

Informed Decision Making in Outpatient Practice

Time to Get Back to Basics

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HOW WELL DO PHYSICIANS FOSTER the informed participation of patients in important clinical decisions? Many clinician-authors have called for a shift toward a view of informed consent in which the emphasis is on a meaningful dialogue between physician and patient instead of a unidirectional, dutiful disclosure of alternatives, risks, and benefits by the physician.¹⁻⁴ This expanded view is termed *informed decision making*. Despite these calls for more sharing of decision making with patients, we know little about the extent to which patient-physician discussions of clinical decisions achieve informed patient participation.

Fully involving patients in clinical decisions is a challenging task for clinicians, and little training exists on the practice of effective informed decision making. What guidance exists is often based on legalistic notions of consent. For instance, the well-known mnemonic *PAR* reminds the clinician to disclose the nature of the procedure, alternatives, and risks in any informed consent discussion. The rationale of this

See also pp 2356 and Patient Page.

Context Many clinicians have called for an increased emphasis on the patient's role in clinical decision making. However, little is known about the extent to which physicians foster patient involvement in decision making, particularly in routine office practice.

Objective To characterize the nature and completeness of informed decision making in routine office visits of both primary care physicians and surgeons.

Design Cross-sectional descriptive evaluation of audiotaped office visits during 1993.

Setting and Participants A total of 1057 encounters among 59 primary care physicians (general internists and family practitioners) and 65 general and orthopedic surgeons; 2 to 12 patients were recruited from each physician's community-based private office.

Main Outcome Measures Analysis of audiotaped patient-physician discussions for elements of informed decision making, using criteria that varied with the level of decision complexity: basic (eg, laboratory test), intermediate (eg, new medication), or complex (eg, procedure). Criteria for basic decisions included discussion of the nature of the decision and asking the patient to voice a preference; other categories had criteria that were progressively more stringent.

Results The 1057 audiotaped encounters contained 3552 clinical decisions. Overall, 9.0% of decisions met our definition of completeness for informed decision making. Basic decisions were most often completely informed (17.2%), while no intermediate decisions were completely informed, and only 1 (0.5%) complex decision was completely informed. Among the elements of informed decision making, discussion of the nature of the intervention occurred most frequently (71%) and assessment of patient understanding least frequently (1.5%).

Conclusions Informed decision making among this group of primary care physicians and surgeons was often incomplete. This deficit was present even when criteria for informed decision making were tailored to expect less extensive discussion for decisions of lower complexity. These findings signal the need for efforts to encourage informed decision making in clinical practice.

JAMA. 1999;282:2313-2320

www.jama.com

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approach either satisfies an administrative requirement or protects oneself from liability, rather than viewing the decision-making process as a meaningful path toward fostering patient involvement.

The challenge to involve patients in decision making has intensified in recent years, as both the range of important clinical decisions and the settings in which they occur have changed. To provide guidance to clinicians in the ef-

fective practice of informed decision making, we need a thorough understanding of how clinicians and patients currently make routine clinical decisions. However, most studies focus on patient or physician reports of what ought to take place in clinical decision making.^{5,6} Still others focus on indirect measures, such as patient recall of patient-physician discussions.⁷⁻¹¹ Only a few studies have used direct observation of decision making. These studies suggest that the dialogue recommended by an ethical model of informed decision making is strikingly rare.¹²⁻¹⁵ No studies to date have examined the practices of both primary care physicians and surgeons, studied large samples, evaluated community-based settings, or evaluated the completeness of informed decision making across the full spectrum of clinical decisions in office practice.

In addition, no previous studies have used criteria for informed decision making that reflect the important influence of the complexity of decisions on the amount of discussion that should reasonably be expected. For example, in our previous work, we found that many important elements of informed decision making were absent from decisions about medications and laboratory tests in routine office practice.¹⁶ That study, like others, applied a single set of criteria for the completeness of informed decision making to all clinical decisions, which does not acknowledge that some decisions are less complex than others and may need less substantive discussion. However, no guidelines exist for how much discussion is adequate for the completeness of informed decision making for clinical decisions of varying complexity.

The process-oriented approach to informed decision making that we present here suggests the need for some dialogue about virtually every clinical decision. We examined a large sample of clinical decisions occurring at offices of various medical specialties, evaluating community-based practices that permit more realistic extrapolations to the more common clinical

Table 1. Elements of Informed Decision Making Required for Each Decision Category

Elements of Informed Decision Making	Basic	Intermediate	Complex
1. Discussion of the patient's role in decision making Rationale: Many patients are not aware that they can and should participate in decision making. Examples: "I'd like us to make this decision together." "It helps me to know how you feel about this."	Required*	Required*	Required
2. Discussion of the clinical issue or nature of the decision Rationale: A clear statement of what is at issue helps clarify what is being decided on and allows the physician to share some of his/her thinking about it. Examples: "This is medication that would help with . . ." "The blood test will tell us . . ."	Required	Required	Required
3. Discussion of the alternatives Rationale: A decision is always a choice among certain options, including doing nothing at all. This is not always clear to the patient without an explicit discussion. Example: "You could try the new medication or continue the one you are on now."	Not required	Required	Required
4. Discussion of the pros (potential benefits) and cons (risks) of the alternatives Rationale: We frequently discuss the pros of one option and the cons of another without fully exploring the pros and cons of each. A more balanced presentation allows the patient's decision to be more informed. Examples: "The new medication is more expensive, but you only need to take it once a day." "Screening for colon cancer using the stool cards is easier for you, but the flexible sigmoidoscopy is more precise."	Not required	Required	Required
5. Discussion of uncertainties associated with the decision Rationale: While often difficult, a discussion of uncertainties is crucial for a patient's comprehensive understanding of the options. Thoughtful discussion can promote trust and encourage adherence. Examples: "The chance that this will help is excellent." "Most patients with this condition respond well to this medication, but not all."	Not required	Not required	Required
6. Assessment of the patient's understanding Rationale: Once the core disclosures are made, the physician must check in with the patient to know if what he/she has said so far makes sense. Fostering understanding is really the central goal of informed decision making. Examples: "Does that make sense to you?" "Are you with me so far?"	Not required	Required	Required
7. Exploration of patient preference Rationale: Physicians may assume that patients will speak up if they disagree with a decision, but patients often need to be asked for their opinion. It should be clear to the patient that it is appropriate to disagree or ask for more time. Examples: "Does that sound reasonable?" "What do you think?"	Required	Required	Required

*Asterisk indicates element 1 or 7 is required for decision making.

Table 2. Domains Influencing Decision Category

Decision Category*	Domain		
	Effect on the Patient	Medical Consensus	Nature of Outcomes
Basic	Minimal	Consensus	Clear, singular
Intermediate	Moderate	Wide support	Moderately uncertain
Complex	Extensive	Controversial	Uncertain, multiple

*An example of a basic decision is a routine laboratory examination; an example of an intermediate decision is medication; and an example of a complex decision is a prostate-specific antigen test.

care settings than prior studies based in teaching hospitals. In addition, we applied a new set of criteria for the completeness of informed decision making, recognizing that standards for the completeness of informed decision making should vary with the complexity of the decision. Using these criteria, we evaluated the completeness of informed decision making by primary care physicians and surgeons by direct assessment of audiotapes of routine office visits. The results of this study will provide data for efforts to improve patient-physician communication and decision making.

METHODS

Conceptual Framework

Using content analysis, we examined the completeness of informed decision making between physicians and their patients. We adapted methods from an approach described in our previous work.¹⁶ The intent of our method is to evaluate the completeness of informed decision making using preestablished and valid criteria. The criteria for informed decision making used in this study include 7 distinct elements (TABLE 1): (1) the patient's role in decision making, (2) the nature of the decision, (3) alternatives, (4) pros (benefits) and cons (risks) of the alternatives, (5) uncertainties associated with the decision, (6) an assessment of the patient's understanding of the decision, and (7) an exploration of the patient's preferences. These criteria represent a synthesis of the bioethics literature and professional consensus on important elements of informed decision making.^{1,17-22}

In our previous work, we applied 6 elements of informed decision making to every decision. We have since re-

vised our schema to add an additional element, which is the discussion of the patient's role in decision making. The need for this new element arises because many patients may be unclear about their role in decision making and hence, adopt a passive or nonparticipatory style. Consequently, in certain decisions, particularly complex ones, the patient may need an explicit invitation to participate in the decision-making process.

Another feature of our revised schema is the inclusion of a sliding scale in which we apply different criteria for completeness for decisions of differing complexity. This hierarchy was based on the observation that requiring complete discussion of all of the proposed elements of informed decision making for all decisions would be burdensome, unachievable, and unnecessary.²³ Rather, we propose that the standard for completeness of informed decision making ought to respond to the complexity of the decision.

We developed a hierarchy of decision complexity in which all clinical decisions were categorized as basic, intermediate, or complex (TABLE 2). We used iterative group techniques among physicians and laypersons to define completeness for each category of decision complexity, designating the specific elements required for completeness of informed decision making (Table 1). These categories were used in our initial analysis of the completeness of informed decision making. To illustrate these distinctions further, we provide examples of complete-, absent-, and partial-informed decision-making discussions in TABLE 3.

We then used the same group process to assign specific kinds of deci-

Table 3. Examples of Complete and Absent Informed Decision Making for Decisions in Different Categories*

Basic
Laboratory test Complete: "I think we should check your thyroid level to see if that is causing your fatigue [2]. Does that seem reasonable [7]?" Absent: "I'd like to check some blood tests. Here's the slip to take to the lab."
Intermediate
Change dose or new medication Complete: "We need to control your blood pressure better [2]. We could increase the dose of your atenolol or add a medication like a water pill [3]. The higher dose of atenolol might make you feel fatigued but the water pill might make you urinate a lot [4]. Are you clear about the pros and cons of these choices [6]? What would you like to do [7]?" Absent: "I'd like you to increase the dose of atenolol you're already taking." All-basic: "We need to control your blood pressure better [2]. Let's increase the dose of your atenolol. Does that sound OK [7]?"
Complex
Prostate cancer screening Complete informed decision making: "At your age, we should start thinking about screening for prostate cancer [2]. You've probably heard about the PSA [prostate-specific antigen] test. This blood test can detect very small prostate cancers but it can also be abnormal if your prostate is enlarged, even if there's no cancer [4,5]. Unfortunately, we're not certain that finding prostate cancer early will help you live any longer [5]. We could do the test or not [3]. Every man has different opinions, as do experts, so I would like your views in this decision [1]. Do you have any questions about the test [6]? What's your thinking, then, about a PSA test [7]?" Absent: "Let's get some blood tests today." All-basic: "Because of your age, we should probably check a PSA test [2]. Is that OK with you [7]?"

*The numbers in brackets represent the element which the preceding statement or phrase meets. All-basic means applying the criteria for a basic decision to all decisions regardless of their complexity. All-basic indicates lowest level of acceptable dialogue for any clinical decision; a moral minimum for informed decision making.

sions (eg, laboratory tests, new medication, or surgery) to each category. We selected the lowest possible category for each decision. Using this model, we presume that there are other influences within any decision, such as the information needs of the individual patient that could bump the decision up a level in the hierarchy. In this way, we established a moral minimum of elements necessary for complete discussion of each kind of clinical decision.

We were also interested in evaluating the completeness of informed decision making using less stringent criteria for completeness. First, we analyzed completeness of all decisions, regardless of complexity, using criteria based on a schema that mostly emphasizes information disclosure. Following the PAR mnemonic, we defined completeness as the presence of any discussion of the nature of the decision (element 2), alternatives (element 3), and pros and cons (element 4). As these disclosure-oriented approaches do not make distinctions between decisions of varying complexity, we applied the PAR definition of completeness to all decisions (basic, intermediate, and complex).

The second modification was to analyze all decisions by the least stringent basic criteria. We assert that some minimum level of discussion should be expected for any important clinical decision. We analyzed all decisions using these minimum criteria, identified as the all-basic analysis. In our model, the all-basic criterion is the lowest level of acceptable dialogue for any clinical decision, operationalizing a moral minimum for informed decision making. For example, a complete decision using this minimum criteria would be, "I'd like you to take this new medicine to manage your blood pressure (element 2). Okay (element 7)?" (Table 3).

Participants

We obtained audiotapes from a 1993 study about the relationship between patient-physician communication and malpractice claims. Physicians were identified from the databases of 2 physician-controlled insurance companies in Colorado and Oregon based on their malpractice history (50% with 2 or more claims) and specialty. Fifty-nine primary care physicians (general internal medicine and family medicine) and 65 surgeons (general and orthopedic surgery) participated. All were in community-based practices. Details of the recruitment process are outlined elsewhere.²⁴

Approximately 10 patients were recruited on a convenience basis from the

waiting area of each participating physician (range, 2-12). Initial visits were included for surgery patients, while primary care patients had seen their physician at least twice. All patients were English speaking, older than 18 years, and not in acute distress. The original study was approved by the institutional review board of Legacy Good Samaritan Hospital (Portland, Ore). Physicians and patients gave informed consent to a study of communication but were unaware of our subsequent focus on informed decision making.

Audiotape Coding

Four trained coders, blinded to identifying characteristics of participants, coded the audiotapes. Coders were trained by 2 of the authors (C.H.B. and K.A.E.) over several weeks through detailed definitions of the elements, joint audiotape listening sessions with discussion of the coding, and independent coding of separate pilot study audiotapes.

Each audiotape was randomly assigned to a coder and was coded directly without transcription. Coders identified all clinical decisions during each office visit. A decision was defined as a verbal commitment to a definitive course of action. Discussions of possible decisions that did not reach a definitive commitment were not included in our data. The coders were also asked to note whether decisions were physician-initiated or patient-initiated. They then recorded the presence of the 7 informed decision-making elements in the discussion of that decision. An element was counted as present if mentioned at all, however briefly. Elements were counted as present whether offered by the patient or the physician.

We evaluated interobserver agreement among the 4 coders by randomly selecting 10% of the audiotapes for double coding. These audiotapes were recoded by another coder who was blinded to the results of prior coding. Overall agreement regarding the presence of any decision was good, with percentage agreement of 73% and κ of 0.44. The κ statistic regarding identification

of the specific type of decision was 0.58. A κ statistic was also calculated for agreement on the presence or absence of each of the informed decision-making elements (element 1, 0.39; element 2, 0.61; element 3, 0.47; element 4, 0.53; element 5, 0.19; element 6, 0.28; and element 7, 0.55). Five percent of the audiotapes were selected at random intervals throughout the coding period and coded twice by the same coder to assess coder drift and intrarater reliability. The κ statistics for intrarater reliability for decision codes ranged from 0.53 to 0.66.

Statistical Analysis

The unit of analysis for this study was the individual clinical decision (N = 3552). Descriptive analysis focused on the completeness of informed decision making for each decision, which was determined by using criteria for completeness for the corresponding decision category. If all the required elements for the relevant decision category were discussed, informed decision making was considered complete. If none of the required elements were present, then informed decision making was labeled absent.

To apply less stringent standards for completeness of informed decision making, we repeated the analysis of completeness using the 2 modifications described above, analyzing all decisions regardless of complexity by the PAR definition and by the all-basic definition.

We used 2-tailed *t* tests to compare the mean number of decisions for primary care physicians and surgeons. We compared the distribution for decisions of differing complexity using the χ^2 test. We compared completeness of informed decision making between primary care physicians and surgeons using a 2-tailed Fisher exact test. Data were analyzed using SPSS software (SPSS Inc, Chicago, Ill).

RESULTS

We reviewed 1105 audiotapes. Forty-eight audiotapes were excluded from analysis because of poor audiotape qual-

ity or interrupted visits ($n = 21$) or because the encounters contained no clinical decisions ($n = 27$). We analyzed 1057 audiotapes, which contained 3552 decisions.

Characteristics of the Participants

Participants' demographic characteristics have been presented in detail elsewhere.²⁴ Most patients were white (85%) and had some college education (63%). The median age was 51 years and 55% were women. Compared with primary care patients, those seeing surgeons were slightly younger, more often white, slightly more educated, and of higher socioeconomic status.

The physicians were mostly white (92%) and male (94%); 59 were primary care physicians and 65 were orthopedic or general surgeons. The number of years since graduation from medical school ranged from 12 to 41 years. Almost all physicians practiced within solo practices (41% primary care, 26% surgery) or single specialty groups (44% primary care, 68% surgery). On average, primary care physicians reported spending 45 hours per week with patients, surgeons reported 58 hours per week.

Nature of the Encounters

Primary care physician visits lasted a mean of 16.5 minutes (95% confidence interval [CI], 16.0-17.0) and included discussion of a median of 3 patient concerns (range of 1-12 as reported on the physician exit questionnaires). The most frequent medical problems were hypertension, depression, diabetes mellitus, gastrointestinal tract disorders, and musculoskeletal problems.

Visits with surgeons lasted a mean of 13.6 minutes (95% CI, 13.3-13.8) and included discussion of a median of 2 concerns (range, 1-8). For orthopedic surgeons, the most common reasons for visits were shoulder disorders, acute knee injuries, and fractures. For general surgeons, the most common reasons included breast disease, abdominal hernia, and cholecystitis or cholelithiasis.

Nature of the Decisions

The majority of encounters had 3 or fewer clinical decisions (29.8% with 1 decision, 26.3% with 2 decisions, and 19.5% with 3 decisions). The basic category ($n = 1857$ [52.3%]) accounted for the majority of all decisions. There were 1478 (41.6%) intermediate decisions and 217 (6.1%) complex decisions. Most decisions were initiated by the physician (85.8%).

The most common types of decisions for primary care physicians were medication decisions (33.4%), follow-up appointments (14.0%), and routine laboratory tests (11.0%). For surgeons, the most common decisions were follow-up appointments (19.6%), medication decisions (12.9%), and counseling regarding activities of daily living (12.8%) (TABLE 4).

Overall, surgeons made more decisions than primary care physicians (1921 and 1631, respectively). However, primary care physicians made more decisions per visit on average than surgeons. The mean number of decisions per visit for primary care physicians was 2.75 (95% CI, 2.67-2.83) while surgeons had 2.51 (95% CI, 2.44-2.58; $P < .001$). Furthermore, there was a significant difference in the distribution of decision complexity between the 2 groups. Primary care physicians made more intermediate decisions than surgeons (48.6% vs 35.7%), while surgeons made more basic (56% vs 47.9%) and more complex (8.3% vs 3.5%) decisions ($P < .001$).

Completeness of Informed Decision Making

Overall, the completeness of informed decision making was low. When examined across all decision categories, few decisions (9.0%) met criteria for completeness of informed decision making. Completeness of discussion of decisions varied by decision complexity. Whereas 17.2% of basic decisions were complete, none of the intermediate and only 1 (0.5%) of the complex decisions were complete. Within the basic category, there was variation in the proportion of decisions that were complete. For instance, 20.9% of the decisions about activities of daily living were complete, whereas routine laboratory test decisions were only complete in 10% of cases.

There was substantial variation across categories in the frequency with which individual elements were discussed (range, 1.5%-71%) (TABLE 5). Patients were often told the nature of the intervention (basic, 66.1%; complex, 83.9%), but there was seldom discussion of alternatives (5.5%-29.5%), pros and cons (2.3%-26.3%), or uncertainties associated with the decision (1.1%-16.6%). Physicians occasionally discussed the patient's role in decision making (5%-18.4%) and elicited patient preferences (17.8%-27.2%). Physicians rarely explored whether patients understood the decision (0.9%-6.9%).

The extent of discussion consistently increased with decision complexity (FIGURE). We found a statistically sig-

Table 4. Most Common Clinical Decisions Among Primary Care Physicians and Surgeons

Category	% of Decisions	
	Primary Care Physicians (n = 1631)	Surgeons (n = 1921)
Basic	Follow-up appointment (14.0)	Follow-up appointment (19.6)
	Routine laboratory tests (11.0)	Activities of daily living counseling (12.8)
	Activities of daily living counseling (7.7)	Routine x-ray tests (5.6)
Intermediate	Medication issue (33.4)	Medication issue (12.9)
	New physical activity regimen (2.5)	New physical activity regimen (5.8)
	Decision to workup vs overlook new problem (2.1)	Office procedure (4.5)
Complex	Prostate cancer screening (1.5)	Counseling regarding surgery (6.2)
	Counseling regarding surgery (0.5)	Type of anesthesia (0.7)
	Smoking cessation (0.3)	Breast cancer screening (0.4)
	Weight management regimen (0.4)	Weight management regimen (0.4)

nificant increase in the frequency of discussion of individual elements when we compared basic with complex decisions. The most striking increases were in alternatives (5-fold increase), pros and cons (10-fold increase), and uncertainties (16-fold increase). Discussion of the patient's role, discussion of the nature of the decision, and ascertainment of patient preference also showed significant increases from basic to complex categories (χ^2 analysis of trend for each element, $P < .001$).

We reanalyzed completeness using the PAR criteria (described earlier) and

found the proportion of complete discussions overall was lower (3.1%). Compared with the initial analysis, completeness was lower in the basic category (0.5%), while discussions were somewhat more frequently complete in the intermediate category (4.6%). Discussions of complex decisions were much more frequently complete by this definition, 15.2% compared with 0.5% using the initial criteria (TABLE 6).

We reanalyzed completeness of informed decision making using the all-basic criteria. This analysis sets the moral minimum for completeness, applying

the least stringent criteria for basic decisions to all decisions regardless of their complexity. Although this improved the overall proportion of complete decisions, fewer than 1 in 5 decision discussions (20.4%) were complete by this minimum measure. The proportion of complete decisions improved in both the intermediate (21.9%) and complex (38.2%) categories.

Considering the low interrater reliability for elements 5 and 6, we also reran the initial analysis for completeness excluding these elements. The results remained largely unchanged with 0.3% of intermediate decisions complete but no change in completeness of complex decisions.

Our focus in this analysis was on decisions rather than individual visits. However, when analyzing decisions by specialty, surgeons had a higher proportion of completeness in informed decision-making discussions than primary care physicians. For basic decisions, 18.0% of decisions were complete for surgeons vs 16.1% for primary care physicians (Fisher exact test, $P = .03$). When all decisions were analyzed using the PAR criteria, 3.7% of decisions were complete for surgeons vs 2.4% for primary care physicians (Fisher exact test, $P = .02$). Finally, when all decisions were analyzed by the moral minimum of the all-basic criteria, surgeons still had a larger proportion of completeness in informed decision making (21.8% compared with 18.9% for primary care physicians; Fisher exact test, $P = .03$) (TABLE 7). Length of visit and length of relationship were not significantly associated with completeness in informed decision making for primary care physicians or surgeons.

Table 5. Frequency of Each Element Overall and for the 3 Categories*

Element	Basic (n = 1857)	Intermediate (n = 1478)	Complex (n = 217)	All Categories (N = 3552)
Patient role	5 (92)	5.2 (77)	18.4 (40)	5.9 (209)
Nature of decision	66.1 (1227)	75.4 (1114)	83.9 (182)	71 (2523)
Alternatives	5.5 (102)	15.8 (234)	29.5 (64)	11.3 (400)
Pros and cons	2.3 (43)	12 (177)	26.3 (57)	7.8 (277)
Uncertainties	1.1 (20)	6 (88)	16.6 (36)	4.1 (144)
Patient understanding	0.9 (17)	1.5 (22)	6.9 (15)	1.5 (54)
Patient preferences	17.8 (331)	24.1 (356)	27.2 (59)	21 (746)

*Values are listed as percentage (number).

Figure. Frequency of Elements of Informed Decision Making by Level of Decision Complexity

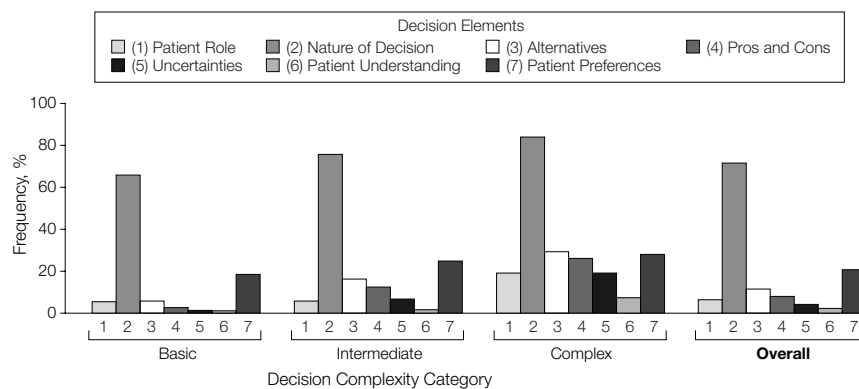


Table 6. Completeness of Informed Decision Making*

Completed	Decision Category			Overall Completeness
	Basic	Intermediate	Complex	
Initial analysis				
All required elements	17.2	0.0	0.5	9.0
Modified analyses				
Procedure, alternatives, risks	0.5	4.6	15.2	3.1
All-basic	17.2	21.9	38.2	20.4

*Values are percentages.

COMMENT

In this study, we set out to determine the completeness with which physicians involved patients in routine, but important, clinical decisions in office practice. We analyzed these discussions with criteria that sought to balance an ethical ideal with practical reality by taking into account important differences in decision complexity. We found that surgeons and primary care

physicians in office practice infrequently had complete discussions of clinical decisions with their patients.

These findings suggest that the ethical model of informed decision making is not routinely applied in office practice. This low level of informed decision making suggests that physicians' typical practice is out of step with ethical ideals. There are practical implications of this missing practice. Inadequate efforts to foster patient involvement in decision making may impair the patient-physician relationship. Furthermore, there are quality-of-care concerns, since there is mounting evidence that inadequate patient involvement may interfere with patient acceptance of treatment and adherence with medical regimens.²⁵

Noting the minimal levels of completeness across decision categories, we decided to reanalyze the data using modified standards. These additional analyses also address the concern that our evaluation sets too high a standard for decision making. Though these analyses (PAR and all-basic) revealed modest improvement in overall completeness of informed decision making, primary care physicians and surgeons frequently made decisions without discussing the intervention with the patient or seeking their involvement. By the most minimal definition consistent with an ethical framework, decision making in clinical practice may fall short of a basic level of patient involvement in routine decisions. The examples in Table 1 and Table 3 illustrate the minimal nature of the discussions that physicians conducted in the audiotapes.

In general, surgeons had more completeness of informed decision making than primary care physicians. Surgeons have more experience in obtaining written consent for surgery, which may carry over into being more accustomed to discussing other decisions with patients. A recent study of patient-surgeon communication demonstrates that surgeons spend almost half of their visit time educating and counseling patients, significantly more than primary care physicians in this type of conversation.²⁶ The full

explanation of this apparent difference warrants further study.

Our model of informed decision making represents a usable framework for involving patients in decision making. Although some patients may wish for more discussion of a particular decision than our model requires, we used a minimal standard for communication. Any particular instance of a decision could become more complex, depending on questions and concerns of both patient and physician. Our model emphasizes patient understanding and explicit discussion of the patient's role in decision making, in part so that patients are given a clear opportunity to expand the nature of the discussion to fit their needs. Our model's sliding scale further prevents the physician from being saddled with the onerous task of having lengthy involved discussions about every clinical decision. Finally, the model maintains a critical link to the ethical foundations of informed decision making, and thereby balances the ideal of theory with the reality of practice.

There are some limitations to this study. As a cross-sectional study, we do not have the benefit of observing the patient-physician relationship over time. Some of the conversations involving decisions may be incomplete because the physician and patient are quite familiar with each other's values, information needs, and decision-making style. Only longitudinal studies of patient-physician decision-making interactions will lay this issue to rest. However, even within a long-term relationship, we argue that our moral minimum would still hold in which the physician at least describes the intervention and solicits patient input before proceeding.

In addition, the physicians who participated in this study were mostly white and male, which could limit the generalizability of these findings. Also, the quality of decision making may have improved since the time the data were collected in 1993. Although there has been increasing interest in patient-centered care, its impact on practice remains unknown.

Table 7. Completeness of Informed Decision Making by Physician Type*

Complete Informed Decision Making	Surgeons (n = 1921)	Primary Care Physicians (n = 1631)
Procedure, alternatives, risks	3.7	2.4
All-basic	21.8	18.9
Overall completeness	10.2	7.7

*Values are percentages.

Because we developed and used a new method for audiotape analysis, it is important to demonstrate that this method is valid and reliable. We believe that our method is a valid characterization of communication in the area of decision making. The method was derived from a synthesis of theoretical constructs about ideal informed decision making and bolstered by iterative group discussions between clinicians and laypersons. Furthermore, the consistent trends in patterns of overall completeness, with completeness increasing with decision complexity despite different definitions of complete, provides further evidence of the validity of our method. Overall, our intrarater and interrater reliability were good, with the exception of low κ statistics for elements 5 and 6. The low reliability of elements 5 and 6 limits our findings only minimally because the majority of decisions were basic, requiring neither element 5 nor 6. As we discovered, completeness for intermediate and complex decisions also remained largely unaffected by the exclusion of these elements.

Most other studies of informed decision making have examined patient recall, patient reports of adequacy of discussion, or analysis of informed consent forms.⁷⁻¹¹ Our approach has the distinct advantage of relying on direct observation of how decision making actually takes place. While there is no evidence in the literature that audiotape recording of visits influences communication, it is likely that any influence it may have would lead to more discussion around decisions as opposed to less.

For too long, informed consent in clinical practice has been influenced by an interpretation of informed decision making as a legal obligation in which the

emphasis is full disclosure, rather than an ethical obligation toward mutual decision making by fostering understanding. Furthermore, most emphasis has been on informed consent for invasive procedures or participation as a research subject. Turning attention to decision making in office practice reveals that this emphasis has not created a positive model of informed decision making that is relevant and achievable in clinical practice in which the majority of decisions are less than complex. Promotion of the patient's understanding, thereby foster-

ing informed participation, is the essence of informed decision making.

A new conception of informed decision making can provide a framework for evaluating the adequacy of current practice, as we have illustrated in this study. It can also serve as a framework for developing skills and behaviors that enhance communication and trust, thereby improving the patient-physician relationship and increasing the potential for the beneficial outcomes that will follow.

Author Contributions: Development of coding method, study design, data analysis, and writing (Dr

Braddock); refinement of coding method, coder training, audiotape coding, and writing (Ms Edwards); data analysis and writing (Ms Hasenberg); audiotape coding and writing (Dr Laidley); and study design, writing, data collection, and data analysis (Dr Levinson). **Funding/Support:** This research project was made possible in part through grant 96-289 from the Bayer Institute for Health Care Communication (West Haven, Conn) and grant RO1-HS07289 from the Agency for Health Care Policy and Research (Washington, DC). Dr Braddock is supported by grant 030812 from the Robert Wood Johnson Foundation Minority Medical Faculty Development Program.

Acknowledgment: Nigel Chaumeton was an invaluable guide to the audiotapes and database from the original communication study. Mark Micek has generously contributed time and thought to the preliminary visit-based analysis. We would also like to thank Ellen Timothy, PhC, and Yoon Pak, PhD, for their help with the audiotape coding.

REFERENCES

1. Appelbaum PS, Lidz CW, Meisel A. *Informed Consent: Legal Theory and Clinical Practice*. New York, NY: Oxford University Press; 1987.
2. Brody H. Transparency: informed consent in primary care. *Hastings Cent Rep*. 1989;19:5-9.
3. Lidz C, Appelbaum P, Meisel A. Two models of implementing informed consent. *Arch Intern Med*. 1988;148:1385-1389.
4. Braddock CH. Advancing the cause of informed consent: from disclosure to understanding. *Am J Med*. 1998;105:354-355.
5. Strull W, Lo B, Charles G. Do patients want to participate in medical decision making? *JAMA*. 1984;252:2990-2994.
6. Deber R, Kraetschmer N, Irvine J. What role do patients wish to play in treatment decision making? *Arch Intern Med*. 1996;156:1414-1420.
7. Aldifi R. Informed consent: a study of patient reaction. *JAMA*. 1971;216:1325-1329.
8. Faden RR. Disclosure and informed consent: does it matter how we tell it? *Health Educ Monogr*. 1977;5:198-214.
9. Faden R. Disclosure of information to patients in medical care. *Med Care*. 1981;19:718-733.
10. Morris LA, Kanouse DE. Informing patients about drug side effects. *J Behav Med*. 1982;5:363-373.
11. Sulmasy DP, Lehmann LS, Levine DM, Faden RR. Patient's perception of the quality of informed consent for common medical procedures. *J Clin Ethics*. 1994;5:189-194.
12. Alfidi RJ. Controversy: alternatives and decisions in complying with the doctrine of informed consent. *Radiology*. 1975;114:231.
13. Katz J. Informed consent and the prescription of nonsteroidal antiinflammatory drugs. *Arthritis Rheum*. 1992;35:1257-1263.
14. Lidz C, Meisel A, Holden J, Marx J, Munetz M, for the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. *Making Health Care Decisions: A Report on Informed Consent and the Structure of Medical Care*. Washington, DC: US Government Printing Office; 1982.
15. Wu W, Pearlman R. Consent in medical decision making: the role of communication. *J Gen Intern Med*. 1988;3:9-14.
16. Braddock CH III, Fihn SD, Levinson W, Jonsen AR, Pearlman RA. How doctors and patients discuss routine clinical decisions: informed decision making in the outpatient setting. *J Gen Intern Med*. 1997;12:339-345.
17. Beauchamp TL, Childress JF. *Principles of Bio-medical Ethics*. 4th ed. New York, NY: Oxford University Press; 1994.
18. Faden RR, Beauchamp TL. *A History and Theory of Informed Consent*. New York, NY: Oxford University Press; 1986.
19. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. *Making Health Care Decisions: A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship*. Washington, DC: US Government Printing Office; 1982.
20. Katz J. *The Silent World of Doctor and Patient*. New York, NY: Free Press; 1984.
21. Jonsen A, Siegler M, Winslade W. *Clinical Ethics*. 3rd ed. New York, NY: McGraw-Hill; 1992.
22. Ramsey P. *The Patient as Person: Explorations in Medical Ethics*. New Haven, Conn: Yale University Press; 1970.
23. Diem SJ. How and when should physicians discuss clinical decisions. *J Gen Intern Med*. 1997;12:397-398.
24. Levinson W, Roter DL, Mullooly JP, Dull VT, Frankel RM. Physician-patient communication: the relationship with malpractice claims among primary care physicians and surgeons. *JAMA*. 1997;277:553-559.
25. Greenfield S, Kaplan S, Ware J. Expanding patient involvement in care: effect on patient outcomes. *Ann Intern Med*. 1985;102:520-528.
26. Levinson W, Chaumeton N. Communication between surgeons and patients in routine office visits. *Surgery*. 1999;125:127-134.