Editorial Comments

JAMIA

A Plea for Controlled Trials in Medical Informatics

The real purpose of the scientific method is to make sure nature hasn't misled you into thinking you know something you don't actually know—ROBERT M. PIRSIG, *Zen and the Art of Motorcycle Maintenance*

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Investigators from McMaster University recently reviewed all published controlled trials of practical applications of electronic medical record systems in physician decision making¹ and quality assurance.² Although these trials effectively used high-quality research methods to assess the effects of information systems on health care delivery and, in a few instances, on patient outcomes, the number of such controlled trials was shockingly small. The reasons for this paucity of high-quality controlled trials are many, with some being more obvious than others.

A controlled trial is difficult to conduct, especially when the site is the clinical arena, the intervention is as unwieldy as an electronic information system, and the outcome is as difficult to define and measure as the quality of health care or its cost. Controlled trials and observational studies are extremely difficult to perform when the subjects are physicians and the intervention is information. How does one prevent bias and contamination? What kinds of physicians would allow themselves to be manipulated in a controlled trial? House officers and academicians would allow themselves to be manipulated which explains their prevalence among the subjects of controlled trials in medical informatics. The barriers to doing such controlled trials in the "real world" are enormous and increasing. A research project may decrease the operational efficiency of a facility at a time when changes in health care financing require increases in efficiency. Those investigators, such as McPhee and his colleagues,³ who have succeeded in overcoming these barriers are to be lauded.

Why are controlled trials of the clinical application of informatics innovations important? First, it is important to demonstrate that new technology adds measurably to clinical results because information can obscure as well as enlighten. In mock battles, military strategists routinely lose when given too little information or too much poorly organized information. When given selected bits of data in an organized format, they routinely win such battles.⁴ Medicine is also suffering from information overload. Only by performing rigorous clinical studies can we define whether a new information system will help, result in no change, or make the problem worse. Moreover, adoption of electronic medical information technology may be accelerated if its benefits can be demonstrated by rigorous clinical trials, whose results are more apt to be published in the medical literature and subsequently disseminated via the popular media.

Second, it is important to identify the limitations of a new product, even when it is an obvious advancement over existing technology. No one would disagree that the picture generated by magnetic resonance imaging (MRI) scanners are better than those generated by computerized tomography (CT) scanners, yet what are the marginal gains in information needed to make clinical decisions? If the MRI scan shows an abnormality in a patient with abdominal pain, would a CT scan do as well? Or even a good physical examination? Which patients need the enhancements of Cadillac technology, and which could be served just as well with Chevrolet technology?

The current focus upon developing a computer-based patient record (CPR) is a case in point. The development of the CPR has been targeted as a national goal in a report from the Institute of Medicine (IOM), which identifies the CPR as perhaps the only way that higher-quality health care can be delivered at a

lower cost.⁵ Governments, hospitals, managed care organizations, and private health care providers would be more likely to invest large amounts of capital into new electronic medical record systems with added functionality to improve clinical care if there were reasonable, unbiased evidence of achieving such benefits at acceptable cost.

Who should pay for conducting clinical trials in medical informatics? In the pharmaceutical industry, pre-marketing and post-marketing trials are considered part of the developmental process. Applied science in the form of well-performed controlled clinical trials has not emanated from the companies that develop medical informatics products. There are potential economic disincentives to such studies. In most markets, the manufacturers' bottom lines depend on maximum distribution of their products, not on cost-effective applications. Moreover, in the traditional health care marketplace, the additional costs of new technology have simply been added to already spiraling costs without many of the checks and balances of a traditional market.

It is those who pay for health care (ultimately, the public) who have a vested interest in knowing the marginal costs and benefits of new information technology. Until recently, however, the research dollars allotted for technology assessment and informatics-related health services research had been skimpy at best. The dual focus of attention upon creation of a national information infrastructure and development of a cost-sensitive health care system may provide an environment in which the level of funding for these activities can be increased. Attention to the infrastructure alone could lead to unnecessary investment. Blind use of technology to cut cost is unlikely to be effective. Careful assessment of the role of a technology, and maximum application of the technology in that niche, will yield the most benefit.

The existing pool of investigators who understand both informatics and the conduct of controlled trials is inadequate. Over the past several years, the number and quality of individuals completing medical informatics training programs has increased. These programs usually require the completing of a research project and provide access to educational programs in epidemiology, statistics, and research models. However, none of the informatics fellowship programs reviewed by Braude in 1990⁶ required formal course work in these areas, and the emphasis on this aspect of training should be increased. The research career development awards (RCDAs) that have been central to the professional development of basic scientists have not been made widely available for clinical

researchers in medical informatics. This lack of project-independent support eliminates the freedom that is so essential to developing creative investigators. Junior faculty members with informatics backgrounds often accept positions supporting electronic record systems for their hospitals or medical centers, adding large administrative loads under which budding careers as clinical investigators are often crushed.

To increase the number of controlled trials of the products of medical informatics research and development, we make the following proposals:

1. Increase research funds for applications proposing controlled trials of informatics in clinical settings and developing new statistical methods for measuring the effects of interventions in complex health care environments (e.g., where multiple patients are cared for by multiple providers during multiple visits).
2. Encourage a minimum competency in research methods and the quantitative sciences to all informatics fellows, those who will become scientists as well as those who will make decisions about the course of informatics in their institutions.
3. Expand the career support mechanisms for junior health services and medical informatics researchers.
4. Establish a clinical research agenda in medical informatics that separates research and development of new technologies from clinical research of their practical applications to guide investigations towards the most urgent needs.

There exists today a wonderful opportunity to make investments in informatics that may ultimately lead to an integrated, national electronic medical information system. Such a system could serve the interests of patients, providers, managers, researchers, and payers. The focus upon that goal must be balanced by attention to studying the costs and benefits of such innovations in informatics. We must develop and support new clinical researchers and well-planned clinical investigations if we are to spend this investment wisely.

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