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REVIEWS

STATE-OF-THE-ART PAPERS

Evidence Base for Quality Control Activities in Cardiovascular Imaging

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ABSTRACT

Quality control is pervasive in most modern business, but, surprisingly, is in its infancy in medicine in general—and cardiovascular imaging in particular. The increasing awareness of the cost of cardiovascular imaging, matched by a desire to show benefits from imaging to patient outcome, suggests that this deficiency should be reassessed. Demonstration of improved quality has been proposed to require a focus on several domains: laboratory organization, patient selection, image acquisition, image interpretation, and results communication. Improvement in these steps will require adoption of a variety of interventions, including laboratory accreditation, appropriate use criteria, and continuous quality control and enhancements in reporting, but the evidence base for the benefit of interventions on these steps has been sparse. The purpose of this review is to evaluate the current status and future goals of developing the evidence base for these processes in cardiovascular imaging. (J Am Coll Cardiol Img 2016;9:294–305) © 2016 by the American College of Cardiology Foundation.

The initial adoption of scientific methods of quality control (QC) from industry to medicine started >50 years ago (1). Despite sporadic interest in QC, several markers point toward ongoing limitations of health care QC, including inappropriate care (2), disagreements among experts (3), geographic and provider variations in practice and care (4), and medical injuries to patients (5). Fortunately, the possibility of harm is limited in imaging (although there are potential risks from stress testing, contrast agents, radiation exposure, or misinterpretation of tests), but the other markers are prevalent in imaging practice.

A series of influential frameworks have sought to address these concerns and to encourage evidence-based medicine (6). Outside of the assessment of process measures, the efficacy of current strategies to improve care remains a subject of ongoing research. The field poses a number of challenges, not the least of which is that the role of the randomized controlled trial—the conventional approach to studying causal relationships and incremental benefit/harm—has limitations in the evaluation of complex social and interpersonal systems that characterize the interaction of imaging services with clinical practice.

The growth of cardiovascular imaging has had a sizable economic impact, but the contribution of imaging to changes in disease outcomes is unclear. Defining the contribution of existing and new tests to patient outcome and building an effective cardiovascular imaging QC process is an important goal (7). This paper reviews the components of imaging QC (including laboratory organization, patient selection, image acquisition, image interpretation, and results communication), the reported experience with QC in the imaging laboratory (including the assessment of ventricular function and valvular disease), and considerations about safety. The purpose

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of this review is to facilitate the wider adoption of the QC process.

QUALITY CONTROL

The ultimate goal of imaging is to provide a single, appropriate test at the right time and to the right patient that is performed, interpreted, and integrated correctly into patient management (**Central Illustration**) (7). The following sections seek to define the evidence base for the 4 defined domains that affect patient outcomes (7) as well as the often-neglected but critical link of appropriate decision-making with outcome.

LABORATORY ORGANIZATION. Setting up the right processes is perceived as having a pivotal role in offering high-quality studies. An accreditation program can ensure that cardiovascular imaging laboratories identify and address potential problems on a regular basis. In the United States, the Intersocietal Accreditation Commission (IAC) provides such a program. Although the process is voluntary, it is recommended by professional bodies (e.g., American Society of Echocardiography [ASE], American Society of Nuclear Cardiology, Society for Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance [SCMR], and other imaging societies) and linked to the reimbursement by a number of payers, including Medicare. The process of accreditation oversees the physical environment, facility and equipment, technical and medical staff, examination, and procedures; assuring that the laboratory meets minimum requirements and has a QC model in place. IAC stipulates that laboratories should have medical directors preferably with level 3 training (or equivalent), technical directors and technical staff with appropriate credentials, and interpreters at level 2 training or higher (8–11). However, the variation in stipulated training levels between jurisdictions (**Table 1**) (12–15) is a reflection of their limited or absent evidence base. The accreditation process is also variable, being voluntary and only provided for echo in Europe (15), whereas Australia lacks a formal assessment for laboratory accreditation. An optimal model in QC in a large laboratory would include the presence of a specific position to facilitate regular assessment of QC measures, organize regular QC meetings, and assure recording and appropriate follow-up of the findings. Optimally, this QC leader would be highly trained and experienced, but most importantly would be knowledgeable about the principles of QC. In most instances, this person would be the technical or medical director.

A second component of the laboratory environment is infrastructure. Funding arrangements in Australia involve differential reimbursement of current and older equipment. With the incorporation of 3-dimensional (3D) echocardiography and myocardial strain in guidelines (16,17), an echocardiography laboratory lacking this equipment or expertise may not be considered "state of the art." Likewise, because image quality is suboptimal in 10% to 15% of echocardiograms and as many as 30% of critically ill patients (18), failure to use ultrasound contrast agents is a marker of suboptimal examinations and the proportion of studies involving contrast is a potential marker of quality. Each laboratory should have a list of indications for contrast, including poor endocardial delineation, suspected left ventricular (LV) thrombus, apical hypertrophic cardiomyopathy, LV noncompaction, and enhancement of suboptimal spectral Doppler signals (19). Similarly, the provision of appropriate equipment for dose minimization for cardiac computed tomography (CT) is likewise an essential marker of quality infrastructure (10).

An accreditation process also assures that academic laboratories involved in training programs have the expertise to offer quality training. The current training task force report mandates that an echocardiography laboratory in which training of cardiology fellows is undertaken should be supervised by a physician with level 3 training (13). For cardiac magnetic resonance (CMR), trainers should be at level 2 or 3 (the latter preferred) (20). The European Association of Cardiovascular Imaging (EACVI) recommends that echo laboratories involved in research and training should be at the "advanced standards" level (15).

Although many of these suggestions are logical, this process would be strengthened if evidence could be gathered to support the impact of these laboratory measures on patient outcome. This is particularly the case in relation to the application (and more importantly mandating) of this process in smaller laboratories and cardiology practices.

PATIENT SELECTION. The initial step to improve patient selection has been the development of appropriate use criteria (AUC). The growth of cardiovascular imaging has been an important catalyst to the development of these guidelines, and although their uptake has been slow outside of North America, this problem is not limited to just that jurisdiction. Thus, although the presence of different workflows may inhibit the implementation of exactly the same model, it seems likely that similar guidance will be needed in other regions of the world.

ABBREVIATIONS AND ACRONYMS

AR = aortic regurgitation
AUC = appropriate use criteria
CTA = computed tomography angiography
CMR = cardiac magnetic resonance
CT = computed tomography
2D = 2-dimensional
3D = 3-dimensional
EF = ejection fraction
FFR = fractional flow reserve
LV = left ventricular
MRI = magnetic resonance imaging
PET = positron emission tomography
RV = right ventricular
QC = quality control
SPECT = single photon emission computed tomography
TEE = transesophageal echocardiography
TTE = transthoracic echocardiography