

29 The Future of Clinical Research: An AAMC Perspective

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This chapter will discuss initiatives at the American Association of Medical Colleges (AAMC) in the last two years that deal with clinical research. Clinical research is an inextricable link between advances in medical research and technology and improved health care.

The AAMC believes that clinical research is a component of medical health research intended to produce knowledge valuable for understanding human disease, preventing and treating illness, and promoting health. This definition embraces a continuum of studies involving interaction with patients, diagnostic clinical materials on data, or populations, in any of these categories: disease mechanisms; translational research; clinical knowledge, detection, diagnosis, and natural history of disease; therapeutic interventions including clinical trials; prevention and health promotion; behavioral research; health services research; epidemiology; and community-based and managed care-based research.

Clinical research is currently challenged in several ways. Many exciting opportunities are coming from advances in biology and technology, such as functional imaging, information technology, and changes in the health system. We now have systems like HMOs (health maintenance organizations) that can begin to chart the effectiveness of care and implement various strategies and control for different approaches to prevention. We are also in a period of robust growth in the budget of the National Institutes of Health (NIH). The pharmaceutical indus-

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try has been a major investor and is now a more significant investor in clinical research, but, in addition to these opportunities, clinical research is being challenged by the financial impact of managed care and Medicaid regulations on academic medical-center revenues. This translates at the faculty level into a shortfall in time and resources. We also see growing public concern about our systems for protection of human subjects, along with conflict of interest issues. We need a sophisticated work force that can take advantage of the scientific opportunities. There are public expectations that clinical research will yield substantial advances in the health of the public.

AAMC, along with the American Medical Association and the Wake Forest University School of Medicine, called together "The Clinical Research Summit," in 1990-1999. Seven foundations supported it. It brought together ten focus groups, each consisting of different stakeholder communities. The insurance and managed care industry, the corporate and government purchasers of health care, and patients and patient advocates, non-physician clinical researchers, basic scientists, and five groups of clinical research physicians at different levels of experience, constituted the ten focus groups. The results of each focus group were summarized and representatives from each focus group were convened in a consensus-development conference. Nine problem areas were identified and agreed to by consensus conference. One, there is no agreed-upon definition of clinical research. This in part contributes to the second problem: an imperfect public understanding of clinical research. Imperfect public understanding means that we have a relatively small percentage of people who volunteer to participate in clinical research trials. For adult patients with cancer, the volunteer rate is only five percent.

The third problem identified by the consensus conference was that the data are inadequate to tell us whether our investment in clinical research is being well spent and whether certain areas need to have more resources. Fourth, the group felt that there is insufficient funding in certain areas of clinical research like outcomes research and the most basic types of clinical research that link the scientists in the laboratory to the earliest examination of disease mechanisms in human subjects.

The fifth and sixth problem areas involved work force issues. The group felt that there was a need for more clinical investigations and that we need to do a better job of educating all practitioners about clinical research so that they can be more informed and apply new data to

their practices. In other words, we need to bring research into practice. The seventh problem was poor coordination between HMOs and the academic medical centers and between schools of nursing and public health on the one hand and schools of medicine on the other.

Eighth was a concern about the financial risk for academic medical centers and their ability to sustain their systems for clinical research. The final point was that there was no clear, dynamic agenda for clinical research.

The definition of clinical research proposed at the outset of this talk came out of the consensus conference. This definition embraces a continuum of studies involving interactions with patients, diagnostic clinical materials or data, and populations. The participants felt that unless the vitality of the whole were addressed, it would be very difficult to translate the advances in science and technology into improved health and clinical practice.

How do we increase public understanding? The group suggested that scientists are perceived as being too arrogant and there is a need for greater mutual understanding related to clinical research and public participation in it. There was a strong feeling that the ethical underpinnings of clinical research need to be strengthened, as well as the oversight mechanisms. We have communities in this country that have been exploited in the context of clinical research. We need to establish trust and trustworthiness so these communities so that we can engage the full diversity of the American public in clinical investigation.

What about better data? Better data start with a better definition. The different categories of clinical research offer the opportunity for a more accurate reporting of support for clinical research from within academic medical centers, health systems and HMOs, as well as clinical research supported by government and industry (the pharmaceutical industry in particular).

The participants felt that federal funding, while it has been generous, has not always resulted in strong support for clinical research. The focus on the RO1 investigator initiated grant mechanism at NIH has not particularly supported clinical research. Under the best estimates only about 30 percent of RO1 grants go to clinical research. If one is going to build an infrastructure for clinical research, the research center mechanisms turn out to be more strongly supportive of all types of clinical research than are the RO1 grants. The General Clinical Research Centers (GCRC) program supported by the National Center for

Research Resources (NCRR) has been a lynchpin of support for translational patient-owned research. In addition to the GCRC program, there is a need to address issues of infrastructure in clinical research including population-based research. The Centers for Disease Control and Prevention and the Agency for Health Research and Quality are critical sources of support for population-based research.

The participants also wanted to see the work force strengthened. NIH has begun some initiatives and the participants felt they are promising. Clinical research needs to be part of the educational programs for nurses, physicians, and other health professionals. Someone needs to monitor the work force across the health professions and across the different categories of clinical research. Do we have enough health services researchers and different types of patient-oriented researchers?

In order to bring research into practice there was a feeling that practice networks that have been developed in psychiatry, pediatrics, and family medicine represent an opportunity to improve practice as well as broaden clinical research. In particular there is a need to strengthen collaboration between the academic medical centers and the HMOs and the insurance industry. Participants shared specific examples where this is happening and the group felt that this is an area that needs greater emphasis.

One area of controversy that was not resolved at the meeting was the place of the academic health center and the academic medical center in clinical research. The academics believe that clinical research rises and falls on the academic health center, but the non-academics believe that clinical research, to truly thrive, needs to be present in multiple venues of care.

The unique role of academic health centers and academic medical centers spans the clinical research area in identifying the causes of diseases, in discovering drugs and inventing medical devices, in evaluating and testing these discoveries, in the early application of these discoveries, in advising about and disseminating information on the value of these innovations, and in educating the next generation of researchers and clinicians. No other sector can perform these functions in this integrated way.

There was little support among the non-academic focus groups for new or increased public support for the academic health centers without “convincing demonstration of financial need” and without a greater commitment to their participation in a broader clinical research agenda involving these other venues. Since the consensus conference, academic health centers and academic medical centers in many parts of

the country are in fiscal crisis. We see examples from the University of Pennsylvania, the major Boston teaching hospitals, Stanford University, and the University of California at San Francisco. Since the shortfall is in the area of clinical research—a traditional source of support—declines in revenue for managed care, and related declines in Medicare oblige the country to confront the question of how medical schools and teaching hospitals should fund social goods like clinical research.

Finally, on the issue of a dynamic agenda, the Summit recommended the creation of a clinical research roundtable to focus national attention on key issues, to monitor and track clinical research investment (including work force opportunities and needs), and to serve as a forum to focus attention through the use of special workshops. The Institute of Medicine has set up this Clinical Research Roundtable, which has now been implemented.

In addition to participating in the Summit, AAMC also set up a clinical research task force to examine what the academic medical centers need to do to strengthen their clinical research programs. The task force divided its role into four specific tasks: examining the current state of clinical research education in medical schools and teaching hospitals, describing the optimal infrastructure for the different categories of clinical research, addressing the organization and administration of clinical trials, and exploring the interface of clinical research with evolving clinical delivery systems that are academically affiliated. As our hospitals have become increasingly corporate to manage their costs and revenue structure, but our medical schools have remained more traditionally academic in their form of governance. The interface is increasingly muddled in terms of how one can begin to address issues that involve investment such as clinical research.

In the area of education and training, the task force said observed that medical students and most residents are not being exposed to the excitement of clinical research. They are not getting it in the curriculum. The recommendation was that clinical research needs to be conveyed in an exciting way to students and residents to stimulate interest in clinical research careers.

Clinical research training programs are very heterogeneous. Many have not yet established required curricula in terms of the expected competencies, skills, and knowledge-based requirements for their program graduates. The group recommended that it is critical that these programs establish curriculum requirements and that they recruit a

demographically diverse cadre of trainees and faculty mentors. Programs should be funded for multiple years and should include funding for trainees and program costs. Training programs should expand the career outlook of graduates. It took us 25 years to realize that the Medical Scientist Training Program, which was set up to generate scientifically sophisticated clinical investigators, was not producing clinical researchers. It was producing basic scientists. We cannot wait 25 years to determine if these new clinical research training programs are producing committed clinical investigators that can successfully compete for grant support.

With regard to infrastructure, the argument was made that we have strategic planning for clinical programs and medical education, but we need strategic planning for clinical research in order to define the infrastructure needs of clinical investigators. Critical infrastructure is an effective, efficient, and responsive program for research compliance and the protection of human subjects. Part of the infrastructure must move beyond the individual investigator and individual department model of organization to collaborations within the medical center, within the university, and even beyond universities. One can readily find examples of collaborations within institutions, but institutional collaborations are less common. When I was with the University of Connecticut Health Center, we had a NIH-funded research center in my department. It was clear by the mid-1980s, that brain imaging and genetics were going to have a profound impact on psychiatric research. I was at a relatively small medical school, but Yale's psychiatry department was 30 miles away. We were able to work out arrangements with Yale University for collaborations in addiction research. The University of Maryland, and Johns Hopkins University share access to a PET scanner.

Critical to infrastructure is a competent biostatistics program and access to comprehensive clinical information systems for the full spectrum of clinical investigation. To reap these opportunities from emerging technologies and particularly from computerized clinical information systems, interinstitutional collaboration may be critical.

In the areas of clinical trials, the group noted that a number of institutions have established central offices that are designed to encourage the placement of industry-sponsored clinical trials in academic medical centers. At the beginning of this decade 80 percent of industry-sponsored clinical trials were placed in academic medical centers. By 1999 the number was down to 40 percent. That does not mean that

they were getting fewer trials, but the percentage had clearly declined. The sense was, that efforts need to be made to reverse at least part of this trend. All trials do not have to be in an academic medical center, but there are advantages to including these centers in many trials.

The interface with evolving clinical delivery systems was a very difficult issue, but the teaching hospital CEOs who participated in this task force were very clear: Clinical research must be included in health planning and implementation. Investment in health services research can strengthen the quality and cost-effectiveness of care. They also looked at the model of the comprehensive cancer center, which was developed at NIH with medical schools and teaching hospitals. This model supports an integrated mission of clinical care, research, and community service. For the most part, it is not a popular model for deans, but it has served well those institutions that have it; and it serves patients well in advancing cancer care through research. No other NIH institute supports this kind of model. The arthritis field supported the multipurpose arthritis center a number of years ago, but the program has been eliminated. The opportunity to bring research to the bedside is represented by comprehensive cancer centers and multipurpose arthritis centers.

Follow-up

As I said above, the Institute of Medicine has established the Clinical Research Roundtable. In the area of education and training, AAMC has recently empanelled a group to recommend changes in the undergraduate medical school curriculum focusing on clinical research. AAMC is also working with NIH to assess the early results of its research training initiatives. We are currently listing all clinical research training programs on our website. AAMC has sponsored a conference on clinical trials management in medical schools and teaching hospitals, and has a number of initiatives to strengthen human subjects protection.

We are doing much more outreach to our members in the area of managing clinical trials and we have made a number of initiatives in the area of protecting human subjects.

But issues that need to be addressed include supporting infrastructure, developing models for shared equipment, applying information systems to clinical research, establishing a general clinical research centers program by the year 2010, and working out productive mechanisms on a competitive basis for faculty.

As we look at the health system we can see that we are still very much in a tremendously fluid state. Blame is always focused through the media and Congress on the managed care industry. But the managed care industry is simply a convenient target to be blamed for a system that is by no means where it is going to be in future years. As we begin to address the problems in the health system, we will need to address the future of the academic health center and to determine where within the health system the unfunded or underfunded components of the mission are, because those are ultimately critical to the future of clinical research.