

Quality of informed consent for invasive procedures

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Abstract

Objective. To assess quality of informed consent among patients undergoing procedures and patient's preferences about decision-making.

Design. Cross-sectional survey of hospitalized patients about informed consent before surgery or other procedures. Preference for decision-making was elicited in hospitalized and ambulatory patients.

Setting. Large academic general hospital and 10 general clinics, over the years 2002–04.

Intervention. Data of initial survey were presented at staff meetings, recommending asking patients to restate what was explained to them.

Main outcome measures. Rate of patient's recall for explanations on risks and alternative options; rate of patients preferring shared, autonomous and paternalistic modes of decision-making; degree of satisfaction from the decision-making.

Results. Half of the patients did not recall receiving explanations about risks and two-third did not remember discussion of alternative options. The intervention failed, <10% of patients being asked to re-state what was explained to them. Expectations about decision varied: ~60% favored shared decision, nearly 20% preferred autonomous decision and the remainder wanted physicians to make decisions. Satisfaction was rated as good or very good by 80% of patients.

Conclusions. Most patients do not remember receiving explanations about risks or alternatives for procedures, and physicians resist attempts to improve informed consent. Tools should be developed to measure the quality of consent. Since patients significantly differ in their preferred mode of decision-making, the informed consent should be patient-specific.

Keywords: informed consent, quality of care

Informed consent of patients undergoing procedures is important not only for ethical and legal reasons [1] but also for the quality of care: patient's understanding allows cooperation, improves results and satisfaction and also helps preventing errors [2]. Procedures to obtain consent must ensure that the patient understands the nature of his or her condition, the risks and benefits of the proposed treatment and its alternatives, and agrees to it voluntarily. Complex decisions such as surgery or other invasive procedure require a discussion of uncertainties. Although informed consent is a well-established practice, it often fails to meet its purpose [3]. Recall of information in the context of the informed consent has been reported as poor by many authors in different settings [4–14] and conspicuously inconsistent: varying from 18 to 81% for surveys conducted on the same day the information had been given to the patient [3].

Since the informed consent is culture-dependent and we were unaware of clinical research on its implementation in

our country, we set about to evaluate some aspects of this process at our institution. Rather than looking at the quantity of information remembered by patients, we wished to look at some qualitative aspects of this exchange: Was the patient satisfied with decision-making? Could the patient recall any mention of risks or alternatives? Had she or he wished to receive more information? What is the preferred mode of decision-making: autonomous, shared or paternalistic? Had the patient signed an informed consent? Had she or he been asked to repeat the explanations?

Although the necessary legal requirements for informed consent have been reviewed in great detail [15], we were more interested in examining and framing the issues from the viewpoint of quality of care. We prospectively surveyed patients surrounding invasive procedures, exploring gaps between perceived and preferred modes of decision, attempting to construct a basis for a standard for the quality of the informed consent.

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METHODS

Survey procedure

Patients undergoing invasive procedures were surveyed using an anonymous questionnaire, with a help from a surveyor to explain unclear questions. The surveyors were medical students doing their MD thesis in one of the different aspects of the present work. The formal pre-testing was carried out on the first 30 patients to verify understanding, using at-face validity criterion and refining formulation of questions until no further comment arose indicative of ambiguity.

The questions focused on patients' recall of information about risks and alternative treatment options, preferences about the decision process and overall satisfaction from the informed consent procedure (Table 1). Additional questions referred to demographic data, education, date and nature of procedure, urgency of treatment and need for an interpreter to answer the questions. Patients were interviewed in different wards before or after undergoing the procedure, usually within a day or two from their signature of the informed consent. Qualitative comments volunteered by patients were written as notes on the back of survey sheet. The survey took on average <15 min to conduct.

Table 1 Main questions included in the questionnaire used for survey

Have you signed an informed consent? Yes/No
To what degree the explanation you received was sufficient, clear and detailed? Explanation was clear/Explanation was partly clear/ Explanation was not clear/Explanation was insufficiently detailed/Explanation was sufficient and detailed/ Explanation was too detailed
Did you receive an explanation about the risks from the treatment? Yes/No/I don't remember ^a /There were no explanations ^a
Would you have wanted more explanation on these risks? Yes/No
Did you receive an explanation about alternative options for this treatment? For instance, were you told that the procedure is not necessary and there are other forms of therapy? Yes/No/I don't remember ^a
To what degree did you want to be involved in the decision on the treatment? Choose the option you prefer: The medical staff decides what is best for me/The medical staff includes me in the decision-making/I get explanations and I decide what is best for me
To what degree did you feel involved in the decision on the present treatment? Too little involved/Involved enough/Too much involved
Would you have wanted to be more involved in the decision on treatment?
How long before the treatment did you get the explanations? (if possible, state number) Minutes/Hours/Days/Weeks/Months
Did you have enough time to think and to seek advice?
From whom did you get most of the explanations? Clinic doctor/Clinic nurse/Hospital physician/Hospital nurse/Other (specify)
Are you on a private medical service? Yes/No
To what degree did you feel you could ask questions? A lot/Somewhat/A little/Not at all
Were you asked to repeat the explanation? Yes/No/I don't remember ^a
Could you repeat it now?
To what degree are you satisfied from the process of decision-making for the treatment (not from the treatment itself): Very much/Satisfied/Somewhat/Not so/Not at all/No opinion ^a

^aSurveyors were instructed to not actively probe for this answer but to register it if would be voluntarily suggested by the patient.

The research was approved by our Institutional Review Board.

Setting

The survey took place in the wards of a large academic general hospital (Hadassah Hebrew University Medical Center, Jerusalem, Israel). In the course of the survey, it became apparent that probing the patient's preferred mode of decision elicited a fairly stable heterogeneity of answers in different wards of the hospital (while slightly over half of patients wished a shared decision-making, the remainder appears to be equally divided between either favoring paternalism or autonomy). We began to perceive that this preference would be important in order to build a standard for appropriate informed consent. We wished to explore the consistency of distribution for preferred modes of decision-making in a population outside the hospital, not contemplating any invasive procedure. We therefore extended this portion of the survey to 350 patients scheduled for ambulatory visits (not scheduled for invasive procedures) in 10 general clinics in the city of Jerusalem (and as part of a different survey on the quality of ambulatory care).

Study participants

Over the years 2002–04, we collected a sample of 613 consecutive hospitalized patients undergoing surgery or invasive procedure in various departments of the Hadassah Hebrew University hospital (General Surgery, Obstetrics and Gynecology and Internal Medicine and Cardiology) to assess the quality of their informed consent to the procedure. Preference for decision-making was elicited from 496 of the hospitalized patients (in internal medicine, the survey included a related but differently worded question and therefore these patients were not included in the analysis of answers to this question).

The types of procedures that the patients were undergoing in the various departments are described in Table 2.

Intervention

The survey was conducted in two periods in three departments. In these departments (General Surgery, Obstetrics

and Gynecology and Cardiology), after the first period, an attempt was made to improve the process of the informed consent. The data of the initial survey were presented at the staff meeting, at which discussion of the results took place, and literature was presented recommending asking patients to restate what was explained to them. In addition, a yellow sticker was attached to all informed consent forms in use in the department, as a reminder for the physician in charge of getting the patient's signature, to ask the patient the following three questions: (i) Do you have any question? (ii) Do you wish to get more information about risks or alternatives for the procedure? (iii) Could you please re-state for me what you understood about the procedure? Several weeks later, the second part of the survey was conducted, including a specific question to the patient: 'Were you asked to repeat the explanation?'

Methods of data analysis

As it became apparent that the intervention had no significant effect on the apparent practice related to the informed consent in any department, the results of the two periods of survey were combined and presented as one set of data. Chi-square testing was applied for the findings presented in the tables. For Table 3, after an overall testing detected significant differences, each department was iteratively compared with another, first for 'Explanations about risks' and then for 'Discussion of alternatives'. Using the Bonferroni's correction for multiple comparisons, α was set at 0.01 for this table.

RESULTS

Response rate was 94% for hospitalized patients (576/613) and 58% in the ambulatory setting (203/350). The patient population was as follows: patient's age ranged from 18 to 83, average 54 (SD, 17). Forty-six percent of patients had been born in Israel, the others been from diverse origins (mostly from Africa, Europe, East Europe or America) but were fluent in Hebrew (help from a translator for answering questionnaire was needed in <10% of cases). High school education was reported in 37%; academic education in 43%; the remainder reporting elementary school or lesser level of education. Outside the obstetrics and gynecology ward, 43%

Table 2 Types of procedures in the various departments

Department	Types of procedures
General surgery	Cholecystectomy, hernia, colectomy, mastectomy, thyroid and parathyroid surgery, gastrectomy, bariatric surgery, Whipple and others
Obstetrics and Gynecology	Cesarean section, termination of pregnancy, dilatation and curettage, vaginal birth after prior cesarean section, polypectomy, myomectomy, hysterectomy, hysteroscopy and diagnostic laparoscopy
Internal medicine	Bone marrow, liver or kidney biopsy, angiography, pleural or abdominal puncture, chemotherapy and radiotherapy
Cardiology	Cardiac angiography and percutaneous coronary intervention

Table 3 Rate of recall for explanations on risks and alternatives

Department	Type of procedure	N	Explanations about risks (%)	Discussion of alternatives (%)
General surgery	Operation	178	60	20
Obstetrics and Gynecology	Operation	198	57	19
Internal Medicine	Diagnostic or therapeutic procedure	117	42*	40***
Cardiology	Cardiac angiography	120	39**	8 [†]

* $P \leq 0.003$ vs. General Surgery; $P \leq 0.01$ vs. Obstetrics and Gynecology. ** $P \leq 0.0004$ vs. General Surgery; $P \leq 0.003$ vs. Obstetrics and Gynecology. *** $P \leq 0.0002$ vs. General Surgery; $P \leq 0.0001$ vs. Obstetrics and Gynecology. [†] $P \leq 0.005$ vs. General Surgery; $P \leq 0.009$ vs. Obstetrics and Gynecology; $P \leq 0.0001$ vs. Internal Medicine. N, number of patients surveyed in each ward.

Table 4 Distribution of patients' preferences for decision-making process in hospital and ambulatory settings

Setting of survey	N	Expressed patient's preference		
		I would want to get all the information and decide on my own (%)	I would prefer a shared decision with the physician (%)	I would prefer the physician to decide for me (%)
Hospital	496	22.3	58.4	19.3
Outpatient	350	18.0	64.0	18.0

N, number of patients surveyed in each setting.

patients were female and 85% were or had been married. The majority of procedures were performed under elective conditions. In general and obstetric surgery, about one-third of the procedures were done under private coverage with a specific surgeon.

Table 3 shows rates of recall for explanations about risks and alternatives during informed consent in different wards. Between 39 and 60% of patients recalled receiving explanations about risks of procedures, and between 8 and 40% remembered discussion about alternative management options. Patients in internal medicine and cardiology had lower recall of risks than patients in surgery and obstetrics and gynecology ($P < 0.0001$). Patients in internal medicine had higher and patients in cardiology had lower recall of alternatives than patients in surgery and obstetrics and gynecology ($P < 0.0001$). Patients who did not recall explanations about risks were asked about their preference for more information on the risks: about one-half of them stated they would have wanted additional information.

Not shown in the table, the explanations about the procedure were described as 'clear and detailed' by 75% of patients. Three quarters of the patients also stated that they had enough time to think about the procedure and the decision. Over 98% of patients recalled having signed the required informed consent for surgery or for the invasive procedure. Less than 10% remembered having been asked to repeat the explanation they had received. The overall satisfaction from the decision-making process was rated as good or very good

by 80% of the patients did not significantly differ between wards and did not correlate with the recall of information.

Table 4 describes the preferences for the decision-making process stated by hospitalized patients and by ambulatory patients. It appears that in both settings a majority of patients favors a shared decision. Preferences about decision varied: while ~60% favored shared decision, nearly 20% preferred an autonomous decision and the remainder wanted the physician to make the decision for them. No consistent correlation was found between the preferred mode of decision and the age, education, ethnic origin or setting of survey.

DISCUSSION

In our survey, most patients did not remember having received information about complications or alternatives for procedures, even though it is an inherent requirement of the voluntary and understanding informed consent they had signed. Our results are consistent with other observations showing that recall from the informed consent is poor [3–14, 16], in part because of the difficulty in the comprehension of the information. Our study differs since we did not ask patients about specific risks or alternatives but only whether they had heard about them. Our study could not examine to what extent the treating physician had attempted to convey information. The clinical setting appeared to influence the degree to which risks and alternatives were

perceived to have been discussed with patients. As shown in Table 3, a surgical setting appears to heighten the perception of risks (both by patients and by physicians), even though absolute risks may not be always higher than in medical wards or invasive cardiology. Conversely, alternatives appear to be discussed more readily in internal medicine, while in cardiology, the perception conveyed by physicians may be that 'there is no really other options' (as reported in discussions of these results with cardiology staff).

Interestingly, despite these apparent major omissions in the informed consent, most patients viewed explanations as 'clear and detailed', with enough time to think about the decision, and overall satisfaction from the decision-making process. This contradiction is only apparent: explanations may be perceived as good about some other aspects of the treatment (such as technicalities on procedure, anesthesia or recovery), while risks and alternative options have not been discussed. In addition, overall high satisfaction reported in surveys often overshadows deficiencies in quality of care apparent on more specific questioning [17].

Failure of recall may occur because of omission in physician's explanation, or inability of patients to understand, assimilate or recollect the information. Several interventions have been suggested, including use of written explanations [18] or audio-visual materials [19] and asking patients to re-state what they have been told during the informed consent [6]. In the present study, we discussed survey results with the staff and suggested asking patients to re-state their understanding before signing. In the repeated survey in three wards (surgery, obstetrics and cardiology) no improvement was seen and <10% of patients were asked to re-state their understanding of the informed consent. During the discussions with staff, it became apparent that the resistance to change relate to several factors, including lack of time, perception of informed consents as legal documents unrelated to quality of care (as discussed by Lemaire [3]) and failure to grasp the extent of health literacy gap, making communication of risks and alternatives a difficult task (although no literature could be found on this issue).

A frequent dilemma in the informed consent, also raised in the discussion with the staff, is how much risk information is appropriate, e.g. should a chance of death in the order of 1 in 1000 be communicated? Some argue that any severe complication should be discussed; others say such details might frighten patients who would put off necessary procedures. An interesting approach would be to ask patients how much information they want [20]. As also shown in Table 4, patients greatly differ in their preferred mode of decision-making, as reported by others [21–27]. Although a majority of patients favor shared decision, a growing proportion prefers autonomy and a significant fraction still adheres to a paternalistic approach, having the physician decides for them. Every approach is legitimate and, as clinical ethicists have proposed, the informed consent process should be patient-specific [28]. Since patients may actually shift from one approach to another depending on the clinical setting, such as in critical illness [29], the informed consent should perhaps be both patient and setting-specific.

Our study has several limitations. We did not observe the actual discussion taking place during the process of the informed consent: our data relate only to subjective perception and recall by patients, a several hours (up to a day or two) after they had signed consent. Admittedly, it would be better to test recall immediately, giving a chance for correction and improvement of the process, with inclusion of the question: do you wish to get more information about risks or alternatives for the procedure? Our work was not intended to define standards for the quality of the informed consent but our findings may be the basis for the development of tools for that goal. Since it was conducted in one city, it may appear difficult to generalize our findings, although our population of both patients and staff is multicultural and probably not too different currently from many institutions in Western countries. Finally, our analyses did not find reliable predictors of recall of explanation, wish for more information, preferred mode of decision, and satisfaction with the decision process or consistent associations between these variables, perhaps because of the limited size of our population.

In conclusion, since routine informed consent appears to be suboptimal, we suggest that its quality be regularly assessed, as part of the evaluation of healthcare processes. The first step should be to encourage efforts to construct accurate tools to measure the quality of consent, a critical step before adopting policies for periodic assessment.

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