Department of Veterans Affairs
Office of Inspector General

Combined Assessment Program Summary Report

Evaluation of Magnetic Resonance Imaging Safety in Veterans Health Administration Facilities

Report No. 09-01038-77 **January 26, 2011**

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations

Call the OIG Hotline – (800) 488-8244
E-Mail: vaoighotline@va.gov
(Hotline Information: http://www.va.gov/oig/contacts/hotline.asp)

Executive Summary

The VA Office of Inspector General, Office of Healthcare Inspections evaluated Veterans Health Administration facilities' magnetic resonance imaging (MRI) safety programs by determining whether facilities: (1) implemented and maintained MRI safety and infection control policies and procedures, (2) provided adequate employee training, (3) completed appropriate patient screening and informed consents, and (4) conducted risk assessments of MRI suites.

Inspectors evaluated 50 MRI suites at 43 facilities during Combined Assessment Program reviews conducted from July 1, 2009, through September 30, 2010. VHA facilities had recognized the importance of safety in the MRI suites and had implemented adequate policies and procedures. We identified four areas where compliance with MRI safety requirements and guidelines needs to improve. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that:

- All employees who may need to enter the MRI suite receive initial and annual MRI safety training.
- Employees screen patients prior to MRI scans, obtain necessary signatures on screening forms, retain screening forms in patient medical records, and document follow-up on potential contraindications for MRI.
- Informed consents specific to MRI with contrast are completed for all high-risk patients and documented in the medical records.
- Physical barriers are in place, call systems are tested and maintained, risk assessments are completed, and emergency drills are conducted.

The Under Secretary for Health concurred with the recommendations and provided implementation plans with target completion dates. We will follow up on the actions until they are completed.

DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Under Secretary for Health (10)

SUBJECT: Combined Assessment Program Summary Report – Evaluation of Magnetic Resonance Imaging Safety in Veterans Health Administration Facilities

Purpose

The VA Office of Inspector General, Office of Healthcare Inspections (OHI) evaluated Veterans Health Administration (VHA) facilities' magnetic resonance imaging (MRI) safety programs. We determined whether facilities: (1) implemented and maintained MRI safety and infection control policies and procedures, (2) provided adequate employee training, (3) completed appropriate patient screening and informed consents, and (4) conducted risk assessments of MRI suites.

Background

MRI uses a powerful magnetic field, radio waves, and a computer to provide detailed images of organs and tissues without the need for x-rays. MRI is generally harmless to patients when employees follow safety precautions. The powerful magnetic field of the scanner can cause metallic objects, known as ferromagnetic objects, to move with great force towards the center of the scanner, creating a safety risk to anyone in the way of the projectile. Employees must take precautions to prevent ferromagnetic objects from entering certain areas in the MRI suite.

More than 10 million MRI scans are performed in the United States each year. In 2007, the American College of Radiology (ACR) issued guidelines establishing industry standards for safe and responsible practices in MRI suites.[1] Although many VHA facilities follow ACR guidelines, VHA has not mandated that all its facilities must follow these guidelines. ACR guidelines define four zones:

Zone I: This area is accessible to the public.

[1] Emanuel Kanal, et al., *ACR Guidance Document for Safe MR Practices: 2007*, *AJR*, 188, June 2007, pp. 1–27.

Zone II: MRI staff greet patients in Zone II and supervise them from this point forward.

Zone III: This is the region in which ferromagnetic objects can result in serious injury. Access is strictly controlled by, and entirely under the supervision of, MRI personnel.

Zone IV: This area contains the magnet and its associated magnetic field and should be clearly marked as potentially hazardous.

In 2008, The Joint Commission (JC) published a Sentinel Event Alert in response to an increase in MRI accidents and injuries over a 10-year period.[2] Also in 2008, VA's National Center for Patient Safety published a hazard summary that encouraged redesign, revised procedures, and training to mitigate MRI risks.[3] In 2009, JC environment of care standards began requiring that facilities use published alerts to assess risk.[4]

In June 2008, OHI conducted a hotline inspection in response to an allegation of patient neglect during an MRI procedure.[5] The patient crawled out of the MRI scanner after his calls for help were unanswered. We determined that the panic button was inoperable and that the facility had not performed routine maintenance checks of the MRI intercom system and panic button.

Scope and Methodology

Inspectors evaluated 50 MRI suites at 43 facilities during Combined Assessment Program (CAP) reviews conducted from July 1, 2009, through September 30, 2010. The facilities reviewed represented a mix of size, affiliation, geographic location, and Veterans Integrated Service Networks (VISNs). The review was limited to facilities with VA-staffed, permanent MRI suites (mobile MRI units were excluded). We interviewed selected program managers and reviewed documents, including MRI safety self-assessments, medical records, and employee training records. We generated an individual CAP report for each facility. For this report, we analyzed the data from the individual facility CAP reviews to identify system-wide trends.

Inspectors conducted the reviews in accordance with *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

[2] The Joint Commission Sentinel Event Alert, "Preventing accidents and injuries in the MRI suite," Issue 38, February 14, 2008.
[3] Lori King, et al., "MR Hazard Summary," VA National Center for Patient Safety, September 29, 2008.
[4] The Joint Commission, "2009 Comprehensive Accreditation Manual for Hospitals (CAMH): The Official Handbook," December 18, 2008.
[5] *Healthcare Inspection – Alleged Patient Neglect During a Magnetic Resonance Imaging Exam, Michael E. DeBakey VA Medical Center Houston, TX,* (Report No. 08-01380-154, June 27, 2008).

Inspection Results

Issue 1: Facility MRI Safety Policies

All 43 facilities reported voluntarily endorsing ACR guidelines, and we found that facilities had implemented policies that were generally consistent with those guidelines. Additionally, employees were able to verbalize appropriate safety and infection control practices.

Issue 2: Employee Training

VA requires initial MRI safety training and annual refresher training for all staff who may need to enter the MRI suite (such as technologists, nurses, and emergency response team members).[6] We reviewed 615 employees' training records and found evidence of training:

- During orientation for 118 (72 percent) of 163 employees in their current positions less than 2 years
- Annually for 404 (89 percent) of 452 employees in their current positions for more than 2 years

We recommended that all employees who may need to enter the MRI suite receive initial and annual MRI safety training. We suggested that VHA develop standardized training modules to improve content consistency and provide the training through an automated system to allow for monitoring compliance.

Issue 3: Screening and Informed Consent

Screening

Establishing effective screening procedures is critical in guarding the safety of all those preparing to enter the MRI suite. The risks associated with the various implants, devices, and other objects that are problematic in the MRI setting must be understood. Most MRI-related incidents have been due to deficiencies in screening methods and/or a lack of properly controlled access to the MRI suite.[7]

VA's Radiology Online Guide (ROG) requires the MRI technologist to screen all patients and employees before they enter the magnet room, and ACR guidelines require that the patient and the technologist sign the screening form.[8] Technologists have a list of equipment, implanted devices, foreign bodies, and other objects and devices not allowed

[6] Lori King, et al.
[7] The Institute for Magnetic Resonance Safety, Education, and Research, <http://www.mrisafety.com/screening_form.asp>.
[8] VA Radiology, "Online Guide," <http://vaww1.va.gov/Radiology/page.cfm?pg=167>, updated December 20, 2007.

in the magnet room. Although not mandated, 30 (70 percent) of the 43 facilities retained the screening forms as part of the medical record. The 13 facilities that did not retain screening forms as part of the medical record are vulnerable in situations where a known patient returns for an emergent MRI and is unable to answer questions. Of 444 medical records of patients who had MRIs with and without contrast,[9] 397 (89 percent) had screening forms available for review. Of the 397 medical records with screening forms, we found the technologist signature in 324 (82 percent) records and the patient signature in 309 (78 percent) records.

ACR guidelines require that patients with contraindications to getting an MRI scan (such as implanted devices, tattoos, and shrapnel) undergo further investigation prior to entering Zone III. Of 241 patients with identified contraindications, we found that the screening forms included documentation of follow-up for only 137 (57 percent).

We recommended that employees screen patients prior to MRI scans, obtain necessary signatures on screening forms, retain screening forms in patient medical records, and document follow-up on potential contraindications for MRI.

Informed Consent

VHA defines clinical procedures and treatments that require informed consent and delineates additional steps for consent to the use of contrast media in high-risk patients.[10] The ROG requires that patients who receive intravenous contrast be given an explanation of risks, benefits, and alternatives. High risk includes prior contrast reaction and impaired kidney function. Use of MRI contrast in these patients could result in permanent injury or death. Of 14 patients identified as high risk, only 7 (50 percent) completed an appropriate informed consent prior to their MRI scans.

We noted a conscious effort to avoid exposure of high-risk patients to contrast across facilities. However, these seven patients identified as high risk received contrast without documented informed consent. We recommended that informed consents specific to MRI with contrast are completed for all high-risk patients and documented in the medical records.

Issue 4: MRI Suite Safety Environment

Signage and Barriers. The ROG requires that all MRI entrances be marked to indicate the presence of a magnetic field hazard. ACR guidelines recommend that Zone IV be clearly marked as potentially hazardous due to the presence of very strong magnetic fields. We found high compliance with signage to prevent unauthorized or accidental access to MRI areas.

[9] Contrast media can improve an MRI scan's ability to visualize organs and tissues. Contrast media include compounds such as iodine or gadolinium.
[10] VHA Handbook 1004.01, *Informed Consent for Clinical Treatments and Procedures,* August 14, 2009.

The ROG requires that facilities establish physical barriers to prevent unauthorized or accidental access to Zones III and IV. We found that such physical barriers were present for only 40 (80 percent) of 50 MRI suites.

Access and Communication. ACR guidelines recommend that employees have direct visual observation of access corridors to Zone IV from their working positions in the MRI scanner control room and that two-way communication be available between the technologist and patient while the patient is in the scanner. We found the direct observation of Zone IV access and two-way communication with patients while in the scanner to be in high compliance.

Emergency Preparedness. ACR guidelines require facilities to make appropriate provisions for the stabilization and resuscitation of patients. In the event that a person within the MRI suite should require emergency medical or mental health attention, it is imperative that those responding to a call for assistance are aware of and comply with MRI safety protocols. Facilities should conduct regular emergency response drills to rehearse and refine protocols to protect patients, employees, and responders. We found that policies and procedures for emergency code response in Zone IV and the MRI technologists' ability to articulate their role during an emergency were in high compliance. However, we identified the following opportunities for improvement:

- Facilities documented call system preventive maintenance for 41 (82 percent) of 50 MRI suites.
- Facilities regularly tested call systems for 37 (74 percent) of 50 MRI suites.
- Facilities conducted risk assessments of 40 (80 percent) of 50 MRI suites.
- Facilities conducted fire drills in 32 (64 percent) of 50 MRI suites.
- Facilities conducted emergency response drills in 24 (48 percent) of 50 MRI suites.
- Facilities conducted medical or mental health emergency drills in 22 (44 percent) of 50 MRI suites.

We recommended that physical barriers are in place, call systems are tested and maintained, risk assessments are completed, and emergency drills are conducted.

Conclusions

VHA facilities had recognized the importance of safety in MRI suites and had implemented adequate policies and procedures. Compliance with MRI safety requirements and guidelines needs to improve in the following areas: (1) employee training, (2) patient screening, (3) informed consent for high-risk patients who receive contrast, and (4) physical barriers and emergency preparedness.

Recommendations

Recommendation 1. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that all employees who may need to enter the MRI suite receive initial and annual MRI safety training.

Recommendation 2. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that employees screen patients prior to MRI scans, obtain necessary signatures on screening forms, retain screening forms in patient medical records, and document follow-up on potential contraindications for MRI.

Recommendation 3. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that informed consents specific to MRI with contrast are completed for all high-risk patients and documented in the medical records.

Recommendation 4. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that physical barriers are in place, call systems are tested and maintained, risk assessments are completed, and emergency drills are conducted.

Comments

The Under Secretary for Health concurred with the recommendations and provided implementation plans with target completion dates. VHA will develop MRI safety training and instruct facilities to monitor completion. The Deputy Under Secretary for Health for Operations and Management (DUSHOM) will reinforce the requirements for screening patients and for obtaining and maintaining informed consents. The DUSHOM will also reinforce the requirements for radiology safety in regards to placement of physical barriers, testing and maintenance of call systems, completing risk assessments, and conducting emergency drills. The full text of the comments is shown in Appendix A (beginning on page 7). The Under Secretary for Health's comments and implementation plans are responsive to the recommendations. We will follow up on the actions until they are completed.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Appendix A

Under Secretary for Health Comments

Department of Veterans Affairs **Memorandum**

Date: Jan 11, 2011

From: Under Secretary for Health (10)

Subject: **OIG Draft Report – Evaluation of Magnetic Resonance Imaging Safety in Veterans Health Administration Facilities (Project No. 2009-01038-HI-0056, VAIQ 7036022)**

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report and concur with all four recommendations. Attached is the Veterans Health Administration's (VHA) corrective action plan for the report's recommendations.

2. VHA concurs with the report's four recommendations for the Under Secretary for Health.

3. Thank you for the opportunity to review the draft report. A complete action plan to address the report's recommendations is attached. If you have any questions, please contact Linda H. Lutes, Director, Management Review Service (10B5) at (202) 461-7014.

Robert A. Petzel, M.D.

Attachment

VETERANS HEALTH ADMINISTRATION (VHA)
Action Plan

OIG Draft Report, Evaluation of Magnetic Resonance Imaging Safety in Veterans Health Administration Facilities (Project No. 2009-01038-HI-0056, VAIQ 7036022)

Date of Draft Report: November 8, 2010

Recommendations/ Actions	Status	Completion Date

Recommendation 1. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that all employees who may need to enter the MRI suite receive initial and annual MRI safety training.

VHA Comments

Concur

The Office of the Deputy Under Secretary for Health for Operations and Management (DUSHOM) will lead a project with the Veterans Health Administration (VHA) Employee Education Service (EES), Patient Care Services, and other appropriate offices to ensure the development of Magnetic Resonance Imaging (MRI) safety training. Then, the DUSHOM will issue instructions to Veterans Integrated Service Networks (VISN) and facilities about which employees must complete the training, and ensure that procedures are developed to monitor that employees receive the training.

In process March 31, 2011

Recommendation 2. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that employees screen patients prior to MRI scans, obtain necessary signatures

on screening forms, retain screening forms in patient medical records, and document follow-up on potential contraindications for MRI.

VHA Comments

Concur

During a Chief Medical Officer (CMO)/Network Director call, the DUSHOM will reinforce the requirements for screening patients prior to MRI scans, and ensuring that screening documentation is maintained in the patient's medical record.

Also, VHA's National Center for Patient Safety (NCPS) will add these requirements to the check list for patient safety rounds. The DUSHOM will issue instructions to advise VISNs and facilities what to do in regard to the checklist, and how to report any noted deficiencies as well as to require the development of an action plan to correct these concerns within a specified timeline after the deficiency is noted. The DUSHOM will consult, as needed, with appropriate offices in regard to policy issues.

In process February 28, 2011

Recommendation 3. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that informed consents specific to MRI with contrast are completed for all high-risk patients and documented in the medical records.

VHA Comments

Concur

During a CMO/Network Director call, the DUSHOM will reinforce the requirements for obtaining consents from patients prior to MRI scans, and ensuring consent documentation is maintained in each patient's medical record. In addition, the DUSHOM will issue instructions requiring VISN Quality Management staff during their site visits to randomly check documentation to ensure compliance with requirements.

In process February 28, 2011

Recommendation 4: We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that

physical barriers are in place, call systems are tested and maintained, risk assessments are completed, and emergency drills are conducted.

VHA Comments

Concur

During a CMO/Network Director call, the DUSHOM will reinforce the requirements for radiology safety in regard to placement of physical barriers, testing and maintaining call systems, completing risk assessments, and conducting emergency drills. VHA's NCPS will add these requirements to the checklist for patient safety rounds. The DUSHOM will issue instructions to advise VISNs and facilities what to do in regard to the checklist and how to report any noted deficiencies, as well as to require the development of an action plan to correct these concerns within a specified timeline after the deficiency is noted. The DUSHOM will consult, as needed, with appropriate offices in regard to policy issues.

In process February 28, 2011

Appendix B

OIG Contact and Staff Acknowledgments

OIG Contact	Linda DeLong Director, Dallas Office of Healthcare Inspections
Acknowledgments	Daisy Arugay Bruce Barnes Paula Chapman Melanie Cool Deborah Howard Gayle Karamanos Cathleen King Jeanne Martin Karen A. Moore Larry Ross James Seitz Barry Simon Christa Sisterhen Randall Snow Maureen Washburn Misti Kincaid, Program Support Assistant

Appendix C

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
National Center for Patient Safety
Office of General Counsel
Office of Medical Inspector
Veterans Integrated Service Network Directors (1–23)

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
House Committee on Oversight and Government Reform
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget

This report is available at http://www.va.gov/oig/publications/reports-list.asp.