

CORONARY ARTERY DISEASE

Feature Topic

Ethical Issues for Invasive Cardiologists: Society for Cardiovascular Angiography and Interventions

Airlie A.C. Cameron,^{1*}MD, Warren K. Laskey,²MD, and William C. Sheldon,³MD, on behalf of the Society for Cardiovascular Angiography and Interventions (SCAI) Ad Hoc Task Force on Ethics in Invasive and Interventional Cardiology

In view of the major impact of medical economic forces, rapidly changing technology, and other pressures on invasive cardiologists, the Society for Cardiovascular Angiography and Interventions determined that a statement of the ethical issues confronting the modern invasive cardiologist was needed. The various conflicts presented to the cardiologist in his or her roles as practicing clinician, administrator of the catheterization laboratory, educator, or clinical researcher were reviewed. In all instances, the major concern was determined to be the welfare of the patient no matter how forceful the pressures from various outside force or concerns for personal advancement might be. *Catheter Cardiovasc Interv* 2004;61:157–162. © 2004 Wiley-Liss, Inc.

Key words: ethics; medical ethics; invasive cardiology

INTRODUCTION

Codes of medical ethics have existed since the earliest recorded history of medicine. As medical practice has changed, they have been restated and modified with each passing generation. The American Medical Association (AMA) first adopted a general code of ethics in 1847 and revised it most recently in 1997 [1]. With evolving specialization virtually all medical specialties have developed codes of ethics focused on issues specific to their practices, and guidelines for medical research, education and for manufacturing and marketing practices have been addressed by various organizations including the AMA, the National Institutes of Health (NIH), and the Food and Drug Administration (FDA).

The Society for Cardiovascular Angiography and Interventions (SCAI) was established in 1978 to provide a forum promoting excellence, quality, and safety in cardiac catheterization laboratories. It has published numerous guidelines for catheterization laboratories and physicians who perform procedures therein. Many ethical considerations are implicit in these guidelines. More recently, SCAI has joined with the American College of Cardiology [2] and other cardiology organizations in issuing recommendations for cardiac catheterization laboratories.

Interventional procedures have changed the face of invasive cardiology and have raised new ethical challenges. Invasive and interventional cardiologists work in a field that is highly dependent on technology in both medical equipment and pharmacology. Both areas have witnessed rapid evolution and rising costs. Because of these technological costs, and because they apply to a very large population of patients with heart disease, their economic impact has become significant. Moreover, car-

¹Division of Cardiology, St. Luke's/Roosevelt Hospital Center and the College of Physicians and Surgeons, Columbia University, New York, New York

²National Naval Medical Center, Bethesda, Maryland

³Department of Cardiology, Cleveland Clinic Foundation, Cleveland, Ohio

Contents approved by the SCAI Executive Committee on 8 September 2003.

*Correspondence to: Dr. Airlie A.C. Cameron, St. Luke's/Roosevelt Hospital Center, 432 West 58th Street, New York, NY 10019.
E-mail: acameron@chpnet.org

Received 26 September 2003; Revision accepted 6 November 2003

DOI 10.1002/ccd.10800

Published online in Wiley InterScience (www.interscience.wiley.com).

diologists have achieved high levels of income among nonsurgical specialties, driven by their skills, the time and investment required for their training, growing success of their procedures as alternatives to surgical treatment, and their value to hospitals and departments of medicine.

The economic impact of invasive and interventional cardiology has led to pressures from several directions. Seeking increased revenues, hospitals and departments of medicine exert pressure on cardiologists for more procedures and higher fees. National and state credentialing standards for minimal procedural volumes (and the publication of individual statistics in some states) influence cardiologists in case selection, especially low-risk cases. Their economic productivity and the inherent risks of the nonsurgical procedures they perform have exposed them to increasing litigation and rising malpractice premiums. Competition for technology creates an incentive to participate in clinical research, often sponsored by industry, another potential source of revenue for individuals, departments, and hospitals. The sponsorship by industry of both formal and informal educational seminars presents potential ethical conflicts to both invited lecturers and invited audiences.

As a result of these pressures, consideration of the ethical challenges for the invasive cardiologist is of timely and vital importance. Accordingly, SCAI [3] has resolved to address the ethical issues confronting the invasive cardiologist of today, drawing from multiple sources, including its own published guidelines. In this document, we shall attempt to identify real and potential conflicts faced by the invasive cardiologist in his or her role as a provider of health care, administrator, clinical investigator, and educator. (Masculine pronouns, considered gender neutral in this article, are employed hereafter.)

RELATIONSHIP OF INVASIVE CARDIOLOGIST TO PATIENT

The invasive cardiologist may have various roles in his relationship to the patient. Commonly, he is the primary physician and the first person to discuss an intervention with the patient. Often, however, he is quite remote and is consulted only after the need for a procedure has been decided and discussed with the patient by another physician. In this role, he is expected to perform the procedure without having participated in the decision for or timing of the procedure. Such a role is inappropriate. The invasive cardiologist is ultimately responsible for informing the patient of the various options, the risks and benefits of therapy, as well as for determining the appropriateness and timing of each invasive procedure. Other roles include acting as a consultant to another cardiologist, another specialist, or to a primary care physician, or interacting with the patient only indirectly in his role as laboratory director, teacher, or clinical researcher. What-

ever the relationship, he must without fail be an advocate for the patient and make decisions in the patient's best interest. His ethical judgment for the patient must not be clouded by any conflict with money, prestige, academic advancement, patient ethnicity, socioeconomic status, or any other factor.

There are many areas in which there can be a conflict between the patient's best interest and the physician's own personal interest. The cardiologist's commitment to his patient takes precedence over his allegiance to an institution. A cardiologist who has an ownership or other financial interest in a facility in which he performs his procedures must disclose this interest to the patient before performing the procedure. The ethical concern is that an ownership interest will lead to inappropriate utilization exemplified by poorly indicated or unnecessary procedures. Thus, in any laboratory, careful monitoring of procedures and their indications by the laboratory director is required. Similarly, if the cardiologist has a financial interest in a drug or device company, or has sole or partial ownership of a patent, this must be disclosed to the patient before embarking on the procedure. Referral fees and fee splitting or sharing are unethical as well as illegal irrespective of the sources of the funds, whether other physicians, hospitals, or equipment vendors.

Great caution and good judgment must be exercised when a cardiologist performs and/or interprets noninvasive tests or procedures for the purpose of supplying patients to his own invasive/interventional practice. While it is preferable to have another physician involved in the decision-making, it is recognized that self-referral commonly occurs. Here again the laboratory director and also colleagues play an important role in monitoring indications for procedures and discouraging inappropriate self-referrals.

Proceeding to an intervention directly after a diagnostic catheterization is commonplace. There are many good reasons justifying interventions that are performed in the same setting and immediately following a diagnostic catheterization (ad hoc interventions). These include cost savings, simplifying vascular access issues, and possibly less risk for the patient. However, informed patient consent is often less than ideal, and there is a potential for abuse if such ad hoc interventions are unmonitored. The patient should be forewarned, advised, and informed consent should be obtained prior to any procedure that may lead to an ad hoc intervention. In situations that are less clear-cut, the cardiologist should consult with another independent cardiologist before proceeding with an interventional procedure on the basis of a diagnostic catheterization. Unnecessary procedures, marginally indicated procedures, and overinterpreted angiograms must be avoided. Each laboratory should have a review mechanism to monitor appropriate patient selection for interventions as described below.

The patient has a right to be fully informed not only about the procedure being planned but also who specifically will be performing the procedure. If a fellow-in-training will play a major role in the procedure or if physician extenders are used, their roles and responsibilities should be explained to the patient. No matter what roles others play, the attending cardiologist is still responsible for every aspect of the procedure.

The attending invasive cardiologist must act as an advocate for his patient even under unusual situations. With an aging patient population, older patients are increasingly being referred for procedures and the invasive cardiologist is often confronted with an ethical dilemma. Given the age-related risk of invasive and interventional procedures, the cardiologist often finds himself balancing the risks imposed by age (and other serious comorbidities, including do not resuscitate (DNR) status) against the potential benefit of a palliative procedure on quality of life. Such decision-making requires detailed discussion with the patient and may benefit also from consultation with the patient's family, cardiologist, cardiac surgery colleagues, and even the hospital's ethics committee. The hospital's written record should reflect these discussions, the level of care the patient desires, and his wishes with regard to resuscitation. Whatever the resultant decision, the fully informed patient should be making his own choice with the assistance of the cardiologist.

Managed care companies have attempted to reduce expenses by requiring various second opinions, utilization reviews, and/or written criteria prior to procedures. The cardiologist must without exception represent the patient's best interest and notify him when a managed care organization interferes with the recommended course of treatment.

The cardiologist must respect at all times the confidence his patient has placed in him. No confidence should be betrayed. In reporting to the patient's insurer, only information related to the condition being treated and procedures related to that condition should be disclosed.

Ethical issues associated with the physician's relationship to industry are often thought of only within the context of research. Equally important are relationships with industry that impact on patient care [4–7]. The cardiologist may not accept gratuities or unusual benefits from industry for use of their equipment, drugs, or devices. He must not publicly endorse a product for financial gain without disclosing his financial interest. He must use the products most appropriate for the patient.

INVASIVE CARDIOLOGIST AS CATHETERIZATION LABORATORY DIRECTOR

While the criteria defining the requisite elements of a catheterization laboratory director were defined over 18

years ago [8], the environment in which this individual functions has changed dramatically [2,9]. Nevertheless, the fundamental mission of a laboratory director has not changed, namely, the provision for, and assurance of, safe and efficacious procedures.

There are three critical areas of commitment that define the contemporary laboratory director's responsibilities: patient safety, the organizational structure of the laboratory leading to efficiency and effectiveness of the laboratory, and the governmental, regulatory, medical, and societal influences of the outside world.

Patient Safety

Most importantly, the laboratory director must commit to excellence in clinical care. The latter, of necessity, translates into a safe and reliable experience for the patient.

The laboratory director must continually assess competence of each cardiologist working in the laboratory. He should review procedural volume, appropriateness of indication, skill of performance, relationships with other laboratory personnel, and complications. The director must oversee and/or maintain an accurate clinical database, an objective reporting mechanism, and a review of procedural outcomes both good and bad. The laboratory director especially must remain objective and unbiased in the assessment of procedural outcomes.

He should establish and supervise laboratory procedure protocols. He must review and monitor research protocols.

He must be responsible for the selection and performance of laboratory equipment and ensure that appropriate quality assurance protocols are in place for equipment.

He must establish and continually supervise the quality assurance program for the laboratory as it applies to cardiologists, other laboratory personnel, and laboratory equipment [10].

Administrative Issues

The laboratory must function under the governance of the sponsoring institution and subscribe to the policies and procedures of the latter. In this position, the director is interposed between the sponsor institution and the administrative structure of the laboratory itself. As such, the director faces many potential challenges to ethical conduct.

The laboratory director must report to the institution's medical staff committee, either directly or via the chairman of the department of medicine, and not primarily to the hospital's lay administrative hierarchy. The laboratory's professional staff report not only to the director, but also to their respective hospital peer authorities (RNs, MDs). The laboratory's nonprofessional staff also report

to the director as well as their supervisors in the laboratory.

He must subscribe to the institution's mission statement and its bylaws. He must also be committed to the laboratory's efficiency and safety, and its reputation in the community as a center of excellence.

He must balance his fiduciary responsibilities to the institution against the fiscal integrity of his laboratory and the quality of its product, i.e., cost-effectiveness vs. cost-competitiveness.

He must balance the programmatic growth of the institution with the service philosophy of his laboratory.

The laboratory director must be involved in the credentialing process. He should work closely with the hospital's credentialing committee, reviewing applications, interviewing candidates, and seeking comments from candidates' previous laboratory directors.

The laboratory director must participate in the recruitment, training, supervision, and performance review of all personnel in the catheterization laboratory.

The laboratory director must be respected as a leader by other professional personnel in the laboratory. The quality of his interactions with others, as a supervisor, mentor, counselor, reviewer, and disciplinarian, will strongly influence the success of the laboratory. As the administrative leader of the catheterization laboratory, the director's interactions with support staff must be consistent, fair, and absolutely clear in their motivation. Acceptance by staff of the director's principal charge can only be accomplished by his strong and visible commitment to quality, safety, and efficiency.

Although the laboratory director may be offered a stipend for his services by the hospital, other financial conflicts must be avoided, including, but not limited to, acceptance of payment, either personally or for the laboratory, for use of products.

The Outside World

The essential nature of interventional cardiology is that it is technology-driven. Combined with intense competition, technological advances fuel the pressure from industry to advance their products. The laboratory director must remain immune from market forces until it can be demonstrated that such forces conform to the same standards as clinical care.

An increasing problem is the use of minimum standards for critical aspects of laboratory function. Regulatory requirements generally define minimum standards that are readily adopted by institutions. The contemporary interventional laboratory, however, requires a more stringent standard than "as low as reasonably allowable." Whether that applies to radiation exposure monitoring, assessment of in-laboratory and out-of-laboratory procedural complications, or operator competence, the director

must again aim to surpass the minimum acceptable standards.

Guidelines and other influences of professional organizations should not theoretically represent a challenge for the director. It is only when the policies and principles of these groups run counter to local realities that the potential for conflict arises. The laboratory director may appropriately deviate from recommendations of professional organizations or the hospital's administrative hierarchy in issues of patient care and credentialing when he believes that such recommendation may be inappropriate for a given situation.

INVASIVE CARDIOLOGIST AND CONTINUING MEDICAL EDUCATION

The quality of patient care is heavily dependent on the level of the practitioner's scientific knowledge. To maintain a skillful and successful medical practice, the physician must be a lifelong student of all aspects relevant to his professional activities. This is particularly true for interventional cardiology where cognitive and technical knowledge must be continually updated. In addition, continuing medical education (CME) is now required for state medical licensure and thus is no longer optional. Thus, the current issues are the type and format of CME. The types of education range from local hospital grand rounds, journals with and without peer review, annual meetings of specialty physician-run organizations, to multimedia sessions with live demonstration of procedures. The program organizer is responsible for the content of the program. He should divulge potential conflicts of interest and try to present a program that is as objective as possible, including the presentations of other points of view.

Journals closely associated with specialty organizations with a large member base and dependent on both membership dues as well as industrial support for financial backing are usually of high quality. Journals unassociated with such organizations are dependent on revenue from advertising and thus questions may be raised about potential bias [11].

A recent study [12] of authors of clinical practice guidelines showed that 87% had some sort of financial relationship (honorarium, travel money, equity, employee, consultant, educational or research support) with the pharmaceutical industry. This study raises the question of the inherent conflict of interest posed by the author/speaker who is himself an investigator supported by commercial funding. While this individual may have extensive knowledge of the drug or device being discussed, if he has a financial interest, his conclusions and representations may still be biased. It is the obligation of the lecturer or demonstrator to divulge any potential

conflicts of interest and his relationship with companies that may have obvious or potential influence. The source of funding should be divulged and the speaker must be an expert in the area under discussion. Too often an articulate but inexpert speaker using drug or device company-provided materials will give a talk, but unfortunately will not have had sufficient knowledge of the device or therapy.

The Accreditation Council for Continuing Medical Education (ACCME) in a recent draft of new standards (www.accme.org) for commercial support of meetings has proposed that a conflict of interest would exclude a person from controlling the content of CME and “an accredited provider will not produce or disseminate CME in a clinical area in which the accredited provider has a commercial interest in a healthcare product or service.” They noted that in some relationships, a simple disclosure of a conflict cannot adequately address this conflict. These stricter requirements, while ensuring the audience of the absence of a bias on the part of the speaker, may well result in the elimination of those who know the most about the topic of interest.

Of concern also is industry-subsidized attendance of physicians at industry-sponsored courses and seminars. While educational grants to fellows in training for meaningful educational experiences are laudable, they are usually unnecessary and probably inappropriate for most practicing cardiologists as a vehicle for continuing medical education.

INVASIVE CARDIOLOGIST IN CLINICAL RESEARCH

Clinical research in invasive cardiology is expanding rapidly with many cardiologists involved in research trials with little if any prior experience in this area. The drug and device manufacturers want to obtain their required data as quickly as possible and thus have expanded the number of sites to include hospitals without established research programs or staff experienced in clinical research. Frequently, the invasive cardiologist serves two simultaneous roles: clinical researcher and treating clinician. Increasingly, industry provides a variety of incentives, financial and nonfinancial, for clinician-researchers to evaluate their products and enroll patients in their trials. However, the physician must remember at all times that his first allegiance is to his patient. The clinician-researcher should withdraw the subject from the research trial if another avenue of treatment is in the subject’s best interest. Patients must be fully informed and great caution should be taken when enrolling subjects who are critically ill or may have difficulty for other reasons in understanding the difference between research and clinical care. The researcher

should be aware that many potential subjects view research opportunities offered by their physicians to be established treatment and do not understand that participation is optional [13]. In some studies, it might be difficult to perform both roles of clinical care and research and in these situations a second physician’s services should be obtained [14]. The busy clinical researcher with many competing research projects must be particularly aware of conflicts. Does he offer the project with the highest compensation, or the one in which he is furthest from his target number of subjects? Does he tell the subject about all opportunities and let the subject choose? This is an ethical dilemma. Again, the patient’s interest is paramount.

The suggested solutions for conflicts of interest range from simple disclosure of this financial conflict to modification of the researcher’s responsibilities so that the individual with the conflict does not have responsibilities for design, data collection, or analysis. Institutions are now required to have a conflict-of-interest policy and to document the conflict and the management of this conflict.

Nonfinancial conflicts of interest [15] have not been seriously addressed and no remedies have been suggested for their identification, disclosure, or management. These conflicts include the desire for personal recognition in order to obtain academic or professional promotions, the pursuit of a longer list of published articles, obtaining or maintaining grant support and any other aspect of academic self-interest. The researcher must be aware at all times of these conflicting pressures and must never allow these pressures to deflect from his duty to the patient. It is not certain that just being aware of these conflicts is enough to prevent unethical behavior. If the culture of the entire institution as stated by both words and deeds of its leaders espouses ethical behavior, then this institutional culture will be a powerful deterrent to unethical behavior.

Many clinical trials are now sponsored by industry. Although the editors of major medical journals [16] outlined the desired arrangements for the contract between the researchers and industry, a recent review [17] of academic institutions showed that these guidelines were not being followed. The trend toward large rapidly performed multicenter trials has limited the ability of the individual researcher to negotiate a contract. Notwithstanding this difficulty, to preserve scientific integrity it is important for the researchers to be involved in the design of the study, to own the data, to have the right of analysis, and to be able to report negative as well as positive results. Although the NIH has increased its research budget, the pharmaceutical and device companies have increased their budgets proportionally more and thus supply the majority of funding for clinical research,

particularly in invasive/interventional cardiology. The physician is interested primarily in scientific validity, safety, and practicality. The industry sponsor, while sharing these interests, is primarily interested in profitability, prompt FDA approval, and marketability. Industry sponsors may be less inclined to address ancillary issues of scientific interest or to report negative results. This divergence of motives means that the study design, analysis, and reporting are viewed differently by the physician-investigator and sponsors. The sponsors in charge of the funding have the upper hand in the development of the contract. The researcher is often left choosing between a contract that gives most of the authority to the sponsors or not participating in the research at all. A new entity, for-profit contract research organizations, has further distanced the researcher from the industrial sponsor. These organizations, funded by industry, serve to expedite the clinical trial by encouraging and facilitating patient recruitment, managing and analyzing the data, and even manuscript writing. With these organizations as an intermediary between industry and the clinical researchers, the physicians have little or no oversight of the entire research process. It is important to publish negative as well as positive results. If there is a reporting bias in favor of only positive results, not only will research be unnecessarily repeated in the future, but future meta-analyses will also be faulty [18].

SUMMARY

The invasive cardiologist must balance his primary responsibility to his patients with his interactions with colleagues, his dependency on industry for new technology, his teaching and research interests, his administrative duties, and his desire to be connected to advance his career. The burgeoning growth of invasive cardiology and the many technological advances in recent years, together with increasing cost consciousness and scrutiny of health care by others, have imposed new challenges to ethical behavior. His position in the economic hierarchy among physicians, with the hospital, and his employment of expensive technology place him in an especially sensitive position. His duty to his patients is paramount in importance.

We have reviewed the ethical principles that must guide the invasive cardiologist with his various constituencies. Implicit in this is the invasive cardiologist's responsibility to maintain and enhance not only his reputation in the community, but the status of cardiology and the entire medical profession. Failure to recognize these principles can only invite erosion of public confidence in the medical community, increasing regulation by governmental bodies, and impairment of the cardiologist's ability to function as his patient's advocate as well as a respected teacher and researcher.

ologist's ability to function as his patient's advocate as well as a respected teacher and researcher.

ACKNOWLEDGMENTS

The authors thank Professor Nancy Dubler, Albert Einstein College of Medicine, for her review and suggestions and Dr. Carl Tommaso for his contribution.

REFERENCES

1. Council on Ethical and Judicial Affairs, American Medical Association. Code of medical ethics. Chicago: American Medical Association; 1997.
2. Bashore TM. American College of Cardiology/Society for Cardiac Angiography and Interventions: clinical expert consensus document on cardiac catheterization laboratory standards. *J Am Coll Cardiol* 2001;37:2171–2214.
3. Feldman T. Growing challenges in clinical research. *Catheter Cardiovasc Interv* 2002;57:277–278.
4. Moynihan R. Who pays for the pizza? redefining the relationships between doctors and drug companies—1, entanglement. *Br Med J* 2003;326:1189–1192.
5. Moynihan R. Who pays for the pizza? redefining the relationships between doctors and drug companies—2, disentanglement. *Br Med J* 2003;326:1193–1196.
6. Abbasi K, Smith R. No more free lunches. *Br Med J* 2003;326:1155–1156.
7. Dana J, Loewenstein G. A social science perspective on gifts to physicians from industry. *JAMA* 2003;290:252–255.
8. Laboratory Performance Standards Committee. Society for Cardiac Angiography guidelines regarding qualifications and responsibilities of a catheterization laboratory director. *Cathet Cardiovasc Diagn* 1983;9:619–621.
9. Laskey WK. Assuring quality in our profession. *Cathet Cardiovasc Diagn* 1997;40:231–233.
10. Heupler FA, Al-Hani AJ, Dear WE. Guidelines for continuous quality improvement in the cardiac catheterization laboratory. *Cathet Cardiovasc Diagn* 1993;30:191–200.
11. Hildner FJ. Ethical issues in cardiovascular publications. *Catheter Cardiovasc Interv* 2003;60:202–207.
12. Choudhry NK, Stelfox HT, Detsky AS. Relationships between authors of clinical practice guidelines and the pharmaceutical industry. *JAMA* 2002;287:612–617.
13. Miller FG, Rosenstein DL. The therapeutic orientation to clinical trials. *N Engl J Med* 2003;348:1383–1386.
14. Council on Ethics, American Medical Association. Managing conflicts of interest in the conduct of clinical trials. *JAMA* 2000;287:78–84.
15. Levinsky NG. Nonfinancial conflicts of interest in research. *N Engl J Med* 2002;347:759–761.
16. Davidoff F, DeAngelis CD, Drazen JM, Hoey J, Hojgaard L, Horton R, Kotzin S, Nicholls MG, Nylenna M, Overbeke AJPM, Sox HC, Van Der Weyden, MB, Wilkes MS. Sponsorship, authorship and accountability. *N Engl J Med* 2001;345:825–827.
17. Schulman KA, Seils DM, Timbie JW, Sugarman J, Dame LA, Weinfurt KP, Mark DB, Califf RM. A national survey of provisions in clinical trial agreements between medical schools and industry sponsors. *N Engl J Med* 2002;347:1335–1341.
18. Johansen HK, Gotzsche PC. Problems in the design and reporting of trials of antifungal agents encountered during meta-analysis. *JAMA* 1999;282:1752–1759.