How Much Information About Adverse Effects of Medication Do Patients Want From Physicians?

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Background: Little information exists concerning the amount of information patients expect from physicians as to the risk for an adverse medication reaction. The present study was designed to determine such opinions in a population sample; to correlate results with sex, age, educational level, and previous experience with adverse effects; and to determine whether patients believe physicians should use discretion in the amount of such information given.

Methods: Two thousand five hundred sequential adults visiting outpatient clinics filled out a 12-item questionnaire. Percentages of subjects desiring information about varying degrees of risk and those believing physicians should and should not use discretion in the amount of such information provided were recorded. Results were correlated with demographic variables and previous experience of adverse effects.

Results: Among the respondents, 76.2% desired to be told of all possible adverse effects; 13.3% only if an adverse effect occurred 1 in 100000 times; and 10.2% only if such occurrence was 1 in 100 times; 0.4% were not interested in any information. (Percentages have been rounded and do not total 100.) Percentages were closely similar to those for the same question that restricted opinion to serious adverse effects. Desire for maximum information was significantly correlated with lower educational level ($P < .001$) and previous frequent experience with adverse effects ($P < .001$) and in older women ($P < .001$). The opinion that the physician should give the same information to all patients was given by 67.6% of the sample, and 73.4% opined that physicians were never justified in withholding any information.

Conclusion: Most individuals desire from physicians all information concerning possible adverse effects of prescribed medication and do not favor physician discretion in these decisions.

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PRACTICING physicians face continually the problem of how much detail concerning risk for adverse effects of prescribed medication they should provide patients. The prevalence of adverse side effects of medication has received increasing attention in recent years.\(^1\)\(^2\) To explain to patients, for each medication prescribed, every possible adverse effect would clearly be a task of unacceptable time consumption and questionable advisability. How, then, is the physician to choose which facts to give?

Two basic ethical principles are involved in this decision. The first is the ancient one embodied in the Hippocratic Oath: to do what is best for the patient. The second is the more recent concept of patient autonomy: the right of the patient to have full control over anything done to his or her body. One translation of the latter principle into practical decision making has been embodied in the concept of informed consent, a medicolegal term for a contract by which a patient acknowledges that he or she has been informed as to the nature and the risks of any prospective treatment and gives consent to that treatment. Written consent is currently used almost exclusively for research studies or invasive procedures. Acceptance by a patient for any treatment, however, implies informed consent.\(^3\)

This problem of the adequacy of the amount of information as to risk provided to patients by physicians has often been before the courts. The following 3 legal concepts have been used by the courts in various jurisdictions to define how much information physicians must give patients to supply criteria of informed consent: (1) the professional practice standard in which “the physicians are expected to disclose the type and amount of information that another physician in the same specialty and location would disclose”; (2) the reasonable-person or lay standard, which states that the practitioner must provide information of a type and amount that a rea-
SUBJECTS AND METHODS

SUBJECTS

The population was a convenience sample consisting of subjects 18 years or older attending outpatient clinics of the University of Kansas Medical Center, Kansas City; family members accompanying such patients; medical students; or nonprofessional employees of the medical center. For 2 weeks, all individuals of these categories in the outpatient clinic areas of the departments of family medicine, internal medicine, neurology, otolaryngology, and ophthalmology present in waiting areas were approached daily by a physician or research assistant (M.B.).

DATA OBTAINED

Subjects were individually handed a 1-page questionnaire, its purpose and nature were read to them from the questionnaire, and their consent to complete it was requested. The first part of the questionnaire consisted of 7 questions, with the first 3 defining demographic variables (age, sex, and years of school completed).

Two subsequent questions asked subjects to select the one answer that best reflected their opinion as to the information they would want from their physician about risk for adverse effects of medication. The first question (question 4) was preceded by the statement that some adverse effects (described as side effects in the questionnaire) of drugs were common and some rare, and noted that opinion on the following statements in this question concerned all adverse effects. The choices were as follows:

1. I want to hear of any side effects from the doctor no matter how rare.
2. I want to be told if a side effect has occurred in 1 in 100000 patients.
3. I want to be told if a side effect has occurred in 1 in 100 patients.
4. I am not interested in being informed as to side effects.

The second question (question 5) was preceded by the statement that some adverse effects are mild and some serious (defined as causing prolonged discomfort, disability, or death). Subjects were asked their opinion about information desired from the physician concerning such serious adverse effects, and given the same choices as in the previous question.

Subjects were then asked to what extent they thought the prescribing physician “should use his/her judgment as to how much detailed information to give the individual patient concerning possible side effects of medication” (question 6). The choices were as follows:

1. The doctor should give the same detailed information to all individuals as to frequent and rare, mild and serious side effects.
2. The doctor should give as much information concerning side effects as he or she thinks best for the individual patient.

Subjects were then asked for a yes or no answer to the question “Do you think there are occasions when a doctor is justified in withholding information about side effects?” (question 7).

Two additional questions asked the individual’s experience with adverse effects of medication in the past year. One question asked about the frequency (none, occasionally, or frequently) of adverse effects experienced, the other, if adverse effects had occurred, their severity (mild, moderate, or severe).

Since a first answer in a series can be preferentially chosen by nonobservant subjects, regardless of subject matter, we tested an additional 143 subjects, reversing in all questions the order of answers.

STATISTICAL ANALYSIS

Results of the questionnaire were tabulated as the proportion of respondents choosing each multiple-choice answer. Responses were then statistically compared for differences among subgroups defined by age, sex, years of education completed, and the frequency and severity of any previous adverse effects experienced. We performed χ² tests for association and multiple logistic regression for determination of adjusted odds ratios (ORs) for choosing a particular option for each of the questions. Variable selection for the regression model was performed using stepwise selection.

It is justified in withholding information about side effects.
Surveys were completed by a total of 2500 subjects. One hundred fifty-two individuals of those approached refused to participate (5.7%). Table 1 provides a summary of the demographic data in the population sample. As shown, 61.2% of the responders were women, the average number of years of education was 14.2, and the average age was 47.2 years.

OVERALL DESIRE FOR INFORMATION

Most subjects (76.2%) responded that they would want to hear of any adverse effects, no matter how rare. A greater percentage, 83.1%, responded that they would want to know of all adverse effects, no matter how rare, according to the demographic characteristic of sex, age category, and education level, and past experiences of adverse effects. Included in Table 2 are univariate analyses of percentages using individual χ² tests and the results of a multivariate logistic regression model.

The univariate analyses indicated that sex, overall, was not associated with choosing this option. Respondents were grouped by age into categories of 18 to 35, 36 to 55, 56 to 65, and 66 years and older; the percentages of respondents choosing this option within each category were analyzed. In the univariate analysis, P = .01 indicated there is at least 1 age category that differs significantly in response from the other categories. It appears that individuals in the youngest category were slightly less likely to wish for complete information. The logistic regression analysis revealed a significant interaction between age and sex, with no difference across ages in men, but in women a highly significant increase in desire for information was associated with increased age.

Although more than 50% of respondents at all educational levels asked to hear about all adverse effects, there was a significant difference between the different educational groups with increasing desire to know all adverse effects in the less well-educated group (P < .001). Also correlated with this option was the previous experience of frequent adverse effects (P = .002) and of severe adverse effects (P = .004).

Because of collinearity of the main effects of age and sex with the interaction, 2 separate models were used. The first was a main-effects model with sex, age, education, experience with frequent adverse effects, and experience with severe adverse effects, and the second model contained the interaction of age and sex without the main effects. This is interpreted as the effect of age among women, since men were used as the reference group.

As seen in Table 2, educational level and whether respondents had experienced frequent adverse effects in the past were again the most important predictors of electing to hear of all adverse effects. Previous experience in both models of severe adverse effects was statistically significant in the univariate analysis (P = .01) but not in the multivariate analysis, since after adjustment for affirmative responses to frequent adverse effects, the responses to severe adverse effects provide no additional information (collinearity).

The analyses of answers to the question concerning risk for serious adverse effects closely paralleled those concerning all adverse effects. A larger difference be-
Two questions were designed to complement each other in discovering opinions regarding how much discretion physicians should be allowed in tailoring the amount of information given to the individual patient. Shown in Table 3 are the results of the univariate and logistic regression analyses for the first of these (question 6). Approximately two thirds of the respondents (67.6%) thought physicians should give the same information to all patients (answer 1) as opposed to giving “as much information as he/she thinks best for the individual patient.” Women were significantly more likely to respond with the first answer ($P = .003$). The youngest and oldest respondents were slightly less likely to give this answer, but after adjustment for other factors in the logistic regression, the differences were not statistically significant. Educational level again was the strongest predictor of response ($P = .001$), with higher percentages of individuals with lower levels of education responding that physicians should give the same information to all individuals.

The frequency and severity of past adverse effects, as seen in Table 3, were both important in the univariate analyses of answers to this question, but, as in the...
previous questions (4 and 5), because of collinearity both were not needed in the multiple regression. In this analysis, it was presence of severe adverse effects that was selected for inclusion in the model instead of frequent adverse effects.

When asked whether a physician is ever justified in withholding information about adverse effects, 73.4% of all individuals answered no. There was no significant difference between the sexes in this response. The youngest group (aged 18-35 years) gave the lowest such response (68.5%), with all other age categories being significantly greater and similar to each other (75.4%, 76.8%, and 74.4% in the groups aged 36-55, 56-65, and ≥66 years, respectively; P <.004).

Educational level again proved the strongest predictor of this response, with more individuals with lower levels of education responding no (P <.001; adjusted OR, 0.67; 95% CI, 0.59-0.76). The presence of severe past adverse effects was also an important predictor of the answer no (P = .006; adjusted OR, 1.58; 95% CI, 1.01-2.48).

High correlations were expected between the opinions that equal information should be given to all patients (question 6) and that the physician is never justified in withholding information (question 7). A similar high correlation was expected between the opinions that physicians can be justified in withholding information and that the physician may use judgment in determining how much information to give. A summary of the responses to question 7, categorized by the responses to question 6, is given in Table 4.

These expected strong associations were detected (P <.001). As to inconsistent responses, only 10.9% of respondents gave responses favoring physicians giving the same detailed information to all patients, overall and by demographic factors. However, of the 794 respondents who indicated that the physician may use his or her judgment in determining how much information to give, 40.7% gave the seemingly inconsistent opinion that the physician is never justified in withholding any information.

The Council on Ethical and Judicial Affairs of the American Medical Association in its code of medical ethics states that “the patient has the right to receive information from physicians and to discuss the benefits, risks, and costs of appropriate treatment alternatives.” High comprehensive information as to risks should be has been a topic of considerable dispute. Do these words obligate the physician to discuss all risks of treatment? The most striking finding of the present study is the high percentage of subjects desiring information from physicians concerning risk for adverse effects of medication, “no matter how rare.” This was the opinion expressed most frequently by all age groups, both sexes,

### Table 3. Respondents Favoring Physicians Giving the Same Detailed Information to All Patients, Overall and by Demographic Factors

<table>
<thead>
<tr>
<th>Demographic Factor</th>
<th>No. of Respondents</th>
<th>Univariate Analysis, % Answering Yes</th>
<th>P*</th>
<th>Adjusted Odds Ratio (95% Confidence Interval)†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>2483</td>
<td>67.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>1511</td>
<td>69.8</td>
<td>.003</td>
<td>1.25 (1.05-1.50)</td>
</tr>
<tr>
<td>M</td>
<td>959</td>
<td>64.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-35</td>
<td>708</td>
<td>65.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36-55</td>
<td>951</td>
<td>71.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>56-65</td>
<td>386</td>
<td>66.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥66</td>
<td>428</td>
<td>65.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Educational level, y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-12</td>
<td>930</td>
<td>75.4</td>
<td>&lt;.001</td>
<td>0.61 (0.54-0.69)†</td>
</tr>
<tr>
<td>13-16</td>
<td>1040</td>
<td>66.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥17</td>
<td>485</td>
<td>55.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have had frequent adverse effects</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>2201</td>
<td>66.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>214</td>
<td>75.2</td>
<td>.002</td>
<td></td>
</tr>
<tr>
<td>Have had severe adverse effects</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>968</td>
<td>67.9</td>
<td>.004</td>
<td>1.89 (1.24-2.99)</td>
</tr>
<tr>
<td>Yes</td>
<td>151</td>
<td>79.5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Determined from a χ² test for association of percentage of yes responses.
† From logistic model containing the main effects sex, age, education, answer 3 to question 11 (have experienced severe adverse effects). No interaction effects were significant.
‡ Odds ratios represent the increment in odds for a 10-year increase in age and a 4-year increase in education.

### Table 4. Cross-tabulation of Responses to Question 6 With Responses to Question 7*

<table>
<thead>
<tr>
<th>Question 6, No. (%)</th>
<th>Question 7</th>
<th>No</th>
<th>Yes</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equal information to all</td>
<td>1587 (89.1)</td>
<td>181 (10.9)</td>
<td>1668</td>
<td></td>
</tr>
<tr>
<td>May use judgment</td>
<td>323 (40.7)</td>
<td>471 (59.3)</td>
<td>794</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1810</td>
<td>652</td>
<td>2462</td>
<td></td>
</tr>
</tbody>
</table>

* Question 6 asked whether the physician may use judgment as to amount of information given; question 7, whether the physician is ever justified in withholding information. P <.001 for χ² test for independence between questions 6 and 7.
and all educational-level groups and for all adverse effects and for serious adverse effects only. The close similarity of results to the questions concerning all adverse effects and serious adverse effects was somewhat surprising. Does this mean that most individuals do not discriminate between the two?

Although, to our knowledge, no previous study has documented patients' desires about this specific information, there have been many relevant studies concerning patients' desires for participation in medical decisions. Controversy exists concerning the degree to which patients wish such participation, but there is agreement that a large percentage of patients desire the information relevant to such decisions.6-10 There are also data on patient dissatisfaction with information received from physicians on this subject. Enlund et al,11 in a community sample of 623 patients taking antihypertensive medication, found that only 31% were satisfied concerning information received about possible adverse effects of the drugs. Other studies have found that 50% to 90% of patients have expressed the desire to have more information about adverse effects of medication.12,13

These studies form an interesting supplement to studies documenting the frequent omission by physicians in providing this information. Wynne and Long,14 for example, found, in a group of patients taking a nonsteroidal anti-inflammatory agent, that only 41% of those without subsequent gastrointestinal tract pain remembered having been warned of this potential side effect. Katz et al,15 in taped encounters between rheumatologists and adult outpatients taking such medication, found that adverse effects apart from epigastric discomfort were mentioned in 15% or fewer of such encounters. Two other studies report that large percentages of patients were not aware of possible adverse effects of medication they were taking.12,16

Patients expressed the desire for all information about risk for adverse effects, no matter how rare, which seems unrealistic to professional personnel. Do patients really want to be briefed on the one-in-a-million adverse response as documented in the fine print? Probably, many did not realize the magnitude of the mass of information involved and gave a stereotyped response on the order of “more knowledge is good.” Subjects who feel uncertain when dealing with numbers in estimating risk and who prefer qualitative to quantitative terms might also tend to choose this alternative. We elected to use a partially quantitative scale to describe risk, rather than a qualitative one using terms such as probable and rare. There is controversy as to which type is preferable,17,18 and it would be of interest to repeat the present study, using all qualitative terms. Patient interpretation of risk expressed quantitatively has rarely been investigated. More attention has been paid to variables affecting interpretation of qualitative terms.17,19

Artifactual results of preferential choice of the first alternative on the list were ruled out by the finding of similar results when the order of alternatives was reversed.

Of the variables studied, increased educational level and, to a lesser degree, youth correlated with what might be called tolerance of flexibility on the part of the physician in providing information as to the risk for adverse effects. The higher educational-level and the younger age groups desired less information about risk. The opinion that physicians should use judgment as to the amount of information provided was also found to be more prevalent in these groups. Related data are those of Busson and Dunn,12 who correlated knowledge of adverse effects of prescribed drugs with socioeconomic class. They found (on the basis of admittedly incomplete data) that knowledge of adverse effects of drugs was markedly less in the lower compared with the higher socioeconomic groups.12 The socioeconomic variable was not included in this study and may be a more important one than education.

There would seem to be several possible reasons for our results concerning educational level. The better-educated group may in general be better informed so that they realize the impracticality of being told of all adverse effects. Conversely, the less well-educated group may be more insecure in their relationship with the physician and therefore less tolerant of flexibility. They also may feel more confident with qualitative answers than with quantitative ones.

Of the other variables, there was a trend for women more than men to opt for information about all adverse effects. The more elderly women significantly expressed this desire for maximum information. The finding in the present study that youth was correlated with lessened demand for information about risk seems to conflict with that of Enlund et al,11 who reported in their series of hypertensive patients an increased need for information among those younger than 49 years. As these authors point out, however, their finding may be an artifact of the increased number in their study who gave the answer “uncertain” rather than yes or no to the question of need for further information. Ende et al17 found that the older groups, similar to the less well-educated groups, desire less participation in medical decision making. Our finding that a history of previous severe adverse effects increases the desire for full information about risk is in accord with that of Enlund et al.11

Both questions concerning the amount of discretion desired from physicians in discussing adverse effects were designed to amplify the information obtained from the questions concerning information about risk. Most subjects opted for a restricted role of physicians' judgment concerning the amount of information given. Even more believed that no information should ever be withheld. These replies are consistent with the large percentage expressing the opinion that information on all adverse effects should be given. Particularly of interest, however, is the quite large number of subjects who answered that physicians should use judgment in the amount of information given but also that no information should be withheld, which were seemingly inconsistent responses. The questions, of course, forced simplistic answers in very complex issues, and many patients stated in written comments their reservations about answers. Many individuals, however, undoubtedly did not realize that using judgment in this area must involve withholding information on occasion.

The responses to these questions concerning physician discretion when studied in conjunction with the
variables of age, sex, and educational level gave results similar to those found for the first 2 questions. Women and respondents with less education were, to a significant degree, less tolerant of a physician varying the amount of risk information given. Similarly, less education correlated with the opinion that no information should be withheld. The latter opinion was also more prevalent in the elderly. These findings, as noted previously, are somewhat at variance with those of other studies, in which elderly respondents desired less information than younger respondents. The factors determining desire for complete knowledge clearly are related to overall trust in a physician. The latter may involve variables such as personality qualities of the patient that would be of interest to study.

There are many limitations of this study. The population sample is not community based. Many respondents were in the process of receiving medical care, and the presence of illness may create bias in favor of receiving maximum information. Because of the necessity brevity of our questionnaire, important variables such as severity of illness for which the hypothetical treatment is being prescribed were not sampled. Furthermore, these opinions were asked for in isolation, and not as a part of a risk-benefit discussion, ie, a highly artificial situation. Others have shown, as noted previously, that although patients wish physicians to take a major role in the therapeutic aspect of decisions, they strongly desire being well informed about variables involved in these decisions.

Other important population variables that we did not study are socioeconomic class and ethnicity. It has recently been pointed out that certain ethnic and cultural groups do not favor complete disclosure to the patient of all medical facts, particularly negative ones. Increasingly, it is possible that other parochial factors influence results found in this population. It would be of interest to repeat the study with a large community-based sample from different sections of the country. Results of such surveys would clarify the possible role of variables such as geographical area or urban-rural site of residence in subjects’ opinions.

The number of subjects who did not completely understand the questions is unknown, although care was taken to give the questionnaire individually and only to alert individuals who gave consent.

As noted, both questions concerning physician behavior in delivering information forced simplified opinions in a very difficult area. The questions were designed to provide a crude measure of the degree of discretion patients were willing to allow physicians. It is of interest that most patients expressed desire for stereotyped behavior on the part of physicians in this area (same information to all patients). It would be of interest to determine whether these individuals believe their physicians behave this way. Of equal interest is that most respondents expressed the opinion that no information about adverse effects should ever be withheld. This opinion clearly is also a highly unrealistic expectation. For many respondents, the answer may have been a stereotyped response to the word withheld being considered a synonym for concealed.

The results suggest the value of follow-up studies to explore in more detail the areas where patients are willing to trust physicians’ judgment and the variables that may affect such attitudes. Deber et al, for example, found that patients have a high desire for information, overall do not wish to be included in the problem-solving process (diagnosis), and wish to be involved in decision making. The present study describes 1 variable bearing on the decision about the amount of information to be transferred. It does not deal with the important issue of whether the amount of such information relates to improved outcome or may have negative effects, as discussed below.

We did not obtain data in this study about how many patients derived this information from sources outside physicians’ offices. Printed information (drug inserts) are used by patients to varying degrees. Nurses and pharmacists have long provided such information, and there has been extensive discussion in the literature of these professions concerning the amount of information these professionals should give patients concerning medication effects. Increasingly, such information is derived from other sources, ie, direct-to-consumer advertising by pharmaceutical manufacturers, the Internet, and pharmacy benefit managers. Such nonphysician information sources may influence attitudes in a variety of ways. Study of the correlation between information given from the various sources has not been performed and would be of interest.

In summary, these results record the expectation on the part of a large percentage of individuals of complete information from physicians concerning risks for adverse effects of medication. Most individuals also indicated they are reluctant to cede to the physician the discretion in this area that he or she obviously uses and must have in clinical practice. As time pressures increase on physicians, the unreality of these expectations becomes more apparent.

The decision about how much information on risks of medication is to be given by the physician obviously involves several variables, eg, the legal standards; the physician’s time; the patient’s intelligence, educational level, and cultural background; the nature and severity of the illness; and the possibility that excess information might adversely affect the treatment, among others. To these we add the patient’s opinion. Although such opinions, as found in this study, clearly exceed the legal requirements, there is a trend, particularly in surgery, for more complete disclosure of the risk for adverse effects of treatment. To what degree such full disclosure can have adverse effects on patient care is uncertain. Two studies relating to the prevalence of adverse effects of medication found that education on the subject did not increase the number of adverse effects or decrease therapy compliance. In surgical patients, however, adverse effects such as refusal of necessary treatment or dissatisfaction with their physician’s behavior have been found. In a controversial editorial, Tobias and Souhami labeled full disclosure of possible adverse effects of medication to every patient “a recipe for needless cruelty and distress.” The complexity of the issue is increased by recent judicial decisions in Europe and South Africa that a physician has legal liability if “excessive disclosure . . . has the effect of causing the patient physical or psy-
chological harm. The view is taken that overinformat-
ing the patient may be tantamount to not informing him or her at all, and that here the physician may be held legal-
ly liable on the same basis as in non-disclosure cases. 31

Results of our study suggest the possible benefit of a brief dialogue with the patient in which the physician routinely describes the more frequent and serious adverse effects of medication prescribed and then men-
tions to the patient that there may well be other rare ad-
verse effects that he or she has not mentioned. In the case of a request by the patient to know all of the latter, printed
information might be supplied. This dialogue would prob-
ably be particularly important in those groups found to be most adamant in desire for all information, eg, the less
well educated, the elderly, and those with previous ex-
perience of adverse effects.

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