ORIGINAL ARTICLES

How Doctors and Patients Discuss Routine Clinical Decisions

Informed Decision Making in the Outpatient Setting

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OBJECTIVE: To characterize the informed consent process in routine, primary care office practice.

DESIGN: Cross-sectional, descriptive evaluation of audio-taped encounters.

SETTING: Offices of primary care physicians in Portland, Oregon.

PARTICIPANTS: Internists (54%) and family physicians (46%), and their patients.

MEASUREMENTS AND MAIN RESULTS: Audiotapes of primary care office visits from a previous study of doctor-patient communication were coded for the number and type of clinical decisions made. The discussion between doctor and patient was scored according to six criteria for informed decision making: description of the nature of the decision, discussion of alternatives, discussion of risks and benefits, discussion of related uncertainties, assessment of the patient's understanding and elicitation of the patient's preference. Discussions leading to decisions included fewer than two of the six described elements of informed decision making (mean 1.23, median 1.0), most frequent of these was description of the nature of the decision (83% of discussion). Discussion of risks and benefits was less frequent (9%), and assessment of understanding was rare (2%). Discussions of management decisions were generally more substantive than discussions of diagnostic decisions ($p = .05$).

CONCLUSIONS: Discussions leading to clinical decisions in these primary care settings did not fulfill the criteria considered integral to informed decision making. Physicians frequently described the nature of the decision, less frequently discussed risks and benefits, and rarely assessed the patient's understanding of the decision.

KEY WORDS: ethics, medical; informed consent; communication; physician-patient relationship; decision making.

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How well do primary care physicians inform patients about routine medical decisions? Informed consent is a widely accepted part of medical practice, yet little is known about how primary care physicians inform their patients during routine care. Virtually all clinicians recognize a duty to obtain the informed consent of patients before surgery, invasive procedures, and participation in biomedical research. Hospital accreditation standards require documen-

tation of informed consent prior to designated procedures and treatments.¹ Furthermore, the courts have established a common law requirement for informed consent.²

Despite the wide acceptance of the general need for informed consent, clinicians have little guidance as to which clinical decisions need informed consent. Influenced by its legal tradition, clinicians often equate informed consent with the practice of obtaining signed authorization for surgery or an invasive procedure. Some authors have criticized this limited view of informed consent, suggesting that its ethical basis requires patient involvement in a much wider range of clinical decisions, including those involving medication prescriptions and laboratory tests.³⁻⁵ Furthermore, many advocate greater involvement of patients in decision making than mere signing of consent forms. Lidz and colleagues called this focus on consent signing the "event model" of informed consent.⁶ They suggest that this should be replaced by a "process model," focusing instead on promotion of the patient's active participation in decision making. Clinicians should foster the informed participation of patients in medical decisions by: providing relevant information about the clinical situation, alternatives, risks and benefits; assessing the patient's understanding; and giving the patient a clear opportunity to voice a preference. This position has been called "shared decision making" by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research and others.^{3,4,7}

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Informed consent is therefore relevant not only to invasive medical procedures but also to other decisions such as prescription of potentially toxic medications or initiating a diagnostic evaluation that might eventuate in expensive or invasive procedures. Such decisions warrant the informed participation of the patient. Informed participation is the product of a thoughtful dialogue between physician and patient leading to a decision. In this article, we shall refer to this informed participation as “informed decision making.”

We know little about the extent to which primary care physicians involve their patients in decision making in the ambulatory setting. To gain insight into which view of informed consent operates in outpatient practice, we sought to characterize the extent of physician-patient discussions leading to clinical decisions during routine, primary care office visits. If clinicians apply the broader concept of informed decision making, then many routine but important decisions should be preceded by the kind of thoughtful dialogue described above. Conversely, if the narrower concept of informed consent predominates, which links informed consent to a signed authorization reserved for surgery or invasive procedures, then patient involvement in the typical outpatient clinical decision would be minimal.

Previously, researchers have mostly used indirect methods to determine the extent of informed consent, such as assessing patient perceptions or recall.⁸⁻¹² These methods allow only limited inference about actual decision making practices. A few authors have used direct observation via participant observers or audiotaping to study informed consent practices.^{13,14} Wu and colleagues studied the type and relative frequency of clinical decisions needing informed consent on inpatient medical wards, but not in the outpatient setting.¹⁵ Katz measured the extent of informed consent for nonsteroidal anti-inflammatory agents prescribed in a rheumatology clinic.¹³ Lidz and Meisel directly observed informed consent discussions on a surgical ward, cardiology ward, and surgical outpatient clinic.¹⁶ To our knowledge, no study has looked at the extent of informed consent across the broad range of clinical decisions in outpatient office practice. We analyzed audiotapes of typical primary care visits in a community setting to address these issues.

METHODS

We performed a cross-sectional, retrospective analysis of doctor-patient encounters that had been recorded on audiotape as part of an earlier randomized trial of an educational program to improve communication skills.¹⁷

Participants

For the earlier study, 53 primary care physicians were recruited from the metropolitan area of Portland, Oregon. From a total of 473 audiotaped encounters with these

physicians, we randomly sampled two office visits with different patients for a random sample of physician participants. We selected 88 visits, involving 44 physicians. All 88 visits occurred before the physicians received any of the training in communication that was part of the randomized trial. No physician was aware that his or her performance in informing patients was being evaluated.

Audiotape Coding

Using data from a pilot qualitative study of 20 audiotaped office visits, and our own clinical experience, we developed and tested a system to classify the most common clinical decisions in office practice into mutually exclusive categories. We defined a clinical decision as “a verbal statement committing to a particular course of action.” Three coders, a physician (CHB) and two graduate students in medical ethics, were trained with the pilot study tapes, including joint tape-listening sessions with discussion of the coding, independent coding of the pilot study tapes, and feedback on tape coding from the principal investigator. The 88 tapes in the actual study were coded directly from the audiotapes without transcription. Each tape was randomly assigned to one of the coders.

The coders categorized all clinical decisions during each office visit according to the classification scheme described above. They also graded the extent of discussion leading to each decision according to the presence or absence of each of six elements of informed decision making (Table 1). This list represents a synthesis by the authors of ethical models of informed consent in the bioethics literature.^{2-4,18-23} An element was counted as present if discussed at all, however briefly.

Coder Reliability

Interobserver agreement among the three coders was calculated for a random sample of 20 tapes, defined as percentage of complete agreement on a given decision. For example, if a decision was made to give a new prescription for ibuprofen, complete agreement required that both coders recognize the same event and assign the same code,

Table 1. Elements of Informed Decision Making*

1. Discussion of the clinical issue and nature of the decision to be made[†]
2. Discussion of the alternatives[†]
3. Discussion of the pros (or benefits) and cons (or risks) of the alternatives[†]
4. Discussion of uncertainties associated with the decision[†]
5. Assessment of patient's understanding
6. Asking the patient to express a preference

*These six elements were developed from synthesis of important models of informed consent in bioethics literature (see text).

[†]During audiotape coding, elements were counted as present if any discussion occurred, however brief.

i.e., "new medication." There was complete agreement on 54 (77%) of 70 decisions. Of the 16 disagreements, 14 were decisions identified by only one of two coders. In the other two cases, the coders disagreed about the classification of a clinical decision identified by both.

Data Analysis

The difference in frequency of all clinical decisions was compared with that of decisions involving office procedures (i.e., requiring a signed informed consent form), in order to test the assumption that such procedures are rare in typical office practice. We tested for significance of this difference using the paired Student's *t* test and Wilcoxon Signed-Rank Test.

For the remainder of our analysis, the focus was on clinical decisions that occurred during an office visit. The unit of analysis was therefore the individual visit ($n = 88$). Comparisons of the extent of discussion leading to different types of clinical decisions were made using the χ^2 contingency table method or one-way analysis of variance (ANOVA). Nonparametric approximations for the χ^2 (Cramer's *V* statistic) and one-way ANOVA (Kruskal-Wallis) methods were used for nominal variables, such as decision type, or variables that did not meet assumptions for the parametric method. When multiple comparisons were made, tests for significance used the least significant difference method, two-tailed at the .05 level. In the analysis of discussion between physicians and patients, which focused on the extent of discussion leading to each clinical decision, the unit of analysis was the clinical decision.

RESULTS

Of the 88 encounters randomly selected for coding, 7 could not be coded because of technical problems, leaving 81 analyzable office visits.

Characteristics of Participants

Eighty-three percent of the physician participants were men. Except for one Asian American, all the physicians were white. Fifty-four percent were practicing general internists, and 46% were family physicians. The patients were mostly women (66%) and white (95%); 92% had at least a high school diploma, and 63% had at least some college education.

Frequency and Types of Clinical Decisions

All 81 office visits had at least one decision, with an average of 3.20 clinical decisions per visit (range 1–8, 95% confidence interval [CI] 2.85, 3.54). The most common types of decisions were new medications (19% of clinical decisions), diagnostic laboratory tests (15%), specific dietary and physical activity regimens (11%), and screening tests (8%) (Table 2). Clinical decisions about procedures that would require a signed informed consent form were significantly less common than those that did not require it ($p < .0001$), occurring in only 8 (10%) of 81 visits (mean 0.1, 95% CI 0.003, 0.16).

Extent of Discussion Leading to Clinical Decisions

The discussions leading to clinical decisions often failed to meet the criteria for informed decision making, usually lacking most of the six elements. Of 262 discussions, 15% included no observable evidence of any of these elements, while 51% included only one element. The following examples illustrate this, as in the case of a diagnostic test ordered with no mention by the physician of the reason for the test or how the result might be used.

Example 1. 81-year-old woman with an episode of mid-epigastric pain a few days prior to visit:

Table 2. Extent of Discussion for Different Types of Clinical Decisions*

Type of Clinical Decision	Frequency(%)	Mean Number of Elements Discussed	95% Confidence Interval
New medication	19	1.41	1.17–1.65
Medication renewal	17	1.36	1.05–1.66
Routine diagnostic laboratory test	15	1.13	0.88–1.37
Office procedure	6	1.56	1.01–2.11
Specific dietary regimen	6	1.27	0.88–1.66
Specific physical activity	5	1.15	0.74–1.57
Routine x-ray/ imaging study	4	1.00	0.52–1.48
Specialist referral	3	1.71	1.02–2.41
Medication dosage change	3	1.33	0.67–2.00
Cholesterol screening	3	1.14	0.50–1.78
Physical therapy referral	2	1.33	0.79–1.88
Cervical cancer screening	2	1.00	0.61–1.94

*Shows the most common clinical decisions in routine office visits and their frequency. The mean number (and 95% confidence interval) of informed decision making elements discussed for each is also shown. A higher number of elements means more extensive discussion took place.

MD: Does it hurt right here?

Patient: Ouch! Yes, that's . . .

MD: Have you had any chest pain.

Patient: No, it's more down here.

MD: We better get an EKG. Wait here; I'll be right back.

There was also a case in which the physician prescribed a medication without stating its name or what it was for.

Example 2, woman with abdominal pain worse after meals:

Patient: I'm having a lot of trouble with gas.

MD: When did this lower abdominal trouble start?

Patient: I've been having trouble with my stomach for years.

MD: If you eat, does it affect the pain?

Patient: Seems like it's worse.

After the examination, the physician makes his prescription.

MD: We'll check the stool for blood, though it looks ok. Then we'll give you some meds.

The patient has some questions about the medication, but still it's not made clear.

MD: I'll give you this, and something in addition . . . something else that should help.

Patient: Which one is that? [silent pause] You don't know what it is?

MD: I know what it is.

Patient: I just want to see if I've had it before.

MD: You haven't had it before.

Patient: Is it Metoclopramide?

MD: No.

The mean number of elements of informed decision making included per discussion was 1.30 (95% CI 1.19, 1.41). Twenty-four percent of discussions included 2 elements, 6% included three, 2% included four, and 1% included five. None of the discussions included all six elements, although some were extensive. The following exchange about whether the patient should get an influenza vaccination included discussion of the nature of the decision, alternatives, the risks and benefits, uncertainty, and an expression of the patient's preferences.

Example 3:

Patient: How do you feel about me getting a flu shot?

MD: Well, how do you feel about getting a flu shot?

Patient: I've been kind of leery because both times my husband ever had one he ended up in the hospital sick. And both times my dad had took them he had the flu worse than if he hadn't.

MD: The way they produce the flu vaccine is such that you can get a mild case of the flu from it, but the chances of doing that are very small, and you

have to sort of weigh that against what are the chances of you getting a serious illness if you get the flu . . . As you age it is a little greater. If you have other underlying diseases, which you really do not, it's also greater.

Patient: Okay, I'll probably get it.

MD: The fact that you're going to be exposed to a lot of people who may get the flu . . . is probably a reason to have it.

The extent of discussion varied according to the type of clinical decision. Decisions about management included significantly more elements of informed decision making than those in the diagnostic category. (χ^2 analysis of trend, $p = .05$) Similarly, 11% of discussions leading to management decisions included three or more elements, compared with only 3% of discussions leading to diagnostic decisions ($p = .04$).

Despite these trends between the two general categories of clinical decisions, few differences were seen between discussions leading to specific types of decisions (Table 2). The one exception was discussion leading to office procedures, which included significantly more elements than discussion leading to routine diagnostic laboratory tests (one-way ANOVA, corrected for multiple comparisons, $p < .05$).

When substantive discussion leading to a clinical decision took place, the element most frequently included was the nature of the clinical problem behind the decision (83% of discussions) (Fig. 1). Discussion of risks and benefits was less frequent (9%). The least frequently included element was discussion of the patient's degree of understanding (2%).

The extent to which individual elements of informed decision making were discussed varied according to the type of clinical decision. In general, management decisions were more likely to include discussion of alternatives and of risks and benefits than diagnostic decisions. Eighteen percent of discussions of management decisions included mention of alternatives, compared with only 4% of discussions of diagnostic decisions (χ^2 , $p = .004$). Similarly, 12% of management category discussions included reference to risks and benefits compared with only 1% of diagnostic category discussions ($p = .008$). There were no statistically significant differences between the diagnostic and management categories in discussion of the other elements of informed decision making.

Comparisons of discussion of individual elements of informed decision making among specific types of clinical decisions revealed similar patterns. Discussion of risks and benefits was more likely for decisions to perform office procedures (included in 13% of discussion), prescribe new medications (10%), and change medication dosage (22%) than for diagnostic laboratory tests (3%), imaging studies (0%), and dietary or activity regimens (0%). These differences were statistically significant (Cramer's V statistic, $p = .03$). The other major difference was in discus-

FIGURE 1. How frequently each element of informed decision making was part of physician-patient discussion.

sion of uncertainty. Discussions leading to office procedures and new prescriptions more commonly included notions of uncertainty than for the other types of decisions (13% and 16%, respectively, Cramer's V statistic, $p = .025$).

DISCUSSION

This study coexamined the extent of discussion between physicians and patients leading to important clinical decisions in office practice. Important clinical decisions were common but were rarely preceded by substantive discussion. Discussion leading to clinical decisions tended to be more extensive for management decisions, particularly new prescriptions. The discussion of alternatives, risks and benefits, and uncertainty was also more common for management decisions.

Our definition of informed consent as informed decision making suggests that substantive discussions between doctors and patients should take place prior to a wide variety of clinical decisions. This study identifies the common clinical decisions in office practice for which such discussion would be important. This includes decisions regarding medications, diagnostic laboratory tests, and imaging studies. Decisions regarding office procedures that require a signed informed consent form, however, are rare. This suggests that applying a traditional concept of informed consent, often equated with written permission for invasive procedures, could result in missed opportunities

to involve patients in the entire range of important clinical decisions in office practice.

The other important finding of this study is that discussions between physicians and patients leading to clinical decisions, so central to this broader concept of informed consent, typically included few of the important elements of informed decision making. Although one element, the description of the clinical decision, was discussed quite frequently, most discussions did not include the other elements of alternatives, risks and benefits, expression of uncertainty, assurance of understanding, and expression of patient preference. Discussion leading to management decisions tended to be more substantive, but still fell far short of fulfilling all these criteria. These findings suggest that informed decision making, as described by the President's Commission and others, is not often achieved in routine office practice.

There are most likely several reasons for failure to achieve this ideal. First, one might ask if clinicians should engage in discussions that include all six elements of informed decision making before every clinical decision. Even a casual analysis of routine clinical practice suggests the answer is no, that extensive discussion is more important for some kinds of clinical decisions than for others. Although there is substantial evidence that patients generally want and expect to be involved in decision making, some authors have suggested that they would rather leave some decisions to physicians.^{24,25} Our study suggests that this kind of "sliding scale" for the extent of

discussion leading to clinical decisions may already be an accepted tenet in medical practice. Physicians in this study typically held more extensive discussions about office procedures than about diagnostic laboratory tests. They were also more likely to discuss risks and benefits for new medication prescriptions than for imaging studies. Nevertheless, the findings of this study show that the importance of substantive discussion is underrecognized, even for clinical decisions recognized to be genuinely important, such as office procedures and new medication prescriptions. Furthermore, the ethical basis of informed consent, in our view, necessitates some level of discussion for virtually all clinical decisions.

The ethical purpose of informed consent is to foster the ability of patients to make informed, autonomous choices. Many bioethicists assert that the related ethical concepts of respect for autonomy and respect for persons entail a duty for physicians to provide the information necessary for the patient to be an informed participant in health care decisions.^{2-4,18-20,26} As stated above, this concept of informed consent focuses on meaningful dialogue about virtually all decisions. Even fairly routine decisions, such as the decision to perform a routine blood test or electrocardiogram, need some form of dialogue to ensure the informed participation of the patient. As decisions become more important and complex, the level of dialogue needed becomes more extensive as well, leading to the comprehensive kinds of exchanges commonplace before invasive or risky surgical procedures.

Another reason physicians may not achieve the ideal level of informed consent is that they are too busy. Pressures to reduce the costs of care may be at odds with the need to spend more time in discussion with patients. Most clinicians presume the additional time needed for such discussion to be substantial, though this belief is untested.²⁷ Insurers do not reimburse for extra time spent in lengthy discussions, though some authors have suggested that they should.³ Many health care systems are beginning to explore the use of other health care providers, support staff, and new interactive technologies in this process.^{7,28} Medical schools and residency training programs need to emphasize communication skills required to conduct brief, focused, yet comprehensive discussions leading to medical decisions.

A third reason clinicians may not fully discuss routine yet important medical decisions is a failure to recognize these decisions as warranting the same kind of attention to patient involvement as an invasive procedure. Perhaps this is a consequence of the inpatient-dominated training of physicians, in which important medical decisions are more likely to involve surgery or invasive procedures. As medical care moves increasingly into ambulatory settings, clinicians and educators need to expand their views of informed consent and recognize that seemingly routine clinical decisions deserve thoughtful discussion and sharing of decision making.

The findings of this study are consistent with those of

previous studies of informed consent practices. Louis Harris and Associates evaluated physician self-reports of informed consent practices and found that although 96% of physicians routinely reported obtaining consent for surgical procedures, less than half did so for routine blood tests, diagnostic radiographs, or minor office procedures. Regarding disclosure, the physicians reported disclosing potential side effects 93% of the time, while patients reported receiving such information only 69% of the time.²⁷ This gap highlights the weakness of evaluating physician practice with self-reporting. Although the difference could also be explained by imperfect patient recall, other studies suggest that physician self-evaluation tends to overestimate performance.²⁹ Sulmasy and colleagues found that physician disclosure of information to patients undergoing routine medical procedures ranged from 90% for explaining the procedure to 53% for explaining the alternatives.¹²

This study has several strengths, one being the direct observation of physician behavior in discussions leading to routine clinical decisions. This has distinct advantages over indirect reports such as surveys or self-reports, which are susceptible to bias and problems with recall. Only a few studies of informed consent have used direct observation methods.¹³⁻¹⁵ Lidz and Meisel studied informed consent practices for inpatient and outpatient surgery and cardiology patients, using a participant observer method. They directly observed interactions between physicians and 43 cardiology and 58 surgical patients. Through analysis of field notes and audiotapes, they found that information disclosure tended to be more formal and complete during inpatient consent than outpatient. In a limited analysis of 15 outpatient clinical decisions, however, they observed that patient involvement in decision making was more extensive in the outpatient setting.¹⁶ Our study used similar techniques to Lidz and Meisel, though on a much larger sample of outpatients and a much broader range of clinical decisions.

Wu and Pearlman evaluated communication surrounding informed consent for inpatient medical procedures, using direct observation. They found that although the rationale for the procedures was discussed frequently, the alternatives, risks, and benefits were discussed significantly less often.¹⁵ Still, their study concentrated on inpatient practice, and on medical procedures. Our study, by contrast, applies a direct observation approach to the full range of outpatient clinical decisions, a distinct strength.

Some possible limitations of this study should be addressed. One limitation of audiotapes is the inability to capture nonverbal communication. Because the analysis of discussion in our study focused mostly on information exchange, however, this is of less importance. Many authorities in doctor-patient communication assert that nonverbal communication is felt to be more important for social and emotional support in the doctor-patient encounter than for information exchange.³⁰

Second, discussion leading to decisions may have taken place during other visits, resulting in an underesti-

mation of the extent of physician-patient discussion related to a given decision. Furthermore, physicians and patients may have already established a method of decision making, in which a low level of information exchange might represent an acceptable norm to each. In an effort to ascertain the extent of this problem, we compared discussions related to decisions to prescribe a new medication with decisions concerning renewal of a medication. Our thinking was that new medication prescriptions represent an example of decisions that were not likely to be discussed in previous visits. We found no evidence that discussions for new medications were any more substantive, even though one might expect more detailed conversations, including intended benefits and side effects.

Because we used a new method for analyzing and coding the audiotaped office visits, the reliability of this method must be closely examined. We believe our method to be valid and reliable. Our method quantitates certain clear, identifiable verbal behaviors, hence meeting important criteria for communication analysis. The interobserver agreement in coding of 77% was well within the range of 70% to 90% that is typical for audiotape coding methods.³⁰

The physicians studied were volunteers in a study of communication skills and may not have been representative of physicians in general. If anything, we suspect they would have engaged in more extensive discussions than the average physician. Also, the participants did not know that their performance relative to informed decision making was being evaluated.

In summary, we found that numerous decisions are made in each office visit, and often involve medications and diagnostic tests. Despite the recognized need to involve patients in these decisions, discussions leading up to routine clinical decisions were lacking in several important elements of informed decision making. Our findings suggest the need for larger, longitudinal studies of informed decision making practices, to further characterize factors that influence the extent of dialogue between physicians and patients and to test strategies to yield improvement.

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