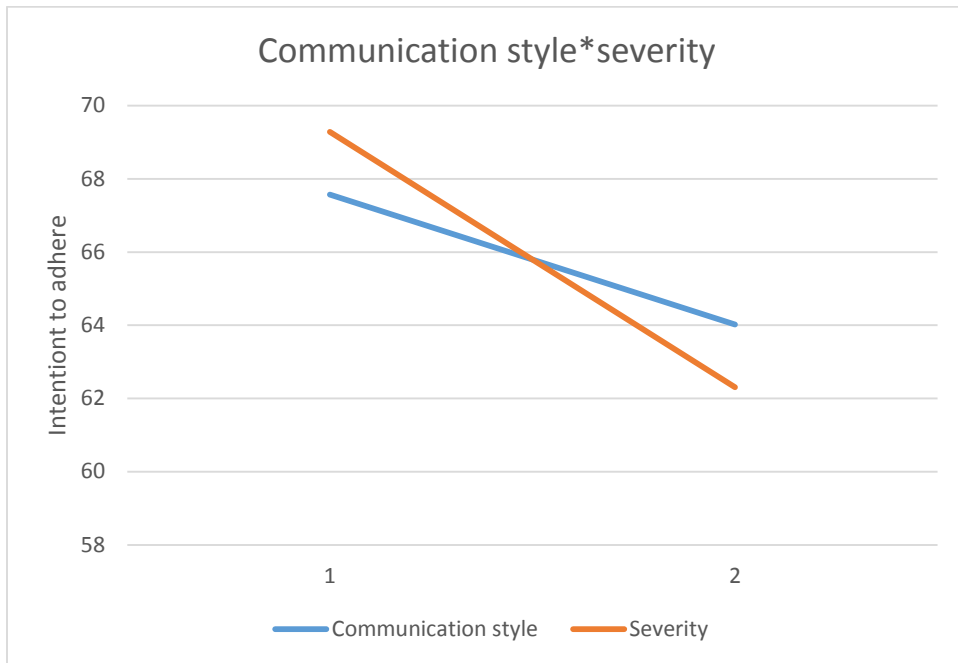


Figure 10: Interaction plot for communication style*frequency

Table 31: Least Square means of Intention to adhere for Communication style*severity interaction

Severity	Communication Style	Mean (95% CI)	Difference between means (95% CI)	P-value
Mild	Verbal	72.10 (86.35 – 75.85)	5.63 (0.57 – 10.68)	0.0291
	Verbal + Natural	66.47		
	Frequency	(62.75 – 70.19)		
Severe	Verbal	63.04 (59.28 – 66.80)	1.47 (-3.59 – 6.53)	0.5683
	Verbal + Natural	61.57		
	Frequency	(57.87 – 65.27)		

I. c. Two-way interaction: Frequency and severity

Intention to adhere had an inverse association with both severity and frequency of side effects i.e. increase in either frequency or severity of side effects lead to a decrease in intention to adhere. Also change in levels of frequency and severity caused change in intention to adhere almost by equal amounts.

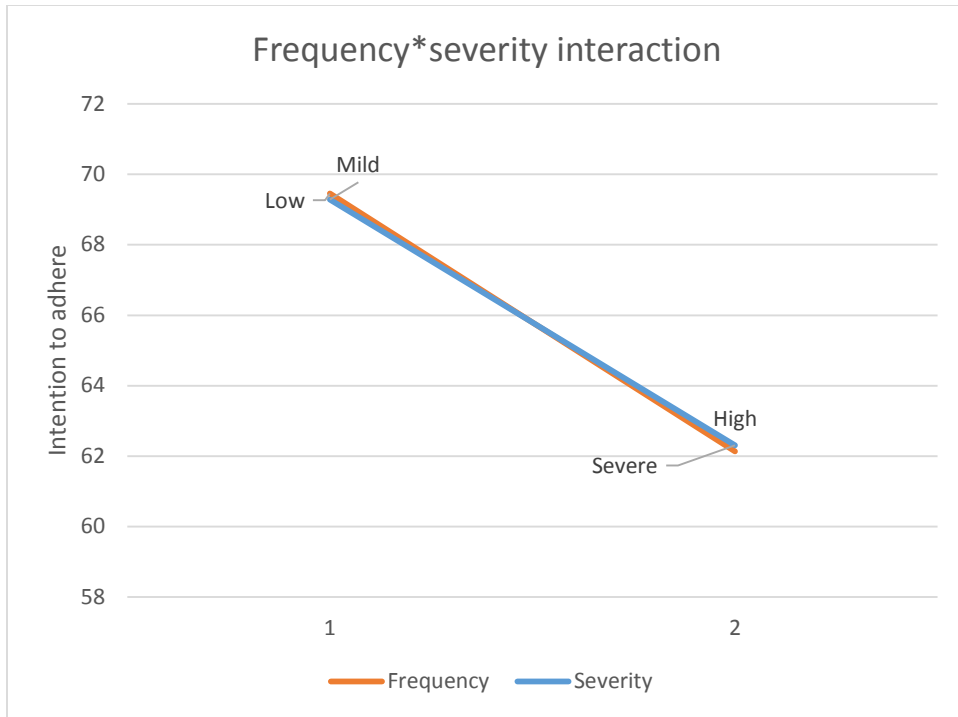


Figure 11: Interaction plot for frequency*severity

Table 32: Least Square means of Intention to adhere for Frequency*severity interaction

Frequency	Severity	Mean (95% CI)	Difference between means (95% CI)	P-value
Low	Mild	72.17 (68.28 – 70.06)	5.43 (0.21 – 10.64)	0.0412
	Severe	66.73 (63.00 – 70.46)		
High	Mild	66.40 (62.74 – 70.06)	8.52 (2.51 – 14.53)	0.0055
	Severe	57.88 (53.41 – 62.34)		

I. d. Three-way interaction: Communication style, Frequency and severity

LS means of risk perception for communication style*frequency*severity interaction showed that mild side effects of low frequency communicated using combined communication style had the lowest risk perception scores and severe side effects of high frequency communicated using combined communication style had the highest risk perception scores as compared to all combinations of communication style*frequency*severity.

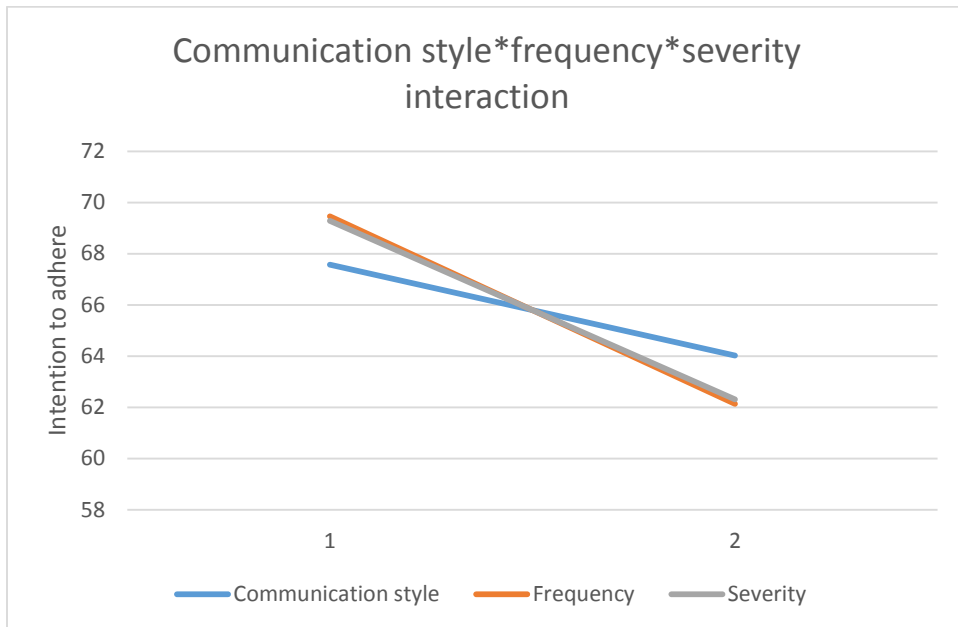


Figure 12: Interaction plot for communication style*frequency*severity

Table 33: Least Square means of Intention to adhere for Communication style*frequency*severity interaction

Frequency	Severity	Communication style	Mean (95% CI)	Difference between (95% CI)	P-value
Low	Mild	Verbal	73.59 (68.48 – 78.71)	2.85 (-4.31 – 10.01)	0.4346
Low	Mild	Combined	70.74 (65.28 – 76.20)		
Low	Severe	Verbal	67.61 (62.59 – 72.63)	1.74 (-5.46 – 8.96)	0.6340
Low	Severe	Combined	65.86 (60.52 – 71.21)		
High	Mild	Verbal	70.60 (65.34 – 75.86)	8.40 (1.22 – 15.58)	0.0219
High	Mild	Combined	62.20 (57.22 – 67.19)		
High	Severe	Verbal	58.47 (52.75 – 64.20)	1.19 (-5.96 – 8.35)	0.7436
High	Severe	Combined	57.28 (51.55 – 63.01)		

The overall effects for interaction between communication style, frequency and severity of side effects were not significant. LS means for the interaction indicated that for high frequency mild side effects, use of combined communication style lead to decrease in risk perception scores as compared to verbal communication style. Given the fact that risk perception and intention to adhere were inversely associated, the results for intention to adhere were in line with those for risk perception as high frequency mild side effects had lower risk perception scores when communicated using combined communication style as compared to verbal communication style.

CHAPTER FIVE

DISCUSSION, LIMITATIONS, IMPLICATIONS AND CONCLUSION

This chapter is divided in four parts. First part presents a discussion of the findings obtained for individual hypothesis tests performed in the study. Second part discusses the potential limitations of the study, which is followed by likely implications of the findings and conclusion as third and fourth parts, respectively.

5.1 Discussion

The primary aim of the study was to assess the effect of communication style, frequency and severity of side effects associated with medications on perceived risk to their health from taking the medications. The study also evaluated the effects of communication style, frequency and severity of side effects on intention to adhere to medications (i.e. take medications as prescribed by the physicians).

5.1.1 Demographic characteristics

The mean age of the sample was 42.20 (SD 12.14) years including almost equal proportion of male and female respondents. A majority of the respondents were non-Hispanic Whites (57.65%).

All of the study participants had at least elementary level education. Majority of the study population i.e. about 89.28% of the participants had a minimum of college level education. It may occur that responses of risk perception and intention to adhere may differ between uneducated or less educated people, however literature has reported that less educated people are less likely to take part in the healthcare surveys (Korkeila et al., 2001).

About 81% of the study population belonged to the non-healthcare profession. The study involved testing of health related information and terms which may have been easier to understand for individuals working in healthcare fields and may have introduced a bias. However since a majority of the study population belonged to non-healthcare professions, it could be said that the results observed are primarily based on the information presented and not due to any prior understanding or knowledge gained from professional healthcare surroundings.

5.1.2 Risk Perception and Intention to adhere

Risk perception of side effects is a subjective evaluation that individuals make depending upon the characteristics of risk involved, in this case the side effects. The characteristics of side effects that were considered for the purpose of study included communication style, frequency and severity and their effects on risk perception, individually as well as in conjunction with each other. Previous studies have reported that manipulations of severity have the greatest impact on peoples' judgements (Wogalter et al., 1999; Berry et al., 2002). However in the current study, of all the three factors, frequency of side effects i.e. the magnitude of the risk was found to have the strongest influence on risk perception followed by severity of side effects. According to Wogalter and co-workers that the ratings of risk or hazard perceptions depended on the content/items presented and that dependence of risk perception on severity or likelihood was based on the type of content. The two levels of frequency used for the current study were far apart from each other and this could be one of the reason for the maximum effect of side effect frequency. As one would expect, high frequency side effects had higher risk perception as compared to low frequency side effects. Similarly side effects

which were more severe had higher risk perception as compared to side effects which were less severe or mild. Frequency and severity of side effects not only had individual main effects but also had significant interaction with each other. Some researchers have argued that perceptions of risk for a hazard are dependent on either only severity or only likelihood of the risk. Some other studies have reported that risk perception are determined by both severity and likelihood of the event (Fischhoff, Bostrom, & Quadrel, 1993). Our study results reinforce the fact that risk perception is an interplay of the severity of consequences and likelihood of the risk and the two effects cannot be separated from each other.

Previous studies have looked at the preferred format or style for communicating risk of medication side effects i.e. percentages or relative frequencies or actual frequencies or using just plain language (verbal terms). However the interaction of these communication styles with frequency and severity of side effects is not yet clear. The current study reported that the use of either verbal or verbal combined with natural frequency affected risk perception scores only for certain combinations of frequency and severity. For low frequency mild side effects, there was no effect of communication style. An explanation for this could be the fact that the overall seriousness of the consequences of suffering from drug side effects was lowered due to the low frequency and low severity of the side effects. As a result people did not perceive side effects as a high risk in comparison to the benefits derived from the medication and based their perceptions only on frequency and severity information ignoring the stylistic factors of the message. Similarly, communication style did not play a role for high frequency severe side effects. These results confirm findings from previous literature which states that for the

participants who were presented with information that described the hazard as high risk and severe, evaluations of personal risk was less likely to be based on the stylistic factors in the message (Griffin, Dunwoody, & Neuwirth, 1999). The only combinations of frequency and severity that showed effects of communication style were low frequency severe side effects and high frequency mild side effects. In both the combinations, it was observed that combining verbal and numeric descriptions of frequency of side effects magnified the effects of frequency. For low frequency high severity side effects, use of verbal combined with numeric descriptors decreased risk perception. Previous research has indicated that when the consequences associated with an event are very serious, the only remaining uncertainty about the outcome is the likelihood of the event (Hendrickx, Vlek, & Oppewal, 1989). Thus for severe side effects like stomach bleeding in the case of our study, people paid attention to the frequency descriptions in order to make judgments regarding the risk. The high level of severity may take perceptions of risk higher, however once the low associated frequency is understood better as with the use of verbal plus numeric descriptions, perceptions of risk lower down. Similarly in the case of high frequency and mild side effects like facial flushing in our study, people's perceptions of risk are initially low due to the low severity of the side effect. However when the high frequency of the side effects is understood better because of the numeric descriptions, the perceptions of risk increases. Thus as we see the change in perception of risk across communication styles is dependent on the associated frequency of side effects.

With respect to intention to adhere, it was observed that there were no effects of communication style on intention to adhere. One reason for this observation could be due to the framing of the question which captured responses of intention to adhere. The

question asked whether the participants would take the medications as directed ‘if prescribed by the physician’. As was observed during the time of data collection, participants seemed to concentrate on the phrase ‘if prescribed by physician’ and less on side effects and hence effects of communication style were not seen. Also the indications for which the medications were used and the associated side effects may have masked the effects of communication style on intention to adhere. For e.g. Medication used to prevent stroke was presented to have a side effect of stomach bleeding, however stroke being already a serious condition, people may have based their intention to adhere mainly on the condition. Similarly the other medication used to maintain cholesterol levels had a side effect of facial flushing which is a mild side effect as compared to the indication. As a result the participants may have ignored the details regarding communication style. It was observed however that high severity and high frequency side effects decreased the intention to adhere to medications. Also another observation was that the scores for intention to adhere were in the range of 59 – 75 units which is in the higher range and this could be due to the fact that since it was a survey people tend to answer more positively.

5.2 Limitations

The results of the study should be viewed within the context of certain limitations. The study tested the effects of communication style only for two side effects and the associated frequencies and severity. The effects observed may not be generalizable for all side effects. Individuals with limited English speaking ability were not included in the study. The results could not be generalizable to normal population. Other factors that might affect risk perception were not taken measured and taken into consideration and may have affected the perceptions of risk and intention to adhere. Another limitation is

inherent to survey studies. This study only measured intent for adherence rather than actual adherence, and was not presented in a real life situation. Additionally, the effects of psychological framing have significant consequences on how people evaluate information, including health risk information (Tversky & Kahneman, 1985)

5.3 Implications

The study results imply that use of numeric descriptors help in better understanding of side effect frequency and thus have an effect on the perceptions of risk associated with experiencing the side effect. As opposed to previous literature which states that verbal descriptions always lead to overestimation of risk, the current study indicates that effect of communication style varies with frequency and severity of side effects. The study also reinforces the observations from previous studies that perceptions of risk are a combined effect of risk severity and frequency and that the effects cannot be separated from each other. An important outcome of the study indicates that special attention is needed while communicating risk of low frequency side effects as often there seems to be an overestimation of associated risk if the risk is not appropriately understood as in the case with verbal descriptions. The findings of this study should be considered by healthcare professionals and caregivers while communicating with the patients.

5.4 Future Research Recommendations

As mentioned earlier, the study effects were limited to only two side effects and medications. However to obtain a clearer understanding of how truly communication style effects perceptions of risk, the study should be replicated with different side effects

of varying degrees of frequency and severity. Also the current study was performed in general population and not patients. Patients might have 4zdifferent perceptions about risk of side effects and intention to adhere as compared to general population thus a study in patients is also warranted.

5.5 Conclusion

Perceptions of risk of experiencing side effects and intention to adhere are primarily affected by the frequency and severity of side effects. Communication style plays a role in conjunction with side effect frequency in affecting perceptions of risk. Low frequency side effects are often associated with overestimation of risk when only verbal descriptions are used and hence should be carefully communicated. Overall, use of numeric descriptors along with verbal descriptors lead to better understanding of side effect frequency.

Appendix A: Drug information boxes

Drug A

Verbal only

Stomach bleeding is the side effect of drug A which is used to prevent stroke after certain surgical procedures. Drug A will very rarely cause stomach bleeding

Verbal combined with numeric frequency

Stomach bleeding is the side effect of drug A which is used to prevent stroke after certain surgical procedures. Drug A will very rarely cause stomach bleeding.
Out of 100 people taking Drug A, 2 will experience stomach bleeding

Drug B

Verbal only

Facial flushing is a side effect of Drug B which is used to lower LDL (bad cholesterol) and raise HDL (good cholesterol). Drug B will very likely cause facial flushing.

Verbal combined with numeric frequency

Facial flushing is a side effect of Drug B which is used to lower LDL (bad cholesterol) and raise HDL (good cholesterol). Drug B will very likely cause facial flushing.
Out of 100 people taking Drug B, 84 will experience facial flushing.

Drug C

Verbal only

Stomach bleeding is the side effect of Drug C which is used to prevent stroke after certain surgical procedures. Drug C will likely cause stomach bleeding.

Verbal combined with numeric frequency

Stomach bleeding is the side effect of Drug C which is used to prevent stroke after certain surgical procedures. Drug C will likely cause stomach bleeding.
Out of 100 people taking the drug, 70 will experience stomach bleeding

Drug D

Verbal only

Facial flushing is a side effect of Drug B which is used to lower LDL (bad cholesterol) and raise HDL (good cholesterol). Drug D will rarely cause facial flushing.

Verbal combined with numeric frequency

Facial flushing is a side effect of Drug B which is used to lower LDL (bad cholesterol) and raise HDL (good cholesterol). Drug D will rarely cause facial flushing.
Out of 100 people taking Drug D, 10 will experience facial flushing.

Appendix B: Consent to participate in the research



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Consent to Participate in Research Study

Dear Participant,

You are being invited to participate in a research project. The purpose of the research is to evaluate the effect of different styles of communicating risk information of medication side effects on an individual's perceptions of risk and intention to take the medication. You will be one of approximately 500 subjects to be asked to participate in this project. It is estimated that it will take approximately 10-15 minutes of your time to complete the information requested and you will not be asked to complete any additional information for this project once you have finished the survey.

Your participation is voluntary and you may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. You may also refuse to answer any question.

Your participation in this project is anonymous. No personal information including your name or email addresses will be collected.

There are no foreseeable risks associated with your participation in this project. While you will not directly benefit from participation, your participation may help investigators better understand the effect of risk information on drug information labels and how that effects patient adherence to medication.

The results of this study may be published in professional and/or scientific journals. It may also be used for educational purposes or for professional presentations. However, no individual subject will be identified. If you have any questions, you may contact Ruta Sawant at rvsawant2@uh.edu. You may also contact Sujit Sansgiry, Ph.D. faculty sponsor, at 713-795-8392.

ANY QUESTIONS REGARDING YOUR RIGHTS AS A RESEARCH SUBJECT MAY BE ADDRESSED TO THE UNIVERSITY OF HOUSTON COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (713-743-9204).

Sincerely,

Ruta Sawant

Principal Investigator

M.S. Candidate 2014

Sujit S. Sansgiry, Ph.D.

Faculty Sponsor

Associate Professor

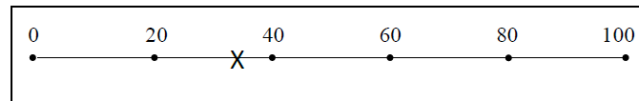
Appendix C: Questionnaire

SECTION A

Instructions: This section of the questionnaire assesses your perception of risk towards medications. Please answer the following questions to the best of your knowledge by checking the options. There are no wrong or right answers. If you are unsure about how to answer, please give the best answer you can.

In the first section you will read information about four drugs (A, B, C, and D) and will be asked to answer three questions after each drug. Please read the information provided in the box carefully. Answer the following questions to the best of your ability by placing an “X” mark on the line below the questions.

For e.g. If you want to indicate a response of 35, you will mark as follows:



Please **DO NOT** turn back to a previous page once you have finished answering the questions for that page.

Please answer the following question to the best of your ability. There is no right or wrong answer. If you are unsure about how to answer, please give the best answer you can.

1] How risky do you believe it is in general to take medications for any condition? Please indicate your risk perception on the scale of 0 (No risk) to 100 (Extreme risk) by placing an "X" mark anywhere on the line below. **Do not circle.**

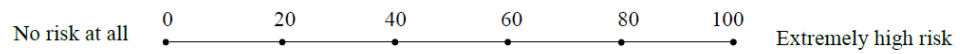


Please turn over

Drug A

Stomach bleeding is the side effect of drug A which is used to prevent stroke after certain surgical procedures. Drug A will very rarely cause stomach bleeding.

1) What do you think is the risk to your health from taking Drug A, bearing in mind its side effects?



2) If you had been prescribed Drug A, how likely is it that you would take the medication as directed by the physician, bearing in mind the drug's side effects?



3) Overall how severe do you consider the illness for which Drug A is prescribed?

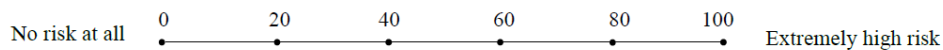


Please turn over

Drug B

Facial flushing is a side effect of Drug B which is used to lower LDL (bad cholesterol) and raise HDL (good cholesterol). Drug B will very likely cause facial flushing. Out of 100 people taking Drug B, 84 will experience facial flushing.

1) What do you think is the risk to your health from taking Drug B, bearing in mind its side effects?



2) If you had been prescribed Drug B, how likely is it that you would take the medication as directed by the physician, bearing in mind the drug's side effects?



3) Overall how severe do you consider the illness for which Drug B is prescribed?



Please turn over

Drug C

Stomach bleeding is the side effect of Drug C which is used to prevent stroke after certain surgical procedures. Drug C will likely cause stomach bleeding. Out of 100 people taking the drug, 70 will experience stomach bleeding.

1) What do you think is the risk to your health from taking Drug C, bearing in mind its side effects?

No risk at all 0 20 40 60 80 100 Extremely high risk

2) If you had been prescribed Drug C, how likely is it that you would take the medication as directed by the physician, bearing in mind the drug's side effects?

Not at all likely 0 20 40 60 80 100 Extremely likely

3) Overall how severe do you consider the illness for which Drug C is prescribed?

Not at all severe 0 20 40 60 80 100 Extremely severe

Please turn over

Drug D

Facial flushing is a side effect of Drug D which is used to lower LDL (bad cholesterol) and raise HDL (good cholesterol). Drug D will rarely cause facial flushing.

1) What do you think is the risk to your health from taking Drug D, bearing in mind its side effects?

No risk at all 0 20 40 60 80 100 Extremely high risk

2) If you had been prescribed Drug D, how likely is it that you would take the medication as directed by the physician, bearing in mind the drug's side effects?

Not at all likely 0 20 40 60 80 100 Extremely likely

3) Overall how severe do you consider the illness for which Drug D is prescribed?

Not at all severe 0 20 40 60 80 100 Extremely severe

Please turn over

SECTION B

Please check or write your answers to the following questions important for the study:

1] Please indicate the year you were born in: 19__ __

2] Please specify your gender: Male Female

3] Please indicate the highest grade or years of school you have completed:

<u>0</u>	<u>1 2 3 4</u>	<u>5 6 7 8</u>	<u>9 10 11 12</u>	<u>13 14 15 16</u>	<u>17 18</u>	<u>19 20 20+</u>
None	Elementary	Middle School	High School	College	Masters	Doctoral (PhD)

4] Please indicate your racial/ethnic background:

White (non-Hispanic) African American Hispanic Native American Asian

Other (Please Specify) _____

5] Please indicate your current occupation or profession in any of the following categories:

Healthcare Non-healthcare

Thank You for your participation!
Your time and efforts are highly appreciated. Please return the completed sheets to the instructor.

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