Chapter 15
MRI: Laboratory Accreditation and Quality Improvement Program

Ibrahim M. Saeed

Abstract Given the complex nature of cardiac magnetic resonance imaging it is important to have in place a robust quality improvement program that is a partnership between the physician and the technologist. Laboratory accreditation will be reviewed as a mechanism for building a high quality laboratory. Key components of this program will be reviewed including physician recognition of artifacts, scheduling, technologist training, review of imaging data and interpreter quality control. It is important to recognize those events which should never occur during a cardiac magnetic resonance imaging study. General and specific safety recommendations will be reviewed.

Keywords Quality improvement • Laboratory accreditation • Imaging artifact • Interpreter quality control • "never" events

Laboratory Accreditation

Accreditation of cardiac magnetic resonance (CMR) laboratories by one of three CMS approved accrediting bodies, the American College of Radiology (ACR), the Intersocietal Accreditation Commission (IAC) or the Joint Commission, is an important recognition of the quality of the entire imaging process. Given that CMR is considered an advanced imaging modality, accreditation is required for reimbursement by Medicare as a result of the Medicare Improvements for Patients and Providers Act of 2008. Each organization has unique aspects of their accreditation program that may make one a better 'fit' than another with regard to a laboratory and its specific characteristics, e.g. hospital based, free standing, or multi-modality.

The ACR model is more often utilized by laboratories that have multiple imaging modalities that are being accredited simultaneously. The Joint Commission pathway

I.M. Saeed, MD, FACC, FAAP
Saint Luke's Mid America Heart Institute Cardiovascular Consultants,
University of Missouri, Kansas City, MO, USA
e-mail: isaeed@saint-lukes.org

P.L. Tilkemeier et al. (eds.), *Quality Evaluation in Non-Invasive Cardiovascular Imaging*, DOI 10.1007/978-3-319-28011-0_15

is commonly used by laboratories that are undergoing routine accreditation visits by the Joint Commission, hospital based facilities for example. The IAC pathway can be utilized by all laboratories and includes a broad assessment of a laboratory's performance from three perspectives: staff qualifications, patient testing and a quality improvement program.

Specifics of the ACR program have been included in Chap. 13. The ACR program has specific requirements to assess image quality and equipment performance using a proprietary phantom, any appropriately designed phantom will suffice as part of a local QC program (ACR reference). Other groups, like The Intersocietal Accreditation Commission (IAC) [1] or the Joint Commission [2], provide similar guidelines, but do not specifically define how the testing is to be performed, only what must be included as part of the QC testing. The ACR model specifically defines both an annual examination (long term monitoring) and a daily/weekly (short term) monitoring schedule.

In distinction to the accreditation of laboratories, physicians can achieve individual certification documenting their skills from the Society of Cardiovascular Magnetic Resonance (SCMR). The process requires board certification in an appropriate cardiovascular subspecialty, initial and ongoing participation in coursework relative to CMR, performing the required number of interpretations and participation in ongoing quality management /improvement programs in the laboratory. Details can be located on the SCMR website, www.scmr.org.

Identifying What Steps Need to Be Evaluated for Quality

Performing a cardiac MR (CMR) study is highly complex and involves multiple steps including, scheduling, patient preparation, sequence optimization, image acquisition, processing and reporting. However, critical to success is the ability to repeat the process again and again, in an efficient manner. To ensure success, follow-up information regarding all aspects of CMR is necessary, including the impact on patient management and outcome. Furthermore, complications and inadequate/inaccurate studies require careful review. The directors (technical and medical) would ideally have a process in place where each of these steps is continually reviewed.

Scheduling is critical to success. Selection of a device, such as a 1.5 T or a 3 T magnet is important as well as when an extended scan is required-both mandate forethought and planning. Schedulers also must prepare the patient, and also serve as the front line for MR safety by reviewing one of the established contraindication checklists. For any concerns or questions, they often communicate with the MR technologists or the directors.

Physician education is important to the success of a CMR program. The interpreting and supervising physicians as well as the medical director for the laboratory must have all of the required training elements to insure appropriate oversight of the individual patient studies and the overall functioning of the

laboratory. This includes the required assessment of the technical quality, patient safety, patient selection and appropriate protocol selection, image review and inter/intra observer interpreter variability and other elements of an ongoing quality assurance program. The physician(s) must participate in ongoing education to insure they are aware of and have implemented the latest techniques to insure the highest quality patient studies possible.

Technologists are critical to the success of a CMR program. While often highly trained, they should also seek guidance from the director to help guide the sequence parameters, which is a significant investment in time from the physician and group practice or hospital. Furthermore, for each indication a **sequence protocol** is reviewed by the medical director or interpreting physician beforehand for appropriateness, with any suggestions to alter the established protocol, such as valvular heart disease or congenital issues. In the meantime, depending on the sequence, the protocol may be "locked" with minor adjustments, so as to maintain efficiency. Finally, regular constructive feedback is given. Technologists must regularly attend educational conferences and maintain appropriate certification.

An MR examination typically generates a large amount of **imaging data**. Most practices have an archival system such as PACS. There are several post-processing solutions that allow the user to calculate the ejection fraction, quantify flow or tissue characterization, 3D rotation for multiplanar reformatting or maximum intensity projections, or viewing a region of interest in orthogonal planes. The ability to recall, reprocess and reinterpret studies after initial acquisition is an important part of the imaging process as the post-acquisition/processing review of a study can often occur on an independent workstation.

Interpreter quality control can be difficult, particularly at a smaller institution where not many CMR readers exist. Multi-modality conferences may help to ensure validation and cross-correlation. This may be done by comparing LVEF measurements between CMR and other modalities and determine why variations may exist, such as whether or not the papillary muscles are included in the assessment. Similarly, comparison of post-gadolinium images with nuclear cardiology techniques is also important. Finally, follow up to see if evaluation of pathology (such as whether viable tissue did or did not recover after revascularization, or if tumor pathology was consistent with interpretation) is critical.

"NEVER-EVENTS" and MR Safety

Introduction

While the use of magnetic resonance does not have any of the inherent risks associated with ionizing radiation, there are still many safety considerations of which to be aware. Of primary concern are the main magnetic field forces, radiofrequency heating, patients with implants or metal working history, and the operating noise from gradient switching [3]. MRI safety requires continued education and

constant vigilance because the magnetic field is always present and the array of implanted medical devices in use is constantly changing.

The Main Magnetic Field

The MR suite is first and foremost designed around the strength of the main magnetic field of the unit. While there are no readily recognized adverse biological effects with exposure to the magnetic fields utilized in clinical MRI, environmental factors can become dangerous [4]. Within this field (which rapidly grows in strength with proximity to the bore) even the most benign seeming objects will become subject to force or torque wanting to move or twist. This can lead to them to become dangerous projectiles. The high field strengths typically in use are also strong enough to pull larger sized items like chairs, floor buffers, and gurneys into the bore [5]. The most effective way to prevent this from occurring is to physically restrict access to and control movement around the vicinity of the magnet and implement a rigorous screening process [6, 7].

Once inside the magnet room (Zone 4) make note of the five Gauss line. This line is a three dimensional bubble surrounding the magnet and defining the point at which the static field strength greatly increases and is regularly defined in site planning prior to installation. Items that normally do not behave as magnetic may exhibit magnetic attraction within this area. Often the line will be marked on the floor of the scanning room to explicitly mark the transition point. All screening should take place outside of the magnet room (see below for suggestions) paying special attention to patients with prior medical implants to ensure their safety as they may be at particularly high risk of injury (see section "Medical implants").

RF Heating

The same RF energy used to excite the hydrogen protons will also cause heating (both core and locally) potentially leading to injury if not controlled [8]. Exposure to RF is measured by the specific absorption rate (SAR), an estimate of heating based on the patient's mass measured in Watts per kilogram [9]. These values are typically presented as a running average of exposure over a 6 min or 10 s period. Clinical limits are based upon standards developed by the International Electrotechnical Commission standards (IEC 60601-2-33). The FDA further recommends RF exposure levels limiting core temperature rise of 1 °C and local heating dependent upon body region. Fortunately, the standard operating modes of all modern scanners limit the amount of RF energy a patient may receive. Local heating is typically limited to the skin's surface and can thus be dissipated in part by utilizing the onboard patient cooling systems. There have been instances of injury due to the use of non-compliant patient monitoring leads, looping wires, and clothing, but these

can be avoided by strict adherence to proper patient preparation guidelines. Patients with prior medical implants may be at particularly high risk of local heating injury and require special attention (see section "Medical implants").

Medical Implants

Special consideration must be given to patients scheduled to undergo an MRI with prior medical devices [3]. There have been a great many advancements in the design and manufacture of medical devices many of which are able to safely be imaged with MR. Devices may experience any or all of the previously mentioned effects. Static devices may displace under the force and torques generated in the magnetic field, electronic devices may malfunction under the RF excitation, and/or the RF excitation may also cause dangerous local heating. This is further complicated by the fact that a device may be MR compatible at one field strength (1.5 T) but not another (3.0 T) so it is important to always confirm that implanted devices are safe for the magnetic field to be used. An excellent resource, "The List" is found online at www.mrisafety.com and is continuously updated and lists whether devices may be safely imaged at particular field strength.

Noise

The gradient switching systems on a clinical MRI scanner generate a lot of loud noise (up over 115 dB) that can permanently damage hearing and result in injury [10].

This is easily addressed by always making sure that all patients are properly fitted with appropriate hearing protection (headphones, earplugs, or both) prior to beginning the exam. Many of these systems incorporate a way for patients to receive instructions from the technologist and also listen to music or other entertainment during the exam. The patient should also be encouraged to maintain communication with the technologist during the exam and notify if at any time the noise level they experience increases because the earplugs/earphones become too loose.

General MRI Safety Suggestions

1. Control the environment
   (a) Limit access to the control room/magnet room
   (b) Everyone clears pockets and is screened for metal items before every entry into magnet room
   (c) Always screen patients before entering the MRI suite/bore

(d) Implement a magnetic detector curtain on door or wand to screen individuals entering the scanning room for metal.
(e) Screen all items to be used in the MR suite. Label all MRI safe items. DO NOT allow unscreened outside items in. Especially while the patient is in the bore. Assume all unscreened items are magnetic.

2. Patient Safety

(a) Be aware of SAR limits.
(b) ALWAYS have hearing protection properly installed on patient.
(c) ALWAYS have multiple methods for communication with the patient.

(i) Engage often with the microphone
(ii) Emergency "squeeze ball"

(d) NO LOOPS in coil wires or on patients
(e) NEVER inject a contrast agent without a physician present.
(f) All patients should use the medical gowns and remove belts, earrings, rings, change in pockets, or any other items that MAY contain metal

(i) Even underwire in bra or other clothing may pose a hazard in the magnet

(g) Screen the patient.

(i) Double check patient medical records
(ii) Implants must be verified as MR SAFE/MR compatible FOR THE FIELD strength of the magnet being used to image (lookup or verify with manufacturer). When in doubt pull the records and verify. DO NOT simply rely on the patients' memory. "Trust… but verify".

(h) Take special care when patient is under anesthesia and unable to communicate.

3. Practice Safety

(a) Have a safety and emergency response plan.

(i) Use signage to clearly mark emergency response items.

(b) Practice rapid removal of patient from magnet.
(c) All necessary safety equipment should be immediately available or on the emergency cart
(d) Use proper monitoring equipment.

Technical: Equipment

A quality assurance program for technical performance of the equipment is essential to assuring high quality images. A rigorous quality assurance program for the laboratory must be developed and monitored by the technologists, physicians and laboratory administrative leadership routinely. The requirements of such a program are outlined in detail in Chap. 13.

Development of a Quality Assurance Program

The development of a quality assurance program must be part of the initial setup of the laboratory and must be designed to meet the specifics of the equipment, physical facility, staff, and most importantly the patients being tested and imaged. Such a program needs to be part of an accreditation program and undergo periodic review to insure it is meeting the needs of the laboratory. This would include revision as new technology and techniques are developed and clinically implemented, new cameras are added, new staff (technologists or physicians) join the laboratory or any other changes are implemented that could affect the quality of the complex CMR imaging chain.

Conclusion

A high quality CMR laboratory must have a multi-dimensional approach to quality assurance and improvement that is based in an accreditation process. The process must include all aspects of a CMR study: appropriate patient selection; patient preparation; technical quality; qualified personnel; selection of appropriate protocols to address the clinical question; image interpretation quality assurance, including comparison to other modalities; addressing "never" events and mechanisms to assure they do not occur; and generating a timely and high quality report communicating the results succinctly and meaningfully. Performance at this high level will insure the continued growth of CMR as a technology to meet increasing patient needs and demands.

References

1. Intersocietal Accreditation Commission. "The IAC Standards and Guidelines for MRI Accreditation." 2012. Available from: http://www.intersocietal.org/mri/main/mri_standards.htm
2. The Joint Commission. Facts about Ambulatory Care Accreditation. [Internet]. 2014 [cited 2014 December 12]. Available from: http://www.jointcommission.org/assets/1/18/Ambulatorycare_1_112.PDF.
3. Levine G, Gomes A, Arai A, Bluemke D, Flamm S, Kanal E, Martin ET, Smith JM, Wilke N, Shellock F. Safety of magnetic resonance imaging in patients with cardiovascular devices: an American Heart Association Scientific Statement From the Committee on Diagnostic and Interventional Cardiac Catheterization, Council on Clinical Cardiology, and the Council on Cardiovascular Radiology and Intervention: Endorsed by the American College of Cardiology Foundation, the North American Society for Cardiac Imaging, and the Society for Cardiovascular Magnetic Resonance. Circulation. 2007; 2878–91.
4. Schenck JF. Safety of strong, static magnetic fields. J Magn Reson Imag. 2000;12(1):2–19.
5. Chaljub G, et al. Projectile cylinder accidents resulting from the presence of ferromagnetic nitrous oxide or oxygen tanks in the MR suite. Am J Roentgenol. 2001;177(1):27–30.
6. Kanal E, et al. American College of Radiology white paper on MR safety. Am J Roentgenol. 2002;178(6):1335–47.

7. Shellock FG, Spinazzi A. MRI safety update 2008: part 2, screening patients for MRI. Am J Roentgenol. 2008;191(4):1140–9.
8. Dempsey MF, Condon B. Thermal injuries associated with MRI. Clin Radiol. 2001;56(6): 457–65.
9. Shellock FG. Radiofrequency energy-induced heating during MR procedures: a review. J Magn Reson Imag. 2000;12(1):30–6.
10. Price DL, De Wilde JP, Papadaki AM, Curran JS, Kitney RI. Investigation of acoustic noise on 15 MRI scanners from 0.2T to 3T. J Magn Reson Imag. 2001;13:288–93. doi:10.1002/1522-2586(200102)13:2<288::AID-JMRI1041>3.0.CO;2-P.