Wireless devices are proliferating with dizzying speed, offering users instant communication and access to information 24/7/365. Cell phones are ubiquitous. A few years ago, the words blackberry or bluetooth conjured images only of delectable fruit or a child's teeth after eating such fruit. Now the words bring to mind connections anytime, anywhere.

“Whether palm pilots, wireless desktops, 'smart' IV pumps, 802.11 systems, cell phones, or walkie-talkies, these devices are part of mainstream society and are here to stay,” notes Ira Tackel, director of the Department of Biomedical Instrumentation at Thomas Jefferson University Hospital in Philadelphia. “And, there's no question that there's tangible value to the use of wireless devices throughout the health care setting.”

For example, now used by clinicians for data acquisition and documentation of clinical billing systems, personal digital assistance devices (PDAs) are expected to proliferate in the near future for physician order entry at the point of care. Handheld computers are being connected with wireless local or wide-area networks, enabling physicians to access patient records, laboratory results, drug formularies, and clinical protocols wherever they are. Wireless bar coding devices are being used to verify that patients and their medications match, and so reduce drug delivery errors.

So what’s the problem? Active medical devices, such as apnea monitors, infusion pumps, and ventilators, and wireless connections, such as medical telemetry systems, may be vulnerable to electromagnetic interference (EMI) from unmanaged radiofrequency emissions. According to Don Witters, chairman of the Food and Drug Administration's Center for Devices and Radiological Health (CDRH) Electromagnetic Compatibility Work Group, EMI has caused medical device malfunctions resulting in suspected death and serious injury (with apnea monitors), misdiagnosis or inappropriate therapy (cell phone EMI to infusion pump), and near misses (with wireless medical telemetry).

Other wireless technologies, such as security and inventory control systems, can also produce EMI that affects medical devices. In addition, the wireless communications link itself can be both the source of EMI and vulnerable to EMI from other wireless emitters.

“The frequency of such occurrences is extremely low, but given the fact that we’re in the business of providing safe patient care, the challenge becomes how to further minimize the risk of untoward patient safety events predicated exclusively on EMI,” says Tackel. “Being cautiously optimistic, I firmly believe that EMI risk is relatively low when managed properly. The operative word is ‘cautiously.’ EMI cannot be ignored for any kind of wireless device, no matter what the sales rep says,” comments Rick Hampton, wireless communications manager for Partners HealthCare Systems in the Boston area.

The goal is achieving electromagnetic compatibility (EMC) of wireless technology in or near medical devices. Both wireless technologies and medical devices must be able to co-exist without adversely affecting the performance of either. Joe Morrissey of Motorola Labs notes "options are available to allow hospitals to deploy, use, and manage fully compatible mobile wireless systems of all types, if appropriate testing, system engineering, medical device management, and user guidelines are implemented."

There have been vast improvements in providing safe technology since the early days of bag phones and analog devices. This quantum improvement in technology and the proliferation of many new devices may prompt clinical engineers and facility managers to take a fresh look at their current policies and how they will manage the deployment of new technology going forward.

The following are practical strategies organizations may wish to consider. Please note that these are not...
JCAHO requirements but are suggestions from a variety of sources to help organizations reduce the risk associated with EMI.

Establish a Framework
“JCAHO standards set the framework for minimizing risk related to medical equipment,” comments John Fishbeck, associate director of the Joint Commission’s Department of Standards. Standards describe the need to be proactive in identifying and taking appropriate measures to minimize risk for known and potential problems related to medical equipment that could cause harm to patients, visitors, or staff. EMI can be addressed proactively.

Consult Available Resources
The literature on the management of EMC and EMI is readily available. Two key resources recommended by the CDRH for biomedical engineers and others involved in medical equipment safety are AAMI TIR 18 and ANSI C63.1 (see Sidebar, above). These documents were published a number of years ago but continue to present relevant recommendations and procedures for managing EMC and EMI in health care facilities. “Many organizations are not aware of TIR 18 and reinvent the wheel in developing programs and policies that address EMC and EMI,” says Jeffrey L. Silberberg, MSEE, senior electronics engineer at the CDRH. Silberberg is co-chair of the AAMI EMC committee that is updating TIR 18. Publication of a new version is not expected for a number of years so Silberberg and others urge health care staff to consult the present version.

Educate Staff, Patients, and Visitors
Staff, contractors, visitors, and patients can be educated about EMI, the potential risk for untoward events, how to recognize EMI, and how to prevent it. Broadcast e-mails to physicians and other providers, notices in staff newsletters, and patient brochures can spread the word.

“The starting point with staff could be a few awareness articles that discuss what EMI is, where it comes from, how wireless devices are becoming ubiquitous in health care, and things you can do to reduce risk associated with EMI,” notes Dale Woodin, deputy executive director of the American Society of Healthcare Engineering (ASHE).

The trick is to present information in understandable and nontechnical terms so patients, visitors, and staff can identify what is risky and understand what safer options might be. For example, many people are aware of restriction in airplanes during the most risky part of air travel—take-off and landing. Likewise, they might be aware of risky areas of the hospital—like the OR, ED, or ICU. Simply being too close to any medical equipment when using electronics may not be a good idea. Offering options, such as “safe areas” to make calls, or suggesting that visitors step away from their loved ones’ medical equipment may be simple concepts that could significantly reduce the probability of these unlikely and unexpected events.

The personnel needing to be aware of EMI used to be limited to engineers. Now it includes all staff using technology, including clinicians, information technology staff, risk management personnel, and others. The American Medical Association is actively encouraging physicians to become knowledgeable about EMC and EMI, recognize EMI as a potential problem in hospital environments, and report suspected EMI problems to appropriate personnel in the organization.4

Assess EMI Risk
Organizations can identify susceptible devices and sensitive areas in the organization where EMI is more likely to occur, and consider ad hoc testing when EMI is suspected. ANSI C63.18 (see Sidebar, above) includes recommended practices for on-site, ad hoc testing for estimating radiated electromagnetic immunity of medical devices to specific radio-frequency transmitters. “It’s always best for organizations to perform their own testing if they have the resources to do so,” says Morrissey.

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However, many organizations have neither the trained staff nor the proper equipment to conduct ad hoc testing. “Since documentation of EMI is difficult, justification for a formal testing procedure may not be practical for some organizations,” says John Collins of ASHE. ASHE is in the early stages of developing a database of test results on various radio frequency-emitting devices. In the future, this could allow small hospitals that are not able to perform their own testing to access test results from other facilities. In this way, possible risk points could be identified.

“The potential risks of EMI need to be quantified. Ad hoc testing for EMI is urgently needed, as is a national system for reporting incidents of EMI,” says Claudia Tessier, executive director of the Mobile Healthcare Alliance (MoHCA). The CDRH recommends reporting EMI problems to the FDA’s MedWatch program (http://www.fda.gov/medwatch).

Not everyone supports ad-hoc testing. Tackel says this: “It provides a mere snapshot in time and does not give an organization comfort that it has necessarily recreated a potentially dangerous situation. Because there are so many variables, ad-hoc testing can provide a false sense of security unless the organization is monitoring on a continuous basis.”

**Establish and Implement Management Policies and Procedures**

Organizations can establish and implement written guidelines that outline how the organization reduces the risk of EMI. Due to the rapid speed with which wireless patient care and information systems are being implemented throughout facilities, each organization should ensure that someone is available and responsible for tracking and managing wireless technologies to minimize adverse interactions, properly train staff (where necessary), and better coordinate installations. The optimal EMI/EMC program identifies technologies currently used in the organization and planned for the future, assesses their potential risks, and identifies how those risks are going to be controlled through implementation of policies and procedures.

Morrissey observes that many hospitals currently implement overly restrictive precautionary policies that can act as an obstacle to beneficial wireless technology, while other facilities allow (or increasingly tolerate) unrestricted use without adequate management. This may lead to unnecessary risk. “Clearly, policies need to move toward more uniform and accepted guidelines that will allow the technology to operate at an optimal level while at the same time mitigate significant EMI issues,” says Morrissey. “Whatever the policy, it must be communicated and everyone must know what to do if the policy is broken,” advises Tackel.

Some hospitals have banned the use of cell phones inside the facility or in certain sensitive areas, such as critical care, intensive care, and telemetry units. “From a practical standpoint, it’s almost impossible to police the use of these devices down to the unit level, and we set ourselves up for a double standard,” comments Tackel. “We might be able to insist that patients and visitors refrain from using such devices, but what about clinicians and staff who forget to turn their phones off when entering a unit? For example, maintenance and facility staff are entering and leaving specific areas and using wireless devices all the time. It’s almost impossible to preclude use from happening, but education can at least help.”

Morrissey comments that cell phone bans do not take into account straightforward management procedures to allow wireless systems of all types to operate compatibly. “Management procedures may not be practical or feasible for every hospital. In cases where they are not practical, policies with a larger element of precaution, including selective restrictions of mobile handsets in areas where life-critical medical devices commonly operate, may be appropriate. However, in all hospitals, distinctions should be made between dedicated mobile handsets operating on a single wireless system used by physicians and staff, and nondedicated handsets that emit a wide variety of different radio frequency (RF) signal types that are randomly brought into the facility by patients, visitors, and staff,” notes Morrissey.

The airline industry’s solution to possible EMI-related catastrophic events is to ask travelers to abstain from using electronic devices during take-off and landing. It’s not so simple in health care where thousands of people have unrestricted access to a facility and are coming and going each day. Could there be a catastrophic event related to EMI? Yes. Is such an event likely? No. “An appropriate middle ground must be determined and adopted if we are to gain the benefits to patient care and patient safety that mobile devices offer,” concludes Tessier. The challenge is to identify and implement consistent policies that simultaneously advance the benefits of wireless technology while also mitigating risks associated with EMI.

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References


