**Using decision aids may improve informed consent for research**

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**A B S T R A C T**

This commentary argues that the existing approach towards obtaining informed consent for clinical research may be improved by using decision aids. Problems with the current approach include i) an emphasis on documentation to the detriment of good quality decision-making; ii) ad hoc rather than theory-based research studying how to improve informed consent; and iii) a lack of clarity around what is meant by ‘comprehension’ and how to measure it. Decision aids, which clearly improve patient treatment decisions but are new to decisions surrounding study participation, have strengths in precisely the areas where the informed consent literature is weak. Decision aids facilitate a process of decision-making, combining clear documentation, exercises to facilitate decision-making, and consultation. They are increasingly informed by theory and clear, empirically-derived standards. Furthermore, decision aid research has clearly defined and operationalized three indicators of good quality decision-making in situations where there is no objectively correct answer: 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. We identify outstanding issues and propose a research approach that will determine whether the use of decision aids can improve the informed consent process.

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The existing approach towards obtaining informed consent from research participants is flawed, and needs to be re-examined. Accumulating evidence shows that research subjects frequently fail to understand basic components of the research to which they have consented. Progressively more stringent regulations about disclosure to potential research subjects have led to longer, more complex consent forms, but these changes may have lessened rather than increased understanding among research participants. Regulators \([1,2]\) have begun to acknowledge the problem by recommending that informed consent focus not just on a document, but on the process of decision-making. Unfortunately, alternative approaches that move beyond complex consent forms as the chief vehicle for informed consent have yet to emerge. Below we argue that patient decision aids, which have been shown effective in improving patient treatment and screening decisions, may provide one such approach.
1. Problems with the existing approach to informed consent

Problems arising from the current informed consent process are not minor, sporadic, or limited to technicalities of specific studies. Participants often enter clinical studies without understanding basic principles of the research. A recent review [3] cited several examples, including 44% of participants in a randomized trial of β-blockers not understanding that they were assigned to treatment or control by chance, and 30% of patients in a review of oncology trials believing their treatment had already been proven as the most effective treatment for their cancer. While such examples may be extremes, variability in the extent to which people understand the studies in which they are participating is almost certainly the norm, with many participants not understanding enough to satisfy even liberal interpretations of informed consent. And it’s not just a matter of putting the relevant information into the consent forms; even when consent forms have the requisite information [4], that information is not being transferred to participants in any meaningful way under standard informed consent processes.

Three primary problems have hampered efforts to improve informed consent. First, empirical work has emphasized improvements in documentation rather than the process of decision-making. While clear documentation serves a variety of useful purposes [5], it is insufficient to support adequately informed decisions [6]. Indeed, evidence suggests that efforts to improve the process of decision-making, for example through improved discussions with study personnel [3] or improved communication skills [7,8] are more likely to be effective than modifications to documentation. Second, most efforts to improve informed consent involve ad hoc interventions that lack any theoretical foundation. For example, of the 42 trials included in the above-mentioned review [3], only one mentions any theoretical framework motivating the work. Without understanding the causal, ‘active ingredients’ underlying different interventions, it is difficult to predict whether successful interventions will generalize, or how failed interventions might be improved [9]. Third, there has been a lack of clarity around the normative standards – and hence appropriate measures – for comprehension. While basic elements of informed consent may be derived from various regulations, which of these key elements are ethically essential to being ‘informed’? Should the criterion be subjective comprehension (whether a participant feels informed), objective and demonstrable comprehension, or both? When should comprehension be measured: at the time of the decision to participate, or throughout participation? Should comprehension be operationalized by recall, given that the two concepts are clearly dissociable? This lack of clarity has led to widely varying operationalizations in this literature.

2. The promise of decision aids

Research on decision aids is promising precisely in the areas where the informed consent literature is demonstrably weak. First, decision aids inherently focus on process rather than documents. They help people make specific, deliberative choices among options, use exercises to explicate what issues they find most important, help determine what further information they need, and provide materials that can be used later for further review and consultation. Second, while decision aids have had a similar history of development without proper input from theory [10], important strides have recently been made in the form of the International Patient Decision Aid Standards [11]. These empirically-derived, consensus-based standards for good decision-making provide detailed recommendations about how to facilitate good decisions, many of which are applicable (and testable) in the context of trial participation decisions. Finally, decision aid research has identified and operationalized three key indicators of ‘good decision-making’ in situations where there is no objectively correct answer: 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 [12]. These empirically validated indicators can serve as a basis for a more consistent measure of what the goal of the informed consent process should be [13].

Within the context of patient treatment decisions, decision aids have been extensively tested, with over 60 trials of their effectiveness complete or in progress [14]. They have been shown to improve the quality of decisions for patients making many difficult treatment decisions (e.g. lumentectomy/mastectomy for breast cancer, hormone replacement therapy, prostate cancer screening and treatment), both in comparison to information documents, and to standard counseling strategies. In the context of informed consent, however, decision aids are almost entirely novel, although early research efforts are under way [15,16].

Because of their novelty in the area of informed consent, there are many questions about using decision aids that will need to be addressed empirically. Which components of decision aids are most helpful in the context of informed consent decisions? How should the decision options (e.g. participate/don’t participate; Drug A, Drug B, or randomize to A or B) be organized? [17] Will incorporation of decision aids into the informed consent process increase the burden on recruiters and recruits, and if so, for what situations should the benefits outweigh such burdens? How should research ethics boards review decision aids? How will the decision aid approach best be applied to special circumstances such as proxy or deferred consent, urgent care, patient deception, or early vs. late phase trials? Furthermore, identifying the decisions best suited to decision aid support should be a priority. It seems unlikely that decision aids will be warranted in all clinical studies. Just as they are considered most useful for treatment decisions where evidence is unclear or patient uncertainty is high, so too will they likely be best suited to a subset of research participation decisions, perhaps where possible outcomes are numerous, where study designs are complex, and where potential consequences of different choices are important.

A systematic, theory-informed program of research is the most efficient route to a more effective informed consent process. While we believe that decision aids have the potential to greatly improve the informed consent process, immediate and uncritical application of decision aids would result in an ad hoc, piecemeal literature that held few generalisable lessons. Instead, preparatory research should take several forms. Evaluations of existing informed consent materials
could include comparisons to principles of good decision-making set out in the decision aid literature, and thereby identify how decision aids can best facilitate the existing process. Interviews eliciting the experiences of trial participants and non-participants across a range of clinical areas could be examined to identify common problems of informed consent that might be targeted within a decision aid. Detailed, systematic, iterative development, including field-testing on both potential participants and their providers, will be required to optimize decision aid methodology for use in this new area. Finally, when trials of decision aids for consent are carried out, they should include the range of outcome measures known to be related to decision quality (e.g. decisional conflict, decision satisfaction, preparation for decision-making, decision regret), as outlined in the decision aid literature.

References