

CATH LAB MANAGEMENT

Making Peer Review Painless

**Interventional Cardiology
Catheterization Laboratory
Quality Self Improvement
Audits and the American
Medical Foundation for
Peer Review and Education**



Andrew Eisenhauer, MD, Donald Cutlip, MD, and Evelyn Baram-Clothier, PhG, JD

The American Medical Foundation for Peer Review and Education, Philadelphia, Pennsylvania

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Recently there have been public reports of a number of interventional cardiovascular programs that have been found to have serious deficiencies and, in some cases, evidence of highly inappropriate or even potentially fraudulent actions on the part of physicians. These quality lapses seemingly came as a surprise to those responsible for program oversight and to some cardiologists, in spite of published guidelines.

We all recognize that the process of external invited peer review can be unnerving to some, but it is important to acknowledge that increasingly we are all under external scrutiny, more than ever before. What can be done to ensure an effective ongoing quality review that will provide an “early warning” of issues that may become an important concern?

The non-profit American Medical Foundation for Peer Review and

Education offers an inexpensive physician audit and appropriateness survey. We review a random sample of each operator’s cases every 6 months. A report is sent to the physician along with the hospital for educational purposes. The number of cases reviewed is based upon an average volume of a physician’s cases per year, and the cost per case and the overall cost are very low.

Physicians and entire departments can also choose to avail themselves of a comprehensive review under the component American Medical Foundation Patient Safety Organization (AMF-PSO.org). Performing a self-audit under a PSO protects the information and findings from any discovery. Thus, hospitals and other providers that contract with the American Medical Foundation’s Patient Safety Organization can provide information to the PSO and have that information, as well as

reports back from the AMF-PSO, protected from discovery in almost any kind of state or federal civil, criminal and administrative proceedings, including malpractice lawsuits.

The AMF views itself and its mission as one of identifying potential problems and offering collegial solutions before less supportive payer, consumer, or statutory entities become involved. There are also sound educational opportunities provided, based on the reviews. In this regard, readers might be interested to learn something more about the AMF’s history and mission.

Evelyn Baram-Clothier, Executive Director of the non-profit American Medical Foundation for Peer Review and Education addresses frequently asked questions about the AMF peer review and the new self-audit program.

How did AMF come to be and where is it going?

The American Medical Foundation for Peer Review and Education was created in response to the Health Care Quality Improvement Act of 1986 and has operated for over 25 years. Almost immediately after the inception of this non-profit foundation, interventional cardiology began to develop as the most dynamic subspecialty in medicine. The AMF has been an active partner in the world of interventional cardiology since the beginning; we were participating in the process from the origin of balloon angioplasty, through the widespread adoption of stenting, to modern drug-eluting technology, and we remain at the forefront of the field today as new technology, unprecedented techniques, and the expansion of interventional practice continue to make interventional cardiology an exciting and pioneering discipline.

We have conducted over 3,000 hospital reviews in all 50 states, including over 375 cath labs and thousands of their cardiologists. The fact is that the rest of medicine has to race to keep up with the evolution of interventional cardiology into other vascular territories — in the peripheral vascular and cerebrovascular arenas — and into other cardiac territories such as transcatheter valve replacement. We can’t point to any other specialty that has been a more profound example of the way a single specialty can deal with such a wide variety of conditions affecting the well being of so many patients.

How long has AMF performed peer review in interventional cardiology?

In 1989, only a few years after the first clinical application of balloon

angioplasty, the non-profit American Medical Foundation for Peer Review and Education (AMF), working with several of the early pioneers, began assisting hospitals to improve quality of care in the fledgling field of interventional cardiology. AMF is now well known in the cardiology community for its dedication to this specialty and is the “go-to” organization with the experience and expertise to help.

AMF reviews coronary, peripheral vascular, carotid and other interventional procedures of individual practitioners or entire departments to determine:

- 1) Quality of care;
- 2) Appropriateness and necessity of procedures;
- 3) Compliance with the current guidelines for interventional procedures;
- 4) Responses to third party audit requests and state or federal investigations.

In performing its individually designed reviews, AMF has developed specialized processes to review cases efficiently and to limit case selection to obtain statistically significant audit results. Each review provides a comprehensive report with suggestions for quality of care improvement regarding issues such as medical necessity, patient selection, equipment and device selection, anticoagulant usage, operator technique and complication avoidance. Based on random case selection, the reports provide both educational opportunities as well as an audit that would satisfy third party challenges, whether for external peer review of individual physicians or entire departments. The AMF individual case analysis not only describes quality of care and appropriateness issues, but most importantly, serves as a guide for technical improvement in specific areas of care addressed by our physician reviewers, all of whom are the leaders and teachers in the field of interventional cardiology. AMF reviews and reports are designed to assist our hospitals and physicians to achieve quality results and withstand inspection if scrutinized by a governmental entity.

What is AMF’s importance to cath labs?

The AMF offers particular relevance to cath labs because we are the only organization with the experience of peer reviewing cath labs for clinical competency. This is an exacting, logistically complicated service to offer, but we have been accomplishing it for years. Currently, we perform almost weekly reviews somewhere in the United States.

Hospitals and other providers that contract with the American Medical Foundation’s Patient Safety Organization can provide information to the PSO and have that information, as well as reports back from the AMF-PSO, protected from discovery in almost any kind of state or federal civil, criminal and administrative proceedings, including malpractice lawsuits. Information being collected by the provider for possible reporting to the PSO is also protected from discovery, as would any analysis of that information by the PSO.

Because of the thoroughness of AMF protocols, the impartial philosophy of AMF non-profit status, and the quality and experience of the AMF review staff, we feel comfortable in saying that the AMF gives true meaning to the term “comprehensive laboratory review.” We can say this because of the legacy of the thousands of doctors and hospitals we have evaluated and helped over nearly a quarter century.

How does the American Medical Foundation make peer review practical and valuable?

We conduct medical staff peer reviews, specialty department assessments, and hospital and laboratory quality of care evaluations. We offer review of a single case of concern, or a statistically significant portion of an individual's entire practice, or reviews of all the individuals in an entire service department, including the supporting staff. We use well known experts and teachers in the field of interventional cardiology and do all the leg work that is required to produce a final report that meets the needs of the practitioners, hospital system, insurers and government oversight bodies.

Tell us more about the AMFPRO.

Interventional cardiovascular physicians and entire departments can select a comprehensive review under our component American Medical Foundation Patient Safety Organization (AMFPRO.org). The advantage of participating in an audit under a PSO is that any information uncovered or conclusion drawn is entirely protected from any litigation-related scrutiny. The Federal Patient Safety and Quality Improvement Act of 2005 and the regulations there under that were issued in November 2008 allow organizations engaged in “patient safety activities” to use and share information related to those activities without fear that the information will be discovered in a lawsuit. As the preamble to the regulations states: “For the first time, there will now be a uniform set of Federal protections that will be available in all states and U.S. territories and that extend to all health care practitioners and institutional providers.” The protected information is referred to as “patient safety work product.”

Thus, in order to gain the protection for patient safety work product provided by the law, health care providers must first establish a relationship with a PSO. PSOs are organizations that share the goal of improving the quality and safety of health care delivery.

By providing both privilege and confidentiality, PSOs create a secure

environment where clinicians and health care organizations can collect, aggregate, and analyze data, thereby improving quality by identifying and reducing the risks and hazards associated with patient care. Hospitals and other providers that contract with the American Medical Foundation's Patient Safety Organization can provide information to the PSO and have that information, as well as reports back from the AMFPRO, protected from discovery in almost any kind of state or federal civil, criminal and administrative proceedings, including malpractice lawsuits. Information being collected by the provider for possible reporting to the PSO is also protected from discovery, as would any analysis of that information by the PSO. The protection provided by the PSQIA goes far beyond anything currently provided by state peer review laws. The information generated can then be safely used for educational purposes. This is a serious option for cath labs to consider and the cost of such a review is related to the number and type of specialties and procedures covered and the size of the program.

Full and comprehensive reviews are sometimes necessary; how can we do something more efficient to monitor our lab? Can you offer cardiologists and their cath labs an inexpensive self-assessment tool?

AMF's purpose is to provide individual hospitals and catheterization laboratories with a process for assessing and improving quality based on appropriate utilization, case selection, and ongoing evaluation of operator performance. In general, we believe that peer review and credentialing are best performed apart from laboratory certification by a professional society. Further, as is the case with individual board certification, a one-time certificate, while helpful, is no substitute for ongoing education and analysis. Yet it is unwieldy and quite expensive for a program to review comprehensively every case it performs.

From our extensive and long-standing experience, we have found that ongoing periodic review of an appropriately chosen subset of cases allows one to assess if there is a warning signal of a more extensive problem. For example, serious adverse events are fortunately uncommon in interventional cardiology and while it is important for organizations to review their own adverse events, it is often quite difficult for peers within an institution to voice their true sentiments because of a concern that next review could be theirs and they could be



Figure 1. At a site visit. *Back row:* Drs. Robb, Shah, Chambers, Kavinsky, Piemonte, and Eisenhower. *Front row:* Drs. Cutlip, Baram-Clothier, Laham, and Cowley.



Figure 2. At a site visit. Left to right: Drs. Schaer, Burket, Sobieszczyk, Vetovec, Baram-Clothier, Hong, Eisenhower, Cowley, and Zhao.

subject to retaliatory negative feedback. In addition, such internal reviews, no matter how well intentioned, do not take into account the experience of the national standard of care — they are sometimes limited by local practice and locally identified expertise.

We can provide an institution with a plan for identifying case samples for review and review the records and imaging for 10-20% of interventional procedures (up to ten) per operator per quarter, and provide an unbiased and objective review of performance with recommendations for improvement of technique and outcomes, as well as systematic recommendations for improvement of internal review. Rather than just a review of “statistics,” we incorporate

an assessment of the individual operator's response to the challenges presented by their patient substrate. This is not a substitute for a well functioning internal quality assurance program — it serves as an efficient but objective external validation of quality in comparison to a national experience.

This program is offered at a fee that is in keeping with our non-profit goals. In view of the professional responsibility we have to all patients, AMF's leading interventional cardiologists have offered to help and are willing to take time from their own duties to participate.

All cases will be reviewed by interventional cardiologists who are

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Figure 3. At a site visit. Left to right: Drs. Brinker, Chambers, Tommaso, Hong, Cowley, Baram-Clothier, Schaer, Robb, Tcheng, and Hodgson.



Figure 4. Hard at work.



Figure 5. At a site visit. Left to right: Drs. Bass, Robb, Kern, Baram-Clothier, Tcheng, Chambers, Hong, and Cowley.

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both educators and practitioners. Cases believed to be of particular concern will be reviewed by two experts before being returned with comments.

The objective is to review a representative sample of both complicated and reportedly uncomplicated cases to evaluate appropriate use based on current appropriate use criteria and angiographic documentation; to assess the overall adequacy and veracity of record keeping and documentation; the technical quality of imaging; interventional technique; and documentation of results — including institution of appropriate medical therapy. We also search for adverse quality markers such as the performance of unnecessary or ill-conceived primary and ancillary procedures, potential staged procedure abuse, appropriate and accurate determination of angiographic lesion severity; adequate and forthright documentation of adverse outcomes, and well-thought out explanations and rationale for the performance of unusual or controversial procedures.

We also recommend that the institution show commitment to quality improvement as evidenced by participation in submission of accurate data to the American College of Cardiology's National Cardiovascular Data Registry (NCDR). We will review reports from the NCDR and local database to assess for potential areas of concerns.

We will prepare individual case review reports for each physician and for internal review by appropriate clinical staff and provide timely bi-annual reports to the hospital documenting performance and recommendations for quality improvement.

What about the education side of the equation?

That's the part of AMF that sometimes gets overlooked, because physicians are often intimidated by the fact that their work is being reviewed. AMF reviews are also a significant educational opportunity. Most physicians have not had their work reviewed systematically since their fellowships. Even though they may go to educational meetings, there are many practical issues that arise in day-to-day practice that we can help address — not only for the individual practitioner, but also for a laboratory or an entire program itself.

For example, an apparent excess of vascular access complications in an individual cardiologist's experience could be tied to laboratory anticoagulation protocol(s), local habit or inadequate protocols for vascular access management by ancillary staff. We would seek to understand the cause of apparent issues of quality and outline solutions. Despite often being viewed with skepticism by those we review, we actually seek to be helpful and supportive and to foster improvement.

AMF utilizes the Appropriate Use Criteria Guidelines of ACCF/SCAI/STS/AATS/AHA/ASNC as a key metric in the assessments of whether survival and other health outcomes would be expected to exceed the potential negative consequences of revascularization procedures.

The AMF subdivision, the **Foundation for Advanced Medical Education (FAME)**, conducts on-site mentoring (and soon telementoring) instruction of physicians. FAME also has a preceptor program and a practitioner skills assessment capability. In simple terms, the organization can assist in improving physicians' performance through knowledge of the field and its transmission to the physician. To help educate cardiologists in the development of peripheral skills in renal and iliac stent placement, AMF (through its FAME subsidiary) gave a \$600,000 grant to the Society for Cardiovascular Angiography and Interventions (SCAI), the American College of Cardiology (ACC) and the Society for Vascular Surgery (SVS) to study the development of interventional skills in practicing physicians and surgeons. We are currently working with one specialty society to provide post-graduate education with remote presence telementoring.

What's in it for the cath lab and hospital?

The best possible use of services is to call AMF in before a

catheterization laboratory or interventional program or hospital even perceives a problem. AMF's experienced reviewers can often see situations developing and bad clinical habits developing long before the people who are actually involved with the work itself do. That's just the nature of peer review — a dispassionate review can spot things that may be too difficult or politically sensitive for an effective internal audit. We can review and evaluate the entire staff, and offer practical suggestions to improve their skills to create better procedures and protocols. The AMF review staff is also skilled at identifying and discussing, with great sensitivity, the political and cultural obstacles that may be the primary impediments to true quality improvement. Much of this is very difficult, if not impossible, for any hospital to do on its own.

Why are cath labs a special problem?

A cath lab and interventional program can rarely simply shut down for review and education. The continuous needs of patients in crisis supersede any notion of doing so. It is precisely because of the AMF's ability to work within the strictures and constraints of this never-ending cycle of care that we can provide the type of services that we offer with a level of effectiveness that respects the particular needs of the laboratory and hospital staff and operation — and above all, the welfare of patients.

Why would a catheterization laboratory, hospital or physician contact the AMF before they believe they have an issue of quality?

Never before have the expectations of receiving optimal care and treatment been higher. Patients,

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their elected representatives in government, insurers and third-party payers of all types, as well as the media, have all become watchful observers of every action that takes place in medicine. By the time a quality concern reaches one of these constituencies, if the hospital is not already aware of it and taken action to remediate, the level of public concern escalates. The AMF can be an institution's best colleague and partner in this vigilance, providing an honest, accurate, dispassionate and confidential assessment. And it is through AMF's educational commitment that we can also provide specialty department review, credentialing support, on-site clinical education and continuous professional improvement.

For most hospitals, we present a rare opportunity for an institution to measure its performance, have experts review its medical personnel and solidify its level of patient care through teaching and instruction. In the absence of the participation of nationally prominent reviewers on behalf of AMF, these opportunities might not even exist. They profoundly understand the non-stop nature of patient care and hospital utilization. It all begins with the quality and experience of AMF reviewers.

What distinguishes the AMF reviewers?

Our reviewers are not "employed" by the AMF — most of our review committee members head distinguished programs, administrate and teach in fellowship programs, or serve in the top positions in academic medical practices throughout their distinguished careers. Many have been past presidents of SCAI or have had significant academic and practical quality assurance experience and all actually practice interventional cardiology. Reviewers participate in AMF reviews out of a sense of service to their profession and to the wider group of patients — they review charts, conduct on-site visits and interviews, provide preceptor programs, mediate and arbitrate problems of both individual practitioners and the entire specialty service, and offer the kind of continued guidance that other physicians can respect. Our reviewers are dedicated teachers who are willing to take the time and trouble to "go on the road" to share their knowledge.

What's the hardest part of the job?

Not all peer reviews are positive. We sometimes find that after careful consideration and re-consideration, a physician cannot perform up to the standard of care that is medically appropriate, and some of these physicians may end up losing privileges. That is always a difficult situation and never an easy thing to be responsible for. But we always act with both the physician and the patients' best interests foremost in mind.

Why wouldn't I just have a professional organization perform a lab survey?

While these groups are fine organizations and do an excellent job, there is an inherent conflict between a certifying professional organization and a peer review organization. Our sole purpose is to provide a framework for continuous quality improvement. Our job is to identify how a group of practitioners and a laboratory can develop a policy of excellence. In the past, several hospitals applied and failed to get certification, because they were not prepared. If a laboratory then wishes to apply for certification, we believe it will more easily achieve that result once any quality and appropriateness issues are identified by AMF.

What are the costs?

While each survey program and its charges are individualized, our physician appropriateness survey costs are very low — for a ten-case periodic review, cost is on the order of \$2500 per physician, per review period. For on-site or comprehensive review of an entire department or practice, our fees are only \$350 per reviewer hour. Given our non-profit status, our fees have remained consistently low over the years.

Is the American Medical Foundation peer review limited to cardiology?

We also have an expert faculty of reviewers in almost all sub-specialties of internal medicine and surgery (including radiology and pathology), and can offer similar expertise in these fields. However, I'd have to say that cath lab review is the "favored child" of this Executive Director. I'm so grateful, personally and on behalf of the AMF, for the support we've received from the nation's leaders in the field of interventional cardiology. They have traveled around the country with me, in three- and four-day review sessions, to help other cardiologists improve their skills. Many luminaries in interventional cardiology have spent hundreds of hours reviewing cases, studying

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Figure 6. Gaining consensus. Seated: Dr. Dehmer. Standing (L-R): Drs Cowley, Robb and Babb.



Figure 7. A "heart healthy" lunch break. Seated: Drs Block, Eisenhower and Chambers. Standing (L-R): Drs Reilly, Robb, Vetrovec, Baram-Clothier, Clemen, Schaer, Tommaso and Laham.

angiograms, assessing systems, and writing reports to help hospitals improve their lab and their staff.

If I have questions or would like to discuss a potential review, how do I contact you?

The American Medical Foundation's main office is in Philadelphia at the Barclay, 237 S. 18th Street. Our phone number is (215) 545-6363. We are online at www.medicalfoundation.org. You may also email us at info@medicalfoundation.org. ■