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Can we make informed consent forms more informative?

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Respect for the individual is a fundamental ethical principle of human subjects research. While informed consent is an essential component of clinical research, it remains unclear how to ensure that consent for study participation is truly informed. Many studies have reported poor comprehension about research information among patients following informed consent discussions. The ethics of informed consent are even more complex in pediatric clinical research, where parents must make proxy informed consent decisions for their children.

Informed consent forms supplement informed consent discussions as an additional source of information for patients who are considering research participation. An informed consent form should contain sufficient and accurate information to ensure potential participants (or their proxies) are equipped to make a valid decision about a given research study. However, these documents have become progressively longer over time,[1] largely in response to increasing regulatory requirements. As a result, key study information can be hard to find, and current informed consent forms often fail to achieve their primary purpose: to inform.

Many proposed interventions to improve informed consent forms have focused on either increasing or condensing the information presented. To date, these strategies have been largely unsuccessful at enhancing participant understanding. While multiple studies have demonstrated that shorter informed consent forms are as effective as longer forms for participant understanding,[1] shorter forms do not represent an improvement per se. Among parents consenting for their children to participate in pediatric studies, interventions such as a summary synopsis cover form have not led to significant improvements in parent comprehension.[2]

It is possible that using alternative methods to present information affects comprehension more than changing the amount of information presented. Tait et al. found that improved formatting and use of graphical displays were two communication strategies that improved parental understanding of key research elements presented in an informed consent form for a hypothetical trial.[3]

In this issue of Archives of Disease in Childhood, Fetal Neonatal Edition, Koonrunsesomboon et al. present results of their randomized clinical trial of a novel informed consent form based on the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER).[4] The SIDCER outlines three basic principles for an informed consent

form: it contains all required elements for relevant ethical regulations and guidelines; it provides only the relevant information for a subject's decision making on study participation; it presents information in a simple format to convey the relevant information to the target population.[5]

In this nested trial, the investigators enrolled pregnant women at risk for preterm delivery who were approached for antenatal consent for their unborn infant to participate in one of two randomized trials of umbilical cord management at birth. The investigators randomly assigned enrolled women to receive the traditional informed consent form or a modified SIDCER informed consent form for the umbilical cord management trial. In contrast with the traditional informed consent form, the SIDCER informed consent form was shorter, had additional text formats (such as highlight keywords and summary text boxes), and included illustrations.

After each woman read the allocated form and had the opportunity to ask questions, the investigators assessed her understanding of trial-related information via a closed-ended questionnaire. Compared with women who read the traditional informed consent form, significantly more women allocated to the SIDCER informed consent form answered at least 80% of items on the questionnaire correctly. Encouragingly, these effects were most pronounced among women with lower educational attainment (high school or less). Within this stratum, 64% of women assigned to the SIDCER informed consent form scored at least 80% on the questionnaire, compared with only 44% of women who read the traditional informed consent form.

These findings are important for several reasons. First, the authors demonstrated that the SIDCER informed consent form improved parental understanding for an actual clinical trial, rather than a hypothetical study.[3] In addition, the treatment effects of SIDCER form were more pronounced among women with lower educational status, a population that is disproportionately affected by poor comprehension of research information. Last, the intervention is relatively straightforward to implement and does not require additional time and cost to the study team for each encounter.

While the principles of the SIDCER form are potentially transferable to other neonatal trials, it remains to be seen if these results will lead to improved parental comprehension or recall in different clinical research settings. Koonrungsomboon et al. conducted their trial in pregnant women attending an outpatient antenatal clinic. The impact of the SIDCER consent form might differ when presented to anxious women facing imminent preterm delivery or scared parents of a critically ill newborn.

Next, enrolled mothers could ask unlimited questions about the research study while reading the informed consent form, but the informed consent forms were not provided to the mothers in the context of a dedicated informed consent discussion. There is a difference between presenting key elements of a research study during an inclusive research conversation and simply responding to a potential participant's questions. It is unclear if the SIDCER form would have the same impact on parent comprehension if both groups had received more comprehensive counseling prior to or while reading the informed consent forms.

Last, although more mothers assigned to the SIDCER informed consent group met the threshold 80% correct response rate for all elements on the questionnaire, they demonstrated worse comprehension of the concept of random treatment allocation compared with parents who read the conventional form. The authors speculate that the colloquial phrasing used to describe random allocation in the conventional informed consent form (“flip of a coin”) may have been more effective than the wording used in the SIDCER informed consent form. This finding suggests that both the content and presentation of information on the informed consent form have an impact on comprehension.

Ultimately, Koonrungsomboon et al. have demonstrated that concise and enhanced methods of presenting information on an informed consent form improve parental understanding of research information in a low resource setting. If these results generalize to other settings, application of the SIDCER principles could represent a low-cost and simple method to make informed consent forms more informative for their readers. Given the fundamental role of informed consent in human subjects research, this is a potentially significant advance for parents and investigators involved in neonatal clinical studies. In the future, investigators, regulatory bodies, and ethics boards may well consider the way information is presented on informed consent forms rather than just the printed words themselves.

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