Version 1.5 Friday, February 06, 2015

A. Basic underlying MR safety principles and building blocks

- 1. Static magnetic field $(B_0, dB_0/dx)$
 - a. Basic Physics
 - i. Ouantities and units
 - ii. Field lines/gradients
 - iii. Magnetic properties of matter
 - b. Biological Effects
 - i. Magnetophosphenes
 - ii. Magnetohydrodynamic effect
 - iii. Flow potentials/EKG perturbations
 - iv. Vertigo, dizziness/nystagmus, nausea with motion in the static field
 - v. Teratogenesis?
 - vi. Pregnancy-related issues: Spontaneous abortion, premature delivery, gender of offspring, low birth weight, infertility
 - c. Mechanical Forces
 - i. Translational Forces (Missile Effect)
 - 1. Magnetic spatial gradient exposure (dB_0/dx)
 - 2. Static field exposure (B_0)
 - 3. Spatial and force-related effect of magnetic shielding
 - a. Active
 - b. Passive
 - 4. 3D location of maximal translational force (i.e., force product; location of maximum $(dB_0/dx)(B_0)$)
 - ii. Rotational Forces (Torque)
 - 1. 3D location of maximal rotational force (i.e., location of maximum B_0)
 - 2. Field orientation (horizontal, vertical)
 - iii. Lenz's Forces
 - 1. Dependence predominantly on:
 - a. Static field B_0 and static field gradient dB_0/dx
 - b. Orientation of electrical conductor relative to the lines of magnetic force
 - c. Rate of motion of electrical conductor relative to B₀
 - d. Dimensions of moving electrical conductor

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2. Time varying magnetic fields

- a. Basic physics
 - i. Induction -Faraday's law
 - ii. E field, Current density J
 - iii. Near and far field
 - iv. Tissue properties conductivity, dielectric constant
- b. Rapidly changing RF magnetic fields (B₁)
 - i. Potential biological concerns
 - ii. Potential thermal concerns; multifactorial determinants, including among others:
 - 1. SAR and energy deposited
 - a. SAR modes
 - i. Normal
 - ii. First level controlled
 - iii. Second level controlled
 - 2. Rate of exposure
 - 3. Route of exposure
 - 4. Transmitting RF coil
 - a. Proximity of patient tissue/device to transmitting RF coil
 - 5. Diameter of induced current loop
 - 6. Orientation of induced current loop relative to transmitted RF power
 - 7. Concentration of induced voltages/currents
 - a. Predominantly in leads, wires, devices with sharp edges/points
 - b. Field strength/transmitted RF frequency relative to the object in which there is an induced voltage/current
 - c. "Hot spots"
 - d. Resonant conditions, critical lengths relative to field strength/frequency dependence
 - 8. Presence/absence of heat sink (other than patient tissue!)
 - 9. Use of padding/insulation
 - a. Between patient and bore (cylindrical magnets)
 - b. Skin to skin contact avoidance vis à vis large caliber induced loops

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- c. Slowly changing Gradient magnetic fields (dB/dt)
 - i. Acoustic/auditory considerations
 - ii. Direct neuromuscular stimulation potential
 - 1. Muscular twitching, fasciculations
 - 2. Arrhythmogenesis potential
- d. Very slowly changing magnetic fields (dB₀/dt)
 - i. System quench
 - ii. Movement/motion within the static magnetic field

3. Gadolinium based contrast agents (GBCA)

- a. Short term adverse effects
 - i. Non-allergic type: Nausea, emesis, headache, local injection site adverse reactions, etc.
 - ii. Allergic type: Hives, sneezing, swelling, etc.
 - iii. Anaphylaxis/anaphylactoid reactions
 - iv. Risk assessment
 - 1. Previous adverse event with a GBCA
 - 2. Previous adverse event with iodinated agents
 - 3. History of allergies or allergic respiratory disorders
- b. Long term adverse effects
 - i. Nephrogenic Systemic Fibrosis
 - ii. Dose related dentate/globus pallidus T1 shortening; retained gadolinium
 - iii. Gadolinium Associated Plagues (GAP)
 - iv. Anthropogenic gadolinium
 - v. Self-published patients with normal renal function and complaints since GBCA administration; elevated 24 hour urinary gadolinium excretion?

4. Cryogen safety considerations

- a. Quench vent pathway considerations
- b. Hypothermia/frostbite
- c. Asphyxia
- d. Changing magnetic fields
- e. Explosive/flammable risk
- f. Pressure related risks (if quench vent pathway failure)
 - i. Ruptured eardrums
 - ii. Pressure "locking" of doors/access

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5. Claustrophobia/Anxiety

6. Monitoring

- a. MR environment effects on ability to accurately monitor
- b. Effects of the monitoring device(s) on MR imaging (artifacts)

B. Clinical situations and considerations

1. ACR Guidance Document for Safe MR Practices: 2013

2. General implant safety considerations

- a. Maximum spatial gradient (clinical application and decision making)
 - i. System maximum (may be behind system shroud/enclosure)
 - ii. Maximum exposure to the patient and health care personnel
- b. Thermal (clinical application and decision making)
- c. Induced voltages
- d. Artifact induction (clinical application and decision making)

3. Specific implant/device safety considerations

- a. Patient implants/devices
 - i. Ferromagnetic risk
 - 1. Magnetic implants (dental, breast implants, ICP monitors, etc.)
 - 2. Intraocular or adjacent to other delicate tissues/organs
 - 3. Artifact consideration
 - ii. Active implants/devices (specific examples follow)
 - 1. Device interfering with the MR scanner/artifact
 - 2. MR fields interfering with the implanted device function
 - 3. Pacemakers
 - a. Classical, one or more leads
 - b. Newest intracardiac, "leadless"
 - 4. ICDs
 - 5. Depth electrodes
 - 6. Neurostimulators (including deep brain stimulators)
 - 7. Bone growth stimulators

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- iii. Passive implants/devices (specific examples follow)
 - 1. Wires/leads/sutures
 - 2. Special consideration/circumstances
 - a. Copper 7/copper T
 - b. Foreign bodies (bullets, shrapnel, BBs, etc.)
 - c. Tattoos
 - i. Thermal
 - ii. Migration
 - d. Foil backed (i.e., electrically conductive) medication patches
 - e. Multiple adjacent or contiguous implants (e.g., skin staples, multiple dermal anchors, piercings)
- b. Fixed Parameter Option:B Operating Mode
- c. Healthcare worker implants
- d. Device labeling and proper use of terminology
 - i. MR Safe
 - ii. MR Unsafe
 - iii. MR Conditional

4. Pregnancy MR safety considerations

- a. Patient pregnancy issues
 - i. Unenhanced
 - ii. Enhanced
- b. Research subject pregnancy considerations
 - i. Risk-benefit assessments we use in clinical scanning do not apply, as the individual undergoing the risk is not the same as the one receiving the potential benefit
 - ii. Unenhanced
 - iii. Enhanced
- c. Healthcare pregnancy issues
 - i. Risk-benefit assessments we use in clinical scanning do not apply, as the individual undergoing the risk is not the same as the one receiving the potential benefit

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5. Limits and standards

- a. IEC, FDA, ICNIRP
 - i. Static field, movement in static field
 - ii. Time varying gradients
 - iii. RF
- b. Occupational exposure

6. Non-MR personnel in the MR environment

- a. Anesthesiologists
- b. Referring physicians (neurosurgeons, neurologists, cardiologists, etc.)
- c. ICU personnel (nursing, respiratory)
- d. Patient transport
- e. Security
- f. Housekeeping/maintenance
- g. Firefighters, police, first responders
 - i. Training content, frequency
- h. Accompanying family/friends/guardians
- i. Prisoners
 - i. House arrest bracelet
 - ii. Handcuffs, other restraining device(s)

7. Screening considerations

- a. Standardization
 - i. By whom?
 - ii. Of whom?
 - iii. How many times?
 - iv. Written? Oral? Both?
- b. Ferromagnetic detection; pros and cons, advances (far fewer false positives)
- c. Standard conventional "airport style" metal detectors are NOT recommended
- d. Gowning considerations
 - i. Decrease risks from ferromagnetic and thermal considerations
 - ii. Whom? (patient? Accompanying family? Accompanying healthcare workers?)
 - iii. How much? (i.e., what constitutes gowning? Top? Whole body? Underwear/socks?)

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8. Handling codes in the MR environment

- a. Prospective designation outside of Zone IV (except anesthesia)
 - i. Location
 - ii. Events/steps to execute
- b. Prospective site design (oxygen, suction, location with ability to safely and reliably defibrillate)

9. 4 Zones concept

- a. Site access restriction for:
 - i. Humans
 - ii. Ferromagnetic devices/objects
 - iii. Ferromagnetic devices/objects
 - 1. Ancillary equipment in Zone 4 (MRI scanner room)
- b. Site access restriction relative to:
 - i. The MR magnet room/Zone IV
 - ii. The quench vent exhaust port
- c. Signage
 - i. Relative to the MR magnet room/Zone IV
 - ii. Relative to the quench vent exhaust port
- d. Authority and responsibility for enforcement

10. Siting considerations for MR safety

- a. Defined at least in part by the patient population to be scanned (e.g., inpatient versus out-patient, pediatric versus adult, sedation, anesthesia and recovery, monitoring, how will codes be handled, etc. etc.)
- b. Diagnostic versus interventional (intraoperative) care
- c. Hybrid scanners (PET/MR, etc.)
- d. Access control, line of sight from MR Technologist/Operator, etc. (4-zone integration)
- e. Siting of ferromagnetic detection units
- f. Patient screening areas
- g. Area for running codes
- h. Area for running induction/recovery (if/as applicable)
- i. Metal/ferromagnetic material storage/quarantine area (e.g., lockers)

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- j. Site planning for gases, suction, etc. access
- k. Proper quench venting pathways
 - i. Design
 - ii. Maintenance
 - iii. The entirety of the cryogen vent pathway falls with Zone III definitions and as such requires physical restriction from inadvertent access by non-MR personnel, even though it may be physically removed from the MR suite itself

11. Infection control (cleaning, venting between patients, etc.)

C. Medicolegal implications of MR safety

- 1. Legal foundations and building blocks
 - a. Standard of care
 - i. This is the basis of it all
 - ii. Expectation of how another similarly trained individual would have behaved in the same clinical situation
 - iii. HOWEVER, defined by the patient's expectation
 - b. Medical malpractice
 - i. Breach of standard of care = Negligence
 - ii. The breach of the standard of care was a proximate cause of an injury
 - c. "Captain of the ship" doctrine for medical malpractice in US
 - d. There can be multiple parties responsible/liable for an injury
 - e. Vicarious liability
 - i. NOT determined by who hires/fires the employee
 - ii. If they respond to your guidance, you can be held vicariously liable for their actions/inactions