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## A. Basic underlying MR safety principles and building blocks

- 1. Static magnetic field  $(B_0, dB_0/dx)$ 
  - a. Basic Physics
    - i. Quantities 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<sub>0</sub>/dx)
      - 2. Static field exposure (B<sub>0</sub>)
      - 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<sub>0</sub> and static field gradient dB<sub>0</sub>/dx
        - b. Orientation of electrical conductor relative to the lines of magnetic force
        - c. Rate of motion of electrical conductor relative to B<sub>0</sub>
        - 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 (B<sub>1</sub>)
  - 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
      - 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 (dB<sub>0</sub>/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 Plaques (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. a . ACR Manual on MR Safety: ACR Manual on MR Safety
  - b. ACR guidance document on MR safe practices: Update and critical information 2019: <a href="https://onlinelibrary.wiley.com/doi/full/10.1002/jmri.26880">https://onlinelibrary.wiley.com/doi/full/10.1002/jmri.26880</a>

#### 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