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ORIGINAL ARTICLE

Elements of informed consent and decision quality were poorly correlated in informed consent documents

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Abstract

Objectives: Although informed consent (IC) documents must contain specific elements, inclusion of these elements may be insufficient to encourage high-quality decision making. We assessed the extent to which documents conform to IC standards and how well conformity to decision quality (DQ) standards can be predicted by IC standards, IC document characteristics, and study characteristics.

Study Design and Setting: We obtained 139 IC documents for trials registered with ClinicalTrials.gov from study investigators. Using a four-point scale, two raters independently assessed each IC document on 36 IC standard items and 9 DQ items.

Results: Overall agreement between raters across all 45 items was 93%. Across the 36 IC standards items, conformity was generally quite high but variable, with 20 items showing conformity of 80% or more and seven items showing conformity of 50% or lower. IC standards concordance, overall length of the IC document, and country of study were all significant predictors of DQ standards but together accounted for less than 20% of the variance in DQ standards.

Conclusion: Conformity to recommendations for improving IC documents was relatively high but variable. The extent to which an IC document conformed to these recommendations was only moderately related to whether it conformed to recommendations for improving DQ. Existing IC regulations may not describe the optimal approach to helping people make good study participation decisions.

Keywords: Informed consent; Decision quality; Clinical trials; Research participants; Trial participation; Decision support

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1. Introduction

The informed consent (IC) process is the chief source of information for potential health research participants making difficult decisions about study participation. Recently, debate has formed around a decision by the U.S. Office of Human Research Protections to question the adequacy of IC in a highly prominent neonatal trial (the SUPPORT trial) [1−7]. This trial, despite having been reviewed and approved by no less than 23 different research ethics boards [7], was determined not to meet IC regulations. Such uncertainty around basic IC issues helps explain why many study participants do not understand even basic components of the studies they have agreed to join [8−10].

Core criteria for IC include a voluntary decision, capacity to understand the relevant information, disclosure of all relevant information, and comprehension of the information [11]. Increasingly, however, a fundamental tension between the latter two criteria has been identified; pressures toward disclosing more relevant information may come at a cost to overall comprehension. Although evidence suggests that disclosure of relevant information has increased over recent years [12,13], so too has the length of IC documents [12,14,15], and many have argued that provision of too much detail in IC documents leads to a poorer process overall [14,16,17].

Efforts to assess IC documents [9,12,13,18−21] have most commonly focused on presence of specific elements within the documents, including (1) core study elements (e.g., rationale, procedures involved, risks/benefits), (2) specific rights (e.g., rights to withdraw, protection of confidentiality) [22−26], and (3) formatting recommendations (e.g., readability, nontechnical language) [23,25,26]. We believe such information is insufficient to ensure IC. Instead, we have argued for an alternative model, where a core goal of the process is ensuring a high-quality decision, defined as one that involves demonstrable knowledge of key aspects of the decision, accurate perceptions of the probabilities of outcomes, and a match between preferred outcomes and the choice made [27,28]. The patient decision aid literature has sought to achieve these ends in the context of treatment and screening decisions [28], and the current work continues our exploration into whether this approach can lead to a better IC process.

As a first step, we assessed IC documents from a random sample of clinical trials in light of a group of recommendations for creating documents that encourage good-quality decisions [decision quality (DQ) or DQ Standards]. These recommendations were based on the International Patient Decision Aids Standards instrument (IPDASi [29−31]), a set of validated, empirically supported standards describing how to encourage good-quality decision making. A sample of 139 IC documents showed less than 10% concordance with 15 of the 32 standards [32].

Despite poor concordance overall, there was considerable variation among IC documents in how well they conformed to individual DQ standards. Different possible explanations for this variation exist. One hypothesis is that concordance with DQ standards is simply determined by how detailed a IC document is; the more information a document provides, the more it is likely to include components conducive to encouraging a better-quality decision. If so, longer IC documents should be correlated with conformity to DQ standards. Another might be that IC documents that conform to existing IC recommendations will lead to better quality decision making; in essence, the degree to which an IC document serves to encourage a high-quality decision-making process is related to the extent to which it conforms to existing IC recommendations. If so, then documents that meet more IC recommendations will conform to more DQ standards.

This study describes the extent to which a sample of IC documents conformed to a range of IC standards (IC Standards; that is, recommendations for the content of IC documents suggested by policy and the IC literature ([22−25]) and whether conformity to these IC standards varied with IC document characteristics (length, readability) and study characteristics. We also sought to understand how well conformity to DQ standards were predicted by IC standards, IC document characteristics (length, readability), or study characteristics (phase of study, clinical area, country of origin).

2. Methods

Analyses for this study are based on the same sample of IC documents described in our previous work [32]. DQ items are described in more detail in the previous study. The present study describes the IC items and their association with a subset of DQ items.

2.1. Item identification

We detailed the process of DQ item identification in our previous study [32]. In brief, we began with an initial set of 47 items organized in 10 domains comprising the IPDAS instrument (IPDASi) by Elwyn et al. [30], an instrument originally designed and validated to evaluate the quality of decision support tools designed for treatment and screening decisions. We went through an iterative process to identify items that fell outside the scope of our study, did not apply well to the IC document application, or overlapped with other items. A total of 17 items were dropped based on this process. Another seven items were added based on team discussions around how to apply IPDAS principles in the IC document context. Several items were split into multiple items, or merged into a single item, to improve clarity for coders. The result was 32 items, organized into five separate domains. Based on previously reported findings [32], a number of the items showed little or no concordance across our sample of IC documents and so were not included in the current