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Introduction

Much effort has gone into identifying how people understand and cope with the risks and benefits of modern technologies.[1] These efforts were motivated by concerns that the development and adoption of "needed" technologies were hampered by undue fears over risks and a lack of appreciation for potential benefits. Subsequently, other investigators, concerned about the effectiveness of public participation in decisions about controversial technologies, sought to identify factors influencing risk and benefit perceptions with the goal of improving participatory processes. The resulting studies focused on controversial technological issues such as atomic power,[2] chemical hazards,[3] and

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1 Otway and Thomas, *Reflections on Risk Perception and Policy*, 2 RISK ANAL. 69 (1982); Slovic, *Perceptions of Risk*, 236 SCIENCE 280 (1987); SOCIAL CONSTRUCTION OF RISK (B. Johnson and Covello eds. 1987).

2 Slovic, Fischhoff and Lichtenstein, *Images of Disaster: Perceptions of Risks from Nuclear Power*, in ENERGY RISK MANAGEMENT (Goodman and Rowe eds. 1979); Brody, Fleischman and Galavotti, *The Importance of Counting Cows: Social and Economic Effects of a High Level Nuclear Waste Repository in Texas*, Proceedings of the Nuclear Waste Issues Conference, Waste Management, Tucson,

electric powerlines.[4] Relatively few reports, however, addressed patients' views of medication risks and benefits. The few studies that have been conducted attempted to locate pharmaceutical risks in the context of a range of technological hazards[5] and to compare patient and physician assessments of the severity of risk.[6]

Traditional views of the physician-patient relationship hold that patients are passive participants in decisions about medical risks and benefits, while physicians are active evaluators and decision makers.[7] Patients, by virtue of having sought medical care, are presumed to have transferred responsibility for making risk/benefit determinations to their physicians. More recently, however, legal doctrines of informed consent have supported patients' rights to know about medical risks and benefits, as well as their right to participate in medical decisions. Such doctrines rest on the assumption that useful risk/benefit information can be communicated to patients who are interested in and capable of using this information to make valid decisions. Although informed consent is, according to these newer constructs, required in most medical situations, it is not uniformly applied; indeed, it is generally only applied in situations involving invasive procedures and experimental therapies.

Routine medication decisions rarely involve informed consent.

AZ, 4 Mar 1987.

3 D. NELKIN AND M. BROWN, WORKERS AT RISK: VIEWS FROM THE WORKPLACE (1984).

4 Morgan, Slovic, Nair et al., *Powerline Frequency Electric and Magnetic Fields. A Pilot Study of Risk Perceptions*, 5 RISK ANAL. 139 (1985).

5 Slovic, Fischhoff, and Lichtenstein, *Facts vs. Fears: Understanding Perceived Risk* in SOCIETAL RISK ASSESSMENT: HOW SAFE IS SAFE ENOUGH? (Schwing and Albers, eds. 1980).

6 Tallarida, Smith, Johnson and Blodget, *Non-physicians and Physicians Assess Severity of Disease States and Adverse Drug Reactions: Applications to Drug Benefit Risk Measurement*, 1 PHARM. MED. 41 (1984).

7 T. PARSONS, THE SOCIAL SYSTEM (1951); E. FREIDSON, PROFESSION OF

Rather, attention tends to focus on compliance with prescribed regimens. In this context, researchers view patient perceptions and preferences regarding drugs as independent factors affecting their compliance with the prescribed regimen.[8] Some experts doubt patients' abilities to view the risks and benefits of drugs in a rational manner, contending that perceptions of drugs involve "irrational" fears that unduly influence patient and physician behavior.

An alternative approach suggests that while researchers cannot expect patients to perform a technical risk/benefit analysis, it is important to elicit their perceptions of drug risks, benefits, and uncertainties.[9] This approach asserts that researchers must emphasize patients' value judgments in risk/benefit decisions. These values are held to be critical in determining the acceptability of therapeutic risks.

MEDICINE (1970).

8 Fleckenstein, Joubert, Lawrence, et al., *Oral Contraceptive Patient Information. A Questionnaire Study of Attitudes, Knowledge, and Preferred Information Sources,* 235 J.A.M.A. 1331 (1976); Joubert and Lasagna, *Patient Package Inserts. I. Nature, Notions, and Needs,* 18 CLIN. PHARMACOL. THER. 507 (1975); Joubert and Lasagna, *Patient Package Inserts. II. Toward a Rational Patient Package Insert,* 18 CLIN. PHARMACOL. THER. 663 (1975); Udkow, Lasagna, Weintraub and Tamoshunas, *The Safety and Efficacy of the Estrogen Patient Package Insert: A Questionnaire Study,* 242 J.A.M.A. 536 (1979); Blydenburgh, *Drug Regulation: A Survey of Public Preferences,* Feb. 1980 Pharm. Tech. 75; Weintraub, Glickstein and Lasagna, *Estrogen Patient Package Insert: Medication Acceptance Despite Negative Attitudes,* 30 CLIN. PHARMACOL. THER. 149 (1981); Morris, *A Survey of Patients' Receipt of Prescription Drug Information,* 20 MED. CARE 596 (1982); L. MORRIS, R. GROSSMAN, ET AL., PATIENT RECEIPT OF PRESCRIPTION DRUG INFORMATION, OPE Study 67 (FDA 1983); COLUMBIA BROADCASTING SYSTEM, THE CBS CONSUMER MODEL: A STUDY OF ATTITUDES, CONCERNS AND INFORMATION NEEDS FOR PRESCRIPTION DRUGS AND RELATED ILLNESSES [*sic?*] (1984). Inman, *Risks in Medical Intervention: Balancing Therapeutic Risks and Benefits,* PEM News, Aug. 1984, at 16.

9 Brody, *The Patient's Role in Clinical Decision-making,* 93 ANN. INTERN. MED. 718 (1980); Strull, Lo and Charles, *Do Patients Want to Participate in Medical Decision-making?,* 252 J.A.M.A. 2990 (1984); Greenfield, Kaplan and Ware, *Expanding Patient Involvement in Care: Effects on Patient Outcomes,* 102 ANN. INTERN. MED. 520 (1985).

Research on factors that affect patients' perceptions of medical risks, in such situations as coronary artery surgery and lung cancer, indicates that there is a correlation between therapeutic choices and patient values.[10] This work suggests that deviations from "rational" decision making, i.e., that which is based on decision analysis,[11] frequently occur. A variety of factors, including the way information is presented, individual preference for gains over losses, availability of alternatives, and desire for certain outcomes, influence both lay and expert decision making abilities.[12]

Previous studies, however, have not evaluated the role of other variables, such as perceived health status or experience with disease and drugs. Furthermore, these studies have failed to apply the findings from other research involving different technological issues, such as nuclear power, to the topic of drug risks and benefits. Such nonmedical research suggests the influence of factors such as the patient's perceived control of the situation, how information is communicated, attitudes towards regulation, and personal relationships between risk takers and risk mediators.[13]

Risk/benefit perceptions play an important role in public policy decisions. Congressional perception of uncontrolled drug risks has

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[10] Pauker, *Coronary Artery Surgery: The Use of Decision Analysis*, 85 ANN. INTERN. MED. 8 (1976); McNeil, Pauker, Sox and Tversky, *On the Elicitation of Preferences for Alternative Therapies*, 306 N. ENGL. J. MED. 1259 (1982).

[11] Eraker and Politser, *How Decisions are Reached: Physician and Patient*, 97 ANN. INTERN. MED. 262 (1982).

[12] Fischhoff, Slovic and Lichtenstein, *Lay Foibles and Expert Fables in Judgments About Risk* in 3 PROGRESS IN RESOURCE MANAGEMENT AND ENVIRONMENTAL PLANNING (O'Riordan and Turner eds. 1981).

[13] NELKIN AND BROWN, *supra* note 3. Weinstein, *Seeking Reassuring or Threatening Information About Environmental Cancer*, 2 J. BEHAV. MED. 125 (1979); Buss and Craik, *Contemporary Worldviews: Personal and Policy Implications*, 13 J. APPL. SO. P. 259 (1983).

prompted more stringent federal drug approval requirements, including the passage of the 1962 Food, Drug and Cosmetic Act Amendments.[14] In contrast, perceptions that some drugs offer overwhelming benefits for patients with specific diseases have led, on occasion, to policy and regulatory changes which result in abbreviated drug review processes. The most current case involved zidovudine, popularly known as AZT, which was approved for acquired immunodeficiency syndrome (AIDS) in only 107 days.

The study reported here was conceived as a pilot effort to elicit patient perceptions of drug risks and benefits and to identify factors that might affect these perceptions. Using a population based in hospital outpatient clinics, we asked patients to identify how they viewed adverse somatic and psychological effects of drugs, as well as presumed benefits, including amelioration of symptoms, elimination of disease, and improvements in psychosocial well-being. The first part of this paper reports our findings of patient perceptions of drug risks and benefits. The second part presents our analysis of factors that previous research suggest may be important in shaping patient perceptions.

Methods

The study was structured around a questionnaire designed to elicit patients' perceptions of the risks and benefits associated with their medications. The questionnaire also extracted information on patients' current health status, experiences with prescription drugs, knowledge of drug effects, perceived level of control, and regulatory and political views.

We sought a population likely to have diverse experiences with prescription medications. For this reason, we recruited participants from the oncology, arthritis, lipid, diabetes, and hypertension outpatient

14 P.L. 87-781, 76 Stat. 780 (1962). *But see, e.g.*, P.L. 98-417, 98 Stat. 1585 § 101 (1984).

clinics at a large, urban medical center. Because of the small number of patients attending the diabetes and hypertension clinics, additional patients with these conditions were enrolled from the general medicine clinic.

Within each clinic, physicians screened their patients for their willingness to participate in our study. The physicians then briefly discussed the project with prospective candidates. Candidates received an information sheet explaining the project and were allowed to decline participation before being interviewed by one of the study investigators. The investigator then approached those who did not decline and, after obtaining the patient's informed consent, conducted, or scheduled for a later time, a twenty to thirty minute interview. Participating patients also completed a brief demographic questionnaire.

Due to constraints imposed by the hospital's institutional review board, physicians were under no obligation to tell us if they or a patient did not want to participate. Thus, we could not identify the patient nonparticipation rate and whether those who did participate were representative of the clinic population as a whole.

Trained interviewers (M.B., C.B. and B. Richard), guided by a standard set of questions, were encouraged to ask follow-up questions that would allow patients to develop well-considered answers. Each interview was tape-recorded and the patients' responses were transcribed and coded by staff unfamiliar with the project.

A coding scale was developed for each question on the interview schedule. To reduce potential interviewer bias, a staff research assistant, unconnected with the project, coded the interviews. The staff then developed a database from the interview responses, imputing missing data values when such information was reliably known.

We analyzed overall frequency responses, as well as responses stratified by clinic, for both patients' perceptions of drug risks and

benefits and the factors possibly related to these perceptions. To determine if inter-clinic differences were significant, we calculated the Chi-square statistic for nonparametric data (Kruskal-Wallis test). A non-parametric test was employed because of the ordinal nature of responses and the small sample sizes when stratified by clinic. The p-values associated with statistically significant findings ($p < 0.10$) are denoted in parentheses.

In addition to the above analyses, we examined the relationship between patients' perceptions of drug risks and benefits and the five factors described above: current health status, experience with medications, knowledge of drug effects, perceived sense of control, and regulatory/political beliefs. To do this, we tested the association of questions describing the five factors with the perception factors using nonparametric correlation tests (Spearman Rank). Significant correlations and associated p-values are specified in parentheses ($p < 0.10$).

Results

Group Characteristics

Of the 124 interviews conducted, 22 contained greater than 20% missing or unintelligible responses, leaving 102 transcripts suitable for analysis. Of the 102 interviewed patients, 26 came from the hypertension clinic, 24 from the arthritis clinic, 23 from the oncology clinic, 16 from the diabetes clinic, and 13 from the lipid clinic. The majority of study participants were Caucasian (85%) and female (60%). The average age was 55 years, with a range of 21 to 87. The average annual household income was $25,000. Although 60% had acquired a high school education, on the whole, the study population was less educated than the average Massachusetts resident.[15]

[15] U.S. BUREAU OF THE CENSUS, STATISTICAL ABSTRACT OF THE UNITED STATES

Perceptions of Risks and Benefits

We first asked a series of questions designed to elicit a general picture of patients' perceptions of drug risks and benefits. These questions focused on patients' expectations of drug therapy, concerns about anticipated drug side effects, projections of side effects severe enough to warrant drug discontinuation, and beliefs about whether drug discontinuation would result in clinical deterioration.

Table 1

Patients' perceptions of drug risks and benefits by clinic

		CLINIC				
	Overall (n = 102)	Oncology (n = 23)	Arthritis (n = 24)	Diabetes (n = 16)	Lipid (n = 13)	Hypertension (n = 26)
PERCEPTION						
Prescribed drug will improve condition[1]	50%	46%	78%	29%	16%	58%
Discontinuation will cause clinical deterioration[2]	84%	80%	90%	76%	76%	89%
Concern about side effects[3]	53%	64%	56%	69%	41%	34%
Can imagine level of side effects that would result in discontinuation[4]	72%	55%	88%	56%	91%	69%

[1] $X^2 = 14.34, p = 0.006$ [2] $X^2 = 7.23, p = 0.12$ [3] $X^2 = 9.38, p = 0.05$ [4] $X^2 = 8.88, p = 0.06$

Overall, the patients in the study had a positive view of their medications and tended to focus on the benefits rather than the adverse

(106th Ed. 1986).

aspects of their therapies. One half of all respondents expected their prescribed medications to ameliorate their condition and to improve their physical and mental well-being. Consistent with this belief, 84% expected that discontinuing their drug treatments would result in clinical deterioration.

A significant proportion of the study population were concerned about the risks of their medications. Fifty-three percent of respondents expressed varying degrees of concern about potential side effects, whereas 47% were unconcerned about the side effects they were told they might experience.

In contrast to views on the medicines they actually use, when asked to envision a hypothetical situation, patients gave greater consideration to drug risks. When asked if they could imagine a level of side effects that would compel them to refuse medication, 72% said they could. Only 24% said they would ignore the risks, asserting that they would never refuse physician ordered medication.

There were inter-clinic differences in response to the question about concern about potential side effects ($p = 0.05$). Diabetic patients expressed the greatest concern (69%), with much of this anxiety related to self administration using needles and syringes. Oncology patients (64%) were also very concerned about side effects. In contrast, nearly two-thirds of the patients in the hypertension clinic did not express any concern about side effects.

A large proportion of arthritis patients (78%) believed that their prescribed medication would greatly benefit their health, whereas lipid (16%) and diabetic patients (29%) felt their medications were not as likely to provide physical improvement ($p = 0.006$). Lipid patients (91%), arthritis patients (88%), and oncology patients (55%) were more likely to state they would refuse medication because of potential side effects than were patients from the other clinics ($p = 0.06$).

Factors Affecting Perceptions

We asked patients questions about five factors that might be associated with their perceptions of drug risks and benefits. These

factors included probing patients' 1) current health status; 2) experiences with prescription drugs; 3) communication of medical and drug information; 4) perceived level of control over their situations; and 5) views on regulation and politics.

Current Health Status: Overall, participants had mixed assessments of their health status. Thirty percent were generally optimistic about their diagnosed condition, 50% expressed some degree of worry, concern, depression, or anger about their medical condition, and 20% expressed indifference. Lipid patients tended to be the most comfortable with their condition, whereas diabetic patients expressed the greatest pessimism. No association was found between attitude towards current health status and any of the factors describing perceptions of drug risks and benefits.

Experience with Medications: Nearly all patients (93%) were currently taking prescription medication. Of those, 87% reported a high degree of compliance in medication use. Self-reported compliance was particularly high among oncology patients, who received chemotherapy in a hospital setting, and hypertension patients ($p = 0.02$). Diabetic and lipid patients reported the least degree of compliance following their diagnosis. Past experience with medication use was also extensive; more than 81% had taken some type of prescription drug in the past two years, and 76% also indicated past or current usage of over-the-counter medications.

Nearly one half (47%) of all surveyed patients said they had experienced anticipated side effects. Additionally, 78% said that they had experienced unexpected side effects. Patients from the oncology, arthritis, and lipid clinics experienced anticipated side effects more frequently than did patients from the other clinics. Hypertension patients reported much fewer experiences with side effects.

Correlation analysis revealed a modest positive association between concern about side effects and experience with expected side effects ($R = 0.31$; $p = 0.004$). In contrast, there was an inverse association between concern about adverse reactions and experience with

unexpected side effects ($R = -0.30$; $p = 0.00$)

Communication of Information: Nearly two-thirds (64%) of the respondents felt that their physician kept them well-informed about their medical condition. In particular, lipid patients (91%) and oncology patients (83%) believed they were well-informed. This finding may be due to the fact that patients from these two clinics often were recruited for organized clinical trials which require informed consent for patient participation. In contrast, diabetic patients (32%) and hypertension patients (38%) felt particularly ignorant about their illnesses.

Most patients (77%) received some type of drug-related information from their physicians, including instructions for use or discontinuation of the drug, benefits of the drug, and possible side effects associated with drug therapy. The remaining 23% reported receiving no drug-related information from their physician.

Although 80% of the respondents expressed satisfaction with and understanding of the information initially given them regarding their prescribed medication, 40% indicated a wish for more information after beginning their medication regimens. In addition, patients (66%) identified other sources of drug information, often relying on other people, including nurses, pharmacists, family, and friends (66%). Patients also referred to getting information from medical texts and journals (49%). In particular, arthritis patients were especially inclined to rely on research of the medical literature for information on their condition and medications (74%; $p = 0.006$).

Overall, information-seeking behavior by patients was weakly correlated with the degree of concern about side effects. There was a slight positive association between concerned patients and discussion of their medical condition and medications with pharmacists, nurses, and people other than their physician ($R = 0.21$; $p = 0.06$). The use of medical texts and journals as additional sources of drug information was also positively associated with concern about drug side effects ($R = 0.21$; $p = 0.07$). In addition, a relationship was also found between the

use of medical texts and potential discontinuation of prescribed drugs due to severe side effects ($R = 0.20$; $p = 0.08$).

Patients' Sense of Control: When asked what was important in deciding to take the prescribed medication, patients gave as reasons that their condition would deteriorate if left untreated (47%), that their physician insisted upon the recommended therapy (38%) or that they felt they had no choice (15%). Hypertension patients (46%), as well as those from the lipid clinic (75%), tended to base their decision largely on their physicians' opinions, expressing a willingness to defer to professional expertise and judgment. Fifty-two percent of oncology patients took their medication because they believed that it would be effective. No one directly referred to a drug's side effect profile as a factor in making their decision to take or refuse the prescribed medication.

Responses indicated a mixed view regarding the level of patient autonomy in decision making. The majority (80%) believed that no treatment alternatives existed to the taking the prescribed drug. This was particularly true of the lipid patients (90%) and oncology patients (90%) ($p = 0.06$). Only 37% of all respondents discussed their decision to take or not take a prescribed drug with people other than their physician.

Correlation analysis revealed a modest positive association between a patient's belief in the existence of alternatives besides the prescribed medication and the future refusal of medication due to the degree of side effects associated with the prescribed drug ($R = 0.19$; $p = 0.09$).

Political and Regulatory Views: Fewer patients responded to questions about their attitudes towards drug regulations and the availability of drugs in society than to questions about other factors associated with perceptions about drug risks and benefits. This may be due to the fact that many of the patients had never before considered the questions posed in this section of the questionnaire.

Less than half (41%) of those who responded ($n = 93$) believed that strict government regulation was necessary to protect the public's

health, safety, and welfare. Forty-nine percent were ambivalent in their assessment of the role of government regulation. Only 10% considered current government regulation excessive.

In regard to drug regulation in particular, 36% trusted that the current system worked well. The remaining respondents, however, were either unaware that a drug regulatory system existed (31%) or, if they were aware of such a system's existence, they mistrusted it (33%).

About half of the respondents (51%) believed that both the FDA and the drug industry were adequately concerned about drug safety. Nearly one third (32%) felt that the flow of new drugs on the market was adequate; however, 26% believed that too few products were available and another 26% believed that too many products were marketed. Forty-eight percent of the oncology patients felt that the supply of available drugs was scant ($p = 0.001$), whereas 40% of the patients from the hypertension clinic considered the number of medications available excessive ($p = 0.001$).

Of those patients who were not concerned about side effects, a large percentage (48%) believed that stringent government regulations were necessary to protect public safety and welfare. Only 26% of the patients who were concerned about side effects indicated that strong government regulation was necessary. One third of those patients who indicated that they would refuse medication if the level of side effects was significant considered the pharmaceutical industry and the FDA to be inadequately concerned about drug safety.

When correlated with the perception factors, only one of the regulatory variables showed an association; concern about side effects was inversely associated with the belief that government regulation was necessary ($R = -0.23$; $p = 0.04$)

Discussion and Conclusions

Our results should be interpreted cautiously, as we had a limited sample and used an open-ended interview structure. Because previous studies have not focused on patients' understanding of risk/benefit issues and decision making processes regarding medications, we were exploring new paths to elicit patient perceptions of drug risks and benefits. We realize that the many statistical relations examined may well have generated spurious probability levels. Because many of the participants had not previously considered the issues raised in the interviews, future studies should evaluate alternative methods of eliciting patient opinions and attitudes towards medication decisions. Researchers may want to corroborate self-reported medication use and health status with physician records to gain an additional perspective. Further studies might be conducted that evaluate cultural and ethnic influences on drug risk/benefit perceptions, as well as other determinants of patient decision making practices. As future research further identifies other variables which influence patients' perceptions of drug risks and, ultimately, their medication-taking behaviors, it will be possible to construct a definitive model which can serve as the basis for more sophisticated studies.

To the extent that patients' perceptions and attitudes identified in this study are representative of the general population, several conclusions are suggested. First, public policy makers should continue to recognize risk/benefit differentials based on the severity and chronicity of the diagnosis. Indeed, the FDA is willing to tolerate more risk with oncologic and AIDS drugs than, for example, with antihypertensive medications. Second, it is possible that public concern about drug risks is dependent upon the degree of government oversight of the drug industry. A high level of regulation may be associated with an increased public acceptance of drug risks. Conversely, decreased government regulation of the pharmaceutical industry might result in an increase in public concern about the safety of their medications.