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Adequacy of informed consent in research carried out in Brazil

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Appendix 1: Focus Group Sessions Interview Guide

The moderator will introduce himself/herself and the observer to the participants. He/she will ask for permission to use the voice recording device and he/she will explain the objective of the session. After mentioning that the session should last one hour, the participants should introduce themselves. The moderator will open the discussion. The observer will note down the seat numbers and identity information of the participants. He/she will write down short informative/indicative notes about the session by using the signs (O=observer) for himself/herself, (M=moderator) for the moderator.

The main topics of the discussion:

a. What do you feel about the death?
b. What is your most basic feeling or attitude defining your approach to a dying patient?
c. How is death conceptualized in medical profession?
d. What kind of attitudes does your current medical education help you acquire regarding death and dying patient?
e. In what ways can the knowledge of approaches towards death affect your daily professional life?

Appendix 2: Response questions

The following options existed. To each there were four options: Totally agree. Partially agree, partially disagree, totally disagree.

During clinical treatment, it may be decided that cardiopulmonary resuscitation and other intensive life sustaining treatments are not indicated anymore for a terminally ill patient.

Decisions, as described above, are ethically right.

When a patient of mine dies, I wonder if something could have been done to save her.

I think it is essential that a dying patient be told of the positive and negative aspects of his progress.

I have a clear definition of "euthanasia" in my mind.

In my opinion, euthanasia is a moral equivalent to suicide or homicide.

Telling a person he is going to die is difficult to me.

I find it more difficult to deal with the family of a dying patient than the families of my other patients

In my opinion, keeping a patient alive when we cannot improve his quality of life, causes suffering.

I believe physicians refer terminal patients to other physicians more often than non-terminal patients.

A patient's death does not depress me when I know there was nothing I could do to save him.

In my opinion, euthanasia contradicts the basic philosophy of medicine, which is summarized as "one should show respect to human life under any circumstances."

In my opinion terminal patients don't want to talk about death.

In my opinion, principles for applying euthanasia should be established and it should be decriminalized.

In my opinion, most of the dying patients are afraid of death.

In my opinion, if physicians perform euthanasia, this will cause distrust towards them in the long run.

In my opinion, most of the dying patients have painful deaths.

I might perform euthanasia if one of my patient's requests it.

I would want euthanasia to be performed on a relative of mine, if he has an irreversible terminal illness.

I do not think about death very much.

In my opinion, terminally ill patients consider death as a comfort.

I would perform euthanasia if a committee makes the decision to authorize it.

I try to avoid telling a patient directly that he is dying.

Treating a dying patient is one of the most unpleasant aspects of my profession..

In my opinion, most of the dying patients have a quiet and peaceful death.

I could approve of euthanasia, if it is decided and performed by a committee.

Whenever possible I avoid a person who is dying from an irreversible condition.

I feel as comfortable with a dying patient as I do with any other patients.

I would want euthanasia to be performed on me, if I had an irreversible terminal illness.

In my opinion, most of the dying patients talk openly about dying.

In my opinion, her family is the best support for the terminal patient and they should be always with her.

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- José Roberto Goldim, MsC, PhD
Bioethics and Science Ethics Research Laboratory
Hospital de Clinicas de Porto Alegre
Rua Ramiro Barcelos, 2350
Porto Alegre, RS – Brazil 90035-903
E-mail: jgoldim@hcpa.ufrgs.br

- Joaquim Clotet, PhD
- Jorge Pinto Ribeiro, MD, PhD
Hospital de Clínicas de Porto Alegre/Universidade Federal do Rio Grande do Sul, Brazil.

Abstract

This cross-sectional study aimed to assess the adequacy of the informed consent process in six research projects carried out at HCPA. The 59 participants were interviewed; all had signed informed consent forms. Most patients were females (relative frequency of 71%); and the mean age was 50.17±15.24. Informed consent adequacy was assessed through the amount of information received and degree of difficulty in understanding the form. Having received previous explanations was reported by 53%, and having had doubts cleared up, by 24%. Comprehension of what was being proposed was reported by 56%, but the text was considered accessible by only 25%. In conclusion, the use of informed consent in research projects should be considered seriously, and Ethics Committees should review all the stages involved. Aspects such as comprehension of information, clearing up of doubts, and access to the investigator should always be guaranteed to participants.

Key words: informed consent, research, Ethics Committees, ethics.

Introduction

The informed consent process involves a relationship between the investigator and the participant that is permeated by mutual respect, dialogue, patience, and persistence.

Beauchamp and Faden (1) established a broad approach to the informed consent process. According to the authors, this process is composed of three stages, and involves seven different elements, involving I - Pre-conditions (Ability to understand and decide, and voluntariness); II - Elements of the information (risks and benefits; the most adequate option; and comprehension); III - Consent elements (option out of at least two alternatives, and authorization).

Several studies have been carried out in different countries about the process of obtaining informed consent in health institutions, not considering the impact of the evaluation carried out by the Ethics Committees.

One study carried out in the United States analyzed the written documents used as the source of information for the obtainment of informed consent in the area of radiology. The study showed that the texts were too complex for the average patient to understand (2). A recent study showed that educational intervention made a difference in comprehension about research risk (3).

In another study, performed in four Veterans Administration hospitals in the United States, 28% of the patients interviewed declared that they were not aware that they were participating in research projects, although all of them had signed specific consent forms prior to the beginning of investigation (4).

In Chile, an assessment was made of 44 research projects submitted to the Ethics Committee of the Medical School at the Pontificia Universidad Católica de Chile during a two-year period. The most frequent problem in the evaluations was absence or inadequacy of the informed consent form (5).

Between 1986 and 1997, a study assessed the use of informed consent in more than 1,348 research projects carried out at Hospital de Clínicas de Porto Alegre (HCPA), Brazil (5). Only 18% of the informed consent forms used in the projects were considered approvable without any repairs. Up to 1993, the most frequent problem at HCPA was the absence of informed consent in most projects; after this date, problems were more related to inadequate information and/or inaccurate writing of the document. It is important to mention that the Ethics Committee of the institution started to work regularly in 1993; before this date, the projects underwent only a methodological evaluation (6).

Up to the present moment, only a few studies about practical aspects related to the process of obtaining informed consent in Brazil have been published. The objective of the present work was to assess the adequacy of the informed consent form used in six health-related research projects carried out at a general hospital in terms of information and consent components. This assessment was accomplished through interviews with the patients.

Methods

Fifty-nine patients taking part in six different research projects at HCPA in the areas of cardiology (n=13), endocrinology (n=14), medical genetics (n=13), gynecology (n=8), and rheumatology (n=11) were interviewed. All the patients had signed informed consent forms. This was a cross-sectional study (patients were interviewed only once).

The selection of projects was done randomly among all the research projects being carried out in the outpatient clinics of the hospital. Six projects were drawn from the ones that had already been approved by the Scientific Commission and by the Ethics Committee. Projects involving patients with psychiatric or neurological diagnoses were excluded from our study.

Most of the 59 individuals studied were females (relative frequency of 71%). In all projects, except for the one on endocrinology, the number of female participants was higher than the number of males. Ages ranged from 25 to 74 years, with an average of 50.17±15.24 years.

The adequacy of the informed consent was assessed according to the amount of information received and the degree of difficulty in understanding the informed consent form. The difficulty in understanding the informed consent forms was assessed by the Flesch-Kincaid and Flesch readability indices. The results obtained with the formula estimate the years of education needed for the adequate comprehension of the text. The most effective values of Flesch-Kincaid's readability index are the ones requiring 6 to 10 years of education. The calculation of the Flesch-Kincaid and Flesch indices was carried out using the Grammatik IV software (7).

The information received and remembered by the participant was assessed with the use of a list for the verification of specific procedures, risks and benefits for each of the projects included in the study. Procedure was defined as any intervention carried out with a research-related aim, such as data collection through an interview, collection of biological material, physical and laboratory tests, use of drugs, and use of placebo. Risk was defined as any probable damage or discomfort resulting from the procedures. Probable benefits to participants ranged from increased information about their state of health or diagnostic characterization to the possibility of alteration in the prognosis due to the use of drugs. Data collected from different projects were standardized so as to allow comparison, in spite of their peculiarities.

The data obtained and/or calculated were analyzed using descriptive and inferential statistics. When data were quantitative and susceptible of being compared to other groups, the ANOVA variance analysis was used. Qualitative data were analyzed using the chi-square test. These analyses were carried out using the EPI-Info software 6.04.

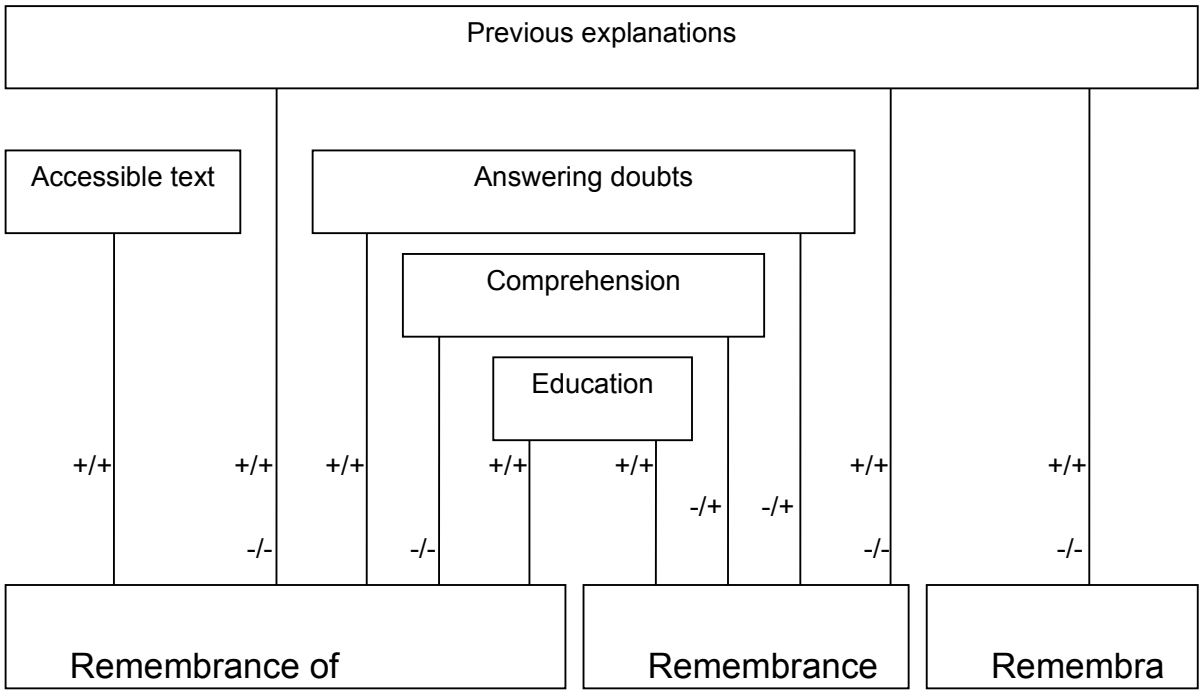
The assessment of multiple interactions between the variables studied was performed through the correspondence analysis (8) which was obtained with the SAS system. The significance level was established at 5%.

The present study assessed only the actual process of obtaining informed consent, and no risks were involved, because only one interview was performed, and the assessment instrument presented no risk of privacy invasion. For these reasons, we asked the Ethics Research Committee at HCPA to be excused from using a written informed consent form, according to item IV.3.f of Resolution 196/96.

Results and Discussion

Values obtained with the Flesch-Kinkaid index in the informed consent forms of the six projects ranged from 12 to 18 years of education, with an average of 14.67±2.16 years. The sample's education level varied from illiteracy up to college education. When compared to data about the Rio Grande do Sul population, the education level presented by the sample was slightly higher. This variable was directly and positively associated only with the remembrance of procedures and benefits: the higher the level of education, the higher the remembrance of procedures and benefits. The opposite was not observed: a lower level of education did not make the remembrance more difficult. Luna had already emphasized, in 1995, that illiteracy does not make a person become unable to give informed consent. (9).

Viegas, in 1998, carried out a qualitative study in a sample of six HCPA patients taking part in research projects in the area of oncology.(10) The experiences of these patients in relation to their participation in the projects were analyzed. The author observed that all the participants agreed or refused to participate in the study before reading the informed consent form, based only on previously received information.



Note: (+) represents an assertion, amplification, or a high value; (-) represents a denial, reduction, or a low value

Figure 1. Explanatory model for the informed consent process, based on the Correspondence Analysis.

All six individuals emphasized the importance of information disclosure and clearing up of doubts (10). So, education is not a limiting factor, but a facilitator of the informed consent process.

In our sample of 59 patients, 53% stated that they had received previous explanations. This information alone already indicates inadequate use of informed consent, since almost half of the participants did not remember having received any information before filling out the informed consent form. Another possible interpretation for this result is that informed consent was obtained as an event, and not as a process: the person's authorization was requested based only on the data presented in the forms.

Receiving previous information or not was the variable that presented the highest explanatory power (highest inertia in the correspondence analysis) when associated with obtainment of informed consent. This was the only aspect directly related (either positively or negatively) with all the other variables of the informed consent process, that is, procedures, benefits, and risks. Patients who had received previous explanations were more able to remember the procedures, benefits, and risks involved in the research project. The opposite was also observed: patients who had not received explanations had more difficulty in remembering this information. These associations manifest the paramount importance of this stage in the informed consent process.

Having received answers to doubts was referred by 24% of the patients, but it is not easy to interpret the complementary value of this result. The fact that 76% of the patients did not receive answers to their doubts may be seen as a deficiency in the informed consent process, or it may be due to the absence of questions on the patient's part, either because he/she did not want to ask questions or because he/she did not feel comfortable in doing so. This issue is not well understood yet. Answers to doubts made the remembrance of procedures easier and the remembrance of benefits more difficult. This apparent contradiction may be explained by the difference in the added value of this information. Procedures are concrete actions, which occur if the patient agrees to participate in the research project, so clearing up a doubt related to the procedure reinforces the certainty of its occurrence. Benefits, on the other hand, are a probability. When a doubt related to a certain benefit is cleared up, this may calm the person and even be decisive in the process of making decisions. If the benefit does not occur, this remembrance may be lost.

Comprehension of what was being proposed in the research project was reported by 56% of the patients. Data regarding this characteristic allowed us to assert that in 44% of the sample, the informed consent was considered morally contestable. According to the results, non-comprehension made the remembrance of procedures more difficult and the remembrance of benefits easier. These people authorized their inclusion in the research project without an exact notion of what would be done, perhaps focused only on the possibility of obtaining some benefit out of the experience.

A similar situation was observed in 1975, in a study involving the informed consent given by 41 volunteers in non-clinical research projects.(11) In this sample, 14 people gave consent without having been adequately informed and without having understood exactly what would be done during the research project. It is worth noting that in the study performed in 1975, only five people, all with medical education, adequately understood what was being proposed in the forms. This professional selection shows that the information was not accessible to most participants in the North American project; it reinforces what had been previously discussed regarding the fact that investigators write according to their pattern of reading.

The text of the informed consent forms was considered accessible by only 25.4% of the participants. This characteristic was associated only with the remembrance of

procedures. Coherently, texts considered accessible made the remembrance of procedures easier, while those considered non-accessible made it more difficult. This value was numerically similar to the number of participants that had an education level compatible with readability indices. Participants with at least high school education constituted 29% of the sample. There was, however, no significant correlation between readability and education level. Similarly, differences between the Flesch-Kincaid and Flesch indices for groups that considered the text accessible and non-accessible were not significant. These results confirm those already observed when education level was assessed.

The analysis of the results obtained with the three elements of the informed consent - procedures, risks, and benefits - also presented some associations that deserve to be analyzed.

Remembrance of procedures was the main element of the informed consent, according to the correspondence analysis. They were remembered in 48% of the cases, which means that 53% of the patients either did not remember what had been proposed and performed with them, or, perhaps, did not consider such situations as being related to the research. The remembrance or not of procedures had no relationship with the time elapsed between the obtainment of the consent and the present data collection. Having received previous explanations and answers to doubts, having considered the text accessible and having an education level superior to elementary school were facilitators for the remembrance of procedures. Not having received previous information, not having understood it, or not having understood what was being proposed, made remembrance become more difficult.

Benefits were remembered in 48% of the cases. Having an education level above elementary school and having received previous explanations contributed to this remembrance. The absence of previous explanations, on the other hand, made the remembrance more difficult. There were two inverse associations: the non-comprehension of information made the remembrance of benefits easier, and the absence of doubts on the patient's part was associated with difficulty in remembering benefits. Although apparently contradictory, both inversions have the same explanation. The non-comprehension may be the result of a non-clarified doubt, which generates insecurity and uncertainty. Remembering benefits may be one way of dealing with this insecurity, even if the benefits are not adequately understood. Complementarily, those who had their doubts clarified and felt more secure were not even able to remember the benefits reported. It is important to emphasize that the participants who did not seek answers for their doubts may have experienced an embarrassing situation, caused by the establishment of a dependence relationship with the investigator.

Remembrance of risks had a considerably lower index than the other aspects, since only 22% of the patients reported it. This means that 88% of the participants did not remember the risks they had taken when authorizing their inclusion in the research project. An important aspect is that only the risks indicated in the informed consent form signed by all subjects were taken into consideration. Only one association was observed between remembrance of risks and another variable: having received previous explanations made it easier to remember risks; the absence of previous explanations made it more difficult. The low rate of remembrance of risks may be a sign that the patient is denying the negative aspects associated with the research project in which he/she agreed to participate.

The results obtained with the remembrance of procedures, benefits, and risks showed that the participants selectively differentiate between these data during the obtainment of informed consent. People preferentially remember what will actually be carried out or what benefits the research can bring to them. Since risks have a negative character and are only probabilities, they are remembered in a lower incidence. None of these characteristics - procedures, benefits, or risks - had an association with the time elapsed between the obtainment of informed consent and the data collection.

The low remembrance of risks may be at least partially explained by the studies carried out by Hofstede, who used another trans-cultural variable: the form by which society deals with conflicts and uncertainties (12). This characteristic may clarify the discussion about the lower remembrance of risks. The Brazilian population was classified into the group of countries that most avoid situations involving uncertainties. This way, information about a risk associated with the research project may generate such anxiety that the risk is denied or forgotten. Procedures, on the other hand, constitute a certainty; as they had already been performed when the present data collection started, they were more easily remembered. Benefits represent favorable information, which was probably decisive for the people to authorize their inclusion in the project. Even constituting a probability or an uncertainty, benefits do not generate insecurity; on the contrary, they make people hope that they are really going to happen.

These results show that it is really necessary that the use of the informed consent in research projects be the object of deep reflections in all instances involved. It is of paramount importance that the informed consent form not be used as a means of responsibility exemption by investigators, research institutes, and sponsors. Ethics Committees play an important role in reviewing all the stages involved in the informed consent process, and not only the text adequacy of the form, as is usual in Brazil. The access to and comprehension of information, the clearing up of patients' doubts, the familiarity with and access to an investigator who is able to clear up potential doubts are conditions that should be formally guaranteed to candidates to participate in research projects.

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