Quality of informed consent for invasive procedures

MAYER BREZIS, SARAH ISRAEL, AVITAL WEINSTEIN-BIRENSHTOCK, PNINA POGODA, AYELET SHARON AND RENANA TAUBER

Center for Clinical Quality and Safety, Hadassah Hebrew University Medical Center, 91120 Jerusalem, Israel

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.

Address reprint requests to: Mayer Brezis, Center for Clinical Quality and Safety, Hadassah Hebrew University Medical Center, 91120 Jerusalem, Israel. Tel: +972-2-6777110; Fax: +972-2-6439730; E-mail: brezis@vms.huji.ac.il
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  Man questions included in the questionnaire used for survey

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you signed an informed consent?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>To what degree the explanation you received was sufficient, clear and detailed?</td>
<td>Explanation was clear/Explanation was partly clear/Explanation was not clear/Explanation was insufficiently detailed/Explanation was sufficient and detailed/Explanation was too detailed</td>
</tr>
<tr>
<td>Did you receive an explanation about the risks from the treatment?</td>
<td>Yes/No/I don't remember/There were no explanations</td>
</tr>
<tr>
<td>Would you have wanted more explanation on these risks?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>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?</td>
<td>Yes/No/I don't remember</td>
</tr>
<tr>
<td>To what degree did you want to be involved in the decision on the treatment? Choose the option you prefer:</td>
<td>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</td>
</tr>
<tr>
<td>To what degree did you feel involved in the decision on the present treatment?</td>
<td>Too little involved/Involved enough/Too much involved</td>
</tr>
<tr>
<td>Would you have wanted to be more involved in the decision on treatment?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>How long before the treatment did you get the explanations? (if possible, state number)</td>
<td>Minutes/Hours/Days/Weeks/Months</td>
</tr>
<tr>
<td>Did you have enough time to think and to seek advice?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>From whom did you get most of the explanations?</td>
<td>Clinic doctor/Clinic nurse/Hospital physician/Hospital nurse/Other (specify)</td>
</tr>
<tr>
<td>Are you on a private medical service?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>To what degree did you feel you could ask questions?</td>
<td>A lot/Somewhat/A little/Not at all</td>
</tr>
<tr>
<td>Were you asked to repeat the explanation?</td>
<td>Yes/No/I don't remember</td>
</tr>
<tr>
<td>Could you repeat it now?</td>
<td></td>
</tr>
<tr>
<td>To what degree are you satisfied from the process of decision-making for the treatment (not from the treatment itself):</td>
<td>Very much/Satisfied/Somewhat/Not so/Not at all/No opinion</td>
</tr>
</tbody>
</table>

*Surveyors 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

<table>
<thead>
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<th>Department</th>
<th>Types of procedures</th>
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<tbody>
<tr>
<td>General surgery</td>
<td>Cholecystectomy, hernia, colectomy, mastectomy, thyroid and parathyroid surgery, gastrectomy, bariatric surgery, Whipple and others</td>
</tr>
<tr>
<td>Obstetrics and Gynecology</td>
<td>Cesarean section, termination of pregnancy, dilatation and curettage, vaginal birth after prior cesarean section, polypectomy, myomectomy, hysterectomy, hysteroscopy and diagnostic laparoscopy</td>
</tr>
<tr>
<td>Internal medicine</td>
<td>Bone marrow, liver or kidney biopsy, angiography, pleural or abdominal puncture, chemotherapy and radiotherapy</td>
</tr>
<tr>
<td>Cardiology</td>
<td>Cardiac angiography and percutaneous coronary intervention</td>
</tr>
</tbody>
</table>
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* ≤ 0.0003 vs. General Surgery; *P* ≤ 0.01 vs. Obstetrics and Gynecology). Patients in internal medicine had higher recall of alternatives than patients in surgery and obstetrics and gynecology (**P* ≤ 0.0004 vs. General Surgery; *P* ≤ 0.0003 vs. Obstetrics and Gynecology). Patients in internal medicine and cardiology had lower recall of alternatives than patients in surgery and obstetrics and gynecology (***P* ≤ 0.0002 vs. General Surgery; *P* ≤ 0.0001 vs. Obstetrics and Gynecology). 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. No consistent correlation was found between the preferred mode of decision and the age, education, ethnic origin or setting of survey.
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 discus-
sions 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 phys-
ician’s explanation, or inability of patients to understand,
assemble 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 discus-
sions with staff, it became apparent that the resistance to
change relate to several factors, including lack of time, per-
ception 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 communi-
cation 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 informa-
tion 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 pro-
portion prefers autonomy and a significant fraction still
adheres to a paternalistic approach, having the physician
decides for them. Every approach is legitimate and, as clini-
cal 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 percep-
tion and recall by patients, a several hours (up to a day or
two) after they had signed consent. Admittedly, it would be
to better to test recall immediately, giving a chance for correction
and improvement of the process, with inclusion of the ques-
tion: 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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