

Informed consent for anesthesia

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SUMMARY

Informed consent has been seen as an ethic disclaimer of those actions that affect others, including medical treatments, clinical research and the use of human tissues. It has been defined as a legal-ethical concept that reflects the respect of Society towards the autonomy of the individuals that are part of it. To exercise his autonomy, it is necessary for an individual to have a previous knowledge of the topic. How much information does a patient need to autonomously accept anesthesia and surgery? The answer is the main purpose of this study. A survey was conducted on 450 patients with a scheduled surgery. The gathered data included: age, gender, and previous anesthetics and surgery experiences, as well as the Amsterdam Preoperative Anxiety and Information Scale in order to detect information needs. The outcome showed a high desire for being informed, however this level of desire was not always high for anesthesia. The level of anxiety and information requirement related to surgery was higher. All these factors make it more difficult to establish an informed consent, moreover in the health institutions where the time of attention to the patient is minimal. Additionally, some other questions arise related to the degree of autonomy that a patient can exercise when his physical needs overpass his will.

Key words: Informed consent, autonomy, information needs anesthesia.

RESUMEN

El consentimiento informado se ha visto como una justificación ética de las acciones que afectan a otros incluyendo los tratamientos médicos, la investigación clínica y el uso de tejidos humanos. Se ha definido como un concepto ético – legal que refleja el respeto que la sociedad brinda a la autonomía de las personas que la conforman. Un individuo para ejercer su autonomía requiere tener un conocimiento previo del tema. ¿Cuánta información necesita un paciente para aceptar autónomamente la anestesia y la cirugía? La respuesta es el objetivo principal de nuestro trabajo. Se encuestaron 450 pacientes programados para cirugía. Los datos encuestados fueron: edad, género, experiencias anestésico-quirúrgicas previas y se incluyó la Escala de Ansiedad e Información Preoperatoria de Amsterdam para detectar principalmente las necesidades de información. Los resultados mostraron un deseo elevado de los pacientes por ser informados pero la intensidad del deseo no siempre fue alta en el caso de la anestesia. El nivel de ansiedad y el requerimiento de información fueron mayores para la cirugía. Todos estos factores dificultan la estructuración del consentimiento informado, sobre todo en instituciones de salud donde el tiempo de atención por paciente es mínimo. Así mismo, surgen cuestionamientos sobre el grado de autonomía que puede ejercer un paciente cuando su necesidad física merma su voluntad.

Palabras clave: Consentimiento informado, autonomía, necesidad de información, anestesia.

INTRODUCTION

For over 25 years, Informed Consent has been the main topic of discussion ethically-acceptable medical practice. It has been viewed as an ethical justification for those actions or activities which have an effect on other people, including medical treatment, research, and the use of human tissues⁽¹⁾. Until recent years, consent has been viewed as one face of the physician-patient relationship which has evolved based on the ideals of individual freedom and freedom of choice⁽²⁾. Polani⁽³⁾ relates the evolution of consent in medicine with several phenomena: 1) With the social changes aimed at human rights and the codes of conduct designed to govern personal interactions; 2) With the development of sophisticated medical treatments; and 3) With the break-up of the one-to-one physician-patient relationship from the advent of multidisciplinary medicine.

Consent has been defined in different ways; in general, it is said to be an ethical-legal concept reflecting the respect that society holds for the autonomy of its members. In medical practice, autonomy refers to an individual's decision-making in his role as patient. In this sense, there is a concomitant aspect which needs to be considered in studies on autonomy; the desire to be informed. Patients actively seeking information are considered generally to have more autonomy, as the information is necessary condition to choose freely and consciously⁽⁴⁾. Considering what has been said above, we must expect that a patient who is about to undergo an anesthetic-surgical procedure must freely and separately accept the benefits and risks implied in both the anesthesia and the surgery.

However, the traditional belief has been that if a patient agrees to the surgery then he is implicitly agreeing to the anesthesia, and this is wrong, as anesthesia carries its own particular risks and consequences. Unfortunately, in our field, the preanesthesia evaluation is not the rule, and is frequently mistaken for the preanesthesia visit which the resident physicians make just a few hours before the surgery. Thus, in most cases, the first contact between the anesthesiologist and the patient takes place in the operating

room, a setting where the conditions in order that the patient exercises his/her autonomy are extremely critical.

Furthermore, discussions on the process of obtaining informed consent frequently focus on how much information the patient needs in order to make a decision, or even how much the patient actually wishes to know about the upcoming procedures. Well, he/she may want to know everything, something or nothing. Studies published in the literature on the need to inform patients actually make more reference to the relief of anxiety rather than the exercising of autonomy⁽⁵⁻⁸⁾. We feel it is necessary to know how much information the patient wishes to have about the anesthesia and the surgical procedure that he/she is about to undergo, since these are important data for the design and acceptance of written informed consent. With this in mind, we designed a prospective survey-type study in patients scheduled for surgery in order to determine how many patients want information about anesthesia, the surgery and, above all, how much information they want; and then compare these results with the degree of concern or anxiety which they indicate on the questionnaire.

MATERIALS AND METHOD

With the prior approval of the hospital's Ethics Committee, 450 patients (over the age of 18) we surveyed during the immediate preoperative period. The questionnaire used for the interview consisted of: a) the patient's identifying information (name, gender, age); b) the number of previous anesthesia experiences; and c) the type of surgery to be carried out. A table containing the Amsterdam Preoperative Anxiety and Information Scale (APAIS) was incorporated. This scale consists of 6 questions which can be categorically answered "yes" or "no" (see Table I). When the answer is "yes", then the intensity of the response is graded on a scale of 1 to 5 (1 being the minimum and 5 being the maximum) using a Visual Analog Scale (VAS). We defined the interpretation of the scale in the following way: Questions 1 and 4 measure the patient's level of concern about the anesthe-

Table I. Amsterdam Preoperative Anxiety and Information Scale (APAIS).

Question	Answer		Visual analog scale				
1. Are you worried by anesthesia?	No	Yes	1	2	3	4	5
2. All day do you think about the anesthesia?	No	Yes	1	2	3	4	5
3. Would you like to know as much as possible about the anesthesia that you will give?	No	Yes	1	2	3	4	5
4. Are you worried about the surgery?	No	Yes	1	2	3	4	5
5. All day do you think about the surgery?	No	Yes	1	2	3	4	5
6. Would you like to know as much as possible about surgery that you will give?	No	Yes	1	2	3	4	5

sia and the surgery, respectively. Questions 2 and 5 refer to anxiety and questions 3 and 6 refer concern the need for information. The intensity of the responses on the VAS was considered minimal for level 1, moderate for levels 2 and 3, and high for levels 4 and 5. The patients were surveyed the day of his/her surgery and only those programmed after 10 a.m. took part.

Five groups were created to analyze the results of the survey. Group 1 included all patients; Group 2 included those patients with no prior anesthesia experiences; Group 3 was composed of all patients older than 60; Group 4 contained all the female patients; Group 5 was composed of all the male patients.

The analysis was performed by measuring the frequencies and percentages of each of the nominal yes and no answers. When the answer was yes, then we measured the frequencies of the intensity of the response indicated on the VAS for each one of the questions. The frequency of the number of previous experiences is presented in tables.

Although the type of surgery was not considered in the survey as a variable of this study, we decided to mention the procedures to the patients, dividing the procedures into 3 categories: a) minimal procedures (e.g. resection of pterygium, supernumerary mammary gland resection, etc); b) moderate procedures (e.g. inguinal hernioplasty, laparoscopic cholecystectomy, salpingoclasia, etc); and c) major procedures (e.g. oncologic procedures, cerebral tumor resection, hip replacement surgery, etc).

RESULTS

Group 1: (Table II) The sample included 450 patients of which 298 were female and 152 were male. The age range was between 18 and 91 years old, with a median age of 47 years old. The most frequent previous anesthetic experiences (239 patients) were in a range of 1 to 2 (Figure 1). Concerning the frequency of yes or no responses on the APAIS, there was an important variation in each of the questions. The highest frequency of yes answer was for question 6 (77%)

followed by question 3 (68%) and question 4 (61%). No answer was the most frequent response for questions 2 (89%), 5 (68%), and 1 (63%). The difference between the two responses was statistically significant for all 6 of the questions, with $p < 0.001$ (see Figure 2).

For the analysis of the intensity of yes answer, several patients were not able to qualify your need. The frequency of intensity 5 was higher in questions 3 (87 patients) and 6 (157 patients) (Figure 3).

Group 2: It was made up of 136 patients, of whom 72 were female and 64 were male. The age of the group ranged from 18 to 91 years old, with a median age of 38 years old (see Table II). Yes responses were most frequent for questions 3 (70%) and 6 (78%). The no answer frequency was higher in question 2 (87.5%) followed by questions 5 (66%) and 1 (63%). The difference between the 2 responses was statistically significant, ranging between $p < 0.01$ and $p < 0.001$. An intensity level of 5 was most frequent for questions 3 (32 patients) and 6 (48 patients) (see Figure 4).

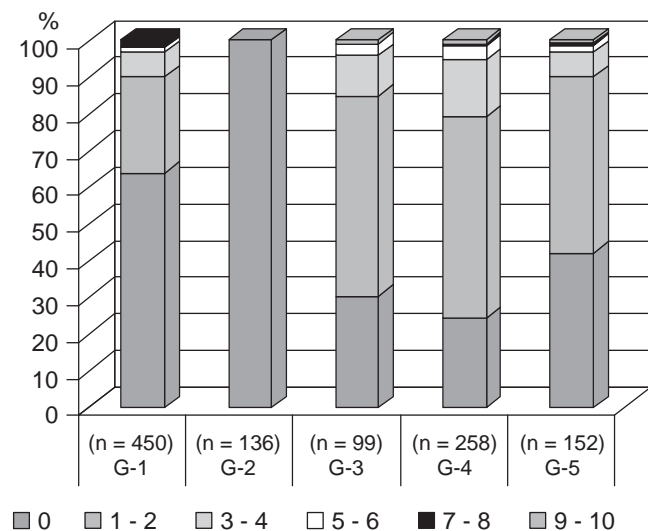


Figure 1. Anesthetic previous experiences referred by the patients.

Table II. General information about each group.

		G - 1 (n = 450)	G - 2 (n = 136)	G - 3 (n = 99)	G - 4 (n = 258)	G - 5 (n = 152)
Gender	Female	298	72	59	258	
	Male	152	64	40		152
Age	Maxim	91	91	91	91	85
	Minimal	18	18	60	18	18
	Medium	47	38	70	48	47

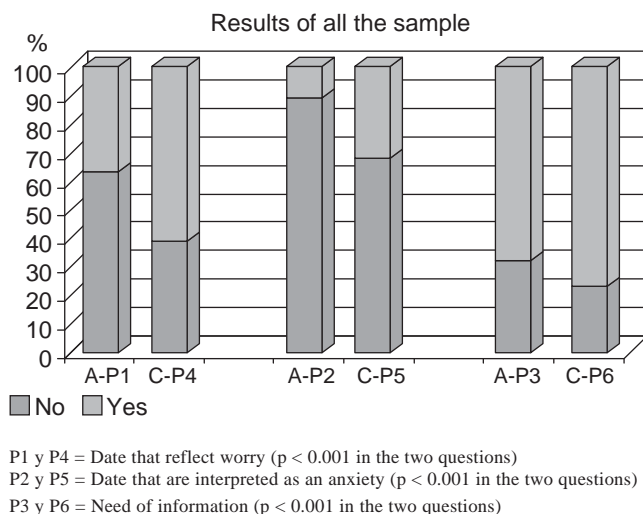


Figure 2. Frequencies of answers yes or not of the G1 (n = 450).

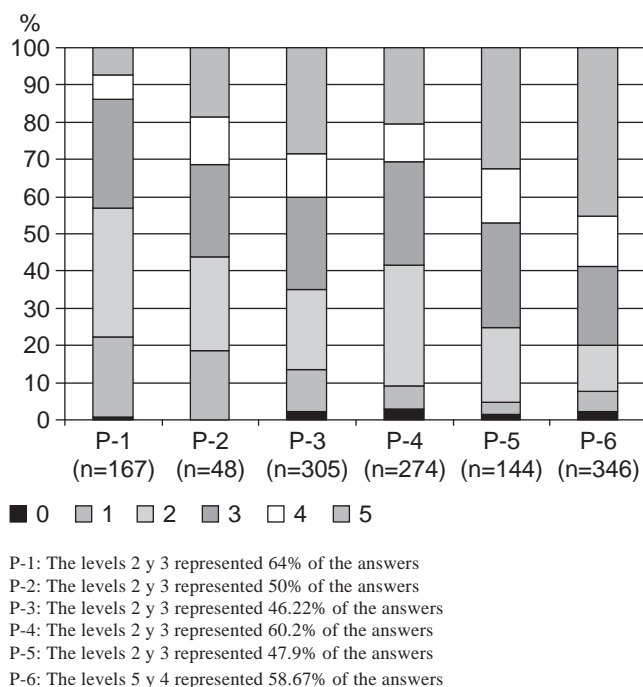


Figure 3. VAS, intensity of the response yes in all sample (G-1, n = 450).

Group 3: It was made up of 99 patients; 59 females and 40 males. The age varied between 60 and 91 years old, with a median age of 70 years old. In this group, 30 patients had not had previous experiences with anesthesia, and higher frequency of previous anesthetic events was in range from 1 to 2 (see Table II). The yes responses were most frequent in questions 6 (63.6%), 4 (52.5%) and 3 (50.5%). The no re-

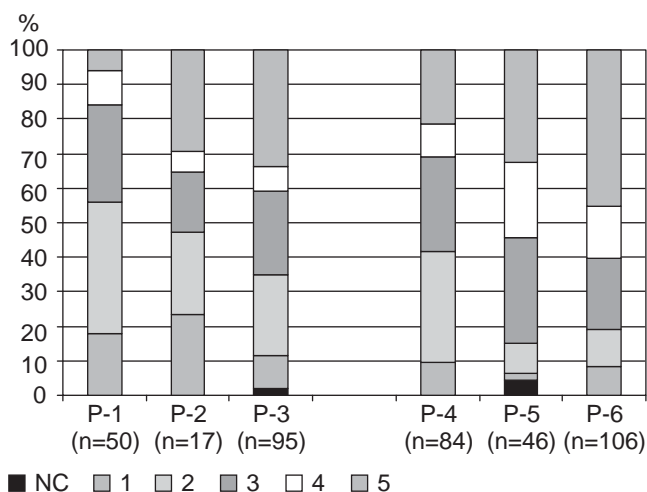
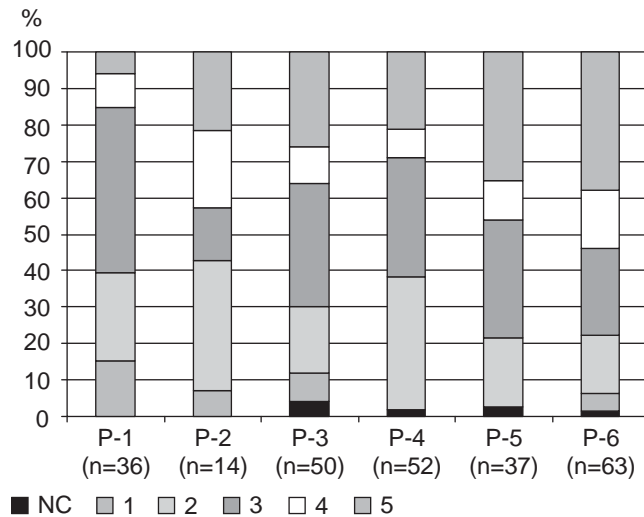


Figure 4. VAS, intensity of the response yes in the patients without previous experiences (G-2, n = 136).

sponses were most frequent for questions 2 (86%), 1 (67%) and 5 (62.6%). The difference between the two responses was significant, except for question 4, where $p > 0.05$. An intensity level of 5 was cited 24 times for question 6, and 13 times for question 3 (see Figure 5).

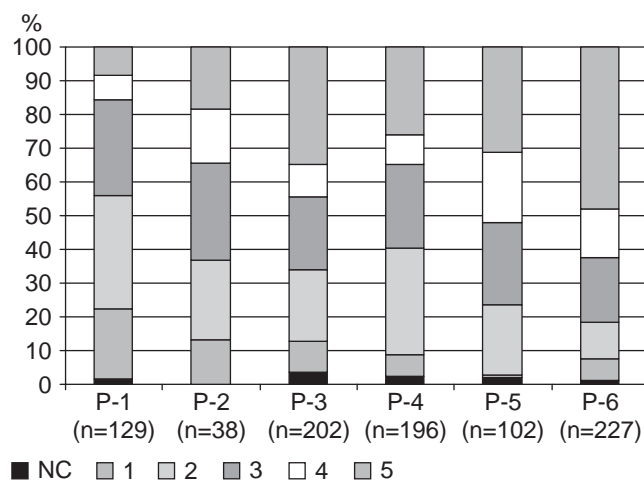
Group 4: It was made up of 298 female patients between 18 and 91 years old, with a median age of 48 years. 72 of them had not been anesthetized before, and the other 164 had been anesthetized between 1 and 2 times (see Table II). With regard to previous experience: 72 had not received anesthesia and 164 patients previously had received 1 to 2 anesthesia (Table II). The yes responses were most frequently given for questions 6 (76.7%), 3 (67.7%) and 4 (65.7%). The frequency of no responses was highest for questions 2 (87.2%) and 5 (65.5%). The difference between yes and no responses was significant for all questions, with $p < 0.05$ to $p < 0.001$. An intensity level of 5 was most often given in questions 6 (109 patients), 3 (70 patients) and 4 (51 patients) (see Figure 6).

Group 5: It was made up of 152 males between 18 and 85 years of age. Of these, 64 had not been anesthetized before and the highest frequency of anesthetic experiences was 1 to 2 (73 patients) (Table II). Highest frequencies of yes answer were in questions 6 (75.6%), 3 (65.7%), and 4 (50.6%). The frequency of no response was more frequent in questions 2 (93.4%), 1 (76.3%), and 5 (73.6%). The difference



P-1: The levels 2 y 3 represented 64% of the answers
 P-2: The levels 3, 4 y 5 represented 57% of the answers
 P-3: The levels 3 y 5 represented 60% of the answers
 P-4: The levels 2 y 3 represented 69% of the answers
 P-5: The levels 3 y 5 represented 67% of the answers
 P-6: The levels 3 y 5 represented 62% of the answers

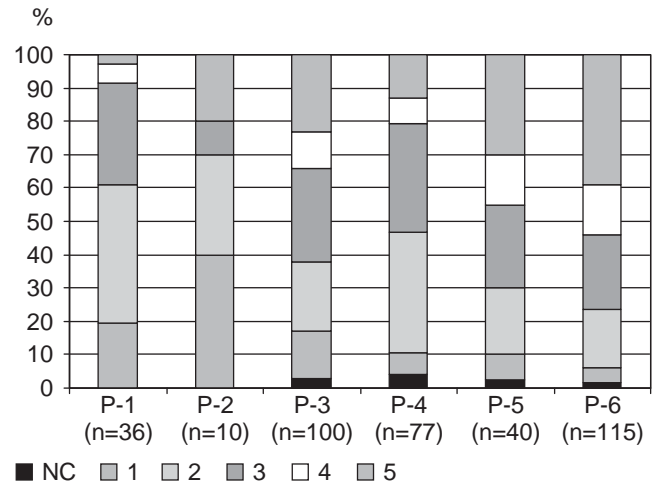
Figure 5. VAS, intensity of response yes in the 60 years old major patients (G-3, n = 99).



P-1: The levels 2 y 3 represented 62% of the answers
 P-2: The levels 2 y 3 represented 52% of the answers
 P-3: The levels 2 y 3 represented 42%, the levels 4 y 5 el 44% of the answers
 P-4: The levels 2 y 3 represented 56% of the answers
 P-5: The levels 4 y 5 represented 52% of the answers
 P-6: The levels 3, 4 y 5 represented 81.5% of the answers

Figure 6. VAS, intensity of response yes in the patients of feminine sex (G-4, n = 298).

between the two responses was significant, except the question 4 where $p > 0.05$. The intensity of the yes is shown in Figure 7.



P-1: The levels 2 y 3 represented 72% of the answers
 P-2: The levels 1 y 2 represented 70% of the answers
 P-3: The levels 2 y 3 represented 49% of the answers
 P-4: The levels 2 y 3 represented 68% of the answers
 P-5: The levels 2, 3 y 4 represented 60% of the answers
 P-6: The levels 2 y 3 represented 40% and the level 5 el 39% of the answers

Figure 7. VAS, intensity of response yes in the patients of masculine sex (G-5, n = 298).

The frequencies of the surgical procedures was highest for major surgical procedures (246 = 54.6%).

DISCUSSION

The structuring of informed consent for research on human subjects contains all the information necessary in order that a person with determined characteristics can either accept or decline to participate in a controlled study by fully exercising his/her autonomy. According to the Patients' Bill of Rights, the physician must give the patient information that is complete and truthful in the medical clinic, by using a language that the patient can understand, as well as information that constitutes the basis for the subject to make a decision about the treatment options offered to him/her and, and exercising his/her autonomy, the patient accepts one of the proposed options, though he/she may not accept any of them. The patient may say no and expose himself to the severe complications of his/her illness. Should we respect the patient's decision, even if that decision is wrong, in order not to undermine his autonomy? Or should we go back a little to the criticized paternalism in order to avoid the patient rejecting what can be the best or the unique opportunity to recover.

The results of our survey clearly show that in terms of information the patient wants to know but sometimes do not know how much. In total, 68% of patients in group 1

who said *yes* I know about anesthesia, only 28% wanted to know everything, 46.2% of patients were interested in moderate information (level 2 and 3). A third of all patients said no, I do not know anything. Further 23% also wanted to know about your surgery.

To dismay of anesthesiologists, patients are more worried, anxious and need more information regarding your surgery, than in relation to anesthesia. Why? We will investigate this in the future. For now, we can infer that the anesthesia creates in the patient an expectation of well being during surgery, while the surgical expectation is a exploration to his/her intimacy, in a possible, probable or certain mutilation no longer going to allow him/her to be the same person.

Regardless of how the patient understands that, the survey shows in all groups a greater concern for the surgery (50 to 66%) than for the anesthesia (23 to 43%). On the questions related to the degree of anxiety generated by the expectation of anesthesia, only 48 (11%) patients said they felt distressed and of them 50% reported a moderate level of anxiety (level 2 and 3). It is important to note that both in the need for information about anesthesia and in the existence of concern and anxiety, highest frequency was accumulated at levels 2 and 3 of the EVA. Regarding the surgery, highest frequency was accumulated at levels 3 and 4 of the EVA of anxiety and need for information. Garden⁽⁹⁾ in a study on need for information, evaluated three documents which contained different degrees of information about the risks of anesthesia. Of the patients who did read only one document, between 64 and 73% thought that the contents were "correct and fair", but when they did read all three documents, 63% of patients expressed that the document of shortest description was hiding information. The question is: Do our patients want moderate amounts of information about the anesthesia/surgery process because they do not have any information? If the answer is *yes*, we are in a serious problem of an ethical and legal nature.

Moerman⁽⁸⁾ points out that according to the literature, patients with no previous experience with anesthesia and surgery require more information than those who have had previous experience. In our study, patients in Group 2 showed the same pattern of need for information as the rest of the groups. The same author mentions that women have higher levels of anxiety than men, and that patients with higher anxiety levels demand more information, which leads us to conclude that if women are more anxious, they will demand more information. In our study, concerning anes-

thesia, only 38 of 298 women reported anxiety and of them 20 were classified with moderate anxiety, coincidentally, their need for information was more frequent in the same level. In contrast to surgery, 102 of 298 patients reported anxiety, 46 showed moderate anxiety and 53 manifested high anxiety. In total, 227 of 298 women stated need for information, 68 required moderate information and 142 required extensive information. In contrast, only 10 of 152 men reported to be slightly anxious due to anesthesia. Men showed slightly increased anxiety for the surgery; but they required more information (115 of 150), 46 patients required a moderate level of information and 62 required a high level of information. As pointed out by Inglis⁽¹⁰⁾, we have few anxious patients who want to be very-well informed.

Farnill D⁽¹¹⁾ and M Lonsdale⁽¹²⁾ refer in their studies that patients older than 50 years have less desire for information than younger ones. In our group, patients older than 60 years had a decrease of approximately 10% of your need for information - about anesthesia and surgery- as compared to other groups (Figure 5). Question of attitudes and expectations?

The truth is that the way to inform patients should be based on the needs of each patient, on the needs of patients, as well as on experience and time. And time and space is what we need for anesthesiologists to know the patient and obtain an informed consent. The lack of a preanesthetic evaluation or a perioperative medicine service leads to a legal and ethical conflict. Perhaps that is why the Japanese Ministry of Health and Welfare has implemented a policy of paying physicians to explain the nature of the patient's medical condition and the treatment plan, and to obtain a informed consent, a policy which has its risks, but as noted Akabayashi A⁽¹³⁾ there is a lesson to be learned from this program.

We know that informed consent as the exercise of autonomy has its own limitations because not all patients are fully autonomous. White SM⁽¹⁴⁾ said that the disease itself limits the Truthful autonomy to varying degrees. The patient with chronic pain is a good example, or a patient in emergency conditions. Thus, White argues: "if patients are always partially autonomous, then there must be a threshold, a level of ability above which the patient's autonomy should be respected and below it, it is considered that the patient do not have sufficient autonomy to decide for itself its treatment". Maybe if we find exact place for the threshold, we can understand why some patients require more information than others and why others do not want nothing.

In conclusion, informed consent in medicine, as an exercise of autonomy, has many details to refine because it involves a physical need controlling the will of man.

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