The Wireless System for Medical Devices – Innovation, Patient Safety and Regulation

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Wireless communications, including Wi-Fi™ and other wireless technologies, have proven themselves to be incredibly useful not just in the healthcare industry, but across virtually every industry. However, the benefits of wireless technologies have been accompanied by...
significant challenges and risks that sometimes are not fully appreciated by healthcare providers or device manufacturers.

By U.S. Food and Drug Administration (FDA) definition, “Radio frequency (RF) wireless medical devices perform at least one function that utilizes wireless RF communication to support healthcare delivery. Examples of functions that can utilize wireless include transferring patient data from the device to another source, device control and programming, and monitoring patients remotely.”¹ “Incorporation of wireless technology in medical devices can have many benefits including increasing patient mobility by eliminating wires that tether a patient to a medical bed, providing health care professionals the ability to remotely program devices, and providing the ability of physicians to remotely access and monitor patient data regardless of the location of the patient or physician (hospital, home, office, etc...).”² These devices are ubiquitous in any hospital, long-term care facility or other healthcare entity. They are also increasingly becoming the center of patient healthcare engagement.

While the failure of a wireless connection in a personal laptop, cell phone or other wireless device due to network congestion or signal interruption may go entirely unnoticed by non-medical device users, interruption or interference in the wireless signals of many FDA-approved medical devices can pose risks to patient health and safety. Additionally, clinicians and other users are becoming dependent on these wireless medical devices, so disruptions to their operation can negatively impact clinical workflows and other business-critical applications. As a result, device manufacturers and healthcare providers should be aware of the risks inherent with those wireless interruptions or interferences and the management solutions available.
to them. Two of the most important of these risks are 1) cybersecurity and 2) the disruption or congestion of the wireless radio frequency spectrum.

Fortunately, regulatory agencies and other organizations are working to help medical device manufacturers and healthcare providers understand, acknowledge, and manage the challenges associated with wireless medical technologies. With regard to all types of medical devices, the FDA recently issued two guidances addressing cybersecurity vulnerabilities. In January 2016, the FDA published guidance, entitled “Postmarket Management of Cybersecurity in Medical Devices Draft Guidance” which provides recommendations for mitigating risks associated with postmarket cybersecurity vulnerabilities for marketed medical devices. The guidance “emphasizes that manufacturers should monitor, identify and address cybersecurity vulnerabilities and exploits as part of their postmarket management of medical devices.” The FDA also issued additional draft guidance, entitled “Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices” to identify considerations for improving the interoperability of medical devices through the stages of their development and design. These guidances demonstrate the FDA’s heightened focus on addressing the cyber risks associated with medical device vulnerabilities, although neither speak directly to the wireless spectrum risks.

The FDA has also addressed the risks of disruption or congestion of the wireless radio frequency spectrum, which is the focus of this article. In 2013, the FDA issued guidance on Radio Frequency Wireless Technology in Medical Devices to address “the increasing use of RF wireless medical devices, continuing innovation and advancements in
wireless technology, and an increasingly crowded RF environment. RF wireless technology considerations should be taken into account to help provide for the safe and effective use of these medical devices.” The FDA encourages manufacturers and users of medical telemetry devices to use the Wireless Medical Telemetry Service (WMTS) spectrum established by the Federal Communications Commission (FCC) and subject to FCC service rules. This regulatory scheme provides for a coordinated oversight function by both the FDA and FCC.

**WMTS Risks and Regulatory Risk Mitigation Efforts**

Wireless medical telemetry is generally used to monitor a patient’s physiological parameters and other patient-related information (e.g. vital signs including pulse and respiration) using RF communication with the advantage of allowing patient movement without restricting patients to a bedside monitor with a hard-wired connection. These telemetry or patient monitoring devices send real time transmissions of physiologic data, which includes alarms, upstream onto the network to a surveillance station. “Interference occurs when a first transmission and at least a second transmission occur at the same time, in the same frequency band, and are received by the same receiver. It is analogous to having two people talking to you at the same time. At the point the interference makes it impossible to understand the transmission, the term ‘harmful interference’ might be applied. A high rate of interference indicates that receivers have harmful interference at a high enough rate that data communications are delayed or fail.” “There is only so much space for radio waves to coexist and not cause interference between devices. Management of this airspace in the healthcare environment is a requirement in order
for medical devices to be used in a safe and effective manner.”¹¹

In a 2012 Science Advisory, the American Heart Association (Heart Association) articulated that network latency may pose significant risks to patients.¹² Considering that “any telemetry system that relies on wireless transmission and a data network is potentially vulnerable to these delays, because transmission errors are inherent to wireless or network communications,” managers of wireless hospital telemetry systems must work to mitigate such delays while also being prepared for occurrences of delay and avoid over-reliance on these systems.¹³ The Science Advisory describes a case in which such network delays apparently nearly resulted in severe injury to a patient in cardiac arrest. More recently, a 2013 FDA Guidance on wireless technology in medical devices noted that “lost, corrupted, or time-delayed transmissions, and degradations in wireless transmissions including when caused by competing wireless signals or electromagnetic interference (EMI) to the medical device or its wireless transmissions” is an example of potentially problematic wireless-related hazards.¹⁴ The FDA also advised that “selection of RF wireless operating frequency and modulation should take into account other RF wireless technologies and users that might be expected to be in the vicinity of the wireless medical device system. These other wireless systems can pose risks that could result in medical device signal loss or delay that should be considered in the risk management process.”¹⁵ The FDA further noted that “an increasingly crowded RF environment could impact the performance of RF wireless medical devices, which makes risk management an important part of integrating RF wireless technology into medical systems.”¹⁶

Today’s hospitals have computers, in-house telephones, infusion
pumps, electrocardiogram carts, pulse oximeters, and some physiological monitoring systems along with devices operating for consumer use operating on the 2.4 GHz region. This is not part of the dedicated WMTS spectrum, and these wireless infrastructures can become overwhelmed with non-critical traffic which may interfere with valuable clinical information.

As noted above, the FCC has dedicated a particular spectrum, the WMTS, to licensed medical wireless technologies. This service provides for a more protected spectrum within certain wireless frequency bands including 608 to 614 MHz, 1395 to 1400 MHz and 1427 to 1432 MHz. These spectrum bands are narrow and provide limited bandwidth or capacity. The WMTS can be used within certain defined healthcare facilities and only by authorized healthcare providers.

Recently, the FCC engaged in rulemaking about allocation and auction of spectrum near the WMTS. In its Report and Order, issued August 2015, the FCC recognized the need to protect WMTS systems from potential interference with personal/portable devices. The FCC attempted to address the potential for interference by further regulation of the spectrum space near the WMTS and by limiting the power of the non-medical devices which might function in those spaces. The FCC also sought to create a three megahertz "guard band" around the WMTS. The FCC’s new rule also allows for fixed and personal/portable non-medical devices to operate within the WMTS with certain power and physical separation distances from healthcare facilities in order to avoid harmful interference.

Many parties submitted comments to the FCC in favor and
opposition to these new rules. The controversy centers around the adequacy of the protections the FCC has put in place, and the controversy has continued with a flurry of filings asking the FCC to reconsider. The common thread throughout all of the filings is that interference within the WTMS is a serious patient safety concern.

**Industry Leadership by the Association for Advancement of Medical Instrumentation**

While no one group or individual has the definitive solution to handling the continuous and evolving challenges of wireless medical technology in healthcare, as an industry leader the Association for Advancement of Medical Instrumentation (AAMI) created a special group called the Wireless Strategy Task Force (WSTF) specifically to address these challenges. The WSTF has been active in the healthcare community and was instrumental in providing subject matter experts for the 2015 FCC and FDA Joint Workshop on Medical Technology Innovation and Wireless Test Beds.

AAMI’s WSTF, which meets at least three times a year, initially emerged from a 2012 event called the Wireless Workshop. The Wireless Workshop produced a document entitled *Healthcare Technology in a Wireless World*, which includes a list of the “Top 10 Mistakes in Implementing Wireless Technology in Healthcare.” The document also identifies several high-priority issues to be addressed, including:

- Clarifying roles and responsibilities in the wireless arena (management of spectrum and devices operating on the spectrum);
- Managing spectrum to improve safety and reliability;
- Designing wireless infrastructure for high reliability; and
In 2014, the WSTF developed a document entitled *FAQs for the Wireless Challenge in Healthcare*, which provides answers to frequently asked questions about wireless issues in the healthcare environment. AAMI has additional resources and updates on its website.

AAMI also has a standards developing committee, called the AAMI Wireless Working Group (SM/WG 06), which is working on a technical information report (TIR) for manufacturers to address wireless coexistence of medical devices. The TIR will address the need for a test method when multiple radio frequency wireless users are in the same frequency range as a medical device. The TIR will also address the need for incorporating risk management principles into the development of wireless medical devices. Although the material presented in any similar AAMI report may need further evaluation by experts, releasing the information is valuable because the industry has a pressing need for it.

**Exponential Growth and Innovation Create Unique Challenges and Opportunities**

Healthcare industry leaders and healthcare information technology (HIT) experts have seen wireless technology in healthcare become pervasive and ubiquitous. The adoption and deployment of wireless medical systems has outpaced the development of applicable standards and regulations. Wireless innovations grounded in wireless communication technologies and applications from food, pharmaceutical, and automated supply chain processes to new mobile health applications are seemingly born daily. Healthcare providers are
using these communication technologies with devices for patient
diagnosis, treatment, monitoring, or therapeutically within facilities
and in patient homes. In fact, consumer and medical home use is a
rapidly-growing segment of the medical device market. The
technology is also being deployed in remote patient monitoring
devices that are ever-expanding in the complexity and depth of data
gathering and communication.

This rapid influx of wireless medical technology into the healthcare
arena is resulting in an increasing demand for expertise in this area,
both technically and legally. There is no common industry “playbook”
for spectrum governance or management. Instead the limited number
of wireless medical device experts rely on one another to find novel
solutions to the myriad challenges they are encountering as wireless
connectivity goes mainstream in the open market. The promise of
digital health is dependent on the safe and effective use of wireless
technology, particularly given the increasing use of wireless wearables
and other components of the Internet of Things (IoT) which refers to
the ability of everyday objects to connect to the Internet and to send
and receive data.

Beyond increasing healthcare provider and HIT vigilance and
compliance, solutions to wireless challenges are requiring the creation
of industry and government wireless networking standards, the
identification of proper implementation methods to ensure
compatibility with existing infrastructure, coexistence with medical and
non-medical devices, and industry-wide educational efforts.
Recognizing these solutions is important; the industry now faces the
challenge of vigorously engaging and expanding them.
Coordinated and innovative efforts for these solutions brought AAMI and the ABA Health Law Section together to co-produce this article and future educationals. We look forward to the future of our partnership and welcome other industry, policy, government and legal organizations to join us.

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1. FDA *Wireless Medical Devices* resource page:

Id.


*Id.* at 4.


47 C.F.R. § 2.106.

47 C.F.R. Part 95 Subpart H.


*FAQs for the Wireless Challenge in Healthcare*, Association for the Advancement of Medical Instrumentation, 2014 at 12.


Turakhia MP, Estes NAM 3rd, Drew BJ, Granger CB, Wang PJ, Knight BP, Page RL; on

Id.


Id.

Id.

Id.

Id.


Amendment of Part 15 of the Commission’s Rules for Unlicensed Operations in the Television Bands, Repurposed 600 MHz Band, 600 MHz Guard Bands and Duplex Gap, and Channel 37, and Amendment of Part 74 of the Commission’s Rules for Low Power Auxiliary

Id. at 31.

Id. at 41-42.

Id. at 81.


Id.

FCC Record DA-15-340. A wireless test bed is an environment where devices can be evaluated across a range of interference scenarios.


Id.

Id.

Id.

Mobile Medical Applications, FDA Guidance, February 9, 2015.