

Bedside manners

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The Crisis in Clinical Research: Overcoming Institutional Obstacles. By Edward H. Ahrens Jr. *Oxford University Press: 1992. Pp. 236. £27.50, \$29.95.*

WHAT is clinical research? What was termed clinical research when I was a student bears little semblance to what is termed clinical research today. Most work then consisted of questioning patients at their bedsides, examining samples collected from patients with disease, relating this to experimental animal models and doing clinical trials.

In this book, Edward Ahrens, an emeritus professor at The Rockefeller University and a clinical investigator for some 40 years, looks at the shift in emphasis in clinical research in the United States from patient-oriented research to research at the cellular and molecular level. In searching out the reasons for this change, he carefully examines the institutional supports for clinical research, including the medical schools and clinical centres in which the research is carried out and the main funding source, the National Institutes of Health (NIH). Ahrens argues that the traditional roles of medical schools — teaching, basic research and providing service to patients — have become so seriously out of balance that US medicine as a whole is in jeopardy. He concludes by prescribing several recommendations aimed at correcting these imbalances.

Research definitions

Unlike others, Ahrens permits no ambiguities in his definition of clinical research. He categorizes it into several kinds of activity, examining each in detail. These include the study of the mechanisms, modelling and management of human diseases, the development of new technologies and the assessment of health care. And he makes a compelling case for why this research is absolutely essential. Among his reasons are that there are no perfect animal models, particularly for chronic degenerative diseases and many infections; that new diseases will continue to appear (AIDS is a mordant reminder); that gene mapping and other reductionist approaches often eventually require the study of diseases in whole humans (cystic fibrosis is one example); and that doctors need to be able to make sound observations and to question why and how clinical phenomena occur.

Yet during the past 15 years there

have been progressively fewer grants awarded to investigators for patient-oriented research; and currently, only half these grants go to MD investigators. In explaining this shift from bed to bench, Ahrens points to the fact that medical students now spend less time studying biochemistry, pharmacology and physiology in the laboratory, and more on rote memorization than on problem solving. With mounting debts, they are enticed more readily into the high-paid careers of clinical practice than into ones as academic physicians. Other disincentives include the increasingly inadequate supervision of novice clinical investigators, particularly in large departments, and the fact that it is more difficult to have papers published on clinical than nonclinical research.

Ahrens believes that both the NIH and medical schools are responsible for throwing serious obstacles in the way of clinical research. The NIH has become a research colossus whose accountability has been called into question. Ahrens suggests that the institutes must establish an outside review mechanism over and above the institutional review groups currently used to assess extramural programmes. He provides some evidence that grant applications for clinical projects are judged by the institutes more on whether valid experimental data will be obtained, than on the originality and inventiveness of the proposals.

As the largest general clinical research centre in the world, the NIH's Warren Grant Magnuson Clinical Center in Bethesda, Maryland, should be the pacesetter for this kind of research. But there have been no internal systematic reviews of the scientific merit of bedside research at the centre. In 1985, though, the Clinical Center was reviewed by a committee chaired by Donald Seldin. The committee showed that "there was substantial variation in the quality of the [research] protocols reviewed from truly outstanding to quite poor — some proposals would not pass the scrutiny of the extramural peer review process."

Ahrens is critical of how the Clinical Center's budget is determined by the individual institutes. Because of the escalating costs of clinical research due to new technology and therapeutics, several directors of institutes have discouraged bedside research. As a result, bed space at the centre has decreased and bed costs have increased. Ahrens suggests that the centre should be allocated a separate budget, independent of those of the institutes. Bedside researchers from the institutes would then compete for funds not with their NIH colleagues who do purely laboratory research, but with each other, as do researchers in clinical centres of medical schools. The most interesting suggestion

made by Ahrens is that patient-oriented basic research should be judged by groups of investigators who are experienced in clinical research.

At medical schools, however, research is only one of the activities on the agenda: teaching and providing services to the public are also essential roles. Clinical departments in most US medical schools are so large as to preclude any collegiate atmosphere and decent supervision, and have all too often become factories for rendering service, but only at a price. There is less time and money for clinical investigators to do research, to teach and to train. And, as Ahrens shows, the criteria for tenure and promotion disadvantages clinical investigators.

Training reforms

Ahrens proposes several reforms that he believes would improve the quality of clinical training. On the basis of Malthusian theory, he shows that productive investigators clone themselves at least once yearly. He fears that well-trained scientists, with research careers lasting say 10–15 years, are in danger of outgrowing the ability of the government to fund them. He indicates ways of making research training more streamlined and productive by establishing working partnerships between clinically skilled MDs and technically trained PhDs.

Ahrens has done a superb job in explaining how the NIH works, how grants are handled and what the problems with the peer-review system are. He backs up commonly held assumptions with the results of studies both inside and outside the NIH. By using questionnaires and interviews and holding a series of two-day meetings with various authorities on clinical research, Ahrens has produced a compendium that is full of data, yet a lot more interesting than the usual NIH guides.

If the book has a weak point, it is Ahrens' attempts in the first two chapters to put clinical research in the context of US medicine. He does not really deal with US medicine in global terms; rather, his commentary covers US medical education. But even here he falls short. His arguments are often dated and he intermingles his databases somewhat indiscriminately.

Nevertheless, Ahrens' conclusion that there is a crisis in clinical research is inescapable. He has done the entire research community a favour with his acute analysis. Every clinical investigator, research administrator and medical educator should be required to read this splendid book. □

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