Model MRI Safety Program
The Mayo Clinic Experience

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AAPM Spring Clinical Meeting
Clinical MRI Safety
Saturday, March 6, 2015: 2-4 PM

Disclosures:
Nothing to disclose

Disclaimer:
Implantable medical devices described within this presentation are for illustrative purposes only and do not constitute endorsement

Acknowledgement:
Robert Watson MD PhD
Mayo Clinic Rochester - MR Medical Director
Chair - MR Safety Committee, Neuroradiology
Outline

1. MR Safety Committee
2. MR Safety Guidelines, Policies and Procedures
3. MR Safety Training
4. MR Safety Events
5. MR Safety Audits

Mayo Midwest Radiology

Large, multispecialty clinic
Mayo Clinic & Mayo Clinic Hospital in Rochester, MN

Associated satellite providers
Mayo Clinic Health System
Mayo Clinic Health System

21 sites offering MRI
11 Fixed Diagnostic MR Scanners
3 Mobile Units visit 11 sites

Mayo Clinic in Rochester, MN

31 Diagnostic MR Scanners
1 PET-MR
3 Research MR Scanners

10 Blocks
Hospital Anesthesia ★
Intraoperative MR/OR
MR-Guided:
- Cryo/laser ablation
- Focused Ultrasound
- Radiation Treatment Planning
- Breast Biopsy
- Liver/Prostate Biopsy
Mayo Clinic in Rochester, MN

### 1.5 T
- 5 GE HDxt
- 1 GE 450
- 6 GE 450w
- 1 SMS Avanto
- 1 SMS Espree

### 3.0 T
- 1 GE HDxt
- 4 GE 750
- 6 GE 750w
- 1 GE PETMR
- 2 SMS Verio
- 2 SMS Skyra
- 1 SMS Prisma

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**A TYPICAL DAY**

Number of procedures typically conducted across Mayo Clinic:
- Breast Imaging: 922
- CT: 1,852
- Diagnostic Radiography: 3,344
- Interventional: 152
- MR: 731
- Nuclear Medicine: 297
- Ultrasound: 968

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Mayo Rochester Radiology

**MRI Practice**

### Radiologists
- 99 staff that can be assigned to MRI
- 25 assigned to interpret MRI each day

### Technologists
- 97 MRI Technologists
- Required to obtain advanced RT(R)(MR) certification

### Physicists
- 7 MRI Diagnostic Physicists
- 2 assigned to clinical support on most days
Clinical Assignments for MRI Physicists

**Interventional procedures**

- MR Guided Focused Ultrasound
  - Uterine fibroid
  - Prostate
  - Bone
- MR Guided Cryoablation
- MR Guided Laser Ablation

**Patients with Active Implanted Devices**

**Pacemakers/ICDs and MR-conditional Pacemakers**

- 1-2 per day M-Thurs
- ~1000 pacemaker patients now scanned

**Deep Brain Stimulators**

- ~50 diagnostic patients in 2015
- Increase with new MR-conditional labeling for body coil Tx (released Dec, 2015)

**Auditory Brainstem Implants and Cochlear Implants**

- ~45 patients in 2015

**Intracranial Pressure Monitors**

- Rare

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**MRI / Cardiac Pacemaker practice**

- Now nearly 3,000,000 pacemaker patients in US
- At least 5,000,000 worldwide
- At least 50% will have clinical reason for MRI during lifetime of the device
- Increasing number published studies supporting
Factors permitting more confident MRI scanning in Pacemaker patients at Mayo today

- RF and gradient effects on the sensing circuits are minimized by shielding & newer engineering of the device

- Wire/lead tip heating is minimized by MRI scanner RF power limits, choice of coils (under operator control)

- Close monitoring during MRI by cardiologist, physicist & specially trained personnel
Mayo MRI / PM practice
Pre MRI

• Radiologist triages case
  • Alternative approach?
  • Consult with physicist – SAR, coils, monitoring equipment

• All pts have Cardiology pre-MRI evaluation
  • Checks that referring MD has note on chart attesting to medical necessity of MRI

• Formerly excluded pts → pacer dependent...

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Mayo MRI / PM practice
Pre MRI

• All cases done at same hospital-based 1.5T sites

• **Cardiologist / PM nurse & Physicist** present throughout
  – Pre-MRI Pacemaker interrogation and reprogramming as necessary
  – Monitors throughout case
    • ECG, pulse ox
    • Code cart immediately available
    • Anesthesia aware of case
  – Post-MRI pt evaluation, pacemaker interrogation and reprogramming
MRI / PM practice

MRI

• Radiologist
  – Obtain informed consent
  – Sequence prescription / SAR constraints (with physicist)
  – Check CXR if pacing nurse detects irregularities
  – Verify that complete exam performed before patient off scanner
  – Document procedure in dictation

Results

• ~1000 patients now scanned at Mayo Rochester
• Proven clinical value
• No known clinically adverse events
• No device dysfunction
• No change in capture or sensing threshold
• Device/MRI interactions observed infrequently
  - Several power on resets in older devices; then reprogrammed
  - Stresses the need for close monitoring during & careful device interrogation after scanning.
Clinical Assignments for MRI Physicists

Role in MRI exams with Active Implanted Devices

- Verify device model and MR-conditions
- Recommendation for MR coil
- Answer patient questions
- Keep MR operation within prescribed limits for the implanted device
  - SAR, B1+rms
  - dB/dt
- Maintain diagnostic quality of the exam
- Employ techniques to reduce artifacts near the device

ICD - Artifacts

FIESTA/SSFP techniques – banding artifacts
- Use localized shim
- Switch to gradient echo sequences

MDE – artifact near lead tip
- Interferes with B1-field
- Flip angle not correct

"cannot exclude the possibility of artifact from nearby intracardiac CRT-D leads"
What can an MR Physicist do? Especially working with the Radiologist!

**Myocarditis/? Subsequent fibrosis (ICD)**

<table>
<thead>
<tr>
<th>Local Shim</th>
<th>Parameter changes</th>
<th>Phase Sensitive? No!</th>
<th>Type in L/R Shim Made it worse!</th>
<th>Type in L/R Shim opposite direction</th>
</tr>
</thead>
</table>

Interactive troubleshooting for these exams

- Can’t anticipate location of implant
- Can’t anticipate disease state or scan protocol
- Geometry within the scanner very important
- Can’t protocol ahead of time

**Cochlear implants (with magnets)**

- **B0**
  - Magnets! Pull and torque
- **B1 (RF)**
  - Leads! Potential for heating
- **dB/dt (Gradients)**
  - Conductive, small surface area
- **Active Device**
  - Clicks and odd noises during scanning

*www.Cochlear.com*
Cochlear implants (with magnets)

- Patient requested anesthesia
- Two prior MRI’s- could not tolerate pain, aborted exam prior to contrast even though highly motivated to complete exam

Even without magnets, pretty large artifact
What can an MR Physicist do?
Especially working with the Radiologist!

**Bilateral Vestibular Schwannoma**
**Cochlear Implant**

**Prior Exam** – chem fatsat

**Dixon Recon Artifact**

“Interactive” Exam – Dixon and localized shimming

**Parallel Imaging Artifact**
Collapsed signal prevents accurate coil element mapping

What can an MR Physicist do?
Especially working with the Radiologist!

**DBS 0.1 W/kg -> 3% of Normal Mode Operation**

My conversation with the radiologist:

- What is the most important sequence, given the patient’s indication?
- Standard 2D spin echo-based imaging techniques require about 1 minute per slice
- Can we limit scan coverage?
- Are you OK with 3D GRE T1’s with reformats? Post-gad too?
- DWI comes for free – no changes needed

**1 hour exam:**
MP-Rage, Cor T2 FLAIR, Ax T2 FSE,
DWI, T2* GRE
Clinical Assignments for MRI Physicists

- Construction, equipment planning and siting
- Upgrades and safety recalls
- Image Quality and artifacts
- Patient device inquiries

MRI Safety Committee/Rochester

Multidisciplinary Membership
- Radiologists
- Physicists
- Technologists
- Nurses
- Healthcare Technology Management (MRI Service)
- Desk staff
- Anesthesia
- Operations Manager
- 23 individuals
Safety Event Reporting

RSAC: Major Strategic Priorities:
- Patient Safety Event Transparency
- Address TJC accreditation standards and National Patient Safety Goals

Safety Event Reporting – What to Report

<table>
<thead>
<tr>
<th>Event Type</th>
<th>SERF Categories/Examples: *list may include but is not limited to items listed below</th>
<th>National Quality Forum “Never Event” examples – mandatory to report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accidental Injury</td>
<td>- Burn - Comminution/bruse - Laceration - Skin tear</td>
<td>Death or serious injury:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- (from) an Air embolus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Associated w/ burn</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Associated w/ use of contaminated drugs/devices</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Associated w/ use of a device</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Associated w/ use of restraints (or lack of use)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- During or immediately after an invasive procedure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Introduction of metallic object into MRI</td>
</tr>
</tbody>
</table>
Safety Event Reporting – Roles and Responsibilities

- Clear expectations from departmental leadership
- Roles and Responsibilities for follow up of Safety Events
- “Promote and ensure reporting is completed in a timely manner. Same day is desirable, w/in 24 hrs. is expected.”
- “Identify the process issue, not blaming individuals”
**SERF – MRI Specific Info**

![MRI Event Questionnaire](image)

For SERF event related questions, please contact your supervisor or the Radiology Quality Office. For web/technical questions, please contact Michael Homan, Department of Radiology.

**SERF – Analysis and Distribution**

*Events Categorized (including near miss/good catch)*

**And Tracked for Follow up**

<table>
<thead>
<tr>
<th>MRI YTD/2016</th>
<th>JAN</th>
<th>YTD Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCIDENTAL INJURY</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>DELAY IN TREATMENT</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>FALLS</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>INAPPROPRIATE EXAM</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>IV</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>MEDICATION</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>MISCELLANEOUS</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Monthly Total</td>
<td>26</td>
<td>26</td>
</tr>
</tbody>
</table>

![RST Executive Summary for Events: December 2015](image)
MRI Safety Committee

“The intent of this effort is to offer guidance, the final decision is at the Staff Radiologist’s discretion.”

MRI Safety Committee – Typical Agenda

- Review MRI Safety related SERFs
  - Significant Event? Invite witnesses to describe what happened
- Update/review MR Safety policies
- Identify workflow for new/revised implanted device conditions for use
- Address MRI safety concerns/questions brought forward by staff
- Identify new goals/projects to enhance MRI safety and workflow

Ferromagnetic Screeners
Enterprise MRI Safety

- Radiologists
- Physicists
- Technologists
- Regional Operations Managers

- Quarterly WebEx meetings to:
  - Standardize guidelines, policies, and best practices
  - Discuss safety events

- Redundancy
  Oral, paper form
- Ferromagnetic screeners
- No extraneous metal objects in the scan room!
- Anything metallic gets screened by a hand magnet before entering Zone IV
Outline

1. MR Safety Committee
2. MR Safety Guidelines, Policies and Procedures
3. MR Safety Training
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Mayo MRI Scan Guidelines updated to reflect new and frequently changing devices and processes.
Mayo Guidelines

• Quick overview for reference
• Standardized formatting
  Summary/Recommendations
  Important Notes
  Checklist

In-depth info + references
• Includes Mayo-specific info
  • Notes for report
  • Mayo staff contacts

Policy Review

• For future policy reviews, include reference to relevant standards (ACR, TJC, CMS)
• Reviewer then knows the purpose and how changing or removing the policy may lead to non-compliance.
RAAAA Workgroup – Proactive alignment with ACR Guidelines

MR Policies and Procedures

1. Radiology MR Safety Website

- Policy on unforeseen ferrous objects in MR scanner room
- Mayo Clinic MRI Safety: Education and Competency

- Policy on thermal burns and SAR

   1. Policy for Performing MRI Scans on Patients Whose Pads Cannot Be Used
   2. Mayo Clinic MRI Safety: Education and Competency
   3. Warning: Burn Incidents on an MRI Scanner Procedure

MR Policies and Procedures Continued

- Policy on reporting of MR accidents to FDA via MedWatch Program
  1. MR Safety Incidents are reported to the MRI Safety Committee
  2. MR Safety Incidents are reported following the Event Reporting: Medical Devices PC-16 Procedure http://www.mayoclinic.org/patient/services/0500003502.html

- Policy on hearing protection for patients/persons in MR scanner room
  1. Documentation of medical director/ MR safety officer’s name and responsibilities
  2. MRI Safety Committee Members: Committee Chair- Dr. Watson

Outline

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MRI Safety Training

ACR: Annual training

Non-MR personnel defined as not MR Safety trained in prior 12 months

MR Personnel

Level 1: Safety trained to ensure own safety in Zone III
Level 2: Safety trained in broader aspects (thermal loading, PNS), Code drills

MRI Safety Training

- Web Modules
- Level I and II exams
- Lectures for incoming residents
- Lectures for language interpreters
- Technologist In-services (Video Recorded with post-viewing exams)
  - HAE – Oct 2015
  - TJC Required Topics
  - HAE – April 2016
  - New MR Conditional Devices and Existing Devices with Revised Labeling
1st Step: Education

Online MRI Safety competency

MRI Safety Education

Residents / nurses

Clinical assistants / schedulers

Interpreters

Fire Department / Emergency personnel
MRI Safety 101

• What do I need to know?

1) The magnet is ALWAYS on!

• On MR Safety Competency Exam, this question is asked 3 times (in different forms).
• If answered incorrectly, automatically fail and cannot have card access to Zone III

Restrict access to Zone III and IV

Electronic ID keycard control of Zone III access
- Card activation tied to passing online MRI Safety test
- NOT cipher lock code which is easily disseminated
Medical Emergency in MRI

- Do NOT enter magnet room!
- Patient is removed from magnet room immediately by MRI technologists
- Treat patient OUTSIDE magnet room

MRI Safety for Ordering Providers

- **What do I need to know?**
- Protect your patients.
- Give **ACCURATE** information about their **IMPLANTED DEVICES** & other **METAL** in body.
MRI Safety Training
Examples from your own institution make a powerful impact during training!

Oxygen tank
Screwdriver
Needle

Situation: An unsafe ladder was brought into an MRI suite by Campus Operations personnel, and it was attracted to the back side of the magnet.

Recommendation: The cart that contained the MRI unsafe ladder and light bulbs should stop outside of Zone 3. In addition, all employees should be thoroughly screened prior to entering Zone 4, regardless of experience within the MR area. The dept. will evaluate the staff not multiskilling and ensure the Campus Operations staff waits until they have been fully cleared by the MR staff.

More to come after the RCA and debrief of the situation. After RCA debrief:
- Light bulb cart will remain outside Zone 3
- Light bulbs will be stored near MR safe ladder in each of the scan areas
- MRI pause will be administered by MR tech prior to entry into Zone 4
- Use this example in upcoming Annual MRI Safety Education

MRI Safety Training
Needs:
• Audience-specific MR Training
• Updating of content!
• Midwest – Generalized content, final jump to site specific info
Outline

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MRI Safety Events

• **Projectiles**
  - Inpatient – tracheostomy stylet
  - Outpatient – eyeglasses case
  - Cleaning staff – mop
  - Inpatient – Flashlight
  - Anesthesia – needle
  - Equipment Services/Maintenance – Screwdriver
  - **Potential – patient cart (2x)**
  - Potential – ferromagnetic oxygen tank

• **Environment**
  - Accidental quench – inadequate button cover

• **Patient care**
  - Sedated patient event
  - Foil backed clonidine patch removal
  - Unread orbit screening exam

• **Devices**
  - Unrecognized cardiac pacemaker leads
  - Unrecognized vagal nerve stimulator
  - Unrecognized Pillcam
  - Unrecognized deep brain stimulator
Lock & key for access control of Zone IV when not in use

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**Anesthesia case**

**Ferromagnetic tracheostomy tube stylet projectile**

**Event Description Summary:**

- Ferromagnetic stylet was not removed from the MRI exam table after intubation.
- Stylet hidden amongst sheets.
- Scout performed and metal blowout artifact detected.
- Patient removed from scanner and lifted slightly.
- Stylet became projectile, flying into bore.

**Injury and Description:** None

**Contributing Factors / Root Cause Analysis**

- New Anesthesia personnel
- Break in routine / distracted
- Concerns about IV, concurrent with intubation
- No organized “time out“ before entering MRI to ensure no MRI unsafe materials present
Change in procedure

- MR techs active participants
- “Time out” to mimic Universal Protocol before proceeding into Zone IV.
- Dedicated box mounted on wall to receive unsafe metallic objects
- – stylet, laryngoscope blade

MRI Safety Events

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  - Unrecognized deep brain stimulator
Unsecured ferromagnetic oxygen tank in Zone III

Unsecured ferromagnetic O2 tank discovered Monday morning

- Anesthesia case over weekend
- "regular" personnel not present

Abandoned O2 tank responses

- Improved education for Anesthesia colleagues
- Empower “stop the line”
- Eliminate ferromagnetic O2 tanks
- Carts must be adapted
- Different diameters – 3/8 inch
- Ergonomic benefits
Replacement of ferromagnetic oxygen tanks completed MCR

New Aluminum Oxygen E Cylinders

In early March, the Respiratory Therapy (RT) Department will begin to exchange empty steel oxygen E cylinders in all patient care areas within the Rochester campus with new aluminum E cylinders. The new aluminum E cylinder is made of aluminum and is four pounds lighter than the steel cylinders. The exchange process could take months as the RT Department is replacing the cylinders once they are empty.

There are no operational changes and no extra safety precautions with these new cylinders. This change will not affect any current policies or procedures.

Direct questions to William Clark, RT.

Other parts on the Aluminum O2 Tanks

- Required to be in cart (prevent tip hazard, “the other missile effect”)
- Ferrous Free carts often get repaired with ferrous parts
- May be replaced with incorrect regulator
- Quarterly QC for any carts in the MRI areas, signature card and pink info tag
- Removal of ferrous O2 tanks significantly decreases attraction to magnet
  - More time to react even if in a ferrous cart
MRI Safety Events

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**Medtronic Announces FDA Approval for the Only Full-Body MR Conditional Deep Brain Stimulation Systems**

December 9, 2015 7:00 AM CT

**Medtronic**

*Updated labeling allows greater patient access to MRI, a critical diagnostic tool*

*Medtronic plc (NYSE: MDT) today announced that systems within its Activa® portfolio of Deep Brain Stimulation (DBS) neurostimulators have received FDA approval for full-body Magnetic Resonance Imaging (MRI) under specific conditions of use. Medtronic’s MR Conditional DBS systems are the only approved for full-body MRI exams. This approval expands access to MRIs, making it safe for patients receiving Medtronic DBS Therapy to also receive this important diagnostic standard of care. Additionally, this approval applies to individuals receiving new Medtronic DBS systems and to an estimated 43,000 people in the U.S. already receiving Medtronic DBS Therapy as long as updated MRI guidelines are followed.*

December 9, 2015

Some DBS systems now permit body coil transmit exams
- No longer limited to only head exams with transmit / receive head coil
Deep Brain Stimulator Event
Patient scanned without proper DBS precautions fortunately without injury

Protective barriers at time of incident related to detecting unsafe devices in MRI

1. Order set – asks about presence of “MRI unsafe devices”
2. Radiologist protocling case – exploring electronic medical record
3. MRI safety screening form
4. MRI technologist verbal screening
MRI order set

Does the Patient Have?

- Aneurysm Clip
- Deep Brain Stimulator
- Pacemaker/Implanted Cardiac Defibrillator/Retained Pacemaker Wires
- Pump-Intra-Thecal
- Programmable Ventricular Shunt
- Vagal Nerve Stimulator
- Other Implanted Device Specify:

DBS event – exam ordered “no devices”

Exam pre-ordered
- DBS implanted at outside institution
- Assistant scheduled for MD
  - MRI safety questions were not asked carefully at original scheduling

Strike 1
Notes mentioning DBS, still in dictation at time of MRI

Strike 2

Patient Screening - Magnetic Resonance Imaging (MRI)

This form collects information that is not part of the medical record. Discard after use.

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Mayo Clinic Number</th>
<th>Birth Date (mm/dd/yy)</th>
<th>Patient Weight (lb)</th>
<th>Date (mm/dd/yy)</th>
</tr>
</thead>
</table>

If someone else is filling out this form for the patient, please print your name below: (Type)

Please check the correct response:

1. Have you ever had an MRI scan done before that you know of?  [ ] Yes [ ] No
   - If yes, please provide date (month/year):
     - [ ] Was your previous MRI scan done at a Mayo facility?  [ ] Yes [ ] No
     - [ ] Did you receive an injection of MRI contrast at that time?  [ ] Yes [ ] No
     - [ ] Did you have any problem with the contrast injection?  [ ] Yes [ ] No

2. Have you ever had a pacemaker?  [ ] Yes [ ] No
   - If yes, please stop and speak to Desk Attendant.

3. Do you have aneurysm clips in your head?  [ ] Yes [ ] No
   - If yes, was the surgery done here?  [ ] Yes [ ] No
     - When (month/year):____________________

4. Do you have any metallic foreign objects in your eyes?  [ ] Yes [ ] No

5. Are you pregnant?  [ ] Yes [ ] No

6. Do you have a tissue expander?  [ ] Yes [ ] No

7. Any reason to leave the IV in place after this exam?  [ ] Yes [ ] No

Comments__________________________________________
### MRI technologist verbal screening script

- Do you have a pacemaker or any other implanted electronic devices?
- Have you ever had a pacemaker or any other implanted electronic device removed?
- Do you have any metal in your body from surgery or an accident, including bullets, BBs or shrapnel?
- Have you had any surgery on your head, eyes, ears or aneurysm clip surgery?
- Do you have any hearing aids, hairpins, transdermal patches or dentures? (if yes to dentures, are they held in by magnets?)
- Do you have any other metal in your body?
- If you feel uncomfortable during your exam such as a tingling, pinching or hot sensation, please let me know. You can always squeeze the ball, and I will stop the scan.

Patient answers no to all of the above questions
3T MRI performed without DBS precautions. **Fortunately without detectable incident.**

Not at Mayo, different patient

Reported thermal injury from DBS in literature:

*Neurosurgery 2005*

Repeat 1.5T MRI performed with DBS precautions to insure no subtle damage or hemorrhage.

How reliable was the patient, given frontal lobe surgery or some patients in general?
DBS event - responses

- Improved education for schedulers & MDs
- No ambiguity on MRI screening form permitted before proceeding
- Augmented patient information about potential dangers of implanted devices in patient appointment guides, with links to “MRI Experience” video
- Institution implementing Enterprise wide “Implanted Devices” module in electronic medical record
Allergies // Medications // Implanted Devices

In contrast to the widely accepted need to reliably access a patient’s
• allergies
• current medications
in a unique and defined site in the electronic health record (EHR), information about a patient’s
• Implanted medical devices
is frequently incomplete and fragmented across multiple locations in the EHR, clearly posing a patient safety risk.

for your allergy in the EMR slides

Diehn, Felix E. M.D.
Sent: Thu 10/1/2015 4:00 AM
To: Watson, Robert E. Jr., M.D., Ph.D. [RO EAST]
Devices module provides alerts to the presence of MRI high risk devices with and

When protocoling MRI exam, again alerts that a “high risk” device is present.

Clicking on this tab brings up screens below; in this case, identifying presence and type of an implanted aneurysm clip.

Transition to new EHR 2017/2018 – Proactively working to transition device data to new platform
MRI Safety Events

**Projectiles**
- Inpatient – tracheostomy stylet
- Outpatient – eyeglasses case
- Cleaning staff – mop
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- Unrecognized cardiac pacemaker leads
- Unrecognized vagal nerve stimulator
- Unrecognized Pillcam
- Unrecognized deep brain stimulator

Patient with abandoned lead scanned without precautions.

Pacemaker patient presented with myelopathic symptoms

Thoracic spine scanned with pacemaker precautions
Pacemaker patient scanned successfully with pacemaker precautions

Thoracic meningioma

- After tumor resection, decided that pacemaker no longer needed, and pulse generator explanted. Lead remains.

Patient returns for post tumor resection followup MRI following removal of pulse generator – but with retained lead

- Root causes
  - No note in order that patient had retained lead
  - MRI safety screening form did not specifically inquire about retained leads
  - Patient did not disclose on oral screening that lead was present
  - Prior MRI report failed to mention pacemaker precautions

| WARNING: Certain implants, devices, or obt MR procedure (i.e. MRI, MR angiography, spine or MR environment if you have any question or Technologist or Radiologist BEFORE entering if |

Please indicate if you have any of the following:
- [ ] Yes  [ ] No Cardiac pacemaker
- [ ] Yes  [ ] No Implanted cardioverter defibrillator (ICD)
- [ ] Yes  [ ] No Electronic implant or device
- [ ] Yes  [ ] No Magnetically-activated implant or device
- [ ] Yes  [ ] No Neurostimulation system
- [ ] Yes  [ ] No Spinal cord stimulator
- [ ] Yes  [ ] No Internal electrodes or wires
- [ ] Yes  [ ] No Bone growth/bone fusion stimulator
- [ ] Yes  [ ] No Cochlear, otologic, or other ear implant
- [ ] Yes  [ ] No Intraspin or other infusion pump
- [ ] Yes  [ ] No Implanted drug infusion device
- [ ] Yes  [ ] No Any type of prosthesis (eye, metal, etc.)
- [ ] Yes  [ ] No Heart valve prosthesis
- [ ] Yes  [ ] No Eyelid spring or wire
- [ ] Yes  [ ] No Artificial or prothetic limb
- [ ] Yes  [ ] No Metallic stent, filter, or coil
Original Research

Pacemaker Lead Tip Heating in Abandoned and Pacemaker-Attached Leads at 1.5 Tesla MRI

Deborah A. Langman, PhD,1,2,* Ira B. Goldberg, PhD,3 J. Paul Finn, MD,1,2
and Daniel B. Ennis, PhD1,2

Purpose: To assess the risk of RF-induced heating in pacemaker-attached and abandoned leads using in vivo temperature measurements at 1.5 Tesla as a function of lead length.

Materials and Methods: Five custom lead lengths, 20–90 cm, were exposed to a uniform magnitude and phase radiofrequency electric field to examine the effect of lead length on pacemaker lead tip heating for pacemaker-attached and abandoned pacemaker leads.

Results: Abandoned and pacemaker-attached leads show resonant heating behavior and maximum heating occurs at different lead lengths due to the differences in termination conditions. For clinical lead lengths (60–90 cm) abandoned leads exhibited greater lead tip heating compared with pacemaker-attached leads.

Conclusion: Current recommendations for MRI pacemaker safety should highlight the possible increased risk for patients with abandoned leads as compared to pacemaker-attached leads.

Key Words: magnetic resonance imaging; medical device safety; pacemaker; RF-induced heating; abandoned leads J. Magn. Reson. Imaging 2011;33:429-433.

are being precluded from diagnosis by MRI due to safety concerns about the interaction between the device and the static magnetic field (B0), gradient magnetic field (B1), and radiofrequency (RF or B1) magnetic field used in MRI.

Since the first report of harmful interactions between MRI and pacemakers in 1983 there have been significant advances in pacemaker design (3). Pacemaker manufacturers have reduced the amount of ferromagnetic material, which has significantly reduced the risk of device displacement due to the static magnetic field (4). The risk of cardiac stimulation from currents induced by the gradient magnetic field has also been largely mitigated by the ability to program pacemakers to a nonstimulating mode during an MRI procedure (5). Research into the risks of gradient-induced stimulation, however, is still on-going. Currently, for the newer generation of devices, the most substantial risk for patients with pacemakers arises from the RF field, which has been shown to cause pacemaker lead tip heating at the myocardial interface (6–8).

The RF field in MRI is a circularly polarized magnetic field that rotates at 64 MHz in 1.5 Tesla (7) MRI systems. The continual rotation of the RF magnetic
In conclusion for a uniform electric field exposure, abandoned pacemaker leads, either capped or gel exposed, exhibit greater lead tip heating than pacemaker-attached leads for clinical lead lengths (40 to 60 cm) at 1.5T.

Both abandoned leads and pacemaker-attached leads show resonant heating behavior; however, maximum heating occurs at different lead lengths due to the differences in termination conditions.

Patients with abandoned leads may be at a greater risk for RF-induced thermal damage due to MRI exposure and risk assessment is complicated by the inability to fully monitor the effect of the MRI exposure for abandoned leads by measuring the pacing capture threshold.

Additional work is needed to establish whether current safety recommendations for MRI scanning of patients with implanted pacemakers can be applied to the safe scanning of patients with abandoned pacemaker leads.

Change in practice

- Change MRI safety questionnaire
  - “Have you EVER had a pacemaker”

- Encourage inclusion of “technical note” at start of radiology report
  - “Due to presence of retained intracardiac pacemaker leads, patient was scanned in presence of Cardiology personnel with monitoring, with MRI physics support…”
MRI Safety Events

- **Projectiles**
  - Inpatient – tracheostomy stylet
  - Outpatient – eyeglasses case
  - Cleaning staff – mop
  - Inpatient – flashlight
  - Anesthesia – needle
  - Equipment Services/Maintenance – screwdriver
  - Potential – patient cart (2x)
  - Potential – ferromagnetic oxygen tank

- **Environment**
  - Accidental quench – inadequate button cover

- **Patient care**
  - Sedated patient event
  - **Foil backed clonidine patch removal**
  - Unread orbit screening exam

- **Devices**
  - Unrecognized cardiac pacemaker leads
  - Unrecognized vagal nerve stimulator
  - Unrecognized Pillcam
  - Unrecognized deep brain stimulator
Transdermal Medication Patches

- RF energy can cause foil to heat
- If using T/R head or extremity coil, removal unwarranted
- When patch removed, clear handoff communication is mandatory to assure it’s reapplied properly.
- Recent event...
- Clonidine patch removed without communication handoff to floor
- Led to hypertensive episode
- Practice change: only nurses manage a medication patch including removing, replacing & documenting

SEE THE BIGGER PICTURE!

MRI Safety Events

- Projectiles
  - Inpatient – tracheostomy stylet
  - Outpatient – eyeglasses case
  - Cleaning staff – mop
  - Inpatient – Flashlight
  - Anesthesia – needle
  - Equipment Services/Maintenance – Screwdriver
  - Potential – patient cart (2x)
  - Potential – ferromagnetic oxygen tank

- Environment
  - Accidental quench – inadequate button cover

- Patient care
  - Sedated patient event
  - Foil backed clonidine patch removal
  - Unread orbit screening exam

- Devices
  - Unrecognized cardiac pacemaker leads
  - Unrecognized vagal nerve stimulator
  - Unrecognized Pillcam
  - Unrecognized deep brain stimulator
FDA poster on MRI Burn Prevention (Partnership with SMRT)

Quick reference for how to avoid burns

Mentions several suggestions from

- Ensure that no items (such as leads) are formed into a loop, since magnetic induction can occur and cause burns.

- If the patient’s body touches the bore of the MRI scanner, use non-conductive foam padding to insulate the patient’s skin and tissues.
Technologist Safety Concerns: “Bowling Alley”

- Mix of vendors, mix of field strengths
- “Where am I working???”
- Distracting environment
- New Signage
- Avoid scheduling implants to that row of scanners

Joint Commission Sentinel Event Alert #38, recommends the following precautions to prevent patient burns during scanning:

A. Ensure that no items are formed into a loop
B. Modify the pulse sequence to minimize RF deposition.
C. Use non-conductive padding to insulate patient from contact with the scanner bore.

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Outline

1. MR Safety Committee
2. MR Safety Guidelines, Policies and Procedures
3. MR Safety Training
4. MR Safety Events
5. MR Safety Audits

New ACR Quality Control Manual for MRI

Requirements go into effect July 1, 2016
“Technologist Contact Person” should have received a link to the digital copy:

FAQ document on ACR website
Describes changes between 2004 and 2015 versions
MR Safety Program Assessment (pgs 111-113)

The resolution, linearity, contrast, and distortion criteria described above should be met.

For more details regarding evaluation of the SMPTE test pattern, see Medical Physicist/MRI Scientist's Appendix, Section VI.C.

F. MR Safety Program Assessment

OBJECTIVE

To minimize risks in the MR environment to patients, health care professionals, and any others that may encounter the fields of the MR scanner, each site must establish, implement, and maintain current safety policies and procedures. Information regarding establishment of a quality MR safety program can be found in the ACR Guidance Document for Safe MR Practices: 2013 [35]. The hazards in the MRI suite may be divided into three categories: 1) facility design, 2) operational, and 3) clinical. Facility design refers to the facility layout in which zones are identified with appropriate signage and strategies for controlled access. Operational refers to procedures for screening both personnel and objects that may be introduced to the MR suite. Clinical refers to procedures that can be used to determine the MR safety and compatibility of implants and other medical devices.

IV. Annual MRI System Performance Evaluation

METHOD

At the time of the annual performance testing, the qualified medical physicist/MRI scientist must review the site's written safety policies and determine that the written policies are readily accessible to facility staff. The categories listed below should be addressed in the policies.

CRITERIA FOR COMPLIANCE

1. Written policies and procedures are present and are being reviewed and updated on a regular basis.

2. Facility has appropriate signage and methods of controlled access.

3. Documentation of regular MR safety training for all MR-designated personnel.
ACR 2015 New Requirements

• Additional form for Annual Report
• Sent to sites two weeks prior to Annual Testing
• Keep links to policies in the spreadsheet for easy review

ACR 2015 New Requirements

• QMP “must review the site’s written safety policies and determine that the written policies are readily accessible to facility staff.”
• Is the QMP reviewing for content?
  • No: QMP is not necessarily familiar with site’s processes and procedures
  • No: QMP is not qualified to assess quality of policies on:
    • Pediatric patients (sedation, anesthesia)?
    • Pregnant patient medical decision making
    • Cryogen safety (deliveries, refills)
    • Contrast agent safety, esp with new info coming out every day
    • Infection control and medical waste
• QMP is reviewing for existence and to make sure updates are being made
The ACR 2015 MRI Quality Control Manual MRI Safety Program Assessment Checklist should include a review of the following policies **EXCEPT**: 

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<tr>
<td>20%</td>
<td>2. Cryogen Safety</td>
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<td>20%</td>
<td>3. Pediatric patients</td>
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<td>20%</td>
<td>4. Pregnant patients</td>
</tr>
<tr>
<td>20%</td>
<td>5. Obese patients and patient lifts</td>
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**Answer:** Obese patients and patient lifts  


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**Findings from initial MRI Safety Program Assessments**

- **RST** – Policy regarding pregnant staff had vanished (not specifically requested for MRI in “Toolkit for Practice Sites”)
- **Helpful for obtaining approvals for construction**
  - Acquired hospital came Zone III-free  
  - Sign off on “Facility has appropriate...methods controlled access”?
- **Review with Mobile MRI Technologist:**
  - Patients were changing in scan room (Zone IV) for privacy  
  - Patient screening challenges lack of access to medical records
MR Safety Policies and Procedures should include considerations for the following EXCEPT:

1. MRI Staff Training
2. MRI emergency response
3. MRI Imaging Protocol Review
4. Patient screening criteria
5. Non-MRI-staff screening criteria

Thank you!

Thanks to my fellow Clinical MRI Physicists: