



The Society for Cardiovascular Angiography and Interventions

SCAI President's Page



The Dilemma

John McB. Hodgson, MD, FSCAI
Heart and Vascular Center
MetroHealth Medical Center
Cleveland, Ohio
President
Society for Cardiovascular Angiography and Interventions

You've all been aware of this ethical dilemma. The Jones family waited anxiously in the visitor's area, not sure what was happening in the catheterization lab. Mr. Jones had been seen by the local Cardiology Specialty Group (CSG) for episodic chest pains (these events are fictitious for illustration only). Dr. Smith, the founding partner of CSG, had recommended a stress sestimibi scan which could conveniently be done right in the offices of the CSG-owned building. After Dr. Smith had reviewed the scan he had recommended a catheterization, which was scheduled for the next day in CSG's newly completed catheterization lab located on the first floor of their building.

Since Dr. Smith was well known in the community and had been written up in the local papers on numerous occasions for his involvement in the latest trials, the Jones's had no hesitation agreeing to his recommendations. Dr. Smith was running late, so he asked his research nurse Kathy to "finish up" with the preparations. Mr. Jones signed several papers which Kathy assured him Dr. Smith would want "just in case" so Mr. Jones could get the latest in investigational therapy.

This morning, the case had started well enough. Dr. Smith joined the team after Mr. Jones was comfortably

sedated. A bit late as usual, Kathy noted. She surmised he had been giving one of his frequent breakfast talks for Cindy, the local pharmaceutical representative. After a few pictures, a 50% smooth lesion was noted in the left anterior descending coronary. He wasn't quite sure, but Dr. Smith recalled that the sestimibi showed a possible inferior defect. Regardless, the patient was perfect for the new atherectomy trial he had waited four years to convince Newdevices Corporation to sponsor. Consent was on the chart and Kathy was ready with the device!

The Jones family was a bit unsettled when they saw three nurses race to the lab area in response to an overhead alarm. Thirty minutes later, a tearful Kathy approached them with the bad news. Dr. Smith had tried valiantly, but could not control the accidental bleeding that had occurred when he treated the coro-

*Correspondence to: John McB. Hodgson, MD, FSCAI, Heart and Vascular Center, MetroHealth Medical Center, 2500 MetroHealth Drive Cleveland, Ohio 44109. E-mail: president@scai.org

DOI 10.1002/ccd.10757

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

nary blockage. How could this have happened, the family asked?

Indeed, we all understand how such things can happen. After all, the patient did have coronary disease and needed to be treated. Or did he? Was his stress test really that “positive?” Was the intermittent pain really the result of the left anterior descending lesion? Was the experimental atherectomy device the best choice for treating this lesion? Did Mr. Jones really understand what he was getting involved in that morning? Had Dr. Smith’s evaluation and treatment been appropriate, ethical, and in the best interest of the patient and his family?

Thorny issues to be sure, issues we face every day. Admittedly, I have taken some liberty in the example presented, but I did so to highlight the importance of ethical issues in our everyday practice.

Your Society has promoted ethical and evidence-based practice since its inception in 1978. While much has been written on the subject of ethics in medicine, it has been difficult to find guidance specific to the unique situations that interventional cardiologists face almost daily. Indeed, the incredible pace of change in our field makes it even more difficult to find relevance in the more general ethical guidelines that are available.

Recognizing this vacuum, one of my predecessors (Dr. Carl Tommaso, SCAI President during 2000–2001) moved your Society into taking a leadership role in this area. He urged the Society to actually take a stand (as it has done in so many other areas) on an important – and potentially controversial – set of issues. How should a physician who also owns lucrative diagnostic equipment behave? What about the physician-inventor or the physician-researcher? What about the common practice of self-referral?

In response, SCAI created an ad-hoc Task Force on Medical Ethics, enlisting the assistance of many previous SCAI presidents and interested members. Their charge: research the field and recommend guidance for the practicing interventionalist. Under the leadership of Society Fellows and past presidents Airlie A. C. Cameron, M.D., Warren K. Laskey, M.D., and William C. Sheldon, M.D., the Task Force prepared an excellent review and recommendation statement, subsequently approved by SCAI’s Executive Committee [1].

How would our fictitious Dr. Smith stack up against the points made in the Ethics Statement? First, he had an obvious conflict of interest in recommending testing (sestimiibi and diagnostic catheterization) using facilities and equipment in which he had ownership. Such relationships should be disclosed at the very least, but additional independent and prospective quality assurance

monitoring should be in place to ensure the appropriateness of such referrals.

A much more common conflict existed in the ad-hoc angioplasty procedure. Again, ongoing quality assurance monitoring by the lab’s medical director of not just outcomes, but also indications, is mandatory. In this case, presumably a “buddy hospital” had agreed to “cover” the freestanding lab for interventional work. That “buddy” institution has an added responsibility to oversee Dr. Smith’s activities. If Dr. Smith was found to be consistently ordering stress tests that frequently resulted in diagnostic catheterization referrals, some red flags should have been raised.

Dr. Smith’s “informed consent” practice leaves much to be desired as well. This was delegated to a research nurse (who, of course, is paid to do research and recruit patients). Mr. Jones wasn’t sure he even *had* coronary disease, let alone be ready to sign up for a treatment or even less certainly an *experimental* treatment. Informed consent in these cases needs to be very detailed and offer much opportunity for questioning and reflection. Updates should be provided to the patient and their family so that they can provide ongoing consent as the procedure evolves from diagnostic to therapeutic to experimental.

Finally, it appears that Dr. Smith may have had a vested interest in the new atherectomy device. His full relationship to the company and any potential financial gain from device success should have been disclosed. In these cases, an independent colleague may be required to “authorize” enrollment in order to avoid overzealous recruitment or over-optimistic procedural execution. Dr. Smith might be deterred from being less than fully ethical if he practiced in an environment that offered close oversight and was empowered to effectively comment on his activities.

The medical director of the catheterization lab should be the point person in this process. Hospitals should support their medical directors with sufficient staff to collect data, committee time to review cases and administrative clout to restrict practices when they are found to be significantly off base. While Dr. Smith’s individual actions may have in each case been medically appropriate, his overall practice raises significant concern that he was not first and foremost acting as his patient’s advocate.

In the stir that would undoubtedly develop after Mr. Jones’ untimely death, Dr. Smith would likely find himself backpedaling rapidly to explain his actions! I suspect he would find himself suddenly quite alone. If a strong oversight environment existed, this system would then be his advocate, indicating a pattern of sound practice endorsed by the hospital and lab quality assurance committees. Oversight therefore provides

safety not only for the patient, but also for the physician.

We are all human. We are all subject to external pressures. I encourage you to read the Ethics Statement and reflect on your own personal situation. Do appropriate safeguards exist to assist you in being the best patient advocate you can be? If not, take a reprint of the statement and meet with your Catheterization Lab Medical Director and hospital administration. It's not too late to start.

By the way, I hear Mrs. Jones just registered to see Dr. Doe at the CSG clinic. It seems that since her husband passed away she too has had intermittent chest pains!

REFERENCE

1. Cameron AAC, Laskey WL, Sheldon WC. Ethical issues for invasive cardiologists. A report from the SCAI ad-hoc task force on medical ethics. *Catheter Cardiovasc Interv* 2004 (in press).