Volume 2, Issue 4

**Topics in Patient Safety** 

July/August 2002

# Could You Say That Again...It's a Little LOUD in Here

Excessive noise levels associated with magnetic resonance imaging (MR) procedures have been known to be a problem for many years. A study published in the *Journal of Magnetic Resonance Imaging* (Volume 13, No. 2, 2001) quantifies noise level exposure for patients and staff in the vicinity of the MR magnet.

The study shows that noise level varies widely among the different MR systems and with all but one exception, are directly related to the strength or Tesla (T) rating of the magnet; the stronger the magnet the louder the noise level. It is worth recognizing that one manufacturer, Toshiba, has significantly reduced the noise level of their 1.5 Tesla magnet by reconfiguring and encasing the gradient coil inside a chamber within the unit.

The accompanying table (see page 4) depicts the noise level of various sounds compared to the noise levels produced by MR systems covered in the *Journal of Magnetic Resonance Imaging* article.

When sound levels or noise is discussed in occupational settings it is discussed in terms of the duration of the exposure (to the sound) as well as the decibel level of the sound. The Occupational Safety and Health Administration (OSHA) has established sound exposure limits that are expressed as time

weighted averages. The OSHA exposure table (see page 4) is included in this article for your reference. If you have any questions consult with your Industrial Hygienist or Occupational Safety Manager.

NCPS recommends that hearing protection be considered for patients undergoing MR procedures, taking into account noise level and duration of exposure. Noise reduction may be accomplished by the use of earplugs or earmuffs. Earplugs that have a Noise Reduction Rating (NRR) of 30 are available. Properly using an earplug with a NRR of 30 would reduce the noise level of a 118 dBA MR scan to 88 dBA. Consult with your Industrial Hygienist or Occupational Safety Manager for recommendations on the earplug or earmuff that should be used with your MR system.

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## **MedWatch Reports**

The Food and Drug Administration (FDA) operates a safety information and adverse event reporting program called MedWatch. Supplied by both mandatory and voluntary reports, MedWatch collects safety information about prescription drugs, biologics, medical devices, and dietary supplements. The Safe Medical Devices Act of 1990 requires manufacturers, risk managers, and other hospital personnel including VA to report suspected medical device-related deaths and serious injuries using the mandatory reporting form. The RCA SAC scoring system is harmonized with MedWatch mandatory report requirements.

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## **PSRS Safety Bulletins Coming Soon**

The Patient Safety Reporting System (PSRS), a NASA/VA collaboration independently operated by NASA to improve patient safety, has begun to receive patient safety reports from VA medical facilities at a rate that will allow the NASA PSRS office to issue deidentified findings. The NASA PSRS office will soon begin issuing PSRS Patient Safety Bulletins. PSRS Patient Safety Bulletins will be different from VHA Patient Safety Alerts. These Bulletins will identify significant vulnerability, however, they will not identify a specific solution that must be implemented. Bulletins will also be different in that each one will be based on reports of adverse events and close calls sent to NASA from your colleagues. VHA Patient Safety Alerts come from various sources including manufacturers' recalls in addition to VHA RCAs and other reports. We recommend that facilities carefully consider, act on as appropriate, and retain the Bulletins -- they will contain information about real hazards and safety issues that are known to affect patients at VA facilities.

## Once upon a time...

I used to be able to walk across the hospital grounds and not think about patient safety. Trees used to offer shade, now I see branches that are too close to the ground (there's a potential hanging point or a place where a patient could climb up and fall), and tree roots heaving the pavement (tripping hazards).

I didn't think much about the building's doors and windows, now I see windows that should be locked that are open (fall hazard) and doors that should be unlocked that are locked (evacuation route blocked). I see doors that open to grassy areas behind shrubs and not directly to sidewalks (how is a wheelchair going to navigate that and what if it snows - who shovels the grass?).

I used to see patients out at the smoking shelter, now I see the oxygen cylinders that they brought with them (fire!). I'd see the new construction and marvel at how fast they were progressing, now I see the construction fence is partially down or I see an open excavation.

The new one I just added to my mental safety

list was that exterior stairway from the basement. It was only six or seven steps up from the basement level to ground level; it looked a lot like the picture below. Who



Unsafe Stairway?

would of thought that a patient in a wheel-chair would fall down these steps and die from the fall? After all, it isn't that far and it even has a handrail! I must have walked by that stairway a few hundred times without really seeing it. No, I'll never look at things the same way again. Oh, we'll be putting up a swinging gate at these exterior stairs, and yes, it will swing in the direction of egress from the building.

I see now that you don't look at things the same way anymore either.

## **MedWatch Reports**

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Voluntary MedWatch reports are stored and are searchable in MAUDE (Manufacturer User Facility Device Experience Database). The FDA relies on voluntary MedWatch reports to maintain safety surveillance of all their regulated products. NCPS has used MAUDE data to expand upon RCA studies pertaining to medical devices such as pacemakers. Having a compendium of events strengthened our case when discussing design issues with manufacturers.

If you are completing your first MedWatch report, then please take note of the following details:

 The user facility number for your first mandatory report is 000000000-2002-0001 (Please note that this number is for use during calendar year 2002). After receiving your first mandatory report, the FDA will assign you a specific number, which you should use in future reports.

 The patient ID number should not contain patient initials, social security number, or personal information like birth date. Make sure, however, that you can cross reference the patient ID number with your records of the adverse event.

For more information about MedWatch reporting, please visit http://www.fda.gov/medwatch/index.html. If you are completing a MedWatch report and need further assistance, contact the FDA at (301) 594-2735. They also have a toll-free number, at (800) FDA-1088.

#### **Could You Say That Again**

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It is also important to recognize that with every change implemented new challenges might arise. Using hearing protection will have an impact on how the MR technician interacts with the patient undergoing the procedure. Think about how communication will take place between these individuals. Also, consult with the MR technicians regarding the impact of using hearing protection during a MR scan. Will it introduce artifacts that could negatively affect the results of the test? With these considerations in mind the correct hearing protection may be selected without compromising patient safety and comfort.

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# SAFEGITY

(On a regular basis we feature teaching examples pulled from medical literature and similar RCAs that we feel are applicable and of interest to the entire VHA health care system. The following represents information taken from an aggregate of RCAs; it is presented to spark discussion and does not represent NCPS policy. Depending on the specific circumstances at any given facility, there are various systems-level solutions that will be most appropriate.)

# **Wrong ID Band**

#### **Description**

Two patients with the same last name and same first initial were admitted to the hospital emergency room within ten minutes of each other. The ER was very busy at the time and the patients were mistakenly given each other's patient identification band by the admissions staff. Both patients were experiencing chest pains and consulted with a cardiologist. It was then discovered that they were wearing each other's ID band, before any type of procedures were performed on them. No harm was caused to either patient.

#### **Identified Vulnerabilities**

The following vulnerabilities and systems weaknesses were identified:

 A lack of a formal process verifying patient identification increased the likelihood that a

- patient may receive the wrong ID band, which could lead to receiving the wrong medical treatment.
- Same name admissions may lead to patients with the same name being misidentified and potentially receiving the wrong medical treatment.

#### **Actions Taken**

In response to this case, the following actions were taken:

- A program will be developed to include a detailed validation process, correct ID band placement, who will place the ID bands, and same name alerts.
- A specific color band will be placed on all same last name patients. These will be placed on the same arm or leg of the ID band. "SAME NAME PATIENT" will be printed across this colored band. Staff who print ID bands will be trained on proper usage of the machines and the need for all patient identification information and barcodes to be clear and legible.

#### **NCPS** Comments

Patients need to be actively included in the identification process whenever possible. Consider this as a key element of patient-provider dialogue (e.g., "This is who I am. Who are you?"). Of note, people with frequently occurring, easily misunderstood, incorrectly pronounced, misspelled or sound-alike names are familiar with how easy it is to be incorrectly identified in daily life.

Engage patients overtly in the identification process dialogue. Asking the patient to state rather than confirm their name helps prevent miscommunication and wrong patient procedures. Patients who are hard of hearing or who are distracted by illness or other temporary or permanent disability may say "yes" to a name that is not theirs, but it is very unlikely that they will misstate their own name when asked. For example, "Hi, I'm John Smith, the nurse who will be taking care of you this afternoon. Even though we met yesterday, I want to be 100% sure I know who you are, so please tell me your full name while I check your ID band ..."

Of course, conversational verification is dependent upon a patient's cognitive and speaking abilities. Where there are cognitive or speech issues, staff should take separate process steps to confirm identification. Also, be aware that some patients are very compliant and will answer to other names if prompted.

## **Sterilizing Medical Devices**

On June 19, 2002, Advanced Sterilization Products (ASP) issued a letter reminding its customers that all manufacturer instructions need to be followed when sterilizing and rinsing medical devices and products. The letter specifically addresses three

ASP brands: CIDEXR OPA Solution, CIDEX Activated Dialdehyde Solution, and CIDEXPLUSR Solution. A copy of this letter is available on the NCPS intranet site at vaww.ncps.med.gov/aspltr.

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#### **Could You Say That Again**

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Additional information on this topic may be found in:

Acoustic Noise and Magnetic Resonance Procedures, written by

Mark McJury, published in the Magnetic Resonance Procedures:

Health Effects and Safety, edited by Frank G. Shellock

Journal of Magnetic Resonance Imaging, Volume 13, No 2. 2001

Decibel Level	Source	MR System		
(dBA)		Mfg	Strength (Tesla)	Sound Level (dBA)
140	Threshold of pain; gunshot, siren at 100'			
135	Jet take-off, amplified music			
120	Chain saw, jack hammer, snowmobile	Varian Bruker Philips GE	3.0 3.0 1.5 1.5	118 114 113 109
100	Tractor, farm equipment, power saw	Picker Siemens Picker Siemens	1.0 1.5 1.5 1.0	108 107 107 104
90	OSHA limit - hearing damage if excessive exposure to noise levels above 90 dBA	Philips Philips Picker Toshiba	1.0 0.5 0.5 0.35	97 94 92 91
85	Inside acoustically insulated tractor cab	GE Toshiba Picker	0.2 1.5 0.23	87 84 83
75	Average radio, vacuum cleaner			
60	Normal conversation			
45	Rustling leaves, soft music			
30	Whisper			
15	Threshold of hearing			
0	Acute threshold of hearing - weakest sound			

# **Ordering AEDs**

VA facilities who order automated external defibrillators for their public facilities should be aware of the different types of AED models in the market. Since the majority of the AEDs will be used by a layperson with little or no CPR training, the devices must be user friendly, intuitive, and provide clear concise audio and visual instructions.

Electric shock is only one of the therapies applied in a CPR. A complete CPR kit should include at a

minimum latex free gloves, a resuscitation bag and mask, electrodes and instructions for use of all the items in the kit. A qualified Biomedical Engineer should conduct a prepurchase evaluation to confirm compatibility with accessories and supplies, and verification of the AED arrhythmia detection software's accuracy (specificity and sensitivity).

To view the complete NCPS recommendations for acquisition and implementation of AEDs in the VA system, visit vaww.ncps.med.gov/aed.

#### **OSHA Exposure Table**

How Long You Can Safely Be Exposed to Sound Level in Cumulative Hours Per Day	Sound Level (dBA)
8 hours	90 or less
4 hours	95
2 hours	100
1 hour	105
30 minutes	110
15 minutes	115
Never	More than 115



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