Commentary

Aligning Cultural and Financial Incentives for Clinical Trials

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One session of the November 2011 Institute of Medicine (IOM) workshop Envisioning a Transformed Clinical Trials Enterprise in the United States: Establishing an Agenda for 2020 focused on the need to develop new economic models for clinical trials and to change the environment in which they currently operate (IOM, 2012). The rationale for this approach is the general agreement that the present climate, in which clinical trials are carried out in the United States, is too expensive and organizationally complicated, resulting in fewer trials being planned, performed, and completed in this country. This fact has serious implications for the U.S. population. The presenters were asked to suggest new approaches that could reverse this situation.

Judith Kramer and Kevin Schulman, Duke University Medical Center, summarized their background paper (Kramer and Schulman, 2012). Their thesis was that advances in information technology (IT) combined with "business" transformation could significantly lower costs and ensure faster completion and better quality of clinical trials. They described the formation of a Clinical Trials Transformation Initiative (CTTI), which is a Food and Drug Administration (FDA)–initiated public–private partnership to identify practices that through broad adoption will increase the quality and efficiency of clinical trials. As an example, they described the possibility of significantly reducing the cost of on-site monitoring of clinical trials (25-30 percent of the trial cost) by centralized electronic monitoring of data. The widespread adoption of electronic health records (EHRs) and the introduction of smart phone–based research should be able to facilitate the transformation of the current inefficient clinical trial milieu.

The first panel speaker, Richard Rudick, Cleveland Clinic, discussed a proposal to integrate clinical trials, and clinical research more broadly, into the U.S. health care system. His thesis is that clinical research and clinical investigators cannot function, let alone thrive, if they are disconnected from the health care system. He stressed that, in his opinion, the public, political leaders, the medical and payer communities, and health system leaders do not adequately understand the causal relationship between clinical and translational research and medical advances, health care value, or public health. In addition, he described how this lack of alignment of clinical research and health care delivery has significant adverse financial implications.

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The second panelist, Chris Beardmore, Translational Research Management, discussed the need to clarify which payer is responsible for covering the costs of clinical trials and clinical research (e.g., health plans, biopharmaceutical companies, federal sponsors, or patients themselves). He commented on the important role that community oncologists play in clinical trials. He also stressed the critical need for increased investment in IT capability, particularly by biopharmaceutical companies. There would be immediate advantages if site information and investigator data could be standardized and moved to a central repository.

Scott Steele, Rochester School of Medicine, discussed the possibility of organizing consortia to deal with the challenges involved in improving the clinical research enterprise and especially to enhance its infrastructure (e.g., the National Institutes of Health, FDA, other governmental agencies, the pharmaceutical industry, patient advocacy groups, academic medical centers [especially through their Clinical and Translational Science Awards] and others). He also commented on the tension that may exist when participation in a clinical trial is superimposed on the doctor–patient relationship.

Arthur Rubenstein, Perelman School of Medicine, University of Pennsylvania, who chaired this session, opened the discussion by drawing attention to the fact that the current economic realities facing the United States will, almost certainly, require the necessary transformation of the clinical trials enterprise to be carried out in a financially constrained environment. He also agreed with the other presenters that there are major gaps in the understanding of clinical research and its link to improved health care, outcomes, and costs by the public, politicians, and other stakeholders. Louis Fiore, Department of Veterans Affairs (VA), pointed out that clinical trials are heterogeneous (e.g., those driven by pharmaceutical companies, those funded and organized by the NIH or the VA, institutional studies of clinical effectiveness, and others). Each has unique characteristics that require specific understanding and approaches to improvement. Sharon Murphy, a pediatric oncologist, raised a key question related to the integration of health care and research information. At present, EHRs do not accomplish this. Schulman agreed and commented on the lack of connectivity of EHRs. Janet Woodcock, FDA, discussed the enormous volume of paperwork generated by clinical trials and the negative impact this has on investigators and their organizations. Finally, Robert Califf, Duke University School of Medicine, added four points: 1) clinical trials are moving to foreign countries because they are cheaper and patient enrollment is more efficient there; 2) the importance of CTTI and the need to make the information on the ClinicalTrials.gov site as useful and valuable as possible; 3) keeping clinical trials in the United States generates jobs and enhances the clinical care of participants; and 4) young people will be much more likely to solve challenging IT problems, like interconnectivity, than the older generation of physicians and their colleagues.

In summary, even a rapid perusal of this session's background paper and presentations will make it clear that there are numerous interesting, creative, and fascinating ideas about how to align the cultural and financial incentives of clinical trials with an emphasis on making them more productive and cost-efficient. The challenging problem, however, is how to translate these transformative ideas into practice, so that the system actually does change in major ways and the old way of doing business is creatively destroyed. There are hopeful initial examples indicating that these new approaches may take hold, but there is also a sober realization that there is a very long way to go before a new system is firmly in place.

References:

IOM (Institute of Medicine). 2012. *Envisioning a Transformed Clinical Trials Enterprise in the United States: Establishing an Agenda for 2020: Workshop Summary*. Washington, DC: The National Academies Press.

Kramer, J., and K. Schulman. 2012. *Transforming the Economics of Clinical Trials*. Discussion Paper, Institute of Medicine, Washington, DC. http://www.iom.edu/Global/Perspectives/2012/TransformingEconomics.aspx (accessed May 4, 2012).