Stiffer Pressure to Move to WMTS Bands…

Hospitals Face Higher Telemetry EMI Risks in 2006

Eileen Putman

The wireless revolution should have been a peaceful one for the healthcare industry—full of wireless telemetry's promise of remote patient monitoring and efficient relay of reliable data that enables good patient care.

But the new technology also brought hidden dangers to patients from electromagnetic interference (EMI), in which electromagnetic energy from a device or system interferes with the operation of another. Managing that risk has created difficult and expensive choices for device makers and hospitals, with the consequences of those choices certain to be felt with greater force in 2006.

The government's answer to telemetry interference—the designation of certain radio frequencies for medical users—has sparked debate over whether that will truly solve the problem. The dispute comes at a time of intense growth in wireless technology and an expanding vision of its potential in the healthcare setting.

It is, in short, a pivotal period in the medical telemetry field, which is buffeted by a host of forces pushing vendors and hospitals—and, accordingly, biomeds—in new and somewhat uncertain directions. Indeed, many believe the situation has given rise to an urgent need for a new biomed function—a radio frequency manager to monitor the ever-changing electromagnetic environment in and around the hospital.

Meanwhile, equipment managers face a hodgepodge of proprietary offerings and an ever-growing demand for wireless products that enhance patient mobility and clinical response in a technology-rich environment already at high risk of EMI.

"Wireless technology is a double-edged sword," says Don Witters, chairman of the Electromagnetic

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Check Points

How are you managing EMI at your facility? Learn how other facilities minimize interference risk:

- ✓ See how Baylor Univeristy Medical Center handled an interference incident.
- ✓ Get to know the registration nuts and bolts.

Compatibility and Wireless group of the FDA's Center for Devices and Radiological Health (CDRH). "While it transmits signals that communicate information, those signals can affect the function of other devices. And the reverse is true with the increasing use of wireless, particularly in the ISM bands, concerns for potential interference remain a priority. Wireless technology can be a valuable tool but it's vulnerable."

Even momentary dropout in a monitor signal can delay a needed caregiver's response, with possible deadly consequences. The stakes are considerable—as is disagreement over what should be done.

Frequency Primer

The story starts with the science. Wireless communication is made possible by electromagnetic waves. At the low end of the electromagnetic spectrum are radio waves, the workhorse of modern communication, the essential backbone of television, radio, cell phones, and medical telemetry. The radio frequency (RF) spectrum refers to the electromagnetic spectrum between the frequencies of about 9 kilohertz and 300 gigahertz. (A Hertz is a unit expressing the number of times a wave form repeats itself per second; one Hertz is one wave cycle per second.)

In wireless radio communications, oscillating radio waves are propagated with certain of their features varied in distinctive ways so as to carry data.

Like much in the world of technology, radio frequencies are regulated. In the United States, that job is divided between the Federal Communications Commission (FCC) and the National Telecommunications and Information Administration (NTIA). FCC administers radio spectrum for non-federal uses; NTIA, which is part of the U.S. Commerce Department, regulates spectrum for federal government use.

Within the FCC, the Office of Engineering and Technology (OET) provides advice on technical and policy issues pertaining to spectrum allocation and use. OET also maintains the FCC's Table of Frequency Allocations, the codified radio spectrum allocation.

Internationally, governments coordinate global telecom networks and services through the International Telecommunication Union (ITU), which maintains the international table of specific frequency allocations.

Regulation is essential, as competition for spectrum is fierce. Wireless networks, the Internet, global positioning systems, garage doors, baby monitors, walkie talkies, even pizza delivery trucks—all clamor for pieces of the RF spectrum.

Over the years, medical telemetry has operated on vacant commercial television channels; on frequencies allocated for private land mobile radio services (PLMRS); and on bands allocated for industrial, scientific, medical (ISM) uses, including wireless local area network (LAN) operations.

With the push to digital television, however, vacant television channels are disappearing. The FCC has provided each local TV station with an additional digital channel and last July began requiring major television network affiliates in the top 100 media markets to operate on assigned digital channels at higher power; that, in turn, increased the interference risk for medical telemetry on those channels. In any case, telemetry has only secondary status on those bands, meaning it must tolerate interference and not interfere with primary users.

The PLMRS frequencies pose an even greater problem for medical users. On Dec. 31, 2005, the FCC lifted a freeze on licenses to high-power PLMRS users in the 460-470 MHz band. By some estimates, as many as a million more users could soon be permitted on those frequencies. Major problems are forecast for healthcare organizations still operating on those bands.

"They're going to be shot out of the water," said John Collins, director of engineering compliance for the American Society for Healthcare Engineering (ASHE), a division of the American Hospital Association. "There's going to be problems with patients. Unfortunately, in the United States that's what it takes—a big nasty incident to get people moving,"

From Furbies to TV Stations

The susceptibility of medical devices to EMI from a variety of sources has long worried authorities. In 1999, Health Canada even tested 13 medical devices for EMI

Interference Incident and Aftermath

On Feb. 27, 1998, cardiac monitors on the 13th floor of a Baylor University Medical Center building in Dallas were disrupted by a television station's digital test signal on VHF channel 9, where the monitors operated. The cause wasn't immediately apparent; it took detective work by clinical engineering staff to solve the mystery.

That wasn't the end of the matter. The incident led Baylor to accelerate the planned replacement of most of the medical center's telemetry and to switch telemetry at other facilities, with an initial cost within a month of the incident of more than $1 million. Since then, the Baylor Health Care System, which has 14 owned or leased hospitals, has spent $4.2 million replacing, updating, and switching telemetry, with another $2.5 million in telemetry expenses projected for 2006.

The following incident timeline and information on ensuing telemetry expenses was provided by the Baylor Health Care System.

Friday, Feb. 27, 1998

- 2:17 p.m. WFAA-TV channel 8 television began broadcasting on digital TV channel 9 and continued until 10:35 p.m., shutting down transmission a few times to allow a tower crew to work on the antenna.
- Baylor University Medical Center (BUMC) immediately started seeing problems with the telemetry system on the 13th floor of its Webb Roberts Hospital. The biomedical engineering department was called to troubleshoot the problem.
- BUMC had a telemetry system installed by Marquette that operated on channels 7, 9, 10, and 12. Forty-eight transmitters of telemetry operated on channel 9 on the 13th floor of Roberts and fourth floor of Jonsson Medical and Surgical Hospital. Since the failure was seen only on 13-Roberts at the time, the biomedical engineering staff focused on troubleshooting the antenna system. The failure would come and go (probably because WFAA was turning their system on and off).
- Late that evening the biomedical engineering staff assumed they had repaired a faulty antenna system because the telemetry system started to work again.

Saturday, Feb. 28, 1998

- WFAA resumed DTV transmission on channel 9 and remained on air until about 10:30 p.m.
- The telemetry problem returned. Biomedical engineering was called again to fix the problem. Administration also called the biomedical engineering director, Dr. Richard Roa. Steve Juett, biomedical engineering's senior clinical engineer, was called in to BUMC to help with the troubleshooting.
- Juett determined from a BUMC facility engineer that WFAA would be broadcasting on channel 9 that weekend. Steve immediately took the department's spectrum analyzer to view the waveforms present on channel 9. He was able to determine that the DTV transmission was filling the full band of channel 9.
- Shortly after 11 p.m., WFAA's newsroom was contacted by Baylor University Medical Center biomedical engineering department. The station agreed to stop transmission until BUMC could change out telemetry equipment.
- During this downtime, several other biomedical engineering staff members helped locate and install extra monitoring equipment so the clinical staff could monitor their patients who were previously on telemetry.

Monday, March 2, 1998

- Dr. Richard Roa met with BUMC administration to determine what equipment would need to be replaced. Most telemetry at BUMC was scheduled to be replaced that calendar year, so the decision was made to accelerate that purchase.
- Within a month or so of the incident, approximately $1 million (see Table 1) was spent to replace the telemetry at BUMC. Four other hospitals in the Baylor Health Care System had to have their telemetry system changed from channel 9 to channel 10. The cost for these upgrades was approximately $50,000.
- BUMC determined that the rest of the telemetry would not be in danger of interference from DTV as long as telemetry did not transmit on any DTV channels scheduled for the Dallas/Ft. Worth area. The main television stations were scheduled to move to higher bands for DTV transmission; BUMC decided to replace telemetry systems operating on the lower TV bands when age or service issues dictated it.
- Later that year, a cardiac rehab company installed their telemetry system in the Baylor System's Waxahachie hospital 30 miles south of BUMC. Despite widespread publicity over the February incident, the company installed the telemetry on channel 9; Baylor officials ordered the company to switch the system to an unused channel.

Date	Facility	Reason	Cost
March 1998	BUMC (Dallas)	age, need to move from channel 9	$1,000,000
	Baylor Medical Center at Ellis County/Ennis	changed antennas from channel 9, reprogrammed transmitters	5,000
	Baylor Medical Center at Ellis County/ Waxahachie	changed antennas from channel 9, reprogrammed transmitters	5,000
	Baylor Medical Center at Garland	changed antennas from channel 9, reprogrammed transmitters	15,000
	Baylor Medical Center at Grapevine	changed antennas from channel 9, reprogrammed transmitters	25,000
2000	Baylor Medical Center at Waxahachie	replacement of telemetry due to age (non WMTS)	122,000
2001	Baylor Medical Center at Garland	replacement of telemetry in Cardiac Rehab with WMTS	125,000
	Baylor Medical Center at Grapevine	expansion of VHF telemetry (non-WMTS)	86,000
2002	Baylor Heart and Vascular Hospital	new hospital, (telemetry costs only)	200,000
	Baylor Medical Center at Irving	replacement of telemetry in Cardiac Rehab	75,000
	Baylor Medical Center at Waxahachie	expansion of telemetry to a new floor	134,000
2004	Baylor Medical Center at Garland	addition of new telemetry floors	200,000
	Baylor Medical Center at Irving	replacement of VHF telemetry in PCU	314,000
	Baylor Regional Medical Center at Plano	new hospital (telemetry costs only)	675,000
2005	Baylor All Saints, Ft. Worth	replacement of all telemetry systems	750,000
	Baylor Regional Medical Center at Grapevine	replacement of telemetry system due to age, expansion needs	450,000
	Baylor Medical Center at Irving	upgrade of VHF telemetry, 4-North	130,000
	Baylor Medical Center at Irving	upgrade of VHF telemetry, CHF clinic	60,000
2006 projected	BUMC/Dallas	replacement of telemetry due to age	1,300,000
	Baylor Medical Center at Garland	replacement of telemetry, 2-East, and centralized monitoring for whole hospital	900,000
	Baylor Regional Medical Center at Grapevine	opening of new telemetry floor	210,000
	Baylor Medical Center at Waxahachie	replacement of telemetry due to age	90,000
		TOTAL	**$6.6 million**

Table 1. *Baylor system telemetry costs since the 1998 incident.*

from the Furby, a popular stuffed toy. (According to a report in the Oct. 19, 1999 *Canadian Medical Association Journal*, the Furby didn't affect the performance of any tested devices at any distance.)

The CDRH has been investigating incidents of EMI affecting medical devices since the late 1960s. Wireless communications have been implicated in various malfunctions. Among them: a man in a powered wheelchair was injured when his chair rode off a cliff near a radio tower and a busy road where mobile radios were likely in use; the failure of a pacemaker during an ambulance ride while the two-way radio was in use; cell phones that interfered with cardiac pacemakers at close distances.

One incident that galvanized the FCC and the FDA to action was the 1998 disruption of cardiac monitors on the 13th floor of Baylor University Medical Center in Dallas. The facility was near a television station's digital test signal on VHF channel 9, where the monitors operated. It wasn't immediately apparent that the TV signal was at fault—the disruption came and went over the course of a weekend. Detective work by clinical engineering staff finally solved the mystery. (See sidebar "Interference Incident and Aftermath.")

In 2000, the FCC allocated specific Wireless Medical Telemetry Service (WMTS) frequencies and urged—but did not require—healthcare organizations to move telemetry into those bands and out of TV and PLMRS bands. Only in WMTS would telemetry be "protected" as a primary user, the FCC said. The other side of that coin, of course, was that the FCC was opening the TV and PLMRS bands to many more users.

Hospitals that continue to operate telemetry in those frequencies—a conservative estimate puts these at several hundred facilities—face sharply higher EMI risks in 2006. And while they are required to register WMTS equipment with ASHE—which coordinates WMTS frequencies for the FCC—hundreds have not, according to ASHE. Given the patient risk posed by EMI, those hospitals may be inviting legal battles.

"The hospital definitely views it as a liability issue," said Tim Moon, clinical engineering project manager for Spectrum Health, which has seven hospitals in West Michigan and has employed WMTS-based systems since 2000.

Many healthcare facilities can't afford to make an immediate or complete switch to WMTS bands; they

choose to replace telemetry at highest risk of EMI and save bigger expenses for new construction. That makes the shift to WMTS more affordable, but also means facilities have to make do with an assortment of telemetry for a time.

Other factors complicate the WMTS picture, including a strong difference of opinion as to whether moving to WMTS is even necessary.

The WMTS Debate

While the FCC's allocation of WMTS frequencies—608-614 MHz, 1395-1400 MHz, and 1427-1432 MHz—was generally supported by the medical device industry, the strategy also created confusion, questions, and debate among hospitals and vendors alike over just how much protection WMTS offers.

Although registered telemetry operating in WMTS bands has primary status—meaning it is not supposed to have harmful interference from other users—there are other primary users, among them radio astronomy, government radar surveillance, and utilities. Hospitals may have to coordinate with them, at added cost, through ASHE and its technical partner, Comsearch. (See sidebar "Registration Nuts and Bolts.")

Overall, there is less bandwidth in WMTS frequencies, compared with the ISM band; that raises the question of whether there will be enough room on WMTS frequencies for all users. Morever, WMTS-based equipment is typically proprietary; there are no interoperability standards akin to the IEEE 802.11 family of standards for wireless local area networking in ISM. Some feel that makes ISM a more robust and less expensive choice for telemetry.

Alan Lipschultz, director of clinical engineering at Christiana Care Health System a 1,000-bed, tertiary care system in Delaware, said he has been "100 percent pleased" with his facility's wireless patient monitors and central monitoring station and has experienced no EMI.

"We were going out on a limb" committing to ISM, Lipschultz said. But at the time he was evaluating products in late 2000, many seemed technically identical to the generation of telemetry he was replacing. "We became convinced that the frequency hopping technology would allow the telemetry signals to go through in spite of other potential interference sources." His institution also utilizes the 2.4 GHz ISM band for many other 802.11b applications and has noticed no interference.

"We've been very happy and have no plans to change," he said.

Some vendors, like GE Healthcare Clinical Systems, use frequency hopping for WMTS-based telemetry; others are moving in that direction, given the hospital's cluttered electromagnetic environment and the growing demand for wireless monitoring.

"Frequency hopping is clearly the best choice," said David Pettijohn, GE's Luminary Accounts Technology Manager. "Theoretically, you can put any number of people on it."

Pettijohn was on the AHA task force—formed after the 1998 Baylor incident—which recommended to the FCC allocation of WMTS frequencies. Initially, the FCC offered the ISM band instead. "We said no because it was crowded in 1998 and we knew it was going to get a lot worse over time," Pettijohn said.

Dale Woodin, ASHE's deputy executive director, noted that while there is more bandwidth in ISM, that is shared by an untold number of devices and users, with no priority given to medical telemetry. With WMTS,

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Registration Nuts and Bolts

Hospitals are required to register telemetry operating on WMTS frequencies and are supposed to do so before using the equipment. Frequencies of registered telemetry units are included in a database maintained by the American Society for Healthcare Engineering (ASHE), a division of the American Hospital Association. The database, which can be accessed by hospitals, is used to determine potential conflicts and help avoid interference with other users.

To register, hospitals can go online to www.ashe.org/ashe/wmts/onlineregistration.html or call ASHE at 312-422-3805. There is a one-time $125 administrative fee to set up an account. The hospital receives a log-in identification and password to access the WMTS Frequency Coordination Database. The hospital must provide site and equipment information, including:

- Location of the equipment-address, longitude and latitude
- Radius of deployment
- Highest floor in the hospital where the deployment will operate
- Number of transmitters in the deployment
- Effective radiated power (ERP) in milliwatts
- Manufacturer and model
- Range of frequencies the equipment uses to transmit or receive.

A facility pays $20 or $30 for each transmitter deployment, depending on which WMTS band is used, up to a maximum of $1,500 or $2,000.

Comsearch, ASHE's technical partner, performs a search of frequencies in the area to determine potential conflicts. If there is a nearby radio astronomy observatory (13 sites around the country) or high-power government surveillance radar (17 sites), frequency coordination with those facilities may be necessary at a cost of $500 each.

Comsearch offers other services, such as assessments of the risk to hospitals from users in non-WMTS bands, wireless planning and consultation, with costs figured on a case-by-case basis.

For more information on pricing, see www.comsearch.com/interactive/wmts.jsp

"we do have a stake in the ground that says this is our home," Woodin said. "Before, we were squatters."

Woodin did not rule out that one day it may be necessary to petition the FCC for more bandwidth for WMTS, though "given the value of spectrum … we better really have our ducks in a row."

Meanwhile, hospitals with telemetry in WMTS bands say they're generally pleased.

At Spectrum Health, Moon said that before switching to WMTS one eight-story facility that sits high on a hill "constantly required tuning adjustments to its antenna system to accommodate TV channel space." While WMTS has not been problem-free—some 608 MHz telemetry has had lower-frequency receivers or amplifiers that required filtering or other measures to eliminate EMI—in general operation has been "pretty clean," Moon said.

David Stiles, biomedical engineering supervisor for Long Beach Memorial Medical Center and Miller Children's Hospital in Long Beach, Calif., said he was "happy as a lark about my new frequency" when he switched toward the end of 2003. Conversion to WMTS bands eliminated interference, especially from nearby ship radios.

"At the old frequencies we would have ships come into the harbor and knock out 30 or 40 of our beds," Stiles said. "The minute I switched over to 608-614 MHz, all my transmitter problems went away."

But the 608-614 MHz bands are the most crowded, and they are also adjacent to TV channels 36 and 38, which could increase interference risks in certain areas; newer telemetry is beginning to move into higher WMTS frequencies.

"We've seen the manufacturers taking their time going to upper bands," Woodin said. "Now you're starting to see installations in upper bands. That's going to offer a lot more flexibility."

Still, the debate shows no sign of dying.

"Many hospitals have decided to not move from the older telemetry bands," said Rick Hampton, wireless communications manager at Boston-based Partners HealthCare System. "From a purely technical standpoint, there's no reason for any of these hospitals to change frequencies as long as they keep track of what other users in their area are doing and can react quickly to avoid any problems. Realistically, only a handful of hospitals have this capability."

Witters is wary. "Our concern is that the safety and effectiveness of the device is maintained," he said. "The WMTS frequency bands were allocated for medical use. … If you have a good system in there, then it should work reasonably well in that environment."

Challenges for Biomeds

Overall, wireless technology's future in the healthcare setting "is extremely bright for opportunities as long as there is a wary eye toward the challenges," Witters said.

Perhaps the biggest challenge is what many say is the most pressing need to emerge from the telemetry debate: a radio frequency manager to actively manage the hospital's wireless environment.

That job involves making regular RF spectrum sweeps, keeping up to date on RF users near and in the hospital, and maintaining current lists of telemetry equipment and frequencies so as to avoid conflicts. Hospitals can access the ASHE WMTS database, for example, as well as FCC records to stay abreast of changes affecting them.

Hospitals without funds to hire an RF manager could share the service with other facilities, says ASHE's Woodin, who contends "the RF environment is a utility to be managed" like any other in the hospital.

Industry competition between ISM and WMTS factions and vendors is partly to blame for confusion among equipment managers over WMTS, says GE's Pettijohn. Now though, "the biomed is in a unique position of moving beyond fixing-the-infusion-pump stuff to being a technology adviser to hospital management" on wireless issues, he said.

"But they've got to know stuff," Pettijohn added. "My advice to the biomeds is to get educated."

Beyond a few conferences and vendor-run training, there haven't been a lot of opportunities to do that.

Some equipment managers, says Hampton, "hold the position the manufacturer sold them equipment, it had better work, and if it doesn't, they go back to the manufacturer for a solution. That's not practicing spectrum management." Constant vigilance is required in today's RF environment, no matter what frequencies telemetry uses, he said.

"The radio spectrum is only becoming more active, more congested," Hampton said. "Hospitals and clinical engineers have to step up to the plate, spending time and resources on developing a management plan to address all of their wireless systems."

Shands HealthCare, a nine-hospital system affiliated with the University of Florida, formed a wireless coordination committee that has worked well, said Craig Bakuzonis, clinical engineering director. "We oversee all wireless applications and installations from the point of view of frequency coordination and bandwidth coordination."

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> —Don Witters

He agrees that equipment managers should not rely on vendors to stay on top of RF issues.

"It really is the hospital's responsibility to coordinate spectrum management within their own walls," he said. "People need to pay attention to what's going on and take this seriously. There are changes. You do have to keep up with those changes. You do have to keep monitoring your patients in a safe environment."

At Spectrum Health, Moon says that although he works closely with information technology personnel, "managing the RF spectrum is totally up to us."

"Clinical engineering maintains a master list of the telemetry frequencies. About once every six months you need to look at it, make sure you're up to speed," he said. "The system is constantly changing, the hospital is always wanting to add more."

At Baylor, one legacy of the 1998 incident with the Dallas television station is that equipment managers now take an active role in managing the RF environment, said Kenneth E. Maddock, corporate director of clinical technology services for Baylor Health Care System.

"Someone is assigned in the department to keep track of what we have installed so that if something does happen we can react quicker," Maddock said. Even so, he adds, the challenges continue: "We feel that opportunities exist to improve the way we manage this environment."

Despite the varied opinions on how to handle the issues surrounding WMTS, one thing is obvious—this is a hot topic for biomedical managers and will continue to be so for the foreseeable future. ■