Envisioning a Health System without Necessary Informed Consent

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INTRODUCTION

Ever since the publication of the Belmont Report and the adoption of the Declaration of Helsinki by the medical community, the cornerstone of ethical human experimentation has been the obtaining of informed consent from the research subject. The emphasis on this necessary, primary step in conducting safe research on human subjects has placed a great duty on the shoulders of clinical researchers—making sure that the subject is aware of and comprehends the various benefits, risks, and procedures involved in the study. Putting the onus of subject safety on the shoulders of researchers and overseers has been an ongoing effort to prevent the kind of unethical activity that has tainted the history of medical research.

ANALYSIS

However, according to a commentary published in the latest issue of the *New England Journal of Medicine* and written by a trio of renowned leaders in bioethics, full informed consent should not be ethically necessary for all kinds of health research. In the piece, Tom L. Beauchamp, Nancy Kass, and Ruth Faden make the argument that acquiring informed consent from a patient can be burdensome and time-consuming in some cases, resulting in a situation that is potentially more harmful than beneficial. “Learning healthcare systems” and randomized comparative effectiveness research (CER) are two such cases that the authors address in their commentary. As described by the Institute of Medicine (IOM), learning healthcare systems are dynamic systems in which the effectiveness and quality of future clinical care is reliant upon the results of continuous research in clinical practice. CER involves the assignment of patients into random treatment groups for the sake of testing and comparing widely accepted and safe interventions. It is within these learning systems that CER could be improved by simplifying the consent process or foregoing informed consent entirely.

The authors note that this is not possible within the current healthcare system, which lacks the sufficient safeguards to make such an approach ethically acceptable. What is missing from today’s system in their eyes is adequate “patient engagement,” in which patients are represented on the ethics committees that approve clinical research. Patients and their advocates are in the best position to recognize when a research study will benefit them or future patients, and the focus on incorporating patient engagement in the approval stage would signal a significant step forward in giving them an increased role in the development of clinical care.

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CONCLUSION

What drove this push toward patient engagement is the sentiment shared by the authors that: "Current consent and oversight practices too often overprotect patients from research that has little impact on what matters to patients, while in other cases oversight practices underprotect patients from medical errors and inappropriate medical management." Therefore, research proposals that pose no negative effects to the clinical outcomes that matter to patients would not be required to obtain informed consent, but researchers would instead have to provide a "public notification" to the patient community. Studies resulting in minor but still meaningful effects would be conveyed via oral consent procedure, with the patient having the option to decline participation; studies with possible negative effects would require written, informed consent. The authors provide two examples of research that would fall under the consent-exempt and oral consent categories. First, comparing the effectiveness of using email or text messages as medication reminders to patients; and second, comparing two commonly used medications for hypertension, with physicians being able to make alterations to the medication at any time.

IOM has made a concerted effort and called on healthcare leaders to begin the transformation of their health systems into learning healthcare systems, capable of taking what is learned through clinical research and incorporating it into the improvement of efficiency and quality. This will require a clear integration of the ethical oversight that is predominant in the field of clinical research and the ethical discretion involved in clinical practice. Beauchamp, Kass, and Faden's commentary seems to find a significant way of blending the two frameworks cohesively so that ethical consideration is still given to research endeavors, while streamlining what can be a convoluted consent process.

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