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Informed consent documents do not encourage good-quality decision making

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Abstract

Objective: Informed consent for research has emphasized information provision over support to people making a difficult decision. We assessed the extent to which existing informed consent documents (ICDs) conform to the International Patient Decision Aid Standards for supporting decision making.

Study Design and Setting: One hundred thirty-nine ICDs for trials registered with ClinicalTrials.gov were obtained from study investigators. Using a four-point scale, two raters assessed each ICD on 32 items.

Results: Overall agreement between raters was 95.1% (linear weighted kappa—0.745). For 12 items focused on providing enough information, conformity was above 50% for three, and 0% for another four. For all eight items focused on how to present outcome probabilities, conformity was below 20%. For two items focused on clarifying and expressing values, conformity was below 10%. For two items focused on improving structured guidance, conformity was below 5%. For four items focused on using evidence, one item showed conformity of 74%; all others showed conformity below 5%. For four items focused on transparency, conformity was high (above 60% for two, above 80% for the others).

Conclusions: Existing ICDs do not meet most validated standards for encouraging good decision making. These standards make clear predictions about how one might improve ICDs ensure that research participants are fully informed.

Keywords: Informed consent; Decision making; Trial participation; Decision aids; Research participants; Clinical trials

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1. Introduction

Informed consent is a cornerstone of ethical clinical research, yet appropriately informed consent for all research participants can be an elusive goal. Examples of clear failures of informed consent are abundant [1−14]. Changes in privacy legislation in Canada and the United States [15,16] have had the effect of adding length and complexity to informed consent documents (ICDs), rather than reducing them [17,18]. A systematic review of efforts to improve the informed consent process showed that many common approaches to improving informed consent are ineffective or have been tested in studies that are methodologically flawed [19]. To achieve the aims of informed consent for research, a systematic approach to improving research participation decisions is warranted.

We have argued that there are three important weaknesses in the literature that have impeded progress in improving informed consent [20]. First, studies often focus on efforts to improve the documents themselves, rather than on understanding and improving the broader process of informed consent. Second, lack of clarity around what is meant by study comprehension has led to different, often incompatible operationalizations of a key component of informed consent. Third, most work on ICDs has lacked a solid theoretical foundation, making it difficult or impossible to determine whether successful interventions can be generalized to other settings or whether failed interventions might be refined [21].

Patient decision aids are designed to evoke a specific, deliberative process of decision making, allowing people to make explicit choices among clearly described options [22]. Patient decision aids not only present the information relevant to the decision, but also prompt decision makers to compare the different decision options, determine which issues are most important to them, and establish what additional information they need. They also provide materials to facilitate later review and consultation. In essence, patient decision aids provide a tool that organizes the entire process of decision making, rather than one that simply provides information. Their effectiveness in improving decision making in many clinical contexts is well documented [22]. Decision aids are being implemented at a population level, including in Canada, where the British Columbia Health Guide [23] includes decision aids as a standard approach for presenting information about common health concerns and in the United States, where in 2007 Washington State passed legislation requiring patient decision aids for elective surgical procedures [24].

In addition to facilitating the process of decision making, use of patient decision aids has two other potential benefits in the context of informed consent. First, they provide a clear, validated conceptualization of what is meant by a ''good quality decision''; from this perspective, such a decision involves demonstrable knowledge of key aspects of the decision, accurate perceptions of the probabilities of various outcomes, and a match between preferred outcomes and the choice made [25]. Second, through the International Patient Decision Aids Standards (IPDAS) [26], a set of empirically derived, consensus-based standards for good decision making, decision aids provide a framework against which one can measure the quality of existing informed consent interventions. This enables principled recommendations for improving such interventions.

In this study, we assessed the extent to which existing ICDs conform to IPDAS standards for designing decision aids. By examining where ICDs do and do not make good decision aids, we hope to spark discussion about which aspects of the decision aids approach may be appropriate for application to ICDs.

2. Methods

2.1. Identifying items

Elwyn et al. [27] derived the IPDAS instrument (IPDASi) [27] from a larger, consensus-based IPDAS checklist [26]. The IPDASi was specifically developed to provide reliable and valid quantitative assessments of the quality of decision support tools (DSTs). It includes 47 items in 10 domains: providing information about options, presenting outcome probabilities, clarifying and expressing values, structured guidance in deliberation and communication, systematic development process, using evidence, disclosure and transparency, using plain language, evaluation, and information around tests or screening decisions. When combined, these 47 items produce a reliable and valid estimate of the quality of the evaluated decision aid [27].

We examined the 47 IPDASi items for relevance to ICDs. Appendix 1 describes in detail our item development process. We first reworded all items to apply to ICDs: ''Decision Support Tools'' was replaced with ''Informed consent documents,'' ''index decision'' was replaced with ''decision whether or not to participate in the trial,'' and ''decision options'' was replaced with ''both options (participate in the trial or not).''

Of the 47 IPDASi items, 17 were dropped because the team agreed that they did not generally apply well to most ICDs (e.g., the ICDs includes information about the chances of having a false positive test result''); another six items were dropped because of overlap with other items, either those reported here or a separate set of 27 items drawn from consent form standards, results from which will be reported separately. We added seven items based on study team discussions around how to apply IPDAS principles in the ICD context (the ICDs describe the disadvantages of participating in a consistent order; describe the disadvantages of nonparticipating in