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## Original Research

# Communicating risk of medication side-effects: role of communication format on risk perception

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### Abstract

**Background:** Medication side-effects often arouse fear in the minds of consumers and therefore need to be communicated in a manner such that the intended message is clearly understood, without causing undue fear.

**Objectives:** Considering the message format and contextual factors that influence perceptions of risk, this study aimed at assessing the interaction effects of message format and contextual factors (rate of occurrence and severity) on risk perception of medication side-effects.

**Methods:** Using Rhormann's risk communication process model, a 2 (message format: words-only vs. words + numeric) X 2 (rate of occurrence: high vs low) X 2 (severity: mild vs severe) experimental factorial study was designed. Participants were presented with four of eight possible combinations of the three factors and were asked to indicate the risk perception with the associated side-effects. Repeated measures analysis was conducted while adjusting for control variables.

**Results:** A total of 196 completed surveys were collected. Communication format did not have significant main effect on risk perception ( $P=0.4237$ ) but demonstrated a significant interaction with rate of occurrence ( $P=0.0001$ ). As compared to words-only format, least square means for words + numeric format were lower among low-rate side-effects but were higher among high-rate side-effects. Rate of occurrence ( $P<0.0001$ ) and severity ( $P<0.0001$ ) had significant main effects on risk perception as well as interaction effect with each other ( $P<0.0001$ ).

**Conclusions:** The results indicated that effect of communication format on risk perception of side-effect is dependent on the underlying rate of occurrence of side-effect. Healthcare providers should therefore carefully construct risk communication messages for effective communication with patients.

### Keywords

Drug-Related Side Effects and Adverse Reactions; Health Risk Behaviors; Risk Reduction Behavior; Health Communication; Models, Theoretical; Surveys and Questionnaires; United States

## INTRODUCTION

Consumers' decision towards a healthcare behavior is dependent on the perceptions of risks and benefits associated with the behavior.<sup>1</sup> Decision making is particularly important in the case of medications for chronic conditions, wherein decision to adhere to treatment regimen and following the appropriate prescribed regimen is an important factor in optimizing treatment effectiveness.<sup>2</sup> It is well known that lack of adherence is one of the causative factors for poor health outcomes and increasing costs.<sup>3</sup> At the same time, problematic patterns of adherence to regimen due to misunderstanding of appropriate medication use instructions or variability in adopting to standardize guidelines for communicating medication use information have been significant challenges faced by the healthcare sector. Previous studies have reported that more information regarding the medication and treatment options may improve adherence among patients.<sup>4,5</sup> Misunderstanding of information provided has been reported to be associated with lack of adherence to intended course of action.<sup>6</sup> Therefore communicating medication information, in an understandable manner is

essential to ensure appropriate medication use.

Consumers and patients prefer specific, detailed and readily-accessible information regarding side-effects<sup>7,8</sup>, and make decisions based on a risk versus benefit assessment of the treatment.<sup>7,9</sup> Patients often correlate safety of the medication to the side-effects and base their decisions to adhere depending on the side effects.<sup>10</sup> Conventionally risk of side-effects is presented using either words-only descriptors or numeric descriptors. Words-only descriptors refer to non-numeric descriptors, which use only words such as 'rarely', 'likely' or 'commonly', to describe the frequency of the side-effects and do not include any numeric information. Such descriptors are often used in spoken as well as written communications and are somewhat vague and difficult to interpret. Healthcare providers often use words-only descriptors to communicate information about side-effects.<sup>11</sup> Patients on the other hand, prefer numbers rather than words such as 'likely', while receiving information about medication side effects.<sup>12</sup> Although numeric information may provide more detailed description of the rate of occurrence of side-effects, the numeric information may not always be correctly interpreted leading to differing perceptions about safety and risk.<sup>13</sup>

The European Commission Pharmaceutical Committee provides some guidance on specific verbal (words-only) descriptors of risk and their corresponding numeric probabilities.<sup>14,15</sup> However a wide variability exists in interpretation of words-only expressions and when

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patient's interpretation differ from that of healthcare providers, compliance problems may arise.<sup>15</sup> In a study evaluating the European Union (EU) and Medicines and Health Products Regulatory Agency's (MHRA) recommendations for words-only descriptions and associated numeric frequencies, the recommendations by the agency failed to correlate with general consumers' interpretations of the words-only descriptions.<sup>16</sup> It was observed that patients, doctors as well as general public overestimated risk based on the recommended descriptions. Recent research conducted by Blalock and colleagues reported that non-numeric (words-only) information on side-effect risk conveys that medication can cause harm and thus decreases willingness to use the medication.<sup>17</sup> Despite the inconsistencies in interpretations with words-only descriptors, pharmacists mostly use vague words-only descriptions in their counseling sessions with patients.<sup>18,19</sup> Words-only descriptions seem to be advantageous because they are more natural to use and better appeal to a person's emotional interests.<sup>20</sup> Although some literature reports that use of terms such as 'may' or 'if...' may lead to positive attitude about the medications or willingness to experiencing side effects, it may not necessarily reflect accurate comprehension.<sup>8,21,22</sup> Numbers or numeric descriptors on the other hand may communicate frequencies of side effects more accurately and may lead to a better understanding of the side effects both by patients and physicians.<sup>23,24</sup>

Words-only and numeric descriptors both have pros and cons. Due to the more natural appeal and familiarity of words-only descriptors, it is unreasonable to eliminate their use in communicating risk information for side-effects.

However, inclusion of numeric descriptors along with the words-only descriptors may account for the advantages of both and mitigate the unintended consequences of misinterpretation. Research in psychology and education has suggested that presentation of information in multiple formats increases understanding.<sup>25</sup> For e.g., in the case of words-only and visual representations, parallel learning from both formats lead to better memory of the information as well as greater integration with the knowledge. However it is yet unclear whether the combination of words-only and numeric descriptors is superior to either communication format alone.<sup>26</sup> Therefore we aimed to examine the effect of two different written communication formats, one with words-only descriptors and the other with a combination of words and numeric descriptors on risk perceptions of experiencing medication side-effects.

An important aspect often overlooked in studies evaluating risk perception with different communication formats is the context in which the risk is embedded. According to a socio-psychological model developed by Rohrmann in 1999 for analyzing risk communication process, the characteristics of the risk message and the context in which the communication process occurs determines the results of risk communication efforts.<sup>27</sup> In the case of the current study, characteristics of the risk message were defined by the communication format. Context of the side-effect risk was defined by the rate of occurrence (henceforth referred to as 'rate') and the severity of the side-effect. Previous studies have reported that rate and severity have an impact on risk perception with manipulations of severity having the greatest impact on individuals' judgement.<sup>28-30</sup>

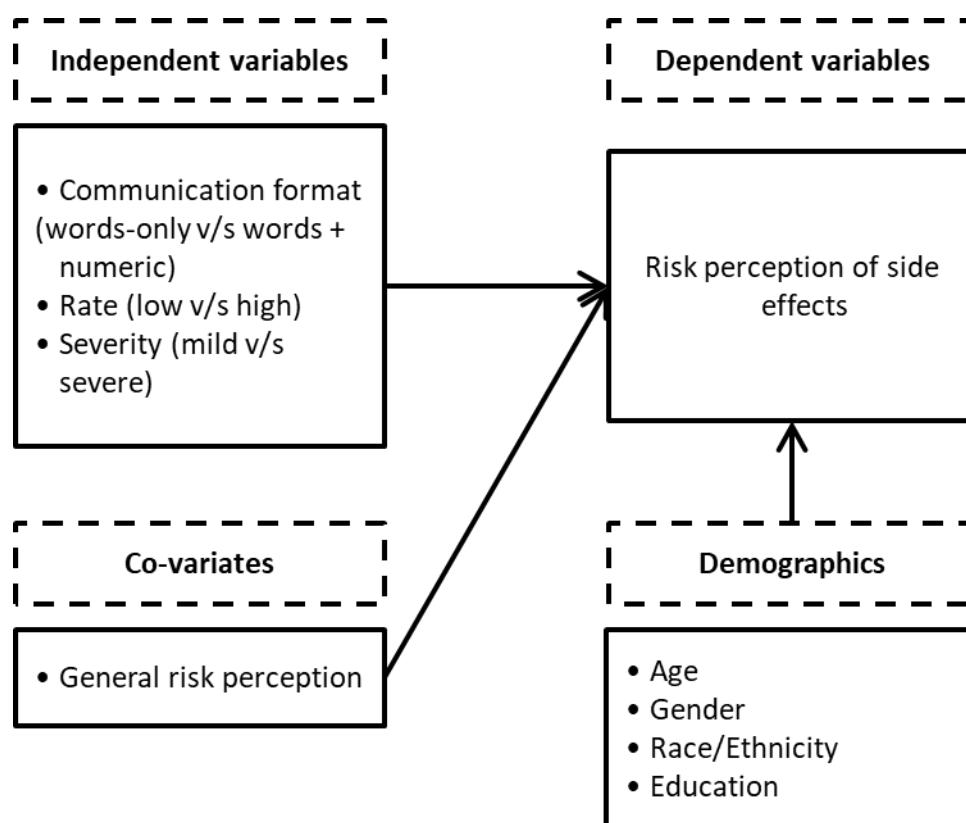


Figure 1. Study Model Based on Rohrmann's Risk Communication Process Framework.

Table 1. Selected study side-effects and associated severity, rate and communication style descriptions				
Side-effect	Severity	Rate	Words-only Description	Numeric Description
Stomach Bleeding	Severe	Low	very rarely	2 out of 100
		High	likely	70 out of 100
Facial Flushing	Mild	Low	rarely	10 out of 100
		High	very likely	85 out of 100

However no study has yet evaluated the interaction of all three factors i.e., the communication format, rate and severity of the side effect in shaping the perceptions of risk associated with medication side-effects. The risk communication process framework also posits that risk appraisal (i.e., risk perception) is also affected by prior risk perception, risk specific biases, and general individual characteristics. A final model based on the risk communication process framework was thus operationalized as seen in Figure 1. The primary objective of the study was to evaluate the impact of communication format, side effect rate and severity on risk perceptions. The communication format in the current study refers to written information about side-effects that may be publicly available to individuals seeking information about medications (example: patient information leaflets).

## METHODS

### Sample and study design

The sample consisted of adults greater than 18 years of age, recruited via convenience sampling method. Data was collected from May 2014 to June 2014 from places of public congregation such as public parks. Individuals were approached, and a short communique was recited regarding the study objectives. Once the participants consented to participate in the study, they were provided with the survey booklet. Participants were briefly explained that they would see some information about a drug followed by some questions regarding the information that they view; and that the process will be repeated four times. After completion, the researcher requested each participant to fold the survey and drop it in a data collected box so that no specific survey could be linked to any participant. Additionally, no identifying information was obtained as a part of the survey thus ensuring anonymity. No incentives were provided for participation in the study. The study was approved by University of Houston's Institutional Review Board.

An experimental cross-sectional factorial design was used to address the study objectives. The factorial design consisted of three factors with two levels each (2x2x2 factorial). The three factors were communication format,

side-effect rate and side-effect severity (Table 1). These three factors represented the characteristics of the side-effect information. The information about side-effects was presented to the participants as a component of a drug information box (DIB). The DIB consisted of drug name (de-identified using labels A, B, C and D to avoid any biases due to prior knowledge, familiarity, or experience with the drugs), drug use and information about one drug side-effect. The side-effect information had three characteristics corresponding to the three factors being tested i.e. communication format, rate and severity, each with two levels. The two levels of communication formats were (i) words-only format and (ii) words + numeric format (combined), those for rate were (i) low and (ii) high and those for severity were (i) mild and (ii) severe. Thus three factors, each with two levels produced a total of eight possible combinations. Information about a side-effect in a DIB could be presented using either of the eight combinations. The experiment was set up in a manner wherein the eight combinations were divided into two groups (Table 2) and each participant was randomly assigned to one of the two groups. Thus, each participant received four DIBs based on the group assignment, and each DIB contained information on one side-effect presented using a combination of the three factors.

### Development and structure of drug information box

Online Appendix presents the DIBs used in the study. The statements for description of side-effects were developed using information from drug package inserts and existing literature and were presented as follows:

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

Combined (words + numeric) 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 = Words-only description of side effect rate

Z = Side effect

W = Numeric description of side effect

Table 2. Study groups based on eight possible combinations in the 2 (communication style: words-only versus words-only combined with numeric) X 2 (rate: low versus high) X 2(severity: mild versus severe) factorial design				
Drug name	Side-effect	Severity	Rate	Communication style
<b>Group 1</b>				
A	Stomach Bleeding	Severe	Low	Words-only
B	Facial Flushing	Mild	Low	Words-only
C	Stomach Bleeding	Severe	High	Combined
D	Facial Flushing	Mild	High	Combined
<b>Group 2</b>				
A	Stomach Bleeding	Severe	Low	Combined
B	Facial Flushing	Mild	Low	Combined
C	Stomach Bleeding	Severe	High	Words-only
D	Facial Flushing	Mild	High	Words-only

Table 3. Repeated Measures Analysis of Covariance for the Effect of Communication Style, Rate, and Severity on Risk Perception of Experiencing Side-Effects			
Variable	DF	F Value	P-value
Communication style (C)	1	0.64	0.42
Rate (R)	1	325.63	<.0001
Severity (S)	1	190.77	<.0001
R x S	1	88.62	<.0001
R x C	1	15.57	0.0001
S x C	1	2.38	0.12
F x S x C	1	0.07	0.80
General risk perception	1	23.41	<0.0001
Age	1	7.38	0.0072
Race/ethnicity	4	3.06	0.0181

Numeric descriptors can be presented in different formats such as natural frequencies (e.g., 5 out of 100), absolute (50 % chance) or relative risks (e.g., 70% risk reduction). Among all these formats, natural frequencies have been reported to be better and easier to understand and lead to more adequate statistical reasoning and more accurate risk estimates.<sup>23,31,32</sup> The current study therefore used natural frequencies for numeric descriptors. With respect to words-only descriptors, 'very rarely' and 'rarely' were used for low rate side-effects and 'very likely' and 'likely' were used for high rate side-effects. This was done to minimize effect of prior exposure/viewing of the descriptors in one DIB on the perception about descriptors in subsequent DIBs.

#### Study variables

Before presenting the DIBs, general risk perception of participants was measured using the question "How risky do you believe it is in general to take medications for any condition?" Responses were measured on a 0 to 100 visual analog scale (VAS). Each DIB was followed by a series of questions based on the information provided in the drug information box. The primary dependent variable of risk perception of experiencing side-effects was measured using the question "What do you think is the risk to your health from taking Drug A, bearing in mind its side-effects?" Risk perception was measured on a visual analog scale ranging from 0-100. Primary independent variables were the three factors of communication format, rate and severity. Control variables included perception of severity of the illness for which the drug was prescribed, general risk perception, profession and demographic information (age, gender, race/ethnicity and education). Perception of severity of the illness was measured using the questions "Overall how severe do you consider the illness for which Drug X is prescribed?" A VAS ranging from 0 to 100 followed the question for recording their responses with respect to risk perception. Higher scores on the VAS indicated higher

perceived risk. The visual analog scale has been previously used to measure perceptions with various behaviors such as weight and other health-related measurements.<sup>33</sup> 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.<sup>34-36</sup>

#### Statistical Analysis

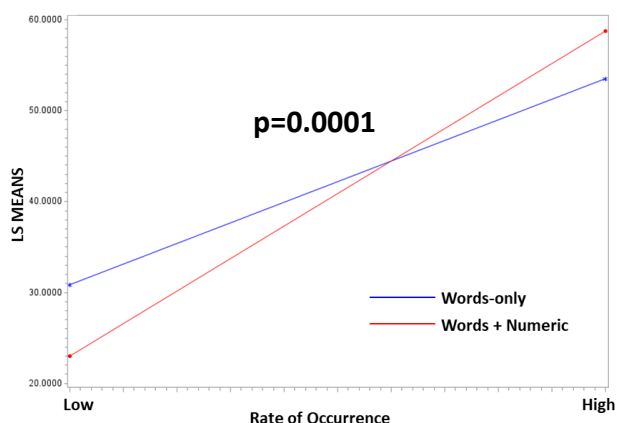
All analyses were conducted using SAS version 9.3. Repeated Measures Analysis of Variance was used to assess the effects of communication format, rate and severity on risk perception while adjusting for general risk perception, perceived severity of illness, age, gender, race/ethnicity and education. General risk perception, perceived severity of illness and age were included as continuous variables. Gender (Male/Female), race/ethnicity (non-Hispanic Whites/African Americans/Hispanic/Asian), education level (college education/bachelor's degree/master's degree/doctoral degree) and profession (Healthcare/non-Healthcare) were included as categorical variables. Descriptive statistics were obtained by calculating means for continuous variables and frequencies for categorical variables. Mean risk perception scores were obtained for eight possible combinations of the three factors of communication format, rate and severity. Pairwise comparisons of mean risk perception scores of all eight combinations were made to evaluate the differences across the combinations. All statistical analyses were performed at an a priori significance level of 0.05.

#### RESULTS

A total of 240 individuals were approached to participate in the study. Forty-two individuals refused to participate and provided reasons such as lack of interest in the study (n=17), language barrier (n=10), lack of time (n=7), and

Table 4. Least Square Means of Risk Perception for Communication Format, Rate and Severity				
Communication style	Rate	Severity	Risk perception [LS Mean (SE)]	Range
Words-only	Low	Mild	25.84 (2.75)	20.42 - 31.26
Words+Numeric	Low	Mild	20.90 (2.90)	15.18 - 26.61
Words-only	Low	Severe	35.87 (2.75)	30.45 - 41.29
Words+Numeric	Low	Severe	25.10 (2.90)	19.38 - 30.82
Words-only	High	Mild	33.67 (2.90)	27.95 - 39.39
Words+Numeric	High	Mild	41.00 (2.75)	35.59 - 46.43
Words-only	High	Severe	73.35 (2.90)	67.63 - 79.07
Words+Numeric	High	Severe	76.53 (2.75)	71.11 - 81.95

LS=Least Square; SE=Standard Error



Rate	Communication format	Least square means (SE)
Low	Words-only	30.85 (2.24)
Low	Words + Numeric	23.00 (2.38)
High	Words-only	53.51 (2.38)
High	Words + Numeric	58.77 (2.24)

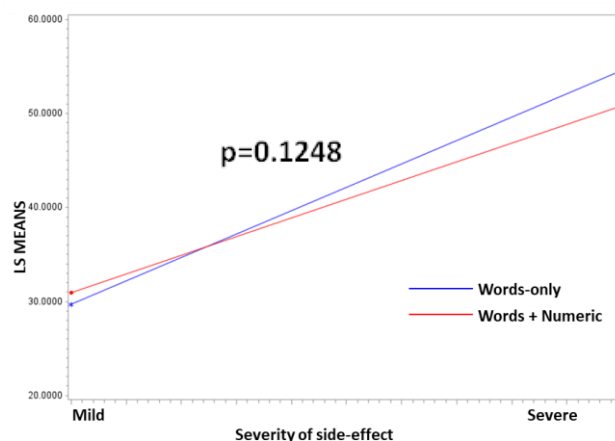
Figure 2. Interaction effect between communication format and rate of occurrence.

Plot of least square means of risk perception across levels of rate of occurrence (low versus high) for words-only and words + numeric communication formats.

other (n=8). Two individuals started the survey but did not complete due to loss of interest and were not included in the final sample. Thus, 196 completed responses were obtained leading to a response rate of 81.6%. Participants' age ranged from 19 to 74 years with a mean of 42 (SD=12) years. A slight majority of participants were females (53%). Most participants were non-Hispanic White (58%) followed by African Americans (18%), Hispanic (16%), and Asian (7%). With respect to education level, 57% had a college education while approximately 32% has masters or doctoral degree. A majority of participants (81%) belonged to non-healthcare profession. When asked to rank the side-effects in the order of their severity from 1 to 4 (1=mild, 4=severe), participants correctly identified stomach bleeding (mean rank =3.33) as severe and flushing of the face (mean rank =2.33) as mild side-effect. Validation of the simulations used for severity was thus achieved.

Repeated Measures analyses were conducted to test independent and interaction effects of communication format, rate and severity on risk perception (Table 3). The results demonstrated main effects of rate of occurrence of side-effects (F value=325.63,  $p<0.0001$ ) and severity (F value=190.77,  $p<0.0001$ ) on risk perception. Two-way interactions between rate X communication style (F value=15.57,  $p=0.0001$ ) and, rate X severity (F value=88.62,  $p<0.0001$ ) and, were found to be significant. Three-way interaction between communication format, rate and severity was not significant (F value=0.07,  $p=0.80$ ). Additionally, general risk perception (F value=23.41,  $p<0.0001$ ), age (F value=7.38,  $p=0.0072$ ) and race/ethnicity (F value=3.06,  $p=0.0181$ ) were also found to have significant effects on risk perception.

Least square means were obtained for the main effects and interaction effects between communication format, rate and severity (Table 4). Further, interaction plots were obtained for the two-way interactions between



Severity	Communication format	Least square means (SE)
Mild	Words-only	29.75 (2.31)
Mild	Words + Numeric	30.95 (2.31)
Severe	Words-only	54.61 (2.31)
Severe	Words + Numeric	50.82 (2.31)

Figure 3. Interaction effect between communication format and severity.

Plot of least square means of risk perception across levels of severity (mild versus severe) for words-only and words + numeric communication formats.

communication format X rate (Figure 2), communication format X severity (Figure 3) and rate X severity (Figure 4). As can be seen in Figure 2, for low-rate side-effects, words-only format had a higher risk perception score as compared to words + numeric format. This effect was reversed for high-rate side-effects i.e. words-only format had lower risk perception scores as compared to words + numeric format. As in Figure 3, although an interaction was observed between communication format and severity, it was not statistically significant. Figure 4 represents the significant interaction between rate and severity such that the difference of least square means between mild and severe side effects was significantly larger when the side-effects occurred at a high-rate as compared to when the side-effects occurred at a low-rate.

## DISCUSSION

The study was one of the first to evaluate the effect of communication format on risk perception of side-effects in the light of contextual factors of rate and severity. An important finding of the study was the interaction between communication format and rate in regards to its effect on risk perception. It was observed that the effect of communication format was different for low-rate side-effects as compared to high-rate side-effects. Among low-rate side-effects, use of numeric descriptors along with words resulted in lower-risk perception as compared to words-only descriptors. These findings correspond to reports from prior studies which have indicated that use of words-only (or verbal) descriptors alone may result in over-estimation of the risk.<sup>15,16,37</sup> On the other hand, for high-rate side-effects, use of words-only descriptors had lower risk perception scores as compared to words + numeric descriptors, indicating that words-only descriptors may not always lead to over-estimation of risk. These interaction





Figure 2c. Interaction effect between rate of occurrence and severity.

Plot of least square means of risk perception across levels of rate of occurrence (low versus high) for mild and severe side-effects.

effects highlight the importance of the contextual factor of rate of occurrence of side-effect in understanding the influence of communication format. Low-rate side-effects which are likely to be over-estimated in term of their risk may benefit from the use of numeric descriptors to avoid over-estimation of the risk. While for high-rate side-effects, risk perception may initially assume a higher value due to words such as 'likely' or 'very likely'. In such cases, numeric descriptors may aid in better understanding of the high rate of occurrence and help in relative evaluation of the risk and benefits of the treatment, resulting in more informed decision. Carling and co-workers in their prior research have suggested that formats of presenting risk information which are in line with patients' values (i.e. relative evaluation of desirable and undesirable outcomes) are most influential in increasing acceptance of the treatment.<sup>38</sup> Thus it may be worthwhile for future studies to evaluate which of the two formats (words versus words + numeric) better align with patients' values.

An important consideration in interpreting results from current study as compared to prior literature is the hypothetical rates used for the side-effects. Knapp and colleagues<sup>16</sup> used actual frequencies of side-effects (common=1-10%; rare=0.01-0.1%) among patients. In the current study, the low-rate used was close to the 'common' description used by Knapp and thus yielded consistent results. The high-rate used in the current study was very high compared to prior studies, which may have influenced the conflicting results. Additional studies evaluating side-effects occurring at a higher rate may help in validating some of the findings from the current study. Overall, it may be inferred from the current study that the use of numeric descriptors aid in better understanding of the underlying rate and associated risk of side-effects. These results correspond to findings from prior studies which have reported that use of numbers or numeric descriptions in

risk communications resulted in better evaluations of the risk.<sup>15,39,40</sup> Research by Blalock and colleagues has also demonstrated that numeric risk information of side-effects may enhance decision making and also increase the willingness to take the medications.<sup>17</sup>

The study findings also hold implications for both written and spoken communications. Healthcare providers such as pharmacists and physicians should avoid vague words-only descriptions when designing communication material or during direct interactions with the patients. The findings from the current study may also help in future efforts to standardize verbal descriptors with their associated numeric frequencies, as the study sheds light onto risk perceptions associated with some verbal descriptors. Standardization of verbal descriptors is of importance considering the familiarity and ease of use of such descriptors. Literature on fuzzy-trace theory concerning risk perceptions indicates that gist interpretations (i.e. subjective representation of information) rather than verbatim interpretations (i.e. exact numbers given in the information) after exposure to risk information guides decision making.<sup>41</sup> Standardization of verbal descriptor may help in minimizing the variability in gist interpretations and more accurate perceptions of risk in the future.

The results of the study should be viewed within the context of certain limitations. The study tested the effects of communication format only for two side effects and the associated frequencies and severity. The effects observed may not be generalizable for all side effects. Individuals were selected into the study depending on accessibility for the researcher (convenience sampling) and thus may not be a representative sample. At the same time, since all the approached participants may not be taking medications in their daily lives, the hypothetical decision making for a hypothetical medication may demonstrate different perceptions as compared to real-life decision making. Individuals with limited English speaking ability were not included in the study thus limiting the generalizability of the sample. Future studies with randomized sampling methods and inclusive of non-English speaking adults are thus warranted. A majority of the participants had high educational attainment i.e. at least a college degree or masters, which may have been due to the proximity of data collection locations to medical center areas. The high education level may have impacted the interpretation of risks associated with side-effects as education may impact knowledge about a particular behavior, event or understanding about the same.<sup>42</sup> Other factors that might affect risk perception were not taken into consideration and may have affected risk perceptions. Finally, no information was collected on the individuals who did not agree to participate in the study. Thus, non-response bias could not be assessed.

## CONCLUSIONS

The effect of communication format on risk perception was significantly impacted by the underlying rate of occurrence. Risk of low rate side effects may be over-estimated when words-only descriptions are used and hence should be carefully communicated. Overall, use of words + numeric descriptors lead to better understanding of the risk and

should be routinely incorporated in communication resources.

## CONFLICT OF INTEREST

The authors have no conflict of interest to disclose.

## FUNDING

None.

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