Clinical Research and the Public: If Not Them, Who?

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Institutions with Clinical and Translational Science Awards (CTSAs) are charged with facilitating and accelerating the conduct of translational clinical research. They, and all institutions engaged in clinical research, have focused on reducing the many logistical hurdles to conducting trials. However, the lack of public engagement in clinical research ultimately may be the greatest hurdle.

Indeed, logistical challenges to clinical trials are protean. Steensma¹ recounted the gauntlet for cancer clinical trials as reported by Dilts and Sandler,² for which the median time from conception to trial activation was 784 days; preactivation included 370 distinct processes (317 work steps, 42 decision points, and 29 processing loops), 63% of which were beyond the direct control of the principal investigator. And that is only the tip of the iceberg; a near-infinite number of things can prevent or abort a trial. But even that iceberg has no ocean in which it can float without the irreplaceable need for clinical trials: participants. No subjects, no study!

There is increasing attention to improving clinical trial processes in the United States, and the CTSA Consortium members are leaders in this effort, which will be very challenging and very expensive. Yet these advances will have minimal impact if we do not engage the public in the clinical research enterprise.

There are many reasons patients and the public do not volunteer for clinical research, and for certain groups, additional historical, conceptual, and logistical reasons. The net result is that a very small proportion of potentially eligible study participants are enrolled; 7% of Americans participate in clinical research.³ Data from a survey by Research!America⁴ give some sense of the problem and its paradoxes. In addition to confirming the low trial participation rate, the survey found that only 6% of the patients reported that their physicians even suggested participation in a clinical trial. Yet 30% said that, if asked, they were *very likely* to participate, and an additional 44% said they were somewhat likely to participate. Moreover, 58% considered clinical research to be of great value (and an additional 38% to be of some value), 92% felt research is important to the US economy, and 70% thought we should be spending more of our health care dollars on research. Thus, the public values and supports clinical research but patients and doctors do not engage in its conduct. And no subjects, no studies!

Research advocacy organizations have jointly promoted funding for clinical research, and CTSAs, academic health centers, and others have worked to facilitate the processes of translational clinical research, but efforts to engage the public have been less coordinated and, to date, less successful. Efforts, such as those by the Center for Information and Study on Clinical Research Participation (CISCRP) (www.ciscrp.org)

and the CTSA Consortium Research Match (www.researchmatch.org), have attempted to provide resources and venues for engaging the public in clinical research. Also, CISCRP focuses on educating and engaging not only the public, but also all other stakeholders in the clinical research enterprise, including health care providers. It is clear that no single organization or initiative can solve this problem. It will require collective coordinated action by public and private entities, by the public and the professions, in implementing initiatives and communicating messages that are consistent and aligned. As clinical researchers, clinicians, and citizens, this broad effort needs our help.

These efforts should inform the public about the processes and benefits of clinical research, and should promote participation in trials as citizenship, community service, and self-interest. However, to succeed on the scale that is needed—and multiples of the proportions of the public now involved are needed—there must be direct public engagement in the research process. CTSAs, practice-based research networks, and community-engaged research sponsored by the Centers for Disease Control and Prevention, National Institutes of Health, Agency for Healthcare Research and Quality, and the Veterans Administration all have this on their agenda, but the proportion of the overall US population so-engaged still is small. Leaders in comparative effectiveness research cite the importance of engaging the public in formulating research questions and clinical outcomes,^{5,6} but such efforts still are limited and just developing. Nonetheless, lessons from these experiences and the increasing numbers of people involved should help promote understanding of and engagement in clinical research.

Will this be enough to improve public engagement in clinical research? It is impossible to know. What is clear is that we need to learn which approaches really work. Recently, I saw billboards and bus signs encouraging participation in clinical research in the local CTSA. We see on hospital and disease-specific websites the opportunities to engage in clinical research. The CTSA Community Engaged Research Key Function Committee provides consultation to others' efforts to engage the community in their efforts. At Washington University's CTSA, outreach by "HealthStreet" have tried to address the fact that especially the elderly, women, persons out of treatment, persons with mental health problems and addiction, and minorities are underrepresented in health research.⁷ They reach these individuals in venues such as parks, laundromats, beauty salons, and grocery stores, where they engage individuals based on their own health concerns and health history, and also refer them to medical and social services as needed. Tufts CTSA has outreach ranging from community health organizations to the Museum of Science. How much impact do such efforts

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have? Which of these or other approaches should be used nationally? CTSAs have this on their agenda,⁸ but knowing what are the most effective approaches requires study. Needed are carefully designed interventions of all types, with rigorously conducted evaluations of their impact, and then widespread implementation. Without this, even with massive improvement of processes and systems, the clinical research enterprise will fail: no subjects, no studies.

It should not be lost on those of us who do clinical research that in addressing this need, we have a chance “to do good and to do well.” This will facilitate our own research and its impact, and it will generate more public support for the research enterprise. The public is both the source of research participants and of support for research. If not them, who?

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