

## Risk language preferred by mothers in considering a hypothetical new vaccine for their children

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**Objectives:** To determine the type of risk language preferred by mothers considering the use of a hypothetical new vaccine for their children and to compare their choice with what their physicians perceived they would prefer.

**Design:** Mail survey.

**Setting:** Thirteen family practices in southwestern Ontario.

**Participants:** Women with at least one child between the ages of 6 months and 5 years and their physicians.

**Main outcome measures:** Preferred risk language and physicians' predictions about patient preference.

**Results:** Of the 226 women sent the questionnaire 208 (92%) responded. Of the 192 who indicated their risk language preference 118 (61%) chose a numeric statement. Of the 11 physicians who answered the question 8 (73%) predicted that their patients would prefer non-numeric statements. Although the women in the study were more likely to be married, were better educated and had higher family incomes than women of the same age in the Ontario population, risk language preference was not found to be related to any of those demographic characteristics.

**Conclusion:** Physicians must be prepared to outline the risks associated with vaccination in both quantitative and qualitative terms.

**Objectifs :** Préciser le type de langage de risque que préfèrent les mères dans l'optique de l'utilisation d'un nouveau vaccin hypothétique pour leurs enfants et comparer leur choix avec ce que leur médecin croyait qu'elles préféreraient.

**Conception :** Sondage postal.

**Cadre :** Treize cabinets de médecine familiale du sud-ouest de l'Ontario.

**Participants :** Femmes qui ont au moins un enfant entre 6 mois et 5 ans et leurs médecins.

**Principales mesures de résultat :** Langage de risque préféré et prévisions des médecins sur la préférence de leurs patientes.

**Résultats :** Des 226 femmes auxquelles on a expédié le questionnaire, 208 (92 %) ont répondu. Des 192 qui ont indiqué leur préférence en matière de langage de risque, 118 (61 %) ont choisi un énoncé numérique. Des 11 médecins qui ont répondu à la question, 8 (73 %) ont prévu que leurs patientes préféreraient des énoncés non numériques. Les femmes de l'étude étaient plus susceptibles d'être mariées, étaient plus scolarisées et disposaient d'un revenu familial plus élevé que les femmes du même âge dans la

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population ontarienne en général, mais leur préférence en matière de langage de risque n'a pu être reliée à l'une ou l'autre de ces caractéristiques démographiques.

**Conclusion :** Les médecins doivent être prêts à préciser les risques associés à la vaccination, en termes quantitatifs et qualitatifs.

Physicians have to communicate the risk of uncommon events to their patients daily. This communication may pertain to such risks as those associated with oral contraceptives, surgical procedures and medications. Informing the patient about the benefit-risk ratio of a proposed treatment is often part of obtaining consent. Recent legislative changes in Ontario require that physicians inform patients or their guardians of the benefits and risks of receiving a vaccine.<sup>1</sup> Moreover, studies of informed consent consistently indicate that the public wants to be informed about the risks of medical procedures.<sup>2-4</sup>

Literature on decision making and how it relates to risk communication urges that such communication become more "recipient centred" to ensure that the necessary information is provided to the patient in an understandable form.<sup>5</sup> Some have suggested that the public prefers it if risk communication emphasizes the qualitative aspects<sup>6</sup> and that qualitative expressions of probability are more influential than numeric or probabilistic statements.<sup>7</sup> Others have suggested that there is a tendency for people to rely on vague quantifiers such as "likely" and "not worth worrying about" when making decisions under conditions of uncertainty.<sup>8</sup> In general, people do not seem to know how to use numeric estimates when asked to make a decision and usually resort to heuristics or shortcuts.<sup>9</sup> The task becomes one of how best to inform people of the risk of uncommon events.

The purpose of this study was to examine the type of risk language preferred by mothers who are considering the use of a hypothetical new vaccine for their children. Risk language refers to the type of terminology used to describe the risk of serious side effects associated with the use of the vaccine. Three types of language were examined: numeric, qualitative and analogous.

## Methods

A self-administered questionnaire (a copy of which is available from the authors upon request) was developed and pretested in the practice of one of us (T.R.F.) in order to assess and reassess its reliability. In addition to eliciting demographic information the questionnaire presented each mother with the hypothetical situation of administering a new vaccine to her child for protection against a disease that is uncommon (1 case per 800 children) but usually very serious and sometimes fatal (1 death

per 250 cases). These incidence rates are similar to those for a pertussis epidemic in a nonvaccinated population.<sup>10</sup>

The risk of severe side effects from the vaccine was stated numerically (e.g., 1 in 1 million), qualitatively (e.g., rarely, infrequently) and in analogous terms (e.g., equal to the chance of being struck and killed by lightning). The option of not receiving the vaccine was also made available. Respondents were asked to indicate which form of risk language they preferred when their physician spoke about vaccination. They were also asked to indicate their level of tolerable risk in each language category. The results of the latter question are presented elsewhere.<sup>11</sup>

The study was approved by the Ethics Committee on Research in Human Subjects, University of Western Ontario, London.

The target group comprised mothers who had at least one child between the ages of 6 months and 5 years. These women would have recently had to think about the issue of vaccination for their children and may have had experience with adverse effects. Eligible mothers were approached by the office nurse or the family physician during a visit to 1 of 13 practices in large and small communities in southwestern Ontario. The physicians were chosen from those who had previously indicated an interest in such research. The purpose of the study was explained to the mothers, and the names of those agreeing to participate were placed on a mailing list. Only two women declined to receive the questionnaire. Mailing of the questionnaire followed the method described by Dillman<sup>12</sup> and shown by others<sup>13</sup> to yield high return rates in studies in family practice.

The questionnaire was prepared in booklet form with a means of identifying respondents to allow for removal of their names from the mailing list. The booklet was sent to the participants with a stamped return envelope and a covering letter that again explained the purpose of the study. Follow-up was done in the recommended pattern.<sup>12</sup> A reminder was sent 1 week after the questionnaire was mailed. At 3 and 7 weeks after the initial mailing non-responders were sent another package comprising another copy of the questionnaire and a modified covering letter.

The family physicians in the 13 practices were asked to complete a similar questionnaire. The vaccination problem presented was identical to that given to their patients. With respect to the risk language preference the physicians were asked which

type of risk language they felt their patients in general would most prefer.

The responses were coded and dichotomous variables tested with the use of the  $\chi^2$  test, significance being set at a *p* value of 0.05.

## Results

In all, 208 (92%) of the 226 women who were sent a questionnaire returned it, as did 12 (92%) of the 13 physicians who had agreed to participate.

We compared the demographic characteristics of the study population with those of the Ontario population as derived from the 1986 census (Table 1).<sup>14,15</sup> The average age of the mothers who responded was 30.7 years. The women in our study were more likely to be married, were better educated and had higher family incomes than women of the same age in the Ontario population.

Of the patients who indicated their preferred risk language the numeric statement was favoured by 61% (Table 2). Most (73%) of the physicians who responded to this question felt that their patients would prefer one of the two non-numeric statements.

The preference of the patients was not found to be related to age, education, income or population of place of residence (Table 3). There was no identifiable characteristic that predicted the preference of the patients.

## Discussion

The task of communicating adequately about the concept of risk involves finding a way to present patients with complex technical information clouded by uncertainty and difficult to understand even by people with specialized training. Despite these difficulties physicians are frequently required to talk to their patients about risks. This may take the form of a discussion of surgical risks and benefits, drug-related risks and benefits or, as in the example used in

this study, vaccination risks. The quality of any communication depends on the communicator's being able to "speak the same language" as the person on the receiving end.

The literature on risk evaluation suggests that the public does not generally use mathematical theory to make decisions<sup>16,17</sup> and would prefer that communications about risk be couched in qualitative terms.<sup>7</sup> Some have suggested that characteristics of good risk communicators include direct, nontechnical language.<sup>18</sup> The response of the patients in our study was therefore unexpected, most of them preferring the numeric risk statements.

There are two potential weaknesses in our study. First, the questionnaire results may not reflect patient preferences in an actual decision-making situation. The women may have chosen the numeric presentation since it was the first one offered. Perhaps another method of non-numerical risk presentation would have been more readily accepted. Second, the study population was better educated and wealthier than the provincial average, which could limit the generalizability of the results. However, neither of these variables was found to be related to risk language preference.

Since it has been repeatedly shown that most people use heuristics or shortcuts to make decisions under conditions of uncertainty<sup>9,19</sup> why did most of the respondents prefer the numeric statements? An explanation offered by one of the respondents was that although she was not sure what the numbers meant she preferred that her physician use such terminology because it gave her more confidence in what he was saying. This may be an example of the public's "thirst for certitude,"<sup>18</sup> or it may be similar to the tendency to use numbers as qualitative markers rather than as numeric terms. This use of probability estimates has been observed in the decision-making process of resident physicians.<sup>20</sup> Jungermann, Schultz and Thuring<sup>21</sup> have suggested that the desire of the public to know all possible side effects

Table 1: Characteristics of mothers asked to indicate their preferred risk language when considering the use of a hypothetical new vaccine for their children and of women of the same age\* in Ontario<sup>14,15</sup>

Characteristic	Study population, no. (and %) of women (n = 208)	Ontario population, % of women
Married	200 (96)	81.4
High-school education or less	100 (48)	57.3
Employed (full-time or part-time)	109 (52)	52.6†
Family income < \$20 000	16 (8)	27.9†

\*From 25 to 44 years.

†Includes women aged 25 to 44 years with children over and under 6 years of age.

of a drug, regardless of their rarity, reflects an attempt to gain some cognitive control over risks and to feel on a more equal basis with the physician.

Overall, the physicians in the study did not accurately predict their patients' preferences, although their perceptions were consistent with the literature. This discrepancy may have arisen because the physicians were asked to base their prediction on their patients in general and not just the study population. It is conceivable that if asked to predict the preferences of the study patients the physicians would have been more accurate.

The results indicate that physicians can expect most of their patients to prefer numeric statements of risk. However, since we did not find any identifying characteristics associated with preference physicians should be able to discuss risks in both quantitative and qualitative terms. Communicating the

risk of rare events requires stating it first in numeric terms, then giving the patient a visual or conceptual way of coming to terms with such numbers. For example, Koren and associates<sup>22</sup> used a visual analogue scale to communicate with pregnant women about the risk of teratogenic effects. A conceptual way of describing the probability of 1 in 1000 is the chance of flipping a coin 10 times and coming up heads each time.<sup>23</sup>

It is necessary to recognize that risks occur in a particular context of decision making. Decisions should be framed in terms of lives saved or illness avoided as well as the risk associated with the procedure. For vaccination this means informing patients about the risk of the disease in the same numeric and qualitative terms used to talk about the risks of vaccination so that an informed choice can be made.

In addition, with respect to drugs as well as vaccines it must be kept in mind that the physician acts as an intermediary in any risk communication and is therefore part of the context of the communication. As a result the risk as perceived by the patient will be influenced by the physician's risk perception and the physician-patient relationship. To improve risk communication it is desirable to find out what is important to the patient and communicate the risk in those terms.

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## References

1. Health Protection and Promotion Amendment Act, 1987, SO 1987, c 18
2. Alfidi RJ: Informed consent: a study of patient reaction. *JAMA* 1971; 216: 1325-1329
3. Roling GT, Pressgrove WL, Keeffe EG et al: An appraisal of patients' reactions to "informed consent" for peroral endoscopy. *Gastrointest Endosc* 1977; 24 (2): 69-70
4. Cassileth B, Zupkis RV, Sutton-Smith K et al: Information and participation preferences among cancer patients. *Ann Intern Med* 1980; 92: 832-836
5. Fischhoff B: Strategies for risk communication. In Committee on Risk Perception and Communication, National Research Council: *Improving Risk Communication*, Natl Acad Pr, Washington, 1989: 282-298
6. Vertinsky IB, Wehrung DA: Risk in perception and drug safety evaluation. In *Proceedings of Workshop on Risk Perception and Drug Evaluation, Ottawa, March 29-30, 1989*, Drugs Directorate, Health Protection Branch, Dept of National Health and Welfare, Ottawa, 1989

Table 2: Type of risk language preferred by the patients and their physicians

Type of risk language	Group; no. (and %) of respondents	
	Patients (n = 192)	Physicians (n = 11)
Numeric	118 (61)	3 (27)
Qualitative	57 (30)	4 (36)
Analogous	17 (9)	4 (36)

Table 3: Characteristics of women by type of preferred risk language

Characteristic	Type of language; no. (and %) of women	
	Numeric (n = 118)	Non-numeric (n = 74)
Age, yr		
18-25	17 (14)	8 (11)
26-30	41 (35)	27 (36)
31-35	46 (39)	29 (39)
≥ 36	14 (12)	10 (14)
Level of education		
High school or less	55 (47)	37 (50)
Postsecondary	63 (53)	37 (50)
Population of place of residence		
< 1 000	41 (35)	35 (47)
< 10 000	13 (11)	3 (4)
< 30 000	47 (40)	27 (36)
≥ 30 000	17 (14)	9 (12)
Income, \$*		
< 20 000	9 (8)	5 (7)
20 000-39 999	38 (33)	33 (45)
40 000-59 999	46 (40)	22 (30)
≥ 60 000	22 (19)	13 (18)

\*Three people who chose the numeric language and one who chose a non-numeric language did not provide this information.

7. Hogarth RM: Cognitive processes and the assessment of subjective probability distributions. *J Am Stat Assoc* 1975; 70: 271-289
8. Fischhoff B: Psychological principles in communication design. In Committee on Risk Perception and Communication, National Research Council: *Improving Risk Communication*, Natl Acad Pr, Washington, 1989: 299-304
9. Tversky A, Kahnemann D: Availability: a heuristic for judging frequency and probability. *Cognit Psychother* 1973; 5: 207-232
10. Koplan JP, Schoenbaum SC, Weinstein MC et al: Pertussis vaccine — an analysis of benefits, risks and costs. *N Engl J Med* 1979; 301: 906-911
11. Freeman TR, Bass MJ: Determinants of maternal tolerance of vaccine-related risks. *Fam Pract* 1992; 9: 36-41
12. Dillman DA: *Mail and Telephone Surveys: the Total Design Method*, Wiley, New York, 1978
13. Hoddinott S, Bass MJ: The total design survey method: a surefire way to get high survey return rates. *Can Fam Physician* 1986; 32: 292-295
14. 1986 *Census of Canada: the Nation — Population and Dwelling Characteristics — Occupation* (cat no 93-111), Statistics Canada, Ottawa, 1989
15. 1986 *Census of Canada: Profiles of Urban and Rural Areas — Canada, Provinces and Territories, Part 1* (cat no 94-129), Statistics Canada, Ottawa, 1988
16. Fjellman SM: Natural and unnatural decision making: a critique of decision theory. *Ethos* 1976; 4: 73-94
17. Howard RA: An assessment of decision analysis. *Oper Res* 1980; 2: 178-182
18. Keeney RL, von Winterfeldt D: Improving risk communication. *Risk Anal* 1986; 6: 417-424
19. Politser P: Decision analysis and clinical judgement. *Med Decis Making* 1981; 1: 361-389
20. Kuipers B, Kassirer JP: Knowledge acquisition by analysis of verbatim protocols. In Kidd AL (ed): *Knowledge Acquisition for Expert Systems Development*, Plenum Pr, New York, 1987: 45-71
21. Jungermann H, Schultz H, Thuring H: Mental models in risk assessment: informing people about drugs. *Risk Anal* 1988; 8: 147-155
22. Koren G, Bologna M, Ling D et al: Perception of teratogenic risk by pregnant women exposed to drugs and chemicals during the first trimester. *Am J Obstet Gynecol* 1989; 160: 1190-1194
23. Selvidge J: A three-step procedure for assigning probabilities to rare events. In Wendt W, Vlek CAJ (eds): *Utility, Probability and Human Decision Making*, Reidel Pub, Drecht, Holland, 1975: 199-216



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**PRECAUTIONS:**

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**Elderly:** There were no significant difference in the safety profile of CYTOTEC in approximately 500 ulcer patients who were 65 years of age or older compared with younger patients.

**Incidence greater than 1%:** In clinical trials, the following adverse reactions were reported by more than 1% of the subjects receiving CYTOTEC and may be casually related to the drug: nausea (3.2%), headache (2.4%), dyspepsia (2%), vomiting (1.3%) and constipation (1.1%). However, there were no clinically significant differences between the incidences of these events for CYTOTEC and placebo.

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**REFERENCES:** 1. Adapted from Langman, MJS. Peptic Ulcer Complications and the use of Non-Aspirin, Non-Steroidal, Anti-Inflammatory Drugs. *Adverse Drug Reaction Bulletin* 1986;120:488-451. 2. *Cytotec Product Monograph* May 1991. 3. Graham DY, Agrawal NM, Roth SH et al. Prevention of NSAID-induced gastric ulcer with misoprostol. *Lancet* 1988;2:1277-1280. 4. Elliot SL, Yeomans ND, Buchanan RRC, et al. Long term epidemiology of gastropathy associated with nonsteroidal antiinflammatory drugs (NSAID) (abstr). *Clin Exp Rheumatol* 1990; (suppl 4) 8:58. 5. Fries JF, Miller SR, Spitz PW, et al. Toward an epidemiology of gastropathy associated with nonsteroidal antiinflammatory drug use. *Gastroenterology* 1989;96:647-655. 6. Gabriel S, Jaakkimainen L, Bombardier C. Risk for serious gastrointestinal complications related to use of nonsteroidal antiinflammatory drugs A meta-analysis. *Annals of Internal Medicine*. 1991;115:787-796.

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