

## Impact of the systematic use of the informed consent form at public dental care units in Galicia (Spain)

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### Abstract

**Aim:** To ascertain the impact of routine application of the informed consent form at the primary dental care units of the Galician Health Service. **Study design:** Non random selection of consecutive patients seeking tooth extraction between 9 January and 7 March 2007 at the dental care units of Burela, Praza do Ferrol and Viveiro (Lugo). The study included sociodemographic, clinical, utilization, behavioural and IC-related variables. **Main results:** A total of 462 patients, mainly males (n=249; 53.9%) entered the study. The mean age of the participants was 57.87±17.54 years. 93.7% of the patients gave their consent for tooth extraction, whereas 47.3% did not want to be informed. The average time employed for obtaining the informed consent was 3.40±1.87 minutes, with a median of 4 and the same mode. The referred stress values did not differ before and after reading the informed consent form 3.28±2.52 vs 3.41±2.45 (p=0.661). **Conclusion:** Routine application of the informed consent form before tooth extraction under local anaesthesia did not impair clinical practice nor is it a barrier to dental care. The use of this form does not require changes beyond the allocation of the time necessary for its completion.

**Key words:** Informed consent, tooth extraction, primary care, dentistry.

### Introduction

The requirement of the informed consent (IC), considered as a particular kind of permission, is surprisingly recent and has not been considered from the medical-legal perspective until recent times, perhaps because the relationship between patients and clinicians used to take place under the traditional paternalistic model.

The laws regulating the informed consent and the clinical records (1,2) emphasize patient's autonomy, grant the subject and his/her rights a leading role in the clinical relationship, and turn the information provided into the cornerstone of the medical treatment (3).

Tooth extraction is a surgical procedure that constitutes the main dental treatment provided to adult patients by the Galician public health service. This treatment is considered as routine by the public, and such familiarity frequently results in poor evaluation of its risks and consequences. Patient's consent for tooth extraction used to be obtained verbally or on a tacit way. However, the laws establish that "a written consent is needed for surgical operation, invasive therapeutic or diagnostic procedures and, in general, for those procedures involving risks or inconveniences with relevant and foreseeable negative repercussion on patient's health" (2). This statement clearly includes the surgical

amputation of elements of the stomatognathic apparatus. Moreover, the law also states that the clinician performing the treatment should be the person who obtains the written informed consent from the patient, being otherwise an offence of professional encroachment.

The requirements set for obtaining the informed consent combined with the circumstances of growing numbers of patients (age, ignorance of the language, handicaps, etc.) and the tight schedules of some clinicians, may have an impact on the activity of the public primary dental care units that may be worth identifying and quantifying in order to introduce organizational changes that ensure both compliance with the regulations and adequate dental care. This is the aim of the present study.

### Patients and Methods

The sample was obtained by a non-probabilistic method applied to consecutive patients seeking tooth extraction at the primary dental care units of Burela, Praza do Ferrol and Viveiro (Lugo), from 9 January to 7 March 2007.

The variables considered were divided into socio-demographic (age, gender, place of residence, educational level, language), use (first or subsequent visits), behavioural (accompanying person yes/no, spontaneous expression of fear yes/no), and IC related (consent yes/no, wants to be informed yes/no/cannot be informed, time employed, stress level before and after reading the IC form). The IC form was the one provided by the Galician Health Service (Fig 1) in both the Spanish and Galician language versions.

The patient's residence was classified by number of inhabitants: urban (>50,000), rural (<5,000) and peri-urban (any other). The educational levels considered were: non-standard education, compulsory education, secondary education and university degree. Patient's languages were divided into Spanish, Galician and other.

### Statistical analysis

The relationships between variables were studied using Student's t test, Chi square and ANOVA with the Scheffé test for post-hoc comparisons. The significance level chosen for all tests was 5%.

### Results

A total of 462 patients entered the study, with a mean age of  $57.87 \pm 17.54$  years. The main features of the sample are described in table 1.

3.7% of the patients could not be informed, 60% (n=9) of these because their legal guardian did not accompany them and the other 40% (n=6) because the subjects were not able to understand any of the languages spoken by the clinician. The mean time employed in obtaining the IC was  $3.40 \pm 1.87$  minutes (mean and mode: 4).

The stress levels registered using a visual analogue scale (VAS) were not significantly different before and after reading the IC form ( $3.28 \pm 2.52$  vs  $3.41 \pm 2.45$  ( $p=0.661$ )).

Table 1. Description of the sample.

<i>Socio-demographic variables</i>		
Gender	N	%
Male	249	53.9
Female	213	46.1
Age		
0 to 14	7	1.5
15 to 20	5	1.1
21 to 40	72	15.6
41 to 64	0	0
65 or more	378	81.8
Address		
Rural	211	45.7
Urban	145	31.4
Peri-urban	106	22.9
Educational level		
Non-standard education	175	37.9
Compulsory education	196	42.4
Secondary education	81	17.5
University degree	10	2.2
Language		
Galician	352	76.2
Spanish	102	22.1
Other	8	1.7
<i>Variables of use</i>		
1st consultation	232	50.2
Subsequent consultation	230	49.8
<i>Behavioural variables</i>		
Accompanied in the clinic		
Yes	306	66.2
No	156	33.8
Spontaneous expression of stress		
Yes	7	1.5
No	455	98.5
<i>IC-related variables</i>		
Gives consent		
Yes	433	93.7
No	29	6.3
Attitude towards the information		
Wants it	226	48.9
Does not want it	219	47.3
Cannot be informed	17	3.7

Fig 1. Oficial Galician Health Service IC form for oral surgery (Spanish version).



### CONSENTIMIENTO INFORMADO PARA CIRUGÍA ORAL

Para la satisfacción de los DERECHOS DEL PACIENTE, como instrumento favorecedor del correcto uso de los procedimientos diagnósticos y terapéuticos y en cumplimiento de la Ley General de Sanidad en relación con la Ley Orgánica 1/1982.

La cirugía oral se realiza para resolver determinados problemas de la cavidad oral, tales como: extracciones de piezas dentarias –valorada su viabilidad y luego de indicarse la exodoncia- o restos de estas (raíces), apertura de mucosa, cirugía preprotésica, frenos labiales, extirpación de quistes maxilares y de pequeños tumores de estos o del resto de la cavidad oral. La intervención se realiza con anestesia local, con el riesgo inherente asociado a esta. Todos estos procedimientos suponen un indudable beneficio, no obstante, no están exentos de complicaciones, las estadísticamente más frecuentes son:

- Alergia al anestésico o a otro medicamento utilizado antes, durante o después de la cirugía.
- Hematoma e hinchazón de la región. Hemorragia postoperatoria. Infección de los puntos de sutura.
- Daño a los dientes vecinos. Heridas en la mucosa de la mejilla o de la lengua.
- Falta de sensibilidad parcial o total, temporal o permanente de los nervios: dental inferior (sensibilidad del labio inferior), lingual (de la lengua o del gusto) e infraorbitario (de la mejilla).
- Infección de los tejidos o del hueso.
- Sinusitis. Comunicación entre la boca y la nariz y los senos maxilares.
- Fracturas óseas (más frecuente de la tuberosidad, tabla externa e interna y tabique interradicular).
- Desplazamiento de dientes a estructuras vecinas.
- Tragado o aspiración de dientes o de alguna de sus partes.
- Rotura de instrumentos. Rotura de la aguja de anestesia.
- Riesgos específicos en cada caso: diabetes, cardiopatía, hipertensión, anemia, estado inmunitario, edad avanzada, obesidad, radioterapia, quimioterapia, etc.
- Complicaciones generales que pueden requerir tratamientos médico-quirúrgicos adicionales y raramente, dejar secuelas definitivas.

En entrevista personal con el Dr.....  
 Fui informado/a, en términos que comprendo, de la naturaleza y propósitos de procedimiento. Tuve y tengo la oportunidad de proponer y resolver mis posibles dudas y de obtener cuanta información complementaria crea necesaria. Por esto, me considero en condiciones de sopesar debidamente tanto los posibles riesgos como la utilidad y beneficios que pueda obtener.  
 Estoy satisfecho/a con la información que se me proporcionó y, por esto, **DOY MI CONSENTIMIENTO** para que se me practique .....

Si surgiese cualquier situación inesperada durante la intervención, autorizo a mi especialista a realizar cualquier procedimiento o maniobra que, en su juicio clínico, estime oportuno para mi mejor tratamiento.

Este consentimiento puede ser revocado por mi, sin necesidad de justificación alguna, en cualquier momento antes de la realización del procedimiento.

Observaciones.....  
 .....

Y, para que así conste, firmo las dos copias del presente documento **después de leerlo**, y se me hace entrega de una de ellas.

En ..... de ..... a ..... de ..... de 200

Firma del paciente (o de su representante legal en caso de incapacidad)  
 D.N.I.

Firma del médico y Nº de  
 colegiado

En caso de negativa por parte del paciente a firmar el consentimiento informado  
 Firma del testigo (DNI)

The time needed for obtaining the IC significantly diminished from the first to the second or subsequent visits ( $3.73 \pm 1.98$  vs  $3.06 \pm 1.69$ ),  $p=0.000$ ). Patients speaking a non-official language needed more time than Spanish (0.039) or Galician ( $p=0.011$ ) speakers to reach a decision. The patients that did not give their consent used more time than those who did ( $4.15 \pm 3.23$  vs  $3.35 \pm 1.75$ ;  $p=0.039$ ). The educational level of the subjects did not influence the length of the time employed ( $p=0.787$ ), as happened with the rest of the variables considered.

The patients that rejected the treatment were significantly older than those who agreed ( $68.86 \pm 12.43$  vs  $57.16 \pm 17.6$ ;  $p=0.000$ ) and scored lower stress values ( $1.88 \pm 1.26$  vs  $3.41 \pm 2.5$ ;  $p=0.001$ ). Speakers of a non-official language reject treatment more frequently than the rest of the sample ( $p=0.000$ ), as happens with those patients that came alone to the clinic ( $p=0.015$ ).

The right to decline information was exerted more frequently by older patients ( $61.06 \pm 15.26$  vs  $53.85 \pm 18.97$ ;  $p=0.000$ ). These patients were mainly from urban areas ( $p=0.002$ ), received non-standard or compulsory education ( $p=0.001$ ), spoke Galician ( $p=0.008$ ) and had a companion in the clinic ( $p=0.000$ ).

## Discussion

Despite what is stated in legal texts (1), the use of informed consent forms before tooth extraction remains controversial: on the one hand, there exists the obligation of the use of a written informed consent and on the other is the reluctance of the clinicians to use of what they interpret as a bureaucratic requirement that slows their activity, and increases patient stress, and thus making it more difficult to manage the situation. From the patient's standpoint, the written informed consent is frequently understood as the clinician's attempt to exempt him/herself from his/her responsibility to the patient; this interpretation has already caused complaints and threats to the dentist. Moreover, some ethical aspects have also arisen against the systematic use of this kind of IC, in that it would be an added difficulty for patient care, susceptible to becoming a barrier to dental treatment that would favour inequities. From the Health Service point of view, the systematic use of these forms seems to be perceived as an unnecessary increment of the time devoted to each patient that would imply a reduction in the number of patients treated per day and cause an increase in waiting lists. In this context, we should consider a recent memorandum dated May 2007, from the Galician Health Service Legal Department stating that "a written informed consent is not needed for non-surgical tooth extraction (sic), unless the clinician decides otherwise, being compulsory for surgical tooth extractions". This statement depicts per se the situation of the primary care dentist regarding this issue.

The time allowed for the patient to make a decision is not free from discussion, as it has been suggested the

need for a 24-hour period for the patient to analyze the information at home, away from the hypothetical pressure of the surgery. However, the law does not state a defined time period but it determines that the patient should be provided with the necessary time to make a decision. The results of this study indicate that this time would fit into an interval from 3 to 4 minutes.

Patients have the right to decline the information about their disorder/treatment (1). In these circumstances, almost half of the sample (47.3%) declined their right to be informed. These patients were more frequently elderly patients with non-standard or compulsory education that perhaps made them feel more comfortable within the traditional paternalistic model of the relationship with the clinician than within the one based upon patient autonomy.

The patients that did not give their consent for treatment constitute a small, but relevant 6.3% of the sample. These patients used more time to make up their minds and scored lower levels of stress, which may indicate a more careful consideration of the information provided. These patients are also distinguished by attending the surgery without a companion who might well have acted as reinforcement for the previous decision of having a tooth extracted.

Refusal of treatment is more frequent among those who do not speak any of the official languages.

A particular group of patients is that of subjects who cannot be informed; most of these situations occurred with patients with evident signs of incapacity whose legal guardian was absent. An emerging set of patients unable to be informed are those immigrants who do not understand neither Spanish, Galician nor any other language the clinician speaks, making communication impossible. In these cases it would be desirable to have IC forms written in the most common languages among this collective or have a translator in the clinic that would ease communication with those who cannot read.

The results of this study indicate that to have a tooth extracted does not cause a high level of stress in patients, scoring a mean VAS value of 3.28 in a range from 0 to 10, without significant differences before and after reading the IC. Thus, the affirmation that IC forms would increase patient stress and complicate patient management is not justified by our results.

A major issue to be considered, despite not being the aim of this investigation, is the amount of information that is actually acquired by the patient after reading the IC form; as the objective of the IC is to provide the necessary data to allow an informed decision by the patient, not a mere list of possible events for the patient to read before the operation. Accordingly, previous reports find that up to 40% of all written ICs would not be valid (4).

Hence, the appearance and wording of the IC forms is very relevant. In this study, the official Galician Health Service IC form for oral surgery was used (fig 1), and it may be worth wondering whether the size of the font, the space

between the lines and other design features are suitable for a population where 81.8% is older than 65. Moreover, the terms employed, the kind of risks described, grammar and readability, together with the lack of space in which to write the patient's data seems to point to the fact that the form used in this study may not follow the standards for this kind of document (5-7).

It would thus be interesting to find out the quantity and quality of the information retained by the patients after reading the IC form – and hence employed in making a decision - as the degree of compliance with the regulations would depend on this result, since to consider the IC as an isolated and defined time point of the clinical relationship, centred on the form and designed primarily for obtaining the patient's signature is a complete ethical and legal mistake (8). Moreover, if the quality and quantity of the information retained by the subject is not acceptable, the IC would miss not only its legal utility but would become a tool of defensive medicine rather than an instrument for easing the relationship between clinicians and patients, thus undermining the necessary confidence that should be present in any clinical interview.

## Conclusions

It is concluded that the systematic use of written IC forms before tooth extractions under local anaesthesia does not hamper clinical practice, does not constitute a barrier for treatment and does not require organizational changes beyond the allocation of the necessary time.

## References

1. Ley básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica, Ley 41/2002, BOE núm. 274, (15/11/2002).
2. Ley gallega reguladora del consentimiento informado y de la historia clínica de los pacientes, Ley Gallega 3/2001, DOG núm. 111, (8/6/2001).
3. Ley General de Sanidad, Ley 14/1986, BOE núm. 102, (29/4/1986).
4. Mohamed Tahir MA, Mason C, Hind V. Informed consent: optimism versus reality. *Br Dent J.* 2002 Aug 24;193(4):221-4.
5. Barrio Cantalejo I, Simón Lorda P. Medición de la legibilidad de textos escritos. Correlación entre método manual de Flesch y métodos informáticos. *Aten Primaria.* 2003 Feb 15;31(2):104-8.
6. Barrio Cantalejo IM, Simón Lorda P. ¿Pueden leer los pacientes lo que pretendemos que lean? Un análisis de la legibilidad de materiales escritos de educación para la salud. *Aten Primaria.* 2003 Apr 30;31(7):409-14.
7. Simón Lorda P, Barrio Cantalejo IM, Concheiro Carro L. Legibilidad de los formularios escritos de consentimiento informado. *Med Clin (Barc).* 1996 Oct 26;107(14):524-9.
8. Simón Lorda P, Júdez Gutiérrez J. Consentimiento informado. *Med Clin (Barc).* 2001 Jun 23;117(3):99-106.

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