One has only to compare the 1980 American College of Cardiology (ACC) Annual Scientific Session program to the 1997 program in Anaheim to be amazed at the marked increase in the number of scientific abstracts presented (400 compared with 2,138). Why, then, is there widespread concern about the future of cardiovascular research in the United States? (1–4).

Before addressing this question, it is important to distinguish among the various types of research that have emerged since 1980. First is basic research, involving genetics and molecular biology. Basic research was virtually absent from the 1980 meeting. This type of research receives the highest funding priority from both the National Institutes of Health (NIH) and the American Heart Association (AHA). Investigators can be either MDs or PhDs, but the considerable extra training required, beyond the usual training in clinical cardiology, makes this an unlikely course for financially indebted cardiovascular trainees to pursue.

The second category involves experimental animal studies, which in 1980 was “basic” research. Such investigators must now have a reasonable understanding of molecular biology, in addition to physiology, and may be either a PhD or MD. Once again, the extra training requirements for this type of research are a disincentive for MDs. Whether any incentive exists to enter either type of basic research is strongly influenced by the closeness of the collaboration between the basic researchers and the clinicians at the trainee’s institution.

Third is clinical research that involves human subjects and human diseases and is virtually always conducted by MDs. Clinical investigators study the epidemiology, pathogenesis of disease and mechanisms of disease management. These studies usually do not require large numbers of patients, but may incur substantial hospital or outpatient costs. Traditionally, clinical research has relied heavily on support from clinical revenues donated by the clinical faculty in addition to outside grant support. This type of research is one of the easiest starting points for cardiovascular trainees interested in research.

Clinical research requires a thorough understanding of pathophysiology and clinical manifestations of disease supported by a background knowledge of molecular cardiology. In addition, the clinical investigator is generally involved in direct patient care and teaching. From this group, some individuals evolve into “master clinicians” who are able to recognize new manifestations of diseases and intuitively understand the value of new diagnostic procedures or therapies. These are the investigators who bring the questions from the bedside to the research laboratory and, conversely, from the basic laboratory to the bedside. It is this type of investigation for which funding and academic encouragement has dramatically declined since 1980 (1,2).

Two new disciplines of research have emerged since 1980—clinical trials and outcomes research. Clinical trials are currently the most glamorous form of cardiovascular research. In fact, cardiovascular medicine leads all other fields in the number and scope of its clinical trials. The researchers are MDs (mostly those who formerly would have performed clinical research). Clinical trials have been an extremely valuable addition to clinical research, but they do have limitations that are not generally appreciated. Trials are often initiated before the mechanism of action of the treatment is fully understood, leading to an inappropriate cessation of research into a promising therapy (e.g., flosequinan, vesnarinone). The patient populations in clinical trials are usually heavily skewed toward the least complex patients and often suffer from referral bias. Thus, only a small percentage of clinical questions can be subjected to trials. Many trials are funded directly by the medical industry, which may have a different agenda than clinicians (5–7). Trials currently enjoy strong support from both the NIH and industry. A worrisome trend is that nonphysician entrepreneurs may steal this show, which could further cloud the interpretation of trials (8).

Finally, there is outcomes research—arguably, this has always been a goal of clinical research. Although outcomes research can be prospective, it is commonly a retrospective, observational analysis. It often deals with practical clinical issues for the purpose of improving daily practice. This is a form of research favored by managed care. Outcomes analyses performed from large clinical databases have provided ex-
tremely useful information, much of which cannot come from trials (8). Indeed, the newly revised ACC Database will be such an instrument (see the report by Weintraub et al. in this issue of the Journal). Outcomes research will be more common in the future; therefore, cardiovascular specialists must be more involved with it to ensure that the data are properly analyzed. Outcomes research is funded by government, industry and managed care.

In summary, the era since 1980 has seen remarkable growth in the size and diversity of cardiovascular research. However, support for classic clinical research has steadily and somewhat quietly eroded; so now, unfortunately, it is not a career readily chosen by current trainees. The clinical research role models are being forced to spend more and more time in clinical care, with little time for contemplating and brainstorming. They have little prospect of national or local research funding. At a time when basic research has provided a “gold mine” for clinical research, it is being eschewed by the next generation of researchers (1).

The result of the trend away from clinical research is shown in Figure 1. This figure compares the number of abstracts submitted to and accepted by the ACC Annual Scientific Sessions since 1992 (in thousands). By the very nature of our meeting, most abstracts submitted represent clinical rather than basic research. It is clear that the number of abstracts submitted and accepted from the United States has plateaued (and actually declined for 1997), whereas the number from outside the United States has steadily increased (from a base of <5% in 1980). The steadily increasing number of submissions from international clinical research has, in a sense, “covered up” the lack of growth in output from the United States.

Is this merely the expected result of progress? Has classic clinical research told us all we need to know about the mechanisms of cardiovascular disease? Is clinical research too inefficient to be conducted in all American medical schools? Should there only be a few research schools, while the remaining schools concentrate only on medical education? (9)

Personally, I reject these notions. As pointed out recently, this would be a regression to the pre-Flexnerian Era (1). Nonresearch schools would become analogous to medieval monasteries, simply passing on what is known but not creating new knowledge. For clinical teachers to be exciting (and up-to-date), they must be in a milieu where clinical research is being performed and new concepts are being discussed. Medical school diversity and research support for young investigators have been the great strengths of the American research system, and this would be lost if research were confined to only a few institutions (1).

Managed care has derived more direct benefit from clinical research than from basic research but up to now has not been willing to pay for it (4). There has been a 30% reduction in clinical income because of reduced payments for clinical care from both managed care and Medicare. This has significantly reduced the nearly 1 billion dollars that clinical faculty had voluntarily relinquished to support clinical research (11).

Likewise, universities do not support clinical research, because, as I noted in an earlier President’s Page, post-MD education and research are not formal university disciplines (10). The NIH does not give high priority to clinical research, except for clinical trials (although there is currently an NIH panel that will advise the director of the NIH on problems facing clinical research). The AHA has also turned toward more basic research in its local and national funding, thus reducing opportunities for young clinical investigators. Industry supports clinical research; but, overall, this is only 10% of the size of NIH support, and industry-sponsored research has become more targeted and is usually not investigator initiated.

If we are to continue to serve our patients by advancing our ability to diagnose and treat cardiovascular disease, it is time for us to point out the threat to the development of new knowledge (12). I have appointed a College task force to develop a position statement on the role of clinical research in the advancement of cardiovascular medicine. As our strategic planning process unfolds this year, this issue will be explored. Two possibilities that immediately come to mind are for the College to establish clinical investigator awards and to convene a meeting of academia, industry and government to discuss solutions to this problem.

References


