



**Department of Veterans Affairs
Office of Inspector General**

Office of Healthcare Inspections

Report No. 15-03804-38

Combined Assessment Program Summary Report

Evaluation of Magnetic Resonance Imaging Safety in Veterans Health Administration Facilities

December 3, 2015

Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations:

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections completed an evaluation of magnetic resonance imaging (MRI) safety in Veterans Health Administration facilities. The purpose of the evaluation was to determine whether facilities ensured safety in MRI in accordance with Veterans Health Administration requirements related to patient screening, employee safety training, and risk assessment of the MRI environment.

We performed this evaluation in conjunction with 49 Combined Assessment Program reviews conducted from April 1, 2014, through March 31, 2015. We noted high compliance in many areas, including patients or caregivers signing the second MRI patient safety screening form, facilities having signage warning of magnetic field hazard and controlled access to the MRI area, and Level 2 MRI personnel receiving annual level-specific MRI safety training.

To improve operations, we recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that:

- Employees consistently conduct initial MRI patient safety screenings.
- Level 2 MRI personnel consistently document when they review the second MRI patient safety screening forms.
- Level 2 MRI personnel document resolution of all identified potential contraindications prior to the MRI exam.
- Facilities routinely conduct contrast reaction drills in MRI areas.
- All designated Level 1 ancillary employees receive annual level-specific MRI safety training.

Comments

The Under Secretary for Health concurred with the findings and recommendations. (See Appendix A, pages 7–11, for the full text of the comments.) The implementation plans are acceptable, and we will follow up until all actions are completed.



JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections completed an evaluation of magnetic resonance imaging (MRI) safety in Veterans Health Administration (VHA) facilities. The purpose of the evaluation was to determine whether facilities ensured safety in MRI in accordance with VHA requirements related to patient screening, employee safety training, and risk assessment of the MRI environment.

Background

The Office of Healthcare Inspections conducted a previous review of MRI safety and recommended that VHA:¹

- Ensure all employees who may enter the MRI suite receive initial and annual MRI safety training.
- Ensure employees screen patients prior to MRI, retain screening forms as part of the electronic health record (EHR), and document MRI contraindications.
- Complete and document informed consents for all high-risk patients prior to administration of contrast media.
- Ensure physical barriers are in place, test and maintain call systems, complete risk assessments, and conduct emergency drills.

In response, VHA published VHA Handbook 1105.05, *Magnetic Resonance Imaging Safety*, July 19, 2012.

In 2008, The Joint Commission issued Sentinel Event Alert Issue 38 on preventing accidents and injuries in the MRI suite. The American College of Radiology produced a 2013 guidance document on magnetic resonance safe practices.

There are two levels of personnel in the MRI area:

- a. Level 1 ancillary employees – Those who have passed minimal training to ensure their own safety as they work within the high magnetic field area(s) within the MRI suite.
- b. Level 2 MRI personnel – Those more extensively trained and educated in the broader aspects of MRI operation and safety issues. The facility will identify those individuals who qualify as Level 2 MRI personnel.

VHA's online Talent Management System training library offers an MRI safety training course designed for Level 1 ancillary or non-MRI personnel (course 9696²). The Joint Commission requires all employees who enter the MRI suite, including clinical personnel, engineers, and housekeepers, to receive safety training. The facility may choose to develop its own Level 1 training in addition to or as a substitute for Talent Management System course 9696. Employees must renew Level 1 training annually

¹ *Combined Assessment Program Summary Report – Evaluation of Magnetic Resonance Imaging Safety in Veterans Health Administration Facilities*, Report No. 09-01038-77, January 26, 2011.

² Information from VHA radiology employees on December 17, 2013.

whether the facility uses Talent Management System course 9696 or a locally developed Level 1 training.

Patient screening is a critical component prior to MRI. VHA requires a two-step patient safety screening process—an initial screening conducted by the ordering clinician, clinic employees, or radiology employees and a second screening immediately prior to the MRI conducted by Level 2 MRI personnel. VHA Handbook 1105.05 provides an example of initial patient safety screening questions and lists information regarding the potentially hazardous effect of the MRI environment on various medical devices, some of which are a contraindication for an MRI scan. Level 2 MRI personnel must scrutinize and investigate these potentially hazardous devices during the second MRI patient safety screening process. The American College of Radiology's 2013 guidance document on magnetic resonance safe practices contains an example of a second patient safety screening form.

VHA requires Level 2 MRI personnel to clarify contraindications and to enter documentation regarding those contraindications in the EHR prior to the MRI exam. For example, if the patient reports having an eye injury by a metallic foreign body, the patient may require x-rays. Level 2 MRI personnel may need to consult with the radiologist or ordering physician to assist in addressing identified contraindications.

Although MRI scanning produces an image without exposing the patient to ionizing radiation, the magnet environment and use of radio frequencies can be hazardous to patients and employees. The powerful magnetic field of the scanner is always on and can attract certain metallic objects known as ferromagnetic objects (for example, substances such as iron and nickel), causing them to move as a projectile with sudden and great velocity towards the center of the magnetic field. This may pose a safety risk to the patient or anyone in the way of the object (such as an oxygen canister or wheelchair). Therefore, great care must be taken to prevent ferromagnetic objects from entering certain areas within the MRI environment. Additionally, the high magnetic field and radio frequencies used to create images can affect some medical devices (such as pacemakers, implanted medicine pumps, and some surgical clamps) and can damage the workings of the device. Identifying and maintaining safety practices and procedures in the MRI environment are essential to the delivery of quality patient care and provide a safe environment for the patient and employees.

Scope and Methodology

We performed this evaluation in conjunction with 49 Combined Assessment Program (CAP) reviews conducted from April 1, 2014, through March 31, 2015. The facilities we visited were a stratified random sample of all VHA facilities and represented a mix of facility size, affiliation, geographic location, and Veterans Integrated Service Networks. OIG generated an individual CAP report for each facility. For this report, we summarized the data collected from the individual facility CAP reviews.

We reviewed facility MRI policies and other applicable documents, including 1,678 patient EHRs, 49 emergency drill reviews, and 2,227 employee training records.

We also performed inspections of 74 MRI areas. We considered a facility compliant with VHA policy and Joint Commission standards if it met requirements for at least 90 percent of its eligible patients.

Sampling. We used a two-stage complex probability sample design to select patients from the study population for the EHR review. In the first stage of sampling, we randomly selected the 56 VHA facilities scheduled for CAP visits, which we had stratified by the 12 catchment areas of the OIG's Office of Healthcare Inspections regional offices. We excluded seven facilities from the review because they did not provide onsite MRI services, resulting in 49 facilities.

In the second stage of sampling, we randomly selected 50 patients from each sampled facility for our EHR review. We excluded sampled patients from the review for one of the following reasons:

- They did not have an MRI completed, or the MRI was completed outside the study period (January 1–December 31, 2013).
- They had the MRI completed at a fee basis or non-VHA site.

For the employee training portion of the review, we statistically randomly selected 30 Level 1 MRI personnel at every facility with 30 or more Level 1 personnel. If a facility had fewer than 30 Level 1 MRI personnel, then we selected all Level 1 personnel. We selected all Level 2 MRI personnel at the 49 facilities we reviewed.

Statistical Data Analysis. We estimated the VA compliant percentages for each of the quality measures, taking into account the complexity of our multi-stage sample design. We used Horvitz-Thompson sampling weights (reciprocal of sampling probabilities) to account for unequal probability sampling and the Taylor expansion method to obtain the sampling errors for the estimates.

We presented 95 percent confidence intervals (CI) for the estimates of the true values (parameters) of the study population. A CI gives an estimated range of values (being calculated from a given set of sample data) that is likely to include an unknown population parameter. The 95 percent CI indicates that among all possible samples we could have selected of the same size and design, 95 percent of the time the population parameter would have been included in the computed intervals.

Percentages can only take non-negative values from 0 to 100, but their logits can have unrestricted range so that the normal approximation can be used. Thus, we calculated the CIs for percentages on the logit scale and then transformed them back to the original scale to ensure that the calculated CIs contained only the proper range of 0 to 100 percent. All data analyses were performed using SAS statistical software, version 9.4 (TS1M0), SAS Institute, Inc. (Cary, NC).

Inspectors conducted the reviews in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

We noted high compliance in many areas, including patients or caregivers signing the second MRI patient safety screening form, facilities having signage warning of magnetic field hazard and controlled access to the MRI area, and Level 2 MRI personnel receiving annual level-specific MRI safety training. However, we identified opportunities for improvement in five areas.

Issue 1: First MRI Patient Safety Screening

VHA requires a two-step safety screening process of individuals who will have an MRI scan, and this process must occur for every MRI imaging session.³ Examples of individuals who can perform the first MRI patient safety screening include the ordering physician or clinic employees, the radiology scheduling clerk, and the radiology receptionist.

We estimated that 18.9 percent (95 percent CI: 17.41–20.41) of patients' EHRs did not contain documentation of the initial MRI patient safety screening.

We recommended that employees consistently conduct initial MRI patient safety screenings.

Issue 2: Second MRI Patient Safety Screening

VHA requires that Level 2 MRI personnel conduct a second MRI patient safety screening shortly before the patient enters the magnet room.⁴

We estimated that 14.1 percent (95 percent CI: 12.83–15.37) of the second MRI patient safety screening forms did not contain dates when Level 2 MRI personnel reviewed the forms. Therefore, we could not determine whether Level 2 MRI personnel reviewed these forms shortly before the MRI exam took place.

We recommended that Level 2 MRI personnel consistently document when they review the second MRI patient safety screening forms.

Issue 3: Clearance of Identified Potential MRI Contraindications

VHA requires that if Level 2 MRI personnel find a potential contraindication during the screening process and decide to proceed with the MRI exam, they must document resolution on the patient safety screening form or in a note and retain this documentation in the EHR.⁵

³ VHA Handbook 1105.05, "Magnetic Resonance Imaging Safety," July 19, 2012.

⁴ VHA Handbook 1105.05.

⁵ VHA Handbook 1105.05.

We estimated that 58.3 percent (95 percent CI: 55.39–61.12) of the second MRI patient safety screening forms did not contain documentation of resolution of all identified potential contraindications by Level 2 MRI personnel prior to MRI. Additionally, we did not find other EHR entries to corroborate resolution of the identified potential contraindications.

We recommended that Level 2 MRI personnel document resolution of all identified potential contraindications prior to the MRI exam.

Issue 4: Emergency Drills

VHA requires facilities to conduct emergency drills to simulate a patient who has an allergic reaction to contrast media while in the magnet, a cardiac arrest in the magnet, a patient who is trapped in the magnet by a ferromagnetic object, and a fire in the magnet room.⁶

We estimated that 28.6 percent (95 percent CI: 17.47–43.05) of facilities did not routinely conduct contrast reaction drills in the MRI area(s).

We recommended that facilities routinely conduct contrast reaction drills in MRI areas.

Issue 5: Level-Specific Safety Training

VHA requires that individuals who need to enter areas in the MRI suite that have a high magnetic field (for example, the control room or magnet room) must be authorized to enter by Level 2 MRI personnel and must take a basic Level 1 MRI safety training course. These employees include unit nurses and physicians who are monitoring patients, any personnel who assist in lifting or moving patients, and housekeeping employees. VHA requires annual renewal of this training.⁷

We estimated that 24.1 percent (95 percent CI: 16.25–34.28) of designated Level 1 ancillary employees did not receive annual level-specific MRI safety training.

We recommended that all designated Level 1 ancillary employees receive annual level-specific MRI safety training.

Conclusions

We noted high compliance in many areas, including patients or caregivers signing the second MRI patient safety screening form, facilities having signage warning of magnetic field hazard and controlled access to the MRI area, and Level 2 MRI personnel receiving annual level-specific MRI safety training.

⁶ VHA Handbook 1105.05.

⁷ VHA Handbook 1105.05.

We identified opportunities for improvement in five areas: (1) conducting initial MRI patient safety screenings, (2) documenting review of second MRI patient safety screening forms before the scan, (3) documenting resolution of all identified potential contraindications, (4) routinely conducting contrast reaction drills in MRI areas, and (5) ensuring all designated Level 1 ancillary employees receive annual level-specific MRI safety training.

Recommendations

1. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that employees consistently conduct initial magnetic resonance imaging patient safety screenings.
2. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that Level 2 magnetic resonance imaging personnel consistently document when they review the second magnetic resonance imaging patient safety screening forms.
3. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that Level 2 magnetic resonance imaging personnel document resolution of all identified potential contraindications prior to the magnetic resonance imaging exam.
4. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that facilities routinely conduct contrast reaction drills in magnetic resonance imaging areas.
5. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that all designated Level 1 ancillary employees receive annual level-specific magnetic resonance imaging safety training.

Under Secretary for Health Comments

**Department of
Veterans Affairs**

Memorandum

Date: October 23, 2015

From: Under Secretary for Health (10)

Subject: Office of Inspector General (OIG) Draft Report, Combined Assessment Program (CAP) Summary Report: Evaluation of Magnetic Resonance Imaging Safety in Veterans Health Administration Facilities (Project No. 2015-03804-HI-0612) (VAIQ 7638391)

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review the draft OIG CAP Summary Report: Evaluation of Magnetic Resonance Imaging Safety in Veterans Health Administration Facilities.

2. I concur with the report and the recommendations. Attached is VHA's corrective action plan for recommendations 1 through 5.

3. Should you have any questions, please contact Karen M. Rasmussen, MD, Director, Management Review Service (10AR) at VHA10ARMRS2@va.gov.



David J. Shulkin, M.D.

Attachment

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

OIG Draft Report, CAP Summary Report – Evaluation of MRI Safety in VHA Facilities

Date of Draft Report: September 8, 2015

Recommendations/ Actions	Status	Completion Date
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OIG Recommendations

Recommendation 1. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that employees consistently conduct initial magnetic resonance imaging patient safety screenings.

VHA Comments: Concur

To improve magnetic resonance imaging (MRI) patient safety screenings VHA Assistant Deputy Under Secretary for Health for Patient Care Services (ADUSH PCS) will require each facility with a MRI to complete a detailed self-audit sheet. This self-audit sheet will be discussed on the Chief Medical Officers (CMO) call to provide guidance to the field. Each facility that has an MRI is to carry out a self-audit, and to report the number of missing documents. If any facility does not meet the required threshold as described in the memo, a corrective action plan will be provided to the Veterans Integrated Service Network (VISN) and rolled up to Veterans Affairs (VA) Central Office. Prior to nation-wide distribution, VHA will obtain input from OIG on the draft memorandum and draft audit plans to ensure they achieve the intent of the recommendation.

To complete this action, VHA will provide documentation of:

1. Deputy Under Secretary for Health for Operations and Management (DUSHOM) memorandum that provides guidance to the field.
2. A copy of the CMO call minutes.
3. Audit results.
4. Corrective action plans for non-compliant facilities.

Status:
In Process

Target Completion Date:
April 2016

Recommendation 2. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that Level 2 magnetic resonance imaging personnel consistently document when they review the second magnetic resonance imaging patient safety screening forms.

VHA Comments: Concur

To improve MRI patient safety screenings PCS will require each facility with a MRI to complete a detailed self-audit sheet. This self-audit sheet will be discussed on the CMO call to provide guidance to the field. Each facility that has an MRI is to carry out a self-audit, and to report the number of missing documents. If any facility does not meet the required threshold as described in the memo, a corrective action plan will be provided to the VISN and rolled up to VA Central Office. Prior to nation-wide distribution, VHA will obtain input from OIG on the draft memorandum and draft audit plans to ensure they achieve the intent of the recommendation.

To complete this action, VHA will provide documentation of:

1. DUSHOM memorandum that provides guidance to the field.
2. A copy of the CMO call minutes.
3. Audit results.
4. Corrective action plans for non-compliant facilities.

Status:
In Process

Target Completion Date:
April 2016

Recommendation 3. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that Level 2 magnetic resonance imaging personnel document resolution of all identified potential contraindications prior to the magnetic resonance imaging exam.

VHA Comments: Concur

To improve MRI patient safety screenings PCS will require each facility with a MRI to complete a detailed self-audit sheet. This self-audit sheet will be discussed on the CMO call to provide guidance to the field. Each facility that has an MRI is to carry out a self-audit, and to report the number of missing documents. If any facility does not meet the required threshold as described in the memo, a corrective action plan will be provided to the VISN and rolled up to VA Central Office. Prior to nation-wide distribution, VHA will obtain input from OIG on the draft memorandum and draft audit plans to ensure they achieve the intent of the recommendation.

To complete this action, VHA will provide documentation of:

1. DUSHOM memorandum that provides guidance to the field.
2. A copy of the CMO call minutes.
3. Audit results.
4. Corrective action plans for non-compliant facilities.

Status:
In Process

Target Completion Date:
April 2016

Recommendation 4. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that facilities routinely conduct contrast reaction drills in magnetic resonance imaging areas.

VHA Comments: Concur

PCS will provide guidance by the DUSHOM memorandum to the field instructing them to return an attestation that safety drills have been conducted within the last year, and that all level 2 personnel participated. VHA's guidance document will indicate that safety drills will be performed annually with all level 2 MRI personnel. Safety drills will be conducted in the areas of contrast reaction, cardio-pulmonary arrest, fire, and patient trapped by metal object. The DUSHOM memo and guidance will be discussed on the CMO call to provide guidance to the field. Prior to nation-wide distribution, VHA will obtain input from OIG on the draft memorandum and draft audit plans to ensure they achieve the intent of the recommendation.

To complete this action, VHA will provide documentation of:

1. DUSHOM memo that provides guidance to the field.
2. A copy of the CMO call minutes.
3. Audit results.
4. Corrective action plans for non-compliant facilities.

Status:
In Process

Target Completion Date:
April 2016

Recommendation 5. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that all designated Level 1 ancillary employees receive annual level-specific magnetic resonance imaging safety training.

VHA Comments: Concur

The DUSHOM will provide guidance to the field that each facility will develop a list of those employees who are not MRI personnel but must often come to the magnet room, including but not limited to, equipment service personnel Intensive Care Unit nurses or Emergency Department nurses, or anesthesiologists as applicable to the facility. The guidance will require all identified personnel will complete the MRI Level 1 Safety Training in the Talent Management System (TMS) annually. Facility and VISN Directors

may use education training records from The Talent Management System (TMS) to ensure annual compliance has been attained.

To complete this action, VHA will provide documentation of:

1. DUSHOM memo that provides guidance to the field.
2. Confirmation that all VISNs are in compliance with the MRI Level 1 Safety Training in TMS.

Status:
In Process

Target Completion Date:
May 2016

Office of Inspector General Contact and Staff Acknowledgments

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