1. Motivation
   a. Patients with implantable devices frequently need MRI examinations
      i. Device patients have chronic/degenerative conditions
         1. Especially brain or spine issues require MRI
      ii. Device patients develop new pathologies, e.g., cancer
      iii. Surveys estimate >50% of patients with active implantable devices will require MRI after device implantation
   b. Implantable devices have known safety-related interactions with MRI systems
      i. Several catastrophic events linked to inappropriate MRI scanning of patients with implantable devices
         1. RF heating [1]
         2. Pacemaker competitive pacing [2]
      ii. Anecdotal reports and in vitro studies find evidence of device malfunction
         1. Range from simple changed settings to device failure
      iii. Likely many more unreported and/or subclinical effects
         1. Voluntary reporting = under-reporting
         2. Difficult to measure subclinical/long-term effects

2. Types of implantable devices: wide variety of forms and functions
   a. Passive (no powered electronic components)
      i. Orthopedic
         1. Hips, knees, rods, screws
      ii. Cardiovascular
         1. Stents, stent-grafts, valves
      iii. Neurovascular
         1. Aneurysm clips, aneurysm coils
   b. Active (with powered electronic components)
      i. Cardiac stimulators
         1. Pacemakers, ICDs
      ii. Neurostimulators
         1. Spinal cord stimulators
         2. Deep brain stimulators
         3. Cochlear implants
         4. Other stimulators—vagus nerve, peripheral nerves
      iii. Drug pumps
         1. Insulin, pain
      iv. Sensors
         1. Loop monitor/recorder
3. Interactions (RF)
   a. RF-induced heating (passive and active devices)
      i. $B_{1\text{rms}}$ is the MRI output variable most directly related to RF heating
         1. $B_{1\text{rms}} \rightarrow$ Local electric fields in patient $\rightarrow$ Coupling/local SAR deposition $\rightarrow$ Temperature rise
         2. RF heating is indirectly related to whole-body SAR
            a. Scales with whole body SAR for a given patient
            b. Cannot be directly determined from whole body SAR without further modeling of local SAR distributions
      ii. Mechanism for heating is local concentration of RF fields in the conductive tissues around implantable devices [3, 4]
         1. ‘Hot spots’ near tips/edges of simple devices (hips, screws)
         2. ‘Resonant’ effects in elongated devices, e.g., with leads [5]
         3. Common misconception is that the device/metal heats
      iii. Local SAR gain
         1. All implantable objects have some effect on local fields
         2. Safety index concept of Yeung and Atalar quantifies local SAR gain and puts it in the context of patient safety [6]
      iv. Tangential electric field coupling mechanism
         1. Demonstrated for long conductive structures
         2. Transfer function concept of Park and Nyenhuis [7]
      v. Heating response is complex and configuration-dependent for long objects
         1. Adding simple loops changes in vitro heating by 10x for some lead designs [8]
   b. RF-induced device malfunction (active devices only)
      i. Mechanism for malfunction is induced voltages/currents in electronic circuits and components
         1. Injected voltage/current from field exposure along leads
            a. Input sensor interference, e.g., ‘over-sensing’
            b. Unintended stimulation due to rectified RF voltages
            c. Damage to input or other circuitry
         2. Induced voltages in communication or charging circuits
            a. Potential standard Electromagnetic Interference issues
      ii. Effects are highly dependent on device design and/or mode of operation
         1. Input filtering
            a. E.g., most pacemakers have EMI filters/capacitors
         2. Special device settings for MRI
            a. E.g., stimulation voltage = 0V, bipolar only, etc.
c. RF-induced image artifacts (passive and active devices)
   i. RF shielding
      1. Reduced local flip angles near metal surfaces [9]
      2. Often dominated by susceptibility-based artifacts
   ii. Induced RF currents
      1. Combined effects of transmit and receive sensitivity variations create complex artifacts [10]
      2. Spatially dependent enhancement and/or cancellation of applied $B_1$, typically around long conductive structures [10, 11]

4. Testing standards: quantifying interactions
   a. Passive devices
      i. ASTM F2182-09 [12]
      1. Prescriptive method for measurement of induced heating in a homogeneous gel phantom
   b. Active devices
      1. Rationale and descriptions of how to design test methods for active devices, including RF heating and EMI
      2. First edition expected publication ~July, 2012

5. Device labeling
   a. ASTM F2503-08 standard defines appropriate terminology and labeling classifications [14]
      i. ‘MR Safe,’ ‘MR Unsafe,’ and ‘MR Conditional’
   b. Few implantable devices are ‘MR Safe’
      i. Implies that there is no possibility of patient harm under any known/potential MRI environments
   c. “MR Conditional”
      i. Scanning can be safe under a specified set of conditions
      1. E.g., ‘Head averaged SAR < 0.1W/kg,’ ‘Normal Mode’
      2. Some conditions are easier to meet than others
   d. Not MR Compatible
      i. Outdated, indistinct terminology

6. Areas of active research
   a. Determining in vivo field distributions under MRI
   b. Linking in vitro testing to in vivo/patient effects
   c. Predicting coupling of energy in a complex patient/device/MRI system
   d. Setting acceptability criteria for heating near devices, by anatomical location/tissue type
   e. Determining impact of emerging RF paradigms in MRI, including parallel RF transmission systems, RF shimming, etc.
References: