PREP Course 16: Radiation, MRI and Laser Safety in Clinical Research

Presented by:
William Robeson
Physicist, NSLIJ Radiology Service Line

Tina Chuck
Policy Specialist, Office of Research Compliance
CME Disclosure Statement

• The North Shore LIJ Health System adheres to the ACCME’s new Standards for Commercial Support. Any individuals in a position to control the content of a CME activity, including faculty, planners, and managers, are required to disclose all financial relationships with commercial interests. All identified potential conflicts of interest are thoroughly vetted by the North Shore-LIJ for fair balance and scientific objectivity and to ensure appropriateness of patient care recommendations.

• Course Director, Kevin Tracey, has disclosed a commercial interest in Setpoint, Inc. as the cofounder, for stock and consulting support. He has resolved his conflicts by identifying a faculty member to conduct content review of this program who has no conflicts.

• William Robeson and Tina Chuck have nothing to disclose
Assumptions

Researchers may need to order radiological procedures as part of their investigation.

Radiological procedures have risks that investigators need to become familiar with.

These risks include radiation exposure or dose, MRI contraindications and operational safety issues associated with the use of medical lasers.
Radiation Dose from Medical Procedures
NCRP Report 160 (2009)

Collective Effective Dose (%) 1988
Average Annual TEDE = 360 mrem

Collective Effective Dose (%) 2006
Average Annual TEDE = 620 mrem

The start of the controversy over dose in diagnostic imaging
Environmental dose to the US population changes very little
Medical dose increases 6 fold
Major culprits: CT, nuclear cardiology, interventional fluoroscopy
Effective Dose = 10 mSv

Young females are the biggest concern
# Comparison of Radiological Doses

<table>
<thead>
<tr>
<th>Examination</th>
<th>Effective dose (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CT scans</strong></td>
<td></td>
</tr>
<tr>
<td>Head CT</td>
<td>1 - 2</td>
</tr>
<tr>
<td>Chest CT</td>
<td>5 - 7</td>
</tr>
<tr>
<td>Abdomen CT</td>
<td>5 - 7</td>
</tr>
<tr>
<td>Abdomen &amp; Pelvis CT</td>
<td>8 - 11</td>
</tr>
<tr>
<td>Calcium scoring</td>
<td>1 - 5</td>
</tr>
<tr>
<td>Cardiac CT Angiography (helical)</td>
<td>10-20</td>
</tr>
<tr>
<td>PET-CT (whole body scans)</td>
<td>20-25 (~10 for CT, ~15 for PET)</td>
</tr>
<tr>
<td><strong>Radiographic &amp; Fluoroscopy procedures</strong></td>
<td></td>
</tr>
<tr>
<td>Chest X-ray</td>
<td>0.1</td>
</tr>
<tr>
<td>Mammography</td>
<td>0.4</td>
</tr>
<tr>
<td>Abdomen</td>
<td>0.7</td>
</tr>
<tr>
<td>Lumbar spine</td>
<td>1.5</td>
</tr>
<tr>
<td>Small bowel series</td>
<td>5.0</td>
</tr>
<tr>
<td>Upper GI series</td>
<td>6.0</td>
</tr>
<tr>
<td>Average background radiation per year ≈ 3.0 mSv</td>
<td></td>
</tr>
</tbody>
</table>
CT Scanning Procedure

A

gantry

bore

patient table

B

CT x-ray beam

moves to position patient and also translates during scanning

centering is important

raises patient up to center in FOV
Clinical CT Scan

Capable of exquisite images of human anatomy
The Problem

- In the U.S. 3M CT scans in 1980, Currently > 70M
- Radiation dose typically 10-100x conventional x-ray
- Over prescription of CT scans by physicians particularly in patients with chronic disorders
- Public perception – CT exams cause cancer?
- When a radiological imaging procedure is clinically appropriate, the benefit-risk balance is almost always overwhelming
The Solution

- **How to Reduce Dose**
  - Improved technology
    - Implementation of low dose CT scanners
  - Reduce radiation
    - Do we need pretty pictures or an accurate diagnosis
  - Replace CT use for certain indications
    - Ultra-sonography for appendicitis, particularly in kids
    - Expanded use of MRI, e.g. liver disease
  - Greater utilization of clinical decision guidelines
    - Decision rules
    - Appropriateness criteria
    - Computerized ordering systems
    - Radiologist consultation
Fluoroscopy

C-arms are popular in the OR

Angiography suites for interventional procedures
Fluoroscopy Induced Skin Injuries

Radiation injury from a cardiology fluoroscopy procedure.
Prolonged fluoroscopy with cumulative dose >1500 rads to a single field became a reportable sentinel event according to the Joint Commission.
Patient Dose: Primary Beam Absorption by the Patient

Why skin dose is the major concern in angiographic procedures
Patient Dose: Primary Beam Absorption by the Patient

This image provides a simulated view of the x-ray tube shining on a patient from two directions, with partial overlapping of the beams. In this case, the peak skin dose is the sum of the doses delivered during each projection in the overlap region. Beam overlap is likely unless judicious utilization of collimation is used during the procedure.

Importance of collimation
Radiation Pattern Near a Fluoroscopy Unit

Staff should position themselves on the exit side of the beam to the extent possible.
Personnel Protection in Interventional Radiology

Two piece apron 0.5mm distributes weight better
Thyroid collar
Side shielded protective eyewear
Fluoroscopy vs. CT

- With CT the concern is effective dose and cancer risk
- With fluoroscopy the concern is acute skin effects with prolonged use
What is MRI?

- Magnetic resonance imaging (MRI) is a noninvasive, usually painless diagnostic imaging procedure that assists physicians with the diagnoses and treatment of medical conditions.

- MR imaging uses a powerful magnetic field, radio waves and a computer to produce detailed images of organs, soft tissues, and virtually all other internal body structures. The images can then be interpreted by a radiologist.

- MRI does not use ionizing radiation (x-rays).
MRI SCANNERS

- MRI scanners have large magnetic fields typically, 15,000 – 30,000 gauss inside the scanner.
- This powerful field requires strict practices to ensure patient and operator safety.
Although not detectable by the human senses, a magnetic field can be dangerous to equipment and to people.

The MRI magnet is always “ON,” safety procedures MUST be followed to prevent accidents.

For the safety of patients and personnel, controlled access areas are established.
<table>
<thead>
<tr>
<th>Zone</th>
<th>Gauss Range</th>
<th>Access/Restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone I</td>
<td>&lt; 0.1 Gauss</td>
<td>Free access to the general public.</td>
</tr>
<tr>
<td>Zone II</td>
<td>0.1 – 1.0 Gauss</td>
<td>Reception / Registration area All individuals must be screened in this area prior to entering Zone III</td>
</tr>
<tr>
<td>Zone III</td>
<td>1.0 – 5.0 Gauss</td>
<td>Access to this area is restricted and must always be under supervision of MRI personnel.</td>
</tr>
<tr>
<td>Zone IV</td>
<td>&gt; 5.0 Gauss</td>
<td>MRI Scanner Room.</td>
</tr>
</tbody>
</table>
These areas are established for the safety of patients and personnel.

The areas are labeled with the use of warning signs and markings to prevent the entry of ferromagnetic objects into the controlled access area and to limit the access of individuals with medical implants near high magnetic fields.

No public access past the 5 Gauss line (0.5 mT).
Metal Objects Becoming Projectiles

Patient Monitoring Equipment

Floor Polishing Machine
SCREENING PROCEDURES

- Static magnetic fields can alter the operation of electrically and mechanically operated implants and **must** remain **OUTSIDE** the 5 gauss line.

- Questions about implants should be discussed with a MRI technologist or a radiologist **before** allowing the patient to be scanned.
ABSOLUTE CONTRAINDICATIONS

- Cardiac pacemakers or defibrillators (except in rare, controlled environments)
- Cochlear (inner ear) implants
- Swan-Ganz catheters with thermodilution tips
- Ferromagnetic or unidentifiable aneurysm clips of the brain
- Implanted neuro stimulators
- Metal or unidentifiable foreign bodies in the eyes
- Shrapnel near a vital organ
**Acoustic Noise**

The MR scanner can produce very high acoustic noise levels. Some patients may experience discomfort from the associated noise of the scanner. Prior to scanning, patients are provided with ear protection to significantly reduce noise levels.

**Burns**

Surface metals such as EKG leads or tattoos may cause burns when RF energy is turned on during the scan.
Medical Lasers

*LASER is an acronym, which stands for:*

- Light
- Amplification by
- Stimulated
- Emission of
- Radiation
Laser Fundamentals

- Light emitted from a laser is **monochromatic**. It is of one color / wavelength.
- Lasers emit light that is a highly **directional**. It is a relatively narrow beam in a specific direction.
- Light from a laser is said to be **coherent**. The wavelengths of the laser light are in phase in space and time.
- Ordinary white light is a combination of many colors (or wavelengths) of light.
- Ordinary light, e.g., from a light bulb, is emitted in many directions away from the source.
- Ordinary light can be a mixture of many wavelengths.

The **three properties** of laser light are what makes it more hazardous than ordinary light. **Laser light can deposit a lot of energy within a small area.**
LASER HAZARD CLASSES

Lasers and laser systems are assigned one of the four broad classes (1 to 4) depending on the potential for causing damage.

(American National Standards Institute’s (ANSI) Z136.1 Safe Use of Lasers.)

Class 1: considered “SAFE" if not disassembled. (e.g., laser printers, CD-rom players/drives)

Class 2: may exceed class 1 exposure limits if viewed more than 0.25 seconds [aversion respond time-blinking], but still not pose a significant eye hazards. (e.g., bar code scanners, laser pointers)

Class 3a: eye hazard if viewed using collecting optics, (e.g., eye pieces or microscopes).

Class 3b: eye hazards if beams are viewed directly or by specular reflections. (e.g., research, medical)

Class 4: eye hazards if beams are viewed directly or by specular reflections and possibly from diffuse reflections. Also skin burns from direct beam exposure. (e.g., research, manufacturing, medical)
Laser Hazards

- Beam Hazards
  - Eye Injuries
  - Skin Injuries

- Non-beam hazards
  - Electrical
  - Fire / Combustion
  - Explosion
  - Chemical
  - Laser Generated Air Contaminants
“DANGER” Warning Sign

Safety instructions may include:
- Eyewear required
- Invisible laser radiation
- Knock Before Entering
- Do Not Enter When Light is “ON”
- Restricted Area
Reflection Hazards

Specular Reflections:
Are mirror-like reflection that can reflect close to 100% of incident light.

Diffuse Reflections:
Results when surface irregularities scatter light in all directions.
Laser Protective Eyewear
Laser Induced OR Fires

Lasers must be kept clear of combustible materials
Preventing Fires

Do not use flammable or combustible materials near the laser application site

Allow flammable prep solutions to dry before draping

Drape the operative site with flame-resistant drapes

Keep a basin of water/saline readily available on the sterile field

Keep a fire extinguisher in the operating room

Use laser-safe (non PVC) endotracheal tubes during laser surgery in the digestive tract

Bowel gasses are flammable and care must be taken when using lasers
Laser Generate Air Contaminants (LGAC)

- Air contaminants may be generated when certain Class 3b and Class 4 lasers interact with matter. LGAC may be gaseous or particulate and can under certain conditions pose occupational concern.

- Patients and health care workers should be protected from inhaling LGAC associated with laser use.

- LGAC content may include:
  - Metallic fumes
  - Bloodborne Pathogens
  - Bacteria
  - Tissue cell particles
  - Viruses
  - Hydrocarbons
  - Chemical fumes
  - Gaseous vapors
Fiber Optics Lasers
Additional Resources on Healthport

- Education and Research
  - Fluoroscopy Credentialing
  - Laser Safety Credentialing
  - Welcome to MRI Safety
Use of Radiation in Human Subject Research

- Health System Policy: GR087
  - Use of radiation in human subject research needs to be approved by the Institutional Review Board (IRB) of record and by that hospital/facility’s Radiation Safety Officer or Radiation Safety Committee from North Shore-LIJ Health System. This policy does not apply to radiation procedures used in a research study that would be performed as standard of care in the course of the patient’s normal treatment plan if the patient was not a part of the research study. This policy also does not apply to cancer cooperative group studies.
Where do you find the health system policy and attachments?

Policy and Procedure Manual Index

- Policy and Procedures SPP team site

Access to the archived policies are restricted. If you are allowed access, click here to see the Archived Policies links for each manual.

- Corporate Policy and Procedures (North Shore - LIJ Health System) (10)
  - Administration Policy and Procedure Manual
  - Corporate Compliance Policies
  - Human Resources Policies and Procedures
  - Information Services Policies and Procedures
  - Procurement Policies
  - Radiology Service Line Policies and Procedures
  - Research Policies
<table>
<thead>
<tr>
<th>Section: Responsible Conduct of Research (14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GR053 Research at the North Shore-LIJ Health System</td>
</tr>
<tr>
<td>GR051 Research Misconduct</td>
</tr>
<tr>
<td>GR052 Maintenance, Storage, and Archiving of Human Subject Research Data</td>
</tr>
<tr>
<td>GR052 Register of Archived Research Data &amp; Records Form</td>
</tr>
<tr>
<td>GR078 Review of External Consulting Agreements with Industry</td>
</tr>
<tr>
<td>GR085 Human Subject Research Training</td>
</tr>
<tr>
<td>GR088 Principal Investigator Exit Process</td>
</tr>
<tr>
<td>GR088 Material Transfer and Disposition Form</td>
</tr>
<tr>
<td>GR087 Use of Radiation in Human Subject Research</td>
</tr>
<tr>
<td>GR087 Radiation Procedures Summary Form</td>
</tr>
<tr>
<td>GR087 Radioactive Drug Research Application</td>
</tr>
<tr>
<td>GR087 Radioactivity Summary Sheet for Protocols</td>
</tr>
<tr>
<td>GR091 Investigator-Initiated Multicenter Human Subject Research</td>
</tr>
<tr>
<td>GR089 Informed Consent and Recruitment for Human Subject Research</td>
</tr>
</tbody>
</table>
Who is your RSO (Radiation Safety Officer)?

- Go to [www.nslij.com/irb](http://www.nslij.com/irb)
- Click on Submission Guidance and find link to RSO spreadsheet at bottom of the page

<table>
<thead>
<tr>
<th>Site</th>
<th>Radiation Safety Officer (RSO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFAM</td>
<td>Josephine Rini</td>
</tr>
<tr>
<td>Flushing imaging</td>
<td>Nan-Ning Chang</td>
</tr>
<tr>
<td>Garden City Imaging</td>
<td>David Revere</td>
</tr>
<tr>
<td>Whitestone Imaging</td>
<td>Christos Vavasis</td>
</tr>
<tr>
<td>Medical Group in Syosset (North Shore Cardiopulmonary Assoc)</td>
<td>Venugopal Palla</td>
</tr>
<tr>
<td>Medical Group in Woodbury (Cardiology Consultants)</td>
<td>Richard Maisel</td>
</tr>
<tr>
<td>Huntington Hospital</td>
<td>William Ruppel</td>
</tr>
<tr>
<td>Plainview Hospital</td>
<td>Dominic Altieri</td>
</tr>
<tr>
<td>Syosset Hospital</td>
<td>Howard Heimowitz</td>
</tr>
<tr>
<td>Forest Hills Hospital</td>
<td>Spyros Harisiadis</td>
</tr>
<tr>
<td>Southside Hospital</td>
<td>Donald Fagelman</td>
</tr>
<tr>
<td>Glen Cove</td>
<td>Thomas Mannino</td>
</tr>
<tr>
<td>Franklin Hospital</td>
<td>Philippe Chu</td>
</tr>
<tr>
<td>NSUH</td>
<td>Miyuki Yoshida-Hay</td>
</tr>
<tr>
<td>LIJ</td>
<td>Jose Antony</td>
</tr>
<tr>
<td>LHH</td>
<td>Stephen Scharf</td>
</tr>
<tr>
<td>SIUH</td>
<td>Arnold Brenner</td>
</tr>
</tbody>
</table>
Remember...

Final IRB approval will not be given until RSO approval is received.