American Association of Physicists in Medicine

Office of the President
Gerald A. White Jr., M.S.
Penrose Cancer Center
2222 N. Nevada Ave.
Colorado Springs , CO 80907
Phone: 719-776-2513 Fax: 719-632-8176
E-mail: gerald.white@mindspring.com

April Stubbs-Smith, MPH
Issues Management Staff
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
U.S. Food and Drug Administration
1350 Piccard Dr.
Rockville, MD 20850

April 21, 2008

Dear Ms. Stubbs-Smith:

The American Association of Physicists in Medicine (AAPM) appreciates the opportunity to provide comments on the DRAFT Preliminary Public Health Notification (PPHN) titled "*Possible Malfunction of Electronic Medical Devices During Computed Tomography (CT) Scanning.*" AAPM applauds FDA's efforts in developing this PPHN; however we have several concerns regarding the content.

Summary remarks: Notification of the potential for CT to interfere with electronic medical devices is appropriate and such preliminary notice will facilitate greater reporting of events. At present, dogma in the field considers CT to be "safe" for these devices and based on the early papers, it is wise to inform medical providers that this may not always be the case and that any suspected interactions should be reported. This will facilitate:

- better understanding of the frequency and severity of events,
- knowledge of the scope of devices affected,
- modification of affected devices by their manufacturers to decrease sensitivity,
- increased risk awareness and avoidance actions by CT operators, and
- appropriate safety guidelines to be established by professional organizations.

The circulated draft, though described as preliminary, overstates the potential risk relative to published data and makes extreme recommendations that have the potential to decrease the quality of patient medical care by:

- potentially not ordering or performing medically necessary CT exams,
- decreasing the image quality or scan coverage of medically necessary exams,
- diverting health care resources or increasing health care costs in order to implement safety policies and procedures that have not been demonstrated to be appropriate or necessary, and
- increasing patient anxiety.

The recommendations would be difficult to implement, even if sufficient data and rationale existed. AAPM applauds the spirit of the notification but respectfully request major revision, taking into account the following comments and the suggested text edits.

1. If the FDA feels that preliminary notification on this topic is required, it must be addressed to a much broader group. Cardiologists, radiation oncologists, and other specialties operate CT devices. Additionally, physicians who care for patients with such devices must be on the alert for unexplained changes in device function or programming and report such to the FDA, when a possible correlation of the event to a CT exam is suspected.

2. It is estimated that over 63 million patients received CT scanning in 2007. As of mid-2007, the FDA's MAUDE database had no reports of adverse effects due to interactions of electronic medical devices with CT (that either the ECRI Institute or AAPM could locate). Thus, this preliminary notification must emphasize that while there is the potential for interaction – and the FDA wants to hear about any such suspected interactions – such events must be rare, if they happen at all in the clinical setting, based on the absence or minimal numbers of reports to the FDA or manufacturers.

3. Some sense of the number of reports needs to be given. Less than 10, 100, 1000? It is reasonable to assume that hundreds of thousands of patients had some sort of implantable medical device during their CT scan in 2007 alone, considering the widespread use of these devices, particularly in older patients who represent a large fraction of CT patients.

4. To date, only 2 peer-reviewed publications exist in the scientific literature, with limited evidence of direct causality available in the Japanese reports of events. Yet, the tone of this notification implies that while "many" have had no adverse effects, "some or possibly many" interactions have been clearly documented. At this point, in vitro phantom demonstration and a mechanistic rationale exist for the interaction, but human studies of confirmed events are not available. The public health notification should make available the numbers of interactions/adverse effects that have been reported to them so that the scope of the problem can be put into perspective, especially since many of the recommendations require significant alteration in current CT practices.

5. In the reports received, were investigations able to determine direct causality? As demonstrated by McCollough et al., some – but not all – implantable cardiac rhythm devices were sensitive to the presence of ionizing radiation exceeding certain dose rates; however, the "oversenses" terminated immediately upon the primary beam moving off the small sensitive region of this device. Very few CT exam types would have the radiation constant over the device beyond 2 seconds. Thus, device interactions may, in fact, be quite frequent but benign, as the effect is transient, lasting at most a few seconds. McCollough et al. were not able to simulate any permanent changes in the programming or resets of the most sensitive device when simulating clinical conditions. Thus careful analysis of reported events is needed to confirm causality.

6. We acknowledge that the data from McCollough et al reflect devices from only one manufacturer. If frequent reports of actual adverse effects (as opposed to transient and benign interactions) are being reported in sufficient numbers to warrant a public health notification, are the reports device or manufacturer specific? The older Medtronics model that was found to be susceptible to program reset has been labeled with this information and patient/physician education performed by the manufacturer. If effects are being reported for devices from multiple manufacturers, are the manufacturers of those devices properly educating their customers (physicians and patients) and noting the potential effects in their labeling information?

7. Shocks imply an actual electrical surge of current or voltage, such as when poking a finger into a power outlet. The effect of x-rays on a neurostimulator may result in unintended or increased stimuli to the nervous system, but is either the voltage or current sufficiently high to use the term "shock?" For members of the general public, this phrase carries a different connotation. Are cardiac defibrillation shocks what are being referred to?

8. Discussions with neurologists and patients with neurostimulators indicates that manufacturers of these devices specifically instruct physicians and patients to temporarily suspend the neurostimulator function during CT scanning, just as they are instructed to do when passing through retail theft-control systems and other EMI-emitting devices. It should be called out that these unintended stimuli to the patient occur when the device is not powered off during CT scanning; that is, if operation is suspended, unintended effects can be avoided.

9. What sort of pump "malfunction"? More specific information is needed in order to help patients and medical providers watch for occurrence of an interaction. Does the pump stop infusing temporarily or permanently? Is the programmed rate of drug delivery altered?

10. Unless the radiation is damaging the device, observed effects are due to interaction of the device with x-rays and are not necessarily malfunctions of the device. For example, it is not considered a malfunction of a microwave oven if it causes an interaction with a pacemaker.

11. For all effects cited as having been observed, please clarify if these were transient or permanent effects. The devices we evaluated demonstrated no permanent changes to programming under clinical conditions, though such have been reported to the manufacturer for at least one model. The majority of devices tested, however, demonstrated no permanent evidence of the CT interaction.

12. For each of the noted likely and potential interaction effects, please note if the unintended behavior of the medical device was observed during, after or either during or after the scan.

13. Please clarify whether the interrogation problems occurred only during scanning and were transient or permanent consequences of the scan.

14. Does patient seizure occur coincident with the CT irradiation or after cessation of the scan?

15. The CT manufacturers have little knowledge, input or control over the types of medical devices discussed and their sensitivity to ionizing radiation. The primary information source for patients with these devices is the physician (typically a cardiologist or neurologist) and the electronic medical device manufacturer. As with the microwave ovens, education/warnings may need to be conveyed to users (CT operators) by the CT manufacturers. Such information would need to be consistent with the education/warnings/labeling of the devices by the device manufacturers. However, CT manufacturers are not the primary point of information nor does the primary responsibility belong to them to determine the quantify interaction affects, develop safety recommendations and communicate appropriate warnings. The CT equipment is operating as intended. It is the electronic device that is showing sensitivity to the CT environment.

16. In the opinion of the AAPM experts who carefully reviewed the draft notification, the recommendations border on irresponsible. Based on the publicly available data, evaluation of the potential for interaction and the most frequent device response, the recommendations are not defendable. Data demonstrated that pacemaker and ICD responses are transient and benign, lasting only for the second or two when the beam is directly over the sensitive portion of the device (with the exception of the one older model, which the manufacturer states is not common in the U.S. but has been reported to potentially experience a reset to the

default program settings). As such, the clinical policy at the Mayo Clinic, where potential interactions were evaluated, does not restrict CT scanning on patients with implantable cardiac devices for routine CT scanning. Only for CT perfusion or interventional scans that irradiate the same portion of tissue for more than several seconds, where the implanted device is in or immediately adjacent to the target irradiation volume, does the Mayo Clinic alter their practice. Such exams are rare (the Mayo Clinic has had none since the official policy inception in mid 2007, even though they scan over 400 patients a day with CT). Their policy states that if a perfusion or interventional scan were to be ordered on or adjacent to a device, they would not proceed until the referring physician and cardiac service were contacted and made aware of the potential interaction. The CT would only be performed with appropriate cardiac guidance and support provided.

The number of patients scanned in the outpatient imaging setting in the U.S. is extremely large. All such settings should, simply because they use iodinated contrast material, have emergency resuscitation measures in place. The requirement for emergency cardiac pacing may be extremely difficult to meet in a typical outpatient setting and may require significant investment in equipment and training, even though a pacing emergency due a CT/pacemaker interaction has not ever been demonstrated in the medical literature. Emergency pacing involves the insertion of a catheter into the heart to place the pacing lead. This is not an outpatient procedure.

The most important safety precaution is the determination of whether or not the device will be in the scan field of view and whether the x-ray will remain over the device for more than 1-2 seconds. Patients with devices that would be in the planned scan plane for extended scan times can be identified at the time of the CT exam, the exam postponed and the patient referred to a hospital for scanning, with appropriate cardiac guidance and support. This would obviate the need for non-trivial practice changes for a not yet well validated or understood risk.

Asking patients during the scheduling procedure if they have a device will cause a heightened level of anxiety for patients when, in fact, the device may not even be in the field of view for the scheduled exam. It is not reasonable or safe to rely on patient memory or anatomic/radiology knowledge in order to identify potentially risky situations. There is no possibility of unknowingly scanning a device if, as is almost universally done, a “scout’ image is taken in advance. Unlike the MR environment, where it may be too late to learn about a metal implant or implanted device once the patient is in the magnet bore, the CT “scout” is a fail-safe method of finding metal (electronic) devices at a dose rate where there no concern has ever being raised. AAPM recommends that operators be trained to look for these devices and to institute a risk reduction plan only if the device is in or immediately adjacent to a scan that will last for several seconds (in the case of cardiac devices). In the case of neurostimular devices, the patient should be asked to suspend device operation. AAPM completely agrees with and support the FDA’s goal of increasing awareness of this potential issue; however, feels that this current notification overstates the risk and suggests unnecessarily restrictive risk mitigation steps that have not been well thought out in terms of practicality. There are many more reasonable approaches that can be taken to ensure safety, and these should be developed with clinical and technical input of imaging providers prior to making any public recommendations.

17. At present it is difficult for MR safety teams to keep up to date with all of the particular devices and manufacturer’s recommendations for safe use (or contraindication of use) in the MR environment, even though numerous websites and clearinghouses of data exist. There is no such information to my knowledge in place for electronic medical devices in the CT environment; thus, asking or implying that imaging providers seek out specific recommendations will be extremely problematic.

18. Again, unlike MR, where it may be "too late" once the patient is in the magnet and a localization scan is performed, knowledge of the presence of a device in a patient need not be known ahead of time, because it is completely obvious during the low-dose and low-dose-rate scout if it is present. It is putting an undue burden on the imaging community, the patient, and the patient's care providers to identify the presence of devices, and worse yet to suggest removal of the device, prior to the time of the CT exam when the device may not even be in or near the required scan region. For example, the location of most pacemakers is such that they would NOT be in the scan range of a typical cardiac CT exam, even though the layperson might assume from this notice that a cardiac CT exam for patients with a pacemaker is not safe. Clearly, for external devices, the suggestion to move or remove the device might be able to be accomplished, but it should not be suggested that devices need to be surgically removed prior to a CT scan. This drastic step may be warranted in the case of radiation therapy dose levels, where permanent damage to the device has been well validated and recommendations regarding safe limits are available from both the manufacturers and the scientific literature.

19. Alerting the patient that the electronic device may not work properly during or after the CT scan is certain to raise the anxiety level of patients. Such disclosure and a mechanism to ensure that the device is operating as programmed needs to be more specific. If a device were located in the directly-irradiated region of a scan, a requirement that this be noted in the physician report would be reasonable, as might a recommendation that the device's programming be reconfirmed. Simply alerting, for example, an 80-year-old patient that his device may not be working properly will cause considerable worry without necessarily accomplishing the desired endpoint of having the programming of the device confirmed. Further, before such a resource-intensive step is taken, a systematic evaluation of patients with pacemakers/ICDs needs to occur, such that the frequency of programming changes is known. Otherwise, considerable resources, anxiety, unnecessary device re-evaluation and/or cancelled scans may occur, when, in fact, the possibility of changes in programming may be extremely remote (as past history suggests). Not performing a CT, such as for suspected PE in a short-of-breath elderly patient, just because the patient has a pacemaker, or because "informed consent" regarding the risk of device failure results in the patient deciding not to have the scan, carries considerable risk of its own. Until the evidence is much stronger, this unintended but not unrealistic scenario should not be set into motion by premature recommendations.

20. As stated above, scanning over the electronic circuitry of the device for routine CT scans – when the table moves through the x-ray plane – appears to cause only transient effects in the device. Until substantial data are provided that permanent changes occur even with these transient irradiations, important anatomy should not be excluded from the scan. Further, most technologists would not be in a position to determine the critical part of the circuit of the device, as opposed to the battery housing. Thus, if avoidance of the device is required, asking the technologist to avoid only the electronic circuitry allows for confusion and error. Simply recommend that the device be avoided altogether.

21. Use of a lower gantry rotation rate can decrease the dose rate while not increasing image noise, which is what would happen by only decreasing tube current. Greater clarity in needed in the discussion of dose rate vs. cumulative dose such that operators have clear guidance as to how to reduce the dose rate without affecting the cumulative dose, and hence the image quality.

22. The ECRI reference is not a peer-reviewed "paper". The Yamaji and McCollough references are the only peer-reviewed publications on this topic. ECRI summarized in their bulletin a warning based on these publications and reports made directly to them from a health care provider.

23. The Moulton study does examine the impact of dose rate on pacemaker function, but was performed with 18 MeV photons. Hence, the conclusions drawn may have no relevance to CT. If this reference is to be

retained, it must be noted that the study was not performed using photons in the diagnostic energy range, as are used in CT.

24. The data available are too sparse to draw conclusions regarding mechanisms, which devices are most sensitive, or to pool all devices together just because they have a battery and microprocessor. Our testing showed no response in many devices.

25. The term "malfunction" is not accurate. The devices are correctly sensing electrical signal. The error is that the electrical signal is being cause by an external device and not the patient. Thus, the device is not malfunctioning but rather being interfered with, just as cell phones, airport magnetic scanners, etc. can interfere with a pacemaker.

26. The mechanism for permanent damage at CT doses and dose rates has not been demonstrated. If the FDA has reports of this, it should be shared more broadly and investigated in peer-reviewed literature.

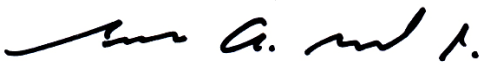
27. The references should follow the temporal development of data regarding CT interactions with electronic medical devices. The McCollough work was performed after learning of the reports in Japan (Yamaji). The ECRI report was subsequent to the McCollough paper and included mention of reports of interactions with neurostimulator devices.

AAPM strongly urges FDA to revisit its draft public health notice in light of these comments. We offer our assistance in revising the document so that it more accurately reflects the science that is currently available on this topic. In particular, Dr. Cynthia McCollough, whose work is an important reference for this notification, and the members of our CT Committee and Imaging Science Council who participated in the formulation of this response, hope that the FDA will find this information to be of value in its efforts to ensure patient safety.

Attached for your consideration is a redline/strikeout version of the PPHD and a "clean draft" for ease of reading.

If you have any questions, please contact Lynne Fairobent, AAPM's Manager of Legislative and Regulatory Affairs at 301-209-3364 or via e-mail at lynne@aapm.org.

Sincerely,



Gerald A. White, Jr., MS, FAAPM

Attachments