The IOM Report on NCI Clinical Trials

A personal commentary from the community perspective

by John E. Feldmann, MD, FACP

The Institute of Medicine (IOM) recently released a long awaited report on the NCI clinical trials system entitled "A National Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program." This publication is available in print and online (*www.iom.edu/Reports.aspx*), and it is well worth the time spent looking through its many recommendations. I had the pleasure of attending the initial meeting on this project, chaired by Dr. John Mendelsohn, that was held in Washington, D.C., in July 2008. I spoke on the second day concerning the increasing financial and regulatory pressure being brought on community programs and emphasized that the valuable contribution brought by investigators in private practice might soon be lost.

The report ultimately issued by the IOM clearly points out many of the problems and summarizes a variety of recommendations. I can tell you, though, that the mood at the conference itself was one of complete frustration with the whole clinical trials process. Everyone who needed to be there was represented and no one was happy with the present system.

Several areas received much attention. Early in the meeting, David Dilts presented work he had done at Vanderbilt University on the length of time required to start a clinical trial after its initial inception. This study was measured in years, and the process was hindered by multiple reviews requiring multiple revisions. As a result, about half of all clinical trials never even opened, despite an enormous amount of time and money having been spent. Attendees expressed frustration at the poor design of many studies and the tendency to add irrelevant ancillary studies—something we all realize as a problem in community centers.

Regulatory issues were discussed in detail. As usual, there was finger pointing in all directions with no one taking primary responsibility for this problem. For example, when the issue of massive (and useless) piles of safety reports was discussed, industry tended to blame the FDA, while the FDA claimed there was no policy requiring this and blamed industry. The NCI put forth its Central IRB as a possible solution for some of the regulatory burden, but others pointed out that local IRB oversight is still required so the volume of regulatory documents is unchanged. I was left with the impression that little would be done in the near future to resolve many of these problems because the regulatory function for clinical trials is spread among several different government agencies and each is protecting its turf. Yet, this very real set of problems contributes to the difficulty of participating in trials at the community level.

In the final report, the Committee did include a very pertinent section addressing problems in the community setting. I was happy to see these recommendations. Even if these are not implemented, they recognize the importance of community physicians' participation over the years in the NCI research effort. Many physicians have realized the importance of these trials and have continued to participate, rather than turn exclusively to more profitable industry trials. The IOM report recognizes that the unfunded time spent preparing these trials, getting them through the regulatory hurdles, and continuing what may be years of important follow-up is clearly not adequately reimbursed. Meanwhile, pressure to reduce expenses and increase productivity is present in both private practice and hospital settings, reducing the enthusiasm of even the most avid investigator.

In its final recommendations, the Committee pointed out this underreimbursed time very clearly. It called for increased NCI funding specifically directed at two areas. First, it proposed increased reimbursement for each trial to compensate for the overall increased expense in setting up and managing the study. Second, it suggested additional funding for principal investigators that recognizes the added time they spend on regulatory and quality issues. In addition, the Committee proposed that the American Medical Association (AMA) develop a new CPT-4 code requiring Medicare and third-party payers to reimburse the additional time spent in getting informed consent and coordinating follow-up care. This latter suggestion is quite unique, but it does hinge on third-party payers and CMS truly recognizing the value of clinical trials. Based on some of the comments made at the meeting, I don't think that situation exists at present, but this may be in part because the inefficiencies of the current NCI trials system create the appearance of waste rather than of a value added.

Having been involved in clinical trials in the community setting for more than 35 years, I have seen these problems recognized and solutions proposed more times than I can count. Basically, I agree with the feelings expressed by the IOM Committee that a complete overhaul of the system is necessary. Each part of the clinical trials process should be examined to see if it really is essential to the conduct of research. Unless this overhaul is done, we will always face the situation so well described years ago by a cartoon character named Pogo who said, "We have met the enemy—and they is us."

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