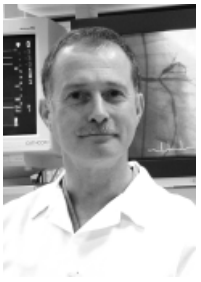
Catheterization and Cardiovascular Interventions 57:277–278 (2002)

The Society for Cardiac Angiography & Interventions

SCA&I President's Page



Growing Challenges in Clinical Research

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It has become increasingly difficult to perform clinical research in Interventional Cardiology. A variety of pressures have developed and are increasing steadily in intensity. This is particularly ironic in light of significant (and widely publicized) increases in the NIH research budget. The perception among the public (and among many of the medical administrators we work with) is that research funding is increasing. The dilemma is that clinical research that we as invasive/interventional cardiologists do is funded instead by other sources–sources which themselves are facing ever greater constraints.

Trials are moving faster and regulatory pressures have at the same time slowed down the institutional review process. The burdens of study monitoring have escalated, FDA oversight has increased, and the amount of time required from study coordinators to service the paperwork has skyrocketed. It has become a daily occurrence to have a study monitor visiting. There is a growing need for space to have a monitor on the premises with room to spread out stacks of charts and case report forms and research staff to work with them. In our hospital, in an urban environment, the space is hard to come by.

Pressures from within institutions include the rapidly escalating administrative costs, institutional review board costs, and other fees or taxes that constitute overhead. Study budgets are ever more difficult to construct, as the internal charges for laboratory testing rise. We need more research staff, but have decreasing budgets to support them. I became painfully aware of this recently when I submitted a study budget for review, and found that even after extra payments had been negotiated with the study sponsor, there remained a negative balance on the bottom line.

We recently had a proposed trial vetted through our trial contract approval and IRB process, and then get canceled by the study sponsor before it actually began. The IRB submission fee and coordinator costs had been paid by the sponsor. Thus on paper there was technically a positive balance for this trial, even though the trial never got off the ground. On the other hand, trials that we have successfully launched are now under so much financial pressure that they may have a negative budget balance. It is a sad commentary that a canceled trial may be financially viable and able to support our research staff to some degree, while a successfully launched and enrolling trial may not be.

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DOI 10.1002/ccd.10356
Published online in Wiley InterScience (www.interscience.wiley.com).

Even more than the financial pressures, are pressures relating to the objectives of clinical research. While numerous device and drug studies are always in development, the studies that remain undone, or those that may never happen, are the greatest research challenge we face. For example, comparisons of angiography as a first strategy for evaluation of chest pain compared with stress testing have never had the kind of support necessary to settle these critical fundamental issues in management.

A case in point: the efforts of SCA&I's Cath Lab Performance Standards Committee (chair: Michael Cowley, M.D., Medical College of Virginia; co-chair: Charles Chambers, M.D., Penn. State) to develop a cath lab phantom for standardized calibration of cath lab radiographic equipment for quality assurance. The effort is tremendously important to promote ongoing quality performance evaluation and maintain cath lab standards. The development of an x-ray phantom has been time-consuming and costly. Neither hospital administrations nor industry has contributed adequately to this effort despite repeated efforts to garner their support, although the Society is optimistic that this will change in the near future. The compromise of quality for lack of a specific mandate, either from government or industry reflects one of the fundamental tensions in supporting interventional clinical research.

Potential conflicts of interest in research are another area of tremendous difficulty. Most of the conflict of interest and disclosure forms that we, as investigators, are asked to sign presume that the conflict we have is one of bias in favor of performing research studies. I recently spent 1-1/2 hours discussing enrollment in a patent foramen ovale closure trial with a patient in the outpatient department. The time spent with patients, the additional time in study procedures, the mountain of paperwork, and some of the pressures on our time for conference calls and study meetings create a reverse conflict of interest.

Keeping pace with changing regulations (how many investigators have read all of the existing regulations?) is difficult and often confusing. The pressures to abandon our clinical research time in favor of day to day clinical activity is a serious conflict that challenges our participation in trials. To address these dilemmas, SCA&I recently created an Ethics Task Force (chair: Airlie Cameron, M.D., St. Lukes/Roosevelt: co-chair: Warren Laskey, M.D., Pasadena, Maryland). The Task Force is charged with preparing an official SCA&I white paper on the subject.

Why must we continue to be involved in interventional clinical research? Two decades of improved technology and technique have reduced clinical restenosis rates by over one-third, significantly decreased acute MI mortality, and improved outcomes in SVG and total occlusion PCI, among other advances.

The excitement we have in this rapidly changing field is based on not only newness of each device and technique, but most importantly in the improved outcomes that are the fruits of this labor. Few if any other areas in medical science can point to such accomplishment, in very large part due to the results of your clinical research. By virtually any measure– economic, mortality/morbidity, quality of life–interventional cardiology clinical research makes an invaluable contribution to society.

In short, we must do everything we can as a profession and as a Society to ensure that such clinical research does not collapse under pressure, but instead flourishes.

ACKNOWLEDGMENT

Special thanks to Norm Linsky, Executive Director, SCA&I for editorial review and comments.