

Understanding of informed consent by patients at the Faculty of Dentistry of the University of Costa Rica.

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Abstract

Introduction: Informed consent is the result of the evolution of the relationship between health professionals and their patients or users where the principle of autonomy is above anything else. There are many articles on informed consent but none of the studies found assessed whether patients really understand it. The objective of this research was to determine the level of understanding of informed consent by the patients of the Clinic of Oral Surgery of the Faculty of Dentistry of the University of Costa Rica, in the period August to September 2022, by means of a questionnaire that would allow correlating the understanding with the level of schooling. **Materials and methods:** A questionnaire was administered to 100 people divided into two parts, one on sociodemographic data and the other to establish the understanding of informed consent and to determine whether the level of schooling was related to the understanding of the same. **Results:** The group between 20 and 30 years of age was the largest, of these 51% had university studies, and although the majority (98%) referred to knowing the concept of informed consent, only 33% obtained the correct answers to the clinical questions asked. **Conclusions:** Even though patients refer to knowing what informed consent is the results suggest an unclear understanding of important concepts such as complications or immediate or late adverse reactions produced by the effect of dental treatments or surgical procedures.

Key words

Informed consent, autonomy, odontology, comprehension
Source: MeSH (Medical Subject Headings)

Introduction

Informed consent (IC) has undergone changes over time and has gone from being a simple formality based on a form to become a human right(1).

Obtaining informed consent is considered a key component in the area of health sciences since it guarantees ethics during the processes and protects the principle of patient or user autonomy(2), in addition to improving their quality (3).

One of the difficulties encountered is that although the ethical and legal requirement is met, it has been evident that in most cases, the documents are unclear to patients and that there is little understanding of what they are signing (2)(4); it has been found that most professionals are aware that it is essential to dedicate time and space to clarify doubts and reduce the fear of users during the realization of the IC(1). Most IC have clear language (5) and meet the basic requirements such as defining the name of the procedure to be performed and the possible risks, but it has been found that only 8% recognize the patient's freedom to reconsider their decision (6), on the other hand; it is important to mention in the document that the professional may also decide to suspend treatments if he considers that the patient does not follow his indications and recommendations(7), this applies both to procedures and to studies or research(8–10).

Materials and methods

The research has a qualitative approach, it is descriptive and transversal. It was carried out within the facilities of the Faculty of Dentistry of the UCR. The participants were one hundred people over 18 years of age, who were starting treatment at the Clinic of Oral and Maxillofacial Surgery, who answered the questionnaire after having signed the informed consent.

To collect the data, a questionnaire was developed, consisting of two parts: the first collects sociodemographic data such as age, sex, place of residence, level of schooling and occupation; the second consists of 26 closed questions in order to know the level of understanding of informed consent. The questionnaire was applied physically (printed), after the informed consent had been signed.

Prior to the application of the questionnaire to patients, it required a validation process, which consisted first of a review and approval by a specialist in statistics and analysis of the information, after that the questionnaire was applied to five patients, to verify the understanding of the questions. Then, the questions that were unclear were analyzed, made the necessary corrections, and applied the corrected questions. Once the understanding of the questions was confirmed, the questionnaire was applied to all patients.

The questionnaire was administered by five members of the research group. Each one applied twenty questionnaires, which were answered by patients who were attended by 5th year students in the oral surgery clinic, after the patient had read and signed the informed consent provided prior to performing a clinical procedure. Before patients completed the questionnaire, they were given informed consent through which they agreed to participate in the research.

All this was done to patients who began their treatment at the Faculty between the months of August and September of the year 2022. The sample is composed of one hundred people on the basis that, in this case, $p = 0.5$ ie 50%, and the precision is 0.1, ie 10%. The exact calculation gives $N=96$, rounded to 100

Inclusion criteria

All patients of the Teaching Clinic of the Faculty of Dentistry of the University of Costa Rica over 18 years of age.

Exclusion criteria

-Minors and people without volitional and cognitive capacity.

Results

The information obtained was classified into three tables: 1) sociodemographic characteristics, 2) form of application of the questionnaire and suggestions; 3) Variables to be analyzed to determine the understanding of informed consent, these variables were divided based on the level of education: patients who had or did not have university studies (complete or incomplete). This was done to analyze whether the level of schooling is related to the understanding of informed consent.

Table 1. Sociodemographic and clinical characteristics of Surgery patients of the Faculty of Dentistry, UCR 2022

Variables		No.	%
Sex	Female	51	51%
	Male	49	49%
Total		100	100%
Age	0<20	4	4%
	20<30	35	35%
	30<40	18	18%
	40<50	11	11%
	50<60	15	15%
	60<70	14	14%
	70<80	3	3%
Total		100	100%
Residence	San Jose	64	64%
	Alajuela	8	8%
	Heredia	8	8%
	Carthage	16	16%
	Guanacaste	2	2%
	Puntarenas	0	0%

	Lemon	2	2%
	Total	100	100%
Schooling	Complete primary	9	9%
	Incomplete primary	10	10%
	Secondary completed	12	12%
	Incomplete secondary	16	16%
	Technician	2	2%
	Complete university	19	19%
	Incomplete university	32	32%
	Total	100	100%
Current type of treatment	Periodontology	2	2%
	Restorative	7	7%
	Endodontics	0	0%
	Surgery	91	91%
	Don't know	0	0%
	Total	100	100%

Source: Questionnaire applied at the Oral and Maxillofacial Surgery Clinic, Faculty of Dentistry UCR 2022.

Table 2. Application and suggestions of informed consent of the Surgery Clinic of the Faculty of Dentistry, UCR 2022.

Variables		No.	%
Reading consent	Patient	69	69%
	Student	31	31%
	Total	100	100%
Possibility to read the consent days before	Yes	44	44%
	No	56	56%
	Total	100	100%
Sufficient time to analyze consent	Yes	93	93%
	No	7	7%
	Total	100	100%

Persuasion when signing consent	Yes	0	0%
	No	100	100%
Total		100	100%
Improvement tools	Drawing	20	20%
	Photos	20	20%
	Video	6	6%
	Nothing	57	57%
Total		100	100%

Source: Questionnaire applied at the Oral and Maxillofacial Surgery Clinic, Faculty of Dentistry UCR 2022

Table 3. Understanding Informed Consent from the School of Dentistry Surgery Clinic, UCR 2022

	Student		Non-university	
	N	%	N	%
Knowledge about the concept of informed consent				
Yes	50	98%	43	88%
No	1	2%	6	12%
Total	51	100%	49	100%
Prior explanation of informed consent				
Yes	36	71%	29	59%
No	15	29%	20	41%
Total	51	100%	49	100%
Clarification of doubts by the teacher				
Yes	11	22%	18	37%
No	16	31%	18	37%
I had no doubts.	24	47%	13	27%
Total	51	100%	49	100%
Explanation of diagnosis				
Yes, before signing the consent	47	92%	46	94%
Yes, after signing the consent	3	6%	3	6%
No	1	2%	0	0%

Total	51	100%	49	100%
Explanation of possible consequences in case of not performing the recommended treatment				
Yes	45	88%	44	90%
No	6	12%	5	10%
Total	51	100%	49	100%
Knowledge of side effects				
Yes	37	73%	33	67%
No	14	27%	16	33%
Total	51	100%	49	100%
Patients who made consultations				
Yes	18	35%	25	51%
No	33	65%	24	49%
Total	51	100%	49	100%
Patients with doubts or who thought about not signing				
Yes	3	6%	2	4%
No	48	94%	47	96%
Total	51	100%	49	100%
Clarity of informed consent				
Very clear	31	61%	28	57%
Of course	19	37%	20	41%
Unclear	1	2%	1	2%
It was unclear	0	0%	0	0%
Total	51	100%	49	100%
Revoke consent				
Yes	9	18%	8	16%
No	42	82%	41	84%
Total	51	100%	49	100%

Source: Source: Questionnaire applied at the Oral and Maxillofacial Surgery Clinic, Faculty of Dentistry UCR 2022

Discussion

Table 1 shows the sociodemographic characteristics of the study participants. With regard to sex, the percentage of men and women was almost the same: 49% and 51% respectively. In terms of age, the highest percentage was between 20-30 years (35%), participants between 70-80 years represent the lowest percentage (3%) and under 20 years 4% (which could be due to the fact that only patients over 18 years of age participated). In relation to the place of residence, 64% live in San José, 2% live in Guanacaste and Limón, no participant resides in Puntarenas. The remoteness between San Jose and provinces like Guanacaste, Limon and Puntarenas could be a reason why patients don't attend dental school to be seen. On the other hand, Alajuela and Heredia, both with 8% of patients residing in these provinces, being a small percentage of attendance at the Faculty, could be due to the long transfer time.

Regarding the level of schooling, the highest percentage of participants were those who have an incomplete university degree with 36%, while 19% have completed or incomplete primary school, 28% have completed or incomplete secondary school and 51% have completed or incomplete university. There was a high percentage of participants who had university studies, later we will analyze how this variable influenced the understanding of informed consent. Finally, 91% of patients presented themselves to receive surgical treatment, 7% restorative and only 2% periodontics, it should be noted that in endodontics there were 0% of patients, this for the type of treatment provided in the clinic, which would be to restore, heal and preserve the teeth.

According to the results obtained regarding the application or suggestions of the patients of the Clinic of Oral Surgery of the UCR, we can observe (see table 2) that 69% of the patients read the IC by themselves, and 31% reported that the document had been read by the student. This document contains clinical vocabulary that, when explained by an advanced student (in this case fifth-year students of the Dentistry career, UCR), could have a more significant scope of understanding than doing the reading by themselves, and thus avoid being classified as a simple protocol act (11).

It is important that 44% selected in the questionnaire that they would like to be able to read the informed consent days in advance. This is contradictory, since the majority of participants, 93%, consider that they had enough time to analyze informed consent. According to the data obtained, it is important to mention that 100% of patients agreed that there was no persuasion to sign the IC.

Regarding the tools for improving the understanding of the document, the patients consulted reported: 20% that it would be clearer to explain it with drawings, another 20% with photos, 6% considered, according to the data obtained, that it would improve the understanding of informed consent with the use of videos, while the highest percentage of participants 57% thought that it was not necessary to use any of these ideas (drawings, photos or videos) to understand the consent, and that with the written information as it was exposed, it would be enough.

Regarding factors that influenced the understanding of informed consent (Table 3), almost all patients with university studies (98%) previously knew what this document was, while the percentage of those without university studies was 88%, so it can be said that almost all participants knew the concept of IC. However,

despite knowing the concept, only 36% of participants with university degrees and 29% without university studies, had been explained at some point what consent was. Given these results, the question arises as to whether the participants understood with total clarity what informed consent is and all that it implies, despite not having received a prior explanation.

A 22% of patients with university studies and 37% without university studies, reported that a teacher clarified doubts after reading the informed consent. While it is true, there were 47% with university studies and 27% without university studies who had no doubts, there are still 31% with university studies and 37% without university studies that indicated that no teacher clarified their doubts.

An important part before signing the informed consent is that the patient knows what his diagnosis is, in this case 92% of patients with university studies and 94% without university studies received an explanation before signing the informed consent. However, there were patients who were explained their diagnosis after having signed the document, 6% with university studies and 5% without university studies, and there was a patient with university studies, who indicated that his diagnosis was not explained either before or after signing the consent.

It is essential that informed consent contains veracity and clarity of the clinical procedures to be performed, what are the risks, benefits, and alternatives available, as well as the possible consequences of not performing the recommended treatment. It is important that this information is written in the informed consent and is not just a verbal explanation. In this regard, a high percentage, 88% of university patients and 90% of non-university patients, mentioned that they were explained what could happen if the recommended treatment was not performed, those who indicated that they had not received the explanation were 12% of university patients and 10% non-university patients.

It is essential that the patient is clear about the possible side effects, because when performing the required procedures there is no surprise, the data obtained in this aspect were not of great difference between university patients who were 73% and non-university 67%, who mentioned that they had knowledge about side effects, On the other hand, 27% and 33% of university and non-university patients respectively had no notion of the effects. In both cases the difference between university and non-university was 5%, so the lack of knowledge about the effects is not associated with the level of schooling, but possibly they were not mentioned or there was no understanding of these and did not express the concern. This is where the data obtained from patients who made consultations during the reading arise, with non-university patients requesting more consultations with 51%, while those who did not ask questions were university patients with 63%. On the other hand, patients who had doubts or who thought about not signing were quite low, 6% university and 4% non-university, these percentages should be at 0% since no one is obliged to sign the consent if they have any doubts.

Regarding the clarity of IC, the results focus on whether it is very clear or clear. Where the percentages of patients who indicated that it was very clear were 61% for university patients and 57% for non-university patients, while those who indicated that consent was clear were 37% (university students) and 41% (non-university students), these data are compatible with other studies where it is evident that there is no total understanding of the information (4) and makes it clear that it needs to be improved(12–17).

Finally, with regard to the principle of revocation of informed consent, 82% and 84% of university and non-university patients indicated that it cannot be revoked, which shows that the principle of revocation is not clear, both in university and non-university students.

Conclusions

From the results obtained in the questionnaires carried out, it can be concluded that the highest percentage of patients participating in this study have a level of university education, and that the majority (93%) reported knowing the concept of informed consent, however; only 33% obtained the correct answers to the clinical questions asked, which led to an unclear understanding of important concepts, such as possible complications or immediate or late adverse reactions produced by the effect of dental treatment or surgical procedure included in informed consent. This may be because the majority, 69% of the participants read the document themselves, and 35% were not previously explained the document they were going to sign.

It is contradictory that most participants (93%) consider that they had enough time to be able to analyze the document, but 44% of the same participants reported that they wish they could read the informed consent days before. It is possible that they consider this document as a legal and important tool, which deserves to be analyzed in detail, perhaps they interpreted that there was time to read it, but not to understand it in depth, this reflects in some way why 40% of patients who filled out the questionnaires consider that consent was "clear", and not sufficiently "clear". Finally, most patients indicated that consent as it currently stands is clear and does not require additional tools to improve, but it is concluded that it is essential for the student to read, explain and fully clarify informed consent, so that they have an excellent understanding of it and assimilate that the purpose of the consent is not to exempt the treating person from responsibility as has been concluded in other studies(10).

Recommendations

- Ensure that informed consent is available in digital form on the website of the Faculty of Dentistry, so that anyone can access it at any time and have enough time to read it and if they have doubts, they can perform them to the student in charge the day they will perform a clinical procedure.
- Ensure that he or the student in charge is the person responsible for reading the informed consent to the patient, to ensure that the patient fully understands each of the parts of this document.
- Encourage that in the theoretical courses prior to the clinical courses, the importance of informed consent is promoted more to the students, so that when this document is applied, all the doubts that arise during its reading are clarified and so that it is explained before being signed; without distinguishing the level of schooling presented by the patient, since according to the results obtained there was no major difference in terms of understanding of the document between patients of university and non-university studies.
- Although most patients report that the document is understood as it is, 46% reported that it would be useful to use different tools (drawings 20%, images 20% and videos 6%) so it is recommended in case a patient is not understanding a specific procedure to devise how to illustrate and provide the necessary support (photos, images or videos) to facilitate the understanding of it.

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