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Recruiting participants for research: Simple explanations, queries from doctors are best

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While a debate was raging between scientists and government regulators on how best to explain to patients the risks of participating in clinical research studies that compare standardized treatments, a team of bioethicists boldly went where no experts had gone before—to the public.

What the respondents said surprised them: Keep it simple, but always ask permission, even when the research only involves gathering data from anonymized medical records.

"We didn't anticipate that people would want to grant permission for medical record searches, a research method that involves much less risk than most randomized studies that compare standard treatment options," said Mildred Cho, PhD, professor of pediatrics and of medicine at the Stanford University School of Medicine. "The good news was that most people said they would forgo documented consent or accept simple approaches to granting permission, even verbal permissions, if requiring written agreements would hinder this type of comparative-effectiveness research."

A paper describing the findings of the patient survey will be published April 14 in the *Annals of Internal Medicine*. Cho, who is also associate director of the Stanford Center for Biomedical Ethics, is the lead author of the paper. Benjamin Wilfond, MD, professor and chief of pediatric bioethics at the University of Washington School of Medicine, is the senior author.

The findings will be used to inform the U.S. Office of Human Research Protections and the Food and Drug Administration as they develop regulations on how to structure patient permissions for research conducted during mainstream clinical care and through mobile devices.

The participants' perspective

The survey was the work of the Research on Medical Practices project, or ROMP, which was launched in the aftermath of a controversial research-consent form used in a study that compared two oxygen-delivery levels for extremely premature babies. While many researchers and bioethicists argued that the research was done in an appropriate fashion, others disagreed.

Even though these at-risk infants were randomly assigned to one of two standard treatment options, some people felt that the clinical risks of standard practices should be disclosed as research risks. Researchers, the public and the bioethics community were deeply divided about whether the consent form adequately warned parents about participation risks. The ROMP study was designed to gather evidence on patient attitudes toward risks and how to best ask for permission to conduct this type of research.

"Creating burdensome consent regulations for minimal-risk research may impede the collection of valuable medical evidence without actually increasing the protection of participants," said David Magnus, PhD, a co-author of the study and the director of the Stanford Center for Biomedical Ethics.

Cho, Magnus and other researchers involved in the project began collecting data in August 2013 through a Web-based survey of 1,095 adults. The survey included questions about attitudes toward research, doctors and health systems, as well as questions to assess understanding

of research concepts, such as variations in prescribing patterns among physicians, randomization and informed consent. The survey also asked questions about preferences for being notified about studies, and their perceptions of risk and willingness to participate in the context of three scenarios. The three scenarios were presented in videos, which are available on the ROMP website.

During the process of developing and testing the videos and survey, the bioethicists learned a great deal about the best way to educate patients on medical research, Magnus said. "One of our first challenges was to dispel the 'doctors know best' myth. Doctors don't always know which treatments are best for individual patients," he said. "In the absence of good evidence, these choices are often influenced by advertising, insurance coverage and local preferences. Busting this myth was essential in explaining why comparative-effectiveness research is so important."

Hearing it from their doctors

One interesting survey finding was that people preferred that their doctors, rather than medical researchers, ask them whether they'd like to participate in research. This runs counter to conventional wisdom in the research community, where the participation of doctors in the recruiting process can be viewed as a potential conflict of interest.

For supporters of comparative research in clinical settings, it was encouraging to learn that 97 percent of the respondents agreed that health systems should conduct this type of research. "I think that patients really want us to make it easier for them to participate in research," said Magnus. "As medical research evolves, the ways that we engage and inform patients must evolve, too."

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