Clinical Research and Future Improvement in Clinical Care

The Health Insurance Portability and Accountability Act (HIPAA) and Future Difficulties but Optimism for the Way Forward

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Drs Kulynych and Korn\(^1\) and Califf and Muhlbaier\(^2\) have provided masterful reviews of the potential impact of the Health Insurance Portability and Accountability Act (HIPAA) on future clinical research and patient care. Potential difficulties to be encountered by physicians, clinical researchers, institutional review boards (IRBs), research institutions, and community providers are emphasized in their reviews. Although well intentioned to protect patient privacy, HIPAA, as currently written, represents an impediment to health-related research and the practice of clinical medicine. IRBs, health research institutions, clinical investigators, hospitals, medical universities, and private physicians are enormously concerned about the additional paperwork, supervisory groups needed to understand and implement HIPAA, and the costs of this implementation process. At a time when there is already excessive regimentation and endless paperwork for physicians in practice, IRBs, and clinical investigators, HIPAA creates additional challenges, uncertainties, and difficulties for all of these entities. Many physicians have abandoned their practices in recent years because of what they believe to be excessive reporting responsibilities that diminish the time available for patient care. Their discouragement impacts future recruitment to the medical field of talented students, who may perceive medicine as being too regimented and these legislated restrictions as minimizing their ability to take care of and interact with their patients. Clinical research, already under siege because of relatively inadequate financial subsidy, indemnification, and lack of support from many medical universities in the United States, is also adversely affected by these additional rules and regulations. Individuals considering clinical research as a career may have second thoughts if they believe the entire process to be exceedingly difficult or bordering on the impossible.

These new regulations come at a time when we stand on the threshold of a revolution in medical discovery resulting from the identification of genes and proteins that play causal roles in the major diseases of our time, including heart and vascular diseases, dementia, diabetes, and many cancers. In the coming years, many of the genes and proteins that code for specific human disease processes will be identified, and we may be in the position of being able to predict these diseases in utero or soon after birth. Identification of future medical risks well in advance of their occurrence could provide an enormous opportunity, in the sense that one might focus preventative therapies that are protective early before a disease develops, and ultimately, we may have the ability to manipulate the gene and protein risks toward prevention and cure of selected diseases. Furthermore, the response of individual patients to various medical treatments, including drugs, may be predictable as a result of genetic/proteomic evaluations. Clearly, we must have an improved ability to protect patient privacy, and that need will only be greater as one identifies the genetic and proteomic risks for individual patients. It will be important that the patient can learn of genetic/proteomic risks he or she may have without this information being made available to future employers, insurance carriers, and others who, if they had such information, might restrict the individual’s access to employment opportunities, insurance options, etc.

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As pointed out eloquently by Drs Califf and Muhlbaier,2 we have great disorder in our medical care system with regard to standardization of records, electronic storage, and communication capabilities. At present, we have a complex array of methods to communicate and store patient information, as well as a disassociation between clinical and billing systems and the retrieval and storage of clinical research data. With the development of the genetic and proteomic advances mentioned above, it will become increasingly possible to identify a patient’s risk for selected medical diseases well before they occur and to predict the most appropriate medications that might be used. This will require improved electronic capability for evaluation of the genetic/proteomic data, application to individuals and large numbers of patients, and record-keeping for the individual patient’s and physician’s benefit. Patient privacy will be essential.

We believe that HIPAA might optimally be viewed as the initial step in this process. As argued by Drs Califf and Muhlbaier,2 there is an immediate need to integrate and simplify patient record and clinical research information so that the advances for disease prevention and improved patient care can be enacted in ways that make medical care and clinical research simpler, more efficient, and more encouraging to all those involved, and yet with data systems that ensure patient privacy. Ideally, the National Institutes of Health, medical care specialties (including the American Heart Association, American Cancer Society, and others), the Institute of Medicine, the Food and Drug Administration, and various accrediting agencies for medical specialties will work together to simplify these processes. Approaches are needed that do not penalize hardworking physicians and clinical investigators, but instead assist them in ensuring patient privacy while contributing to the information that will ultimately lead to disease prevention and reduction in medical morbidity for countless numbers of patients throughout the world.

References
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