



## Original article

# Evaluation and Improvement of the Comprehension of Informed Consent Documents<sup>☆</sup>



Julio José López-Picazo Ferrer,<sup>\*</sup> Nuria Tomás García

Unidad de Calidad Asistencial, Hospital Clínico Universitario Virgen de la Arrixaca, Área 1 Murcia-Oeste, Murcia, Spain

## ARTICLE INFO

## Article history:

Received 7 September 2015

Accepted 3 November 2015

Available online 25 March 2016

## Keywords:

Evaluation studies

Consent forms

Readability

## A B S T R A C T

**Introduction:** The information contained in a good informed consent form (ICF) must be understood by the patients. The aim of this study is to assess and improve the readability of the ICF submitted for accreditation in a tertiary hospital.

**Methods:** Study of assessment and improvement of the quality of 132 ICF from 2 departments of a public tertiary hospital, divided into 3 phases: initial assessment, intervention and reassessment. Both length and readability are assessed. Length is measured in words (adequate to 470, excessive over 940), and readability in INFLESZ points (suitable if over 55). The ICF contents initially proposed by departments were adapted by non-health-related trained persons, whose doubts about medical terms were resolved by the authors. To compare results between evaluations, relative improvement (in both length and INFLESZ) and statistical significances were calculated.

**Results:** Baseline data: 78.8% of the ICFs showed a desired length (CI 95% 86.5–71.1) and a mean of 44.1 INFLESZ points (3.8% >55 points, CI 95% 6.0–1.6). After the intervention, INFLESZ raised to 61.9 points (improvement 40.3%,  $P < .001$ ), all ICF showing >55 points. The resulting ICFs had a longer description of the nature of the procedure ( $P < .0001$ ) and a shorter description of their consequences, risks ( $P < .0001$ ) and alternatives ( $P < .05$ ).

**Conclusions:** The introduction of improvement dynamics in the design of ICFs is possible and necessary because it produces more effective and easily readable ICFs.

© 2015 AEC. Published by Elsevier España, S.L.U. All rights reserved.

## Evaluación y mejora de la comprensión de los documentos de consentimiento informado

## R E S U M E N

**Introducción:** Contar con documentos de consentimiento informado (DCI) de calidad implica que la información pueda ser comprendida y asimilada por el paciente. El propósito de este estudio es evaluar y mejorar la facilidad de comprensión de los DCI presentados para su acreditación en un hospital de tercer nivel.

## Palabras clave:

Estudios de evaluación

Formularios de consentimiento

Legibilidad

<sup>☆</sup> Please cite this article as: López-Picazo Ferrer JJ, Tomás García N. Evaluación y mejora de la comprensión de los documentos de consentimiento informado. *Cir Esp*. 2016;94:221-226.

<sup>\*</sup> Corresponding author.

E-mail address: [Julioj.lopez-picazo@carm.es](mailto:Julioj.lopez-picazo@carm.es) (J.J. López-Picazo Ferrer).

**Métodos:** Estudio de evaluación y mejora de la calidad de 132 DCI provenientes de 2 servicios de un hospital público de tercer nivel, estructurado en 3 fases: evaluación inicial, intervención y reevaluación. Se utilizaron 2 criterios: extensión (deseable inferior a 490 palabras) e índice de legibilidad INFLESZ (adecuado si >55 puntos), tanto del DCI completo como de cada uno de sus apartados. Los contenidos propuestos por los servicios fueron adaptados por una persona entrenada no sanitaria, cuyas dudas sobre términos médicos fueron resueltas por los autores. Para comparar los resultados entre evaluaciones se calcularon mejoras relativas en extensión e INFLESZ, y su significación estadística.

**Resultados:** Antes de la intervención, el 78,8% de los DCI eran de extensión deseable (IC 95%: 86,5-71,1) con un INFLESZ medio de 44,1 puntos (3,8% > 55 puntos) (IC 95%: 6,0-1,6). Tras ella, el INFLESZ fue de 61,9 puntos (mejora relativa 40,3%,  $p < 0,001$ ), con el 100% > 55. Los DCI resultantes dedican una mayor extensión a describir la naturaleza del procedimiento ( $p < 0,0001$ ) y menor a consecuencias, riesgos ( $p < 0,0001$ ) y alternativas ( $p < 0,05$ ).

**Conclusiones:** Introducir dinámicas de mejora en el diseño de DCI es posible y necesario, ya que produce DCI de mayor calidad y más fáciles de comprender por los pacientes.

© 2015 AEC. Publicado por Elsevier España, S.L.U. Todos los derechos reservados.

## Introduction

Informed consent has the purpose of ensuring that patients reach a free decision on all procedures that affect their health.<sup>1</sup>

This communication process is therefore complex, in which the signed consent document (ICD) is a vitally important item as a documental support and tool for the transmission of information.<sup>2,3</sup> This is why it is essential to have a high quality ICD, which in practice basically means 3 things: that its content covers the whole spectrum of information that the patient needs to know, that the information it contains is valid (according to the evidence) and that it is written in a way that the patient is able to understand and assimilate. It is therefore advisable to use homogeneous documents or ICD recording, accreditation and updating systems, as several authors point out.<sup>4-6</sup>

Nevertheless, these measures have not to date been able to guarantee these requisites in a uniform way. Thus while it is easy to structure the information contained in an ICD according to the needs of the patient,<sup>4,7,8</sup> and its validity can be checked with the help of scientific societies<sup>9,10</sup> or other methods,<sup>6,11</sup> the way in which it is written hinders comprehension by many patients. The low legibility of ICD is a widespread problem in Spain<sup>12-15</sup> as well as in Europe<sup>16-18</sup> and America.<sup>19,20</sup> The texts proposed by scientific societies are not immune from this either.<sup>21</sup>

The purpose of this study is to evaluate and improve the ease of comprehension of the ICD presented for accreditation in a third level hospital.

## Methods

The 'Hospital Clínico Universitario Virgen de la Arrixaca' is a public hospital located in the Region of Murcia (Spain). It has used an ICD accreditation system since 2012.<sup>6</sup> This study is part of a project to improve the procedures for delivering and

signing ICDs in the hospital, and the documents used in the Orthopaedic and Urology Departments were analysed. These use 132 ICD (64 and 68, respectively) divided into 6 sections: description, purpose, consequences, risks, contraindications and alternatives. The analytical criteria of the programme for the Evaluation and Improvement of Care Quality (EMCA) of the Board of Health and Social Policy of the Region of Murcia were used in this study.<sup>4</sup>

The evaluation and improvement study was undertaken in 3 successive phases: an initial evaluation (to measure the basic quality of the ICD), intervention (with the aim of improving their quality) and re-evaluation (to investigate the improvement attained).

### Initial Evaluation

132 ICD in the form originally proposed by both departments were received for accreditation and evaluated for ease of comprehension. 2 criteria were used for this: their length and the INFLESZ index. These were applied to the complete ICD as well as to each one of their sections. Measurements of the sections "consequences" and "contraindications" were excluded when the text proposed by the department indicated the absence of any such situation. For example, "this procedure has no consequences", "it has no contraindications" or similar expressions), given that the hospital Accreditation Committee would replace it with the phrase "There are none" (142.5 INFLESZ points).

- Length was measured in words, and it was considered desirable that these documents were shorter than one page. In the ICD format of our hospital, which uses DIN A4 paper and size 12 pp fonts, one page equals 470 words. It was considered to be too long or unadvisable for it to be longer than 2 pages (more than 940 words). It is therefore possible to classify ICD in 3 types according to their length: desirable (up to 470 words), acceptable (471-940 words) and too long (more than 940 words).

Download English Version:

<https://daneshyari.com/en/article/4255094>

Download Persian Version:

<https://daneshyari.com/article/4255094>

[Daneshyari.com](https://daneshyari.com)