Home

MRI Related Videos

MRI Safety Poster

Functions and Activities

Disclaimer

Advisory Boards

Medical, Scientific, and Technology Advisory Board

Corporate Advisory Board

Corporate Sponsors

MRI Safety Guidelines

MR Safety Papers

Contact Us

- **GUIDELINES FOR SCREENING PATIENTS FOR MR PROCEDURES AND INDIVIDUALS FOR THE MR ENVIRONMENT**

Note: Forms and Content, Fully-Updated 2010

GUIDELINES FOR SCREENING PATIENTS FOR MR PROCEDURES AND INDIVIDUALS FOR THE MR ENVIRONMENT

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Note: Forms and Content, Fully-Updated 2010

Patients for MRI Procedures and Individuals for the MRI Environment* The establishment of thorough and effective screening procedures for patients and other individuals is one of the most critical components of a program that guards the safety of all those preparing to undergo magnetic resonance (MR) procedures or to enter the MR environment. An important aspect of protecting patients and individuals from MR system-related accidents and injuries involves an understanding of the risks associated with the various implants, devices, accessories, and other objects that may cause problems in this setting. This requires constant attention and diligence to obtain information and documentation about these objects in order to provide the safest MR setting possible.

In addition, because most MR-related incidents have been due to deficiencies in screening methods and/or the lack of properly controlling access to the MR environment (especially with regard to preventing personal items and other potentially problematic objects from entering the MR system room), it is crucial to set up procedures and guidelines to prevent such incidents from occurring.

Magnetic Resonance (MR) Procedure Screening for Patients Certain aspects of screening patients for MR procedures may take place during the scheduling process. These activities should be conducted by a healthcare worker specially trained in MR-safety (i.e., trained to understand the potential hazards and issues associated with the MR environment and MR procedures and to be familiar with the information contained on the screening forms for patients and individuals). While scheduling the patient, it may be ascertained if the patient has an implant or device that may be contraindicated or requires special attention for the MR procedure (e.g., a ferromagnetic aneurysm clip, pacemaker, neurostimulation system, etc.) or if there is a condition that needs careful consideration (e.g., the patient is pregnant, has a disability, history of renal failure, metallic foreign body, etc.). Preliminary screening helps to prevent scheduling patients that may be inappropriate candidates for MR

examinations.

After preliminary screening, the patient must undergo comprehensive screening in preparation for the MR procedure. Comprehensive screening involves the use of a printed form to document the screening procedure, a review of the information on the screening form, and a verbal interview to verify the information on the form and to allow for discussion of concerns that the patient may have. An MR-safety trained healthcare professional must conduct this important aspect of patient screening.

The screening form entitled, Magnetic Resonance (MR) Procedure Screening Form for Patients was created in conjunction with the Medical, Scientific, and Technology Advisory Board and the Corporate Advisory Board of the Institute for Magnetic Resonance Safety, Education, and Research (IMRSER). A "downloadable" version of this form may be obtained from the web sites, www.IMRSER.org and www.MRIsafety.com. This form is also available in Spanish (Translated by Olga Fernandez-Flygare, M.S., Brain Mapping Center, UCLA School of Medicine, Los Angeles, CA and Maelesa Rachele Oriente-Padilla', Loyola-Marymount University, Los Angeles, CA).

Page one of the screening form requests general patient-related information (name, age, sex, height, weight, etc.) as well as information regarding the reason for the MR examination and/or symptoms that may be present. Pertinent information about the patient is required not only to ensure that the medical records are up-to-date, but also in the event that the MRI facility needs to contact the referring physician for additional information regarding the examination or to verify the patient's medical condition.

The form requests information regarding a prior surgical procedure to help determine if there may be an implant or device present that could create a problem. Information is also requested pertaining to prior diagnostic imaging studies that may be helpful to review for assessment of the patient's condition.

Next, questions are posed to determine if there are issues that should be discussed with the patient prior to permitting entry to the MR environment. For example, information is requested regarding any problem with a previous MR examination, an injury to the eye involving a metallic object, or injury from a metallic foreign body. Questions are posed to obtain information about current or recently taken medications as well as the presence of drug allergies. There are also questions asked to assess past and present medical conditions that may affect the MR procedure or the use of an MRI contrast agent.

Important Information: MRI Contrast Agents and Nephrogenic Systemic Fibrosis (NSF). The American College of Radiology (ACR) Contrast Committee and the Subcommittee for MR Safety members recommend pre-screening patients prior to the administration of Gadolinium-Based MR Contrast Agents (GBMCA), as follows:

A recent (e.g., last 6 weeks) Glomerular Filtration Rate (GFR) assessment be reviewed for patients with a history of: -Renal disease (including solitary kidney, renal transplant, renal tumor) -Age >60 years old -History of Hypertension -History of Diabetes -History of severe hepatic disease/liver transplant/pending liver transplant. For patients in this category, only, it is recommended that the patient's GFR assessment be nearly contemporaneous with the MR examination for which the GBMCA is to be administered.

In consideration of the above, questions are posed to the patient to determine if there are conditions that may need to be considered relative to the use of MRI contrast agents and the issue of NSF. For more information on this topic, refer to the section entitled, **MRI Contrast Agents and Nephrogenic Systemic Fibrosis (NSF)*.**

At the bottom of page one, there is a section for female patients that questions that may impact MR procedures. For example, questions regarding the date of the last

menstrual period, pregnancy or late menstrual period are included. A definite or possible pregnancy must be identified prior to permitting the patient into the MR environment so that the risk vs. the benefit of the MR procedure can be considered and discussed with the patient. MR examinations should only be performed in pregnant patients to address important clinical questions. MR facilities should have a clearly defined procedure to follow in the event that the patient has a possible or confirmed pregnancy.

Questions pertaining to the date of the last menstrual period, use of oral contraceptives or hormonal therapy, and fertility medication are necessary for female patients undergoing MR procedures that are performed to evaluate breast disease or for OB/GYN applications, as these may alter tissue contrast on MR imaging. An inquiry about breastfeeding is included in case the administration of MRI contrast media is being considered for use in nursing mothers.

Page 2 of the form has the following statement at the top of the page: **"WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure (i.e., MRI, MR angiography, functional MRI, MR spectroscopy). Do not enter the MR system room or MR environment if you have any question or concern regarding an implant, device, or object. Consult the MRI Technologist or Radiologist BEFORE entering the MR system room. The MR system magnet is ALWAYS on."**

Next, there is a section that lists various implants, devices, and objects to identify anything that could be hazardous to the patient undergoing the MR procedure or that may produce an artifact that could interfere with the interpretation of the MR examination. In general, these items are arranged on the checklist in order of the relative safety hazard or risk (e.g., aneurysm clip, cardiac pacemaker, implantable cardioverter defibrillator, electronic implant, etc.), followed by items that may produce imaging artifacts that could be problematic for the interpretation of the MR procedure. Additionally, questions are posed to determine if the patient has a breathing problem, movement disorder, or claustrophobia.

Figures of the human body are included on the second page of the form as a means of showing the location of any object inside of or on the body. This information allows the patient to indicate the approximate position of an object that may be hazardous or that could interfere with the interpretation of the MR procedure as a result of producing an artifact.

Page 2 of the screening form also has an Important Instructions section that states: "Before entering the MR environment or MR system room, you must remove all metallic objects including hearing aids, dentures, partial plates, keys, beeper, cell phone, eyeglasses, hair pins, barrettes, jewelry, body piercing jewelry, watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, tools, clothing with metal fasteners, & clothing with metallic threads. Please consult the MRI Technologist or Radiologist if you have any question or concern BEFORE you enter the MR system room."

Finally, there is a statement that indicates hearing protection is "advised or required" to prevent possible problems or hazards related to acoustic noise. In general, this should not be an option for a patient undergoing an MR procedure on a high-field-strength MR system. Alternatively, it may be unnecessary for a patient to use hearing protection if undergoing an MR procedure on a low-field-strength MR system.

Importantly, undergoing previous MR procedures without incidents does not guarantee a safe subsequent MR examination. Various factors (e.g., the field strength of the MR system, the orientation of the patient, the orientation of a metallic implant or object, etc.) can substantially change the scenario. Thus, a written screening form must be completed each time a patient prepares to undergo an MR examination.

With the use of any type of written questionnaire, limitations exist related to

incomplete or incorrect answers provided by the patient. For example, there may be difficulties associated with patients that are impaired with respect to their vision, language fluency, or level of literacy. Therefore, an appropriate accompanying family member or other individual (e.g., referring physician) should be involved in the screening process to verify any information that may impact patient safety. Versions of this form should also be available in other languages, as needed (i.e., specific to the demographics of the MRI facility).

In the event that the patient is comatose or unable to communicate, the written screening form should be completed by the most qualified individual (e.g., physician, family member, etc.) who has knowledge about the patient's medical history and present condition. If the screening information is inadequate, it is advisable to look for surgical scars on the patient and/or to obtain plain films of the skull and/or chest to search for implants that may be hazardous in the MR environment (e.g., aneurysm clips, cardiac pacemakers, neurostimulation systems, etc.).

Following completion of the Magnetic Resonance (MR) Procedure Screening Form for Patients, an MR-safety trained healthcare worker should review the form's content. Next, a verbal interview should be conducted by the MR-safety trained healthcare worker to verify the information on the form and to allow discussion of any question or concern that the patient may have. This provides a mechanism for clarification or confirmation of the answers to the questions posed to the patient so that there is no miscommunication regarding important MR safety issues. In addition, because the patient may not be fully aware of the medical terminology used for a particular implant or device, it is imperative that this particular information on the form be discussed during the verbal interview.

After the comprehensive screening procedure is completed, a patient that is transferred by a stretcher, gurney, or wheelchair to the MR system room should be checked thoroughly for metallic objects such as ferromagnetic oxygen tanks, monitors, or other objects that could pose a hazard. Obviously, only nonferromagnetic stretchers, gurneys, wheelchairs and accessories should be allowed into the MR system room.

Magnetic Resonance (MR) Environment Screening for Individuals Before any non-patient individual (e.g., MRI technologist, physician, relative, visitor, allied health professional, maintenance worker, custodial worker, fire fighter, security officer, etc.) is allowed into the MR environment, he or she must be screened by an MR-safety trained healthcare worker. Proper screening for individuals involves the use of a printed form to document the procedure, a review of the information on the form, and a verbal interview to verify the information on the form and to allow discussion of any question or concern that the individual may have before being permitted into the MR environment.

Important Note: If for any reason the individual undergoing screening may need to enter the MR system and, thus, become exposed to the electromagnetic fields used for an MR procedure, this person must be screened using the Magnetic Resonance (MR) Procedure Screening Form for Patients.

In general, magnetic resonance (MR) screening forms were developed with patients in mind and, therefore, tend to pose many questions that are inappropriate or confusing to other individuals that may need to enter the MR environment. Therefore, a screening form was created specifically for individuals that need to enter the MR environment and/or MR system room. This form, entitled, Magnetic Resonance (MR) Environment Screening Form for Individuals was developed in conjunction with the Medical, Scientific, and Technology Advisory Board and the Corporate Advisory Board of the Institute for Magnetic Resonance Safety, Education, and Research (IMRSER). A "downloadable" version of this form may be obtained from the web sites, www.IMRSER.org and www.MRIsafety.com.

At the top of this form, the following statement is displayed: "The MR system has a very strong magnetic field that may be hazardous to individuals entering the MR environment or MR system room if they have certain metallic, electronic, magnetic, or mechanical implants, devices, or objects. Therefore, all individuals are required to fill out this form BEFORE entering the MR environment or MR system room. Be advised, the MR system magnet is ALWAYS on."

The screening form for individuals requests general information (name, age, address, etc.) and poses important questions to determine if there are possible problems or issues that should be discussed with the individual prior to permitting entry to the MR environment. A warning statement is also provided on the form, as follows: "WARNING: Certain implants, devices, or objects may be hazardous to you in the MR environment or MR system room. Do not enter the MR environment or MR system room if you have any question or concern regarding an implant, device, or object."

In addition, there is a section that lists implants, devices, and objects to identify the presence of an object that may be hazardous to an individual in the MR environment (e.g., an aneurysm clip, cardiac pacemaker, implantable cardioverter defibrillator (ICD), electronic or magnetically activated device, metallic foreign body, etc).

Finally, there is an Important Instructions section on the form that states: "Remove all metallic objects before entering the MR environment or MR system room including hearing aids, beeper, cell phone, keys, eyeglasses, hair pins, barrettes, jewelry (including body piercing jewelry), watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, steel-toed boots/shoes, and tools. Loose metallic objects are especially prohibited in the MR system room and MR environment. Please consult the MRI Technologist or Radiologist if you have any question or concern BEFORE you enter the MR system room."

The proper use of this written form along with thorough verbal screening of the individual by an MR safety trained healthcare worker will prevent accidents and injuries in the MR environment.

[*The screening forms, Magnetic Resonance (MR) Procedure Screening Form For Patients and Magnetic Resonance (MR) Environment Screening Form for Individuals were developed in conjunction with the Institute for Magnetic Resonance Safety, Education, and Research (IMRSER) and published with permission.]

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Functions and Activities

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MRI Safety Guidelines

MR Safety Papers

Contact Us

- GUIDELINES TO PREVENT EXCESSIVE HEATING AND BURNS ASSOCIATED WITH MAGNETIC RESONANCE PROCEDURES

GUIDELINES TO PREVENT EXCESSIVE HEATING AND BURNS ASSOCIATED WITH MAGNETIC RESONANCE PROCEDURES

In general, magnetic resonance (MR) imaging is considered to be a relatively safe diagnostic modality. However, the use of radiofrequency coils, physiologic monitors, electronically-activated devices, and external accessories or objects made from conductive materials has caused excessive heating, resulting in burn injuries to patients undergoing MR procedures. Heating of implants and similar devices may also occur in association with MR procedures, but this tends be problematic primarily for objects made from conductive materials that have elongated shapes such as leads, guidewires, and certain types of catheters (e.g., catheters with thermistors or other conducting components).

Notably, more than 30 incidents of excessive heating have been reported in patients undergoing MR procedures in the United States that were unrelated to equipment problems or the presence of conductive external or internal implants or materials [review of data files from U.S. Food and Drug Administration, Center for Devices and Radiological Health, Manufacturer and User Facility Device Experience Database, MAUDE, http://www.fda.gov/cdrh/maude.html and U.S. Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Report, (http://www.fda.gov/CDRH/mdrfile.html)]. These incidents included first, second, and third degree burns that were experienced by patients. In many of these cases, the reports indicated that the limbs or other body parts of the patients were in direct contact with body radiofrequency (RF) coils or other RF transmit coils of the MR systems or there were skin-to-skin contact points suspected to be responsible for these injuries.

MR systems require the use of RF pulses to create the MR signal. This RF energy is transmitted readily through free space from the transmit RF coil to the patient. When conducting materials are placed within the RF field, the result may be a concentration of electrical currents sufficient to cause excessive heating and tissue damage. The nature of high frequency electromagnetic fields is such that the energy can be transmitted across open space and through insulators. Therefore, only devices with carefully designed current paths can be made safe for use during MR procedures. Simply insulating conductive material (e.g., wire or lead) or separating it from the patient may not be sufficient to prevent excessive heating or burns from occurring.

Furthermore, certain geometrical shapes exhibit the phenomenon of “resonance” which increases their propensity to concentrate RF currents. At the operating frequencies of present day MR systems, conducting loops of tens of centimeters in

size may create problems and, therefore, must be avoided, unless high impedance is used to limit RF current. Importantly, even loops that include small gaps separated by insulation may still conduct current.

To prevent patients from experiencing excessive heating and possible burns in association with MR procedures, the following guidelines are recommended:

(1) Prepare the patient for the MR procedure by ensuring that there are no unnecessary metallic objects contacting the patient's skin (e.g., metallic drug delivery patches, jewelry, necklaces, bracelets, key chains, etc.).

(2) Prepare the patient for the MR procedure by using insulation material (i.e., appropriate padding) to prevent skin-to-skin contact points and the formation of "closed-loops" from touching body parts.

(3) Insulating material (minimum recommended thickness, 1-cm) should be placed between the patient's skin and transmit RF coil that is used for the MR procedure (alternatively, the RF coil itself should be padded). For example, position the patient so that there is no direct contact between the patient's skin and the body RF coil of the MR system. This may be accomplished by having the patient place his/her arms over his/her head or by using elbow pads or foam padding between the patient's tissue and the body RF coil of the MR system. This is especially important for those MR examinations that use the body coil or other large RF coils for transmission of RF energy.

(4) Use only electrically conductive devices, equipment, accessories (e.g., ECG leads, electrodes, etc.), and materials that have been thoroughly tested and determined to be safe and compatible for MR procedures.

(5) Carefully follow specific MR safety criteria and recommendations for implants made from electrically-conductive materials (e.g., bone fusion stimulators, neurostimulation systems, etc.).

(6) Before using electrical equipment, check the integrity of the insulation and/or housing of all components including surface RF coils, monitoring leads, cables, and wires. Preventive maintenance should be practiced routinely for such equipment.

(7) Remove all non-essential electrically conductive materials from the MR system (i.e., unused surface RF coils, ECG leads, cables, wires, etc.).

(8) Keep electrically conductive materials that must remain in the MR system from directly contacting the patient by placing thermal and/or electrical insulation between the conductive material and the patient.

(9) Keep electrically conductive materials that must remain within the body RF coil or other transmit RF coil of the MR system from forming conductive loops. Note: The patient's tissue is conductive and, therefore, may be involved in the formation of a conductive loop, which can be circular, U-shaped, or S-shaped.

(10) Position electrically conductive materials to prevent "cross points". For example, a cross point is the point where a cable crosses another cable, where a cable loops across itself, or where a cable touches either the patient or sides of the transmit RF coil more than once. Notably, even the close proximity of conductive materials with each other should be avoided because some cables and RF coils can capacitively-couple (without any contact or crossover) when placed close together.

(11) Position electrically conductive materials to exit down the center of the MR system (i.e., not along the side of the MR system or close to the body RF coil or other transmit RF coil).

(12) Do not position electrically conductive materials across an external metallic prosthesis (e.g., external fixation device, cervical fixation device, etc.) or similar

device that is in direct contact with the patient.

(13) Allow only properly trained individuals to operate devices (e.g., monitoring equipment) in the MR environment.

(14) Follow all manufacturer instructions for the proper operation and maintenance of physiologic monitoring or other similar electronic equipment intended for use during MR procedures.

(15) Electrical devices that do not appear to be operating properly during the MR procedure should be removed from the patient immediately.

(16) Closely monitor the patient during the MR procedure. If the patient reports sensations of heating or other unusual sensation, discontinue the MR procedure immediately and perform a thorough assessment of the situation.

(17) RF surface coil decoupling failures can cause localized RF power deposition levels to reach excessive levels. The MR system operator will recognize such a failure as a set of concentric semicircles in the tissue on the associated MR image or as an unusual amount of image non-uniformity related to the position of the RF coil.

The adoption of these guidelines will help to ensure that patient safety is maintained, especially as more conductive materials and electronically-activated devices are used in association with MR procedures.

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- GUIDELINES FOR THE MANAGEMENT OF THE POST-OPERATIVE PATIENT REFERRED FOR A MAGNETIC RESONANCE PROCEDURE

GUIDELINES FOR THE MANAGEMENT OF THE POST-OPERATIVE PATIENT REFERRED FOR A MAGNETIC RESONANCE PROCEDURE

There is often confusion regarding the issue of performing a magnetic resonance (MR) procedure during the post-operative period in a patient with a metallic implant or device. Studies have supported that, if a metallic object is a "passive implant" (i.e., there is no electronically- or magnetically-activated component associated with the operation of the device) and it is made from nonferromagnetic material, the patient may undergo an MR procedure immediately after implantation using an MR system operating at 1.5-Tesla or less (or, the field strength that was used to test the device, including 3-Tesla). In fact, there are several reports that describe placement of vascular stents, coils, filters, and other implants using MR-guided procedures that include the use of high-field-strength (1.5- and 3-Tesla) MR systems.

Additionally, a patient or individual with a nonferromagnetic, passive implant is allowed to enter the MR environment associated with a scanner operating at 1.5-Tesla (or, the field strength that was used to test the device, including 3-Tesla) or less immediately after implantation of such an object. For an implant or device that exhibits "weakly magnetic" qualities, it may be necessary to wait a period of at least six weeks after implantation before performing an MR procedure or allowing the individual or patient to enter the MR environment. For example, certain intravascular and intracavitary coils, stents, and filters designated as "weakly magnetic" become firmly incorporated into tissue a minimum of six weeks following placement. In these cases, retentive or counter-forces provided by tissue ingrowth, scarring, or granulation serve to prevent these objects from presenting risks or hazards to patients or individuals in the MR environment.

However, patients with implants or devices that are "weakly magnetic" but rigidly fixed in the body (e.g., bone screws, other orthopedic implants, or other devices) may be studied immediately after implantation. Specific information pertaining to the recommended post-operative waiting period may be found in the labeling or product insert for an implant or device.

Special Note: If there is any concern regarding the integrity of the tissue with respect to its ability to retain the implant or object in place or the implant cannot be properly identified, the patient or individual should not be exposed to the MR environment.

[*The document, Guidelines for the Management of the Post-Operative Patient Referred for a Magnetic Resonance Procedure, was developed by the Institute for Magnetic Resonance Safety, Education, and Research (IMRSER) and published with permission.]

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