Experts discuss ways to embed patient voices and values in clinical research

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There is worldwide concern in the biomedical research community that enrollment in clinical trials is lagging, putting clinical research and consequent benefits to society in jeopardy. Experts explore ways to embed patient voices and values in clinical research in the current issue of *Mayo Clinic Proceedings*.

Clinical trials of new drugs, devices, or procedures require the active participation of human volunteers. Mark A. Yarborough, PhD, of the Bioethics Program, University of California Davis, calls for greater transparency about the social value of research in recruiting patients to participate in clinical trials, as part of the initial informed consent process.

"Not all clinical research is equal," Dr. Yarborough says, comparing research into the use of stem cells to improve the life of Huntington's disease patients with "me too" drug studies that are competing with existing and effective (and often cheaper) medicines to treat conditions such as hypertension. "Clinical research has produced a lot of good, life-improving and life-saving drugs that have really improved the lot of patients. But we need to remain mindful that some trials are more deserving of public trust than others." He proposes the incorporation of a clear declaration in informed consent forms that states whether a trial is investigating a way to potentially improve current medical care and explains why it does or does not have the potential to do so.

"We owe the public honest disclosure about why any given trial is being

conducted so that they understand the extent to which a trial, if completed, could promote the common good," Dr. Yarborough explains. "The informed consent process is one way to provide this disclosure to prospective research participants."

Yarborough acknowledges that there may be critics but, he continues, "One possible good outcome is just to have discussion about transparency about the research setting. I hope a consensus will emerge from this conversation that increased transparency will help to build the public's trust."

In the same issue, investigators at the Cleveland Clinic and McMaster University report on a prospective observational trial to explore the effect of the timing of obtaining consent. They monitored the timing of seeking informed consent for a moderate- to high-risk trial of clonidine and aspirin in patients undergoing non-cardiac surgery and found that, contrary to expectations, patients did not have increased anxiety or decreased understanding if they are asked on the same day as the surgery is due to take place.

"This is the first study, to our knowledge, to specifically compare the impact of consenting on the day of surgery with consenting before that time on patient comprehension," observes lead investigator Daniel I. Sessler, MD, of the Department of Outcomes Research, Cleveland Clinic. "From a practical perspective, consenting before the day of surgery appears preferable, but proposing moderate- to high-risk research on the day of surgery itself does not compromise essential elements of the consent process."

In an accompanying Editorial, Barbara A. Koenig, PhD, of the Institute for Health & Aging, University of California, San Francisco, notes that both articles focus on just a single component of human research protection: the informed consent process. "We must reform a system

that valorizes the informed consent process to the exclusion of other elements of human research participant protection," says Dr. Koenig.

"I applaud efforts to conduct empirical research interrogating standard informed consent practices and we need more well-designed studies," Koenig comments, referring to the study by Sessler and colleagues. "However, current efforts to reform the conduct of human research rest too heavily on revising the informed consent process and place too much emphasis on disclosure of risk or potential researcher conflict of interest to the human research participant, to the relative exclusion of other equally important or potentially more important components of the research approval process."

Koenig also questions whether explaining the social value of a clinical trial to research participants is the answer. "Although I share Yarborough's desire to make certain that the social utility of research is highlighted ... his disclosure-based reform assumes that individual patients, confronted by information and data, will 'just say no' to research that lacks social value, in the same way they might seek to minimize personal risk," she says.

Koenig believes that a renewed focus on promoting and enabling authentic ethical reflection as well as a new pathway for embedding patient values and voices into the practice of research is needed. "We cannot simply ask individual patients, unaided, to weigh risk levels and evaluate projects by themselves."

More information: "Commentary: Increasing Enrollment in Drug Trials: The Need for Greater Transparency About the Social Value of Research in Recruitment Efforts," by Mark A. Yarborough, PhD (dx.doi.org/10.1016/j.mayocp.2013.03.001).

"Protocol Understanding and Anxiety in Perioperative Clinical Trial

Patients Approached for Consent on the Day of Surgery," by Alexandra Chludzinski, BS; Crissy Irani, MD; Edward J. Mascha, PhD; Andrea Kurz, MD; P. J. Devereaux, MD, PhD; and Daniel I. Sessler, MD (dx.doi.org/10.1016/j.mayocp.2012.12.014)

"Editorial: Fixing Research Participant Protection in the United States: Moving Beyond Consent," by Barbara A. Koenig, PhD (dx.doi.org/10.1016/j.mayocp.2013.03.010)

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