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Wireless Technologies and Patient Safety in Hospitals

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ABSTRACT

In the development of policies for wireless technologies, it is important for healthcare organizations to reduce risks to patients from use of wireless devices. Policy should be devised for instructing hospital staff, visitors, and patients, avoiding unwarranted restrictions but not ignoring evidence regarding potential interference problems, and allowing comparison with other clinical facilities of benefits of policy. To inform policy developers and a general audience of hospital personnel, a review was conducted on the safety of wireless devices for communication within hospitals. This review targeted electromagnetic interference effects of devices on medical devices and summarises key recommendations from published reports and international standards. There is consensus that the highest risk of interference occurs with two-way radios used by emergency crews, followed by mobile phones, while radio local area networks produce negligible interference. Wireless technologies are deemed suitable for use throughout hospital areas including intensive care units and operating rooms, given that recommended separation distances from medical equipment are observed.

INTRODUCTION

THE OBJECTIVE of this paper was to formulate a guide that can be used by policy makers regarding the introduction of wireless technologies in hospitals. In this section, benefits of wireless technologies are described from the perspective of both healthcare organizations and clinicians. Several issues surrounding wireless system implementation are then identified, one of which is patient safety, which should be the focus of policy developers.

The benefits of wireless communication systems in health environments have been reported previously.[1–4] In addition to the obvious need to communicate via technology based on wireless connectivity (e.g., mobile phones, pagers and two-way radios), there are other reasons to embrace wireless communication:

1. Healthcare workers rely on a constant flow of information in order to manage their patients effectively. In the past, this information may have been delivered to each ward through a single computer station, which is cumbersome, time-consuming, and takes valuable time away from monitoring and caring for patients. Real-time access to patient charts, laboratory results, and medical histories can be made

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available through wireless devices at the bedside.[4] There are also benefits in reducing paperwork and needless human traffic. Less time is required inputting notes and more time available to spend with patients.

2. There are benefits relating to decision-support and computer-assisted medicine. Wilcox and La Trella[5] describe the need for mobile "evidence-carts," consisting of evidence-based medicine and medical reference material at the point-of-care. Adverse drug events are primarily caused by physician error and many of these errors result from problems with point-of-care drug knowledge.[4,5]
3. Connecting patients to monitors and monitors to local area networks requires a large number of cables. This wiring is generally inconvenient and particularly troublesome if a patient needs to be mobile or a patient is stationary but the layout of equipment (operating table, anaesthesia equipment and monitors) is rearranged.[6]

There are pressures within healthcare to minimize error rates, conduct diagnoses on the bases of real-time patient data, improve efficiency, and reduce costs.[4] Implementing wireless technologies is a solution to these pressures. Specific healthcare areas that can benefit from real-time wireless access to data include admissions, laboratories, medical records, radiology, nursing and bedside care, emergency services, and home health care. Benefits to clinicians include documentation of a patient encounter that is prompt, complete and legible, not having to spend additional time at the end of a shift entering scribbled notes, and access to reference databases and evidence-based practice guidelines (decision-support).[4]

While wireless systems appear to have many benefits, there are a number of technical issues surrounding wireless implementation that developers of hospital policy may need to address, such as coverage, security, performance and patient safety.[7] Of these issues, ensuring the safety of patents must be the focus for policy developers. Misinformation regarding mobile wireless systems, electromagnetic interference, and management procedures has lead to a broad range of inconsistent policies among healthcare organizations.[8] A balanced approach is needed between overly restrictive policies that may act as obstacles to beneficial technology and may not address the growing need for personal communication of patients, visitors and the workforce, and the unmanaged use of mobile communications that can place patients at risk.

The remainder of this paper provides an overview of the electromagnetic spectrum and the problem of electromagnetic interference and radiation exposure. Applicable standards and recommendations for classes of wireless communication systems are presented. Other aspects which are relevant to the implementation of wireless communication systems (e.g., security, network connectivity) are not covered in this article.

WIRELESS COMMUNICATION

Wireless communication refers to conveying information via the electromagnetic spectrum, as opposed to transmission by a wire or cable. This spectrum depicted below in Figure 1 is the distribution of electromagnetic radiation according to frequency (wavelength).

Most wireless communication is via radiofrequency (RF) electromagnetic signals. Although acoustic transmission of physiological signals has been demonstrated through water, acoustic methods are not widespread.[9] Communication within the infrared (IR) band has found popu-

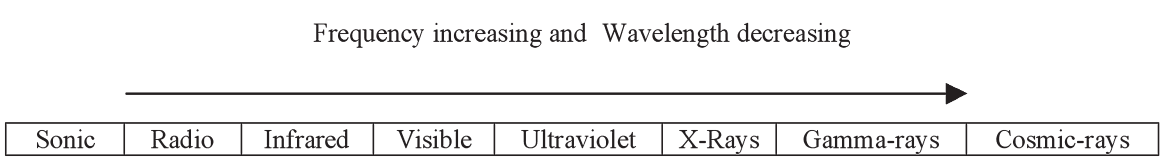

FIG. 1. Electromagnetic radiation spectrum.

larity in computer peripherals, using specifications defined by Infrared Data Association (IrDA). Experiments assessing the suitability of infrared wireless local area network (LAN) in the operating room found there was no evidence of electromagnetic interference when testing several medical devices (infusion pumps, syringe pumps, and cardiac pacemakers) and transmission performance was comparable to wired connection.[6] However infrared transmission is limited by line-of-sight requirements for communication—communication is blocked when objects pass between transmitter and receiver and hence is not suitable for mobile applications.[10] Hence the advantages of communication via RF transmission.

Ultra-wideband (UWB) is a wireless communication technology that challenges the notion that use of particular frequencies or bands is necessarily mutually exclusive, by using very narrow or short-duration pulses that result in very large or wideband transmission bandwidths. With adherence to appropriate technical standards, UWB devices can operate using spectrum occupied by existing radio services without causing interference, thereby permitting scarce spectrum resources to be used more efficiently. Other advantages of UWB systems are high data rates, the ability of wideband signals to penetrate through walls, making high resolution through wall imaging a reality, a spread power density causing the signal to almost disappear among noises (low probability of detection RF signature), and low power level requirements.

The RF spectrum (3 kHz to 3000 GHz) is managed on an international level by an agency of the United Nations, the International Telecommunication Union (ITU), by means of the Radio Regulations. These regulations contain a table of frequency allocations, in which ranges of frequencies (called spectral bands) are allocated to particular services. These Radio Regulations are annexed to the International Telecommunication Convention signed by all Member States of the ITU, and therefore it is mandatory for domestic spectrum plans to align with the international regulations. The use of the radio frequency spectrum within countries is managed by various national authorities, for example, the National Telecommunications and Information Administration (NTIA) and the Federal Communications Commission (FCC) in the United States, the Australian Communications Authority, and the European Conference of Post and Telecommunications Administrations (CEPT), comprising 46 European countries.

New wireless applications are constantly being developed to meet consumer demand for broadband and untethered communications.[11] This inevitably means that more spectrum is needed for new services, particularly in those bands that are already allocated. The growing demand for wireless Internet has prompted demand for more spectrum around 2 GHz.[11]

With regards to patient safety, wireless technologies have the potential for impact in two areas: electromagnetic interference (EMI) with medical devices and electromagnetic radiation exposure. These two issues are discussed separately below.

ELECTROMAGNETIC INTERFERENCE (EMI)

As the use of mobile wireless equipment by healthcare providers, patients and the public continues to increase, concerns of potential EMI with life-critical medical devices has also increased, prompting many hospitals to establish broad precautionary policies banning mobile phones and other wireless equipment from the entire facility.[12] Since the early 1990s, reports of medical device failure from EMI have increased as a result of several factors.[13] The number of electronically controlled medical devices has burgeoned in hospitals and other medical facilities. Newer instruments are often more sensitive to EMI because they incorporate low-power–integrated electronic circuitry that can be much more sensitive to electromagnetic fields than their electrical and electromechanical predecessors. A useful compilation of publications concerning electromagnetic interference is included in Silberberg,[14] who has also compiled over 100 reports to the Food and Drug Administration (FDA) of adverse incidents of EMI with medical devices.[15] Entering the search term "EMI" into the FDA's medical device databases for the mandatory Medical Device Reporting (MDR) program and voluntary MAUDE program yields numerous reports on death or serious injury.[16] Some examples relating to patient telemetry systems include "flat-line" monitor displays when a paging company transmitted digital control information to remote sites and a pulse oximeter displaying saturation of 100% and pulse rate of 60 on a patient who had expired.[17]

A report of the American Medical Association consisting of a MEDLINE review of the risks of EMI from wireless devices in hospitals concludes that it is difficult to predict EMI patterns and characteristics reliably, and it is difficult to identify which devices may interact adversely and what specific power levels are necessary to cause interference.[18]

However, the Committee on Man and Radiation (COMAR), which forms part of the IEEE Engineering in Medicine and Biology Society states that many factors affect the severity of EMI in medical devices, including (1) the coupling between a source of interference and the medical device, (2) the frequency of the carrier, (3) the modulation imposed on the fields from each source, and (4) the distance between the source and the susceptible medical device.[13] This is supported by Adler et al.[19] who states that the effects of the radiated EM signal depend on the field strength (volts per meter) at the location of the device and the wavelength (or frequency) of the transmitted signals, relative to the size of the device and its connected cables acting as undesirable antennas.[19]

The United Kingdom (UK) Department of Health supports the view that the frequency of transmission affects the probability of interference for any particular field strength.[20] Furthermore general transmissions below 500 MHz (e.g., emergency radios and two-way radios) are more prone to cause interference than those transmitting above 1GHz. Some known sources of interference in hospitals are shown in Table 1.

Of all these sources, mains electricity (50/60 Hz) is the frequency likely to cause the most problems. Inadequate transformers within equipment and inappropriate location of electrophysiological measurement rooms near to medium voltage cables are the most common sources of problems.[21] The effects of widespread use of UWB systems discussed earlier that have very large transmission bandwidths are not yet fully known. While interference could impact critical spectrum users, the extremely low power of these systems (e.g., approximately 1 μW) make this unlikely.

Standards

The relevant standard applicable to medical electronic equipment is ANSI/AAMI/IEC/EN 60601-1-2:2001, "Medical electrical equipment—Part 1–2: General requirements for safety—collateral standard: Electromagnetic compatibility—Requirements and tests." This edition incorporates tests for different types of electromagnetic disturbances, and states that equipment must be immune to radiated field strengths of up to 3 V/m at frequencies from 80–2500 MHz (10 V/m for life-support equipment).[22] Fixed transmitters for radio and television produce a lot of power but are far away,

TABLE 1. SOURCES OF ELECTROMAGNETIC INTERFERENCE IN HOSPITALS

Frequency	*Frequency in MHz*	*Source*
50/60 Hz	0.00005/0.00006	All mains powered electrical equipment
~200 kHz	~0.0002	Magnetic card security readers
~1 MHz	~1	Surgical diathermy
27 MHz	27	Continuous shortwave physiotherapy diathermy
~50 MHz	~50	Pagers
~70–200 MHz	~70–200	Ambulance radios
~400 MHz	~400	TETRA radios
850, 900, 1800, 1900 MHz	850, 900, 1800, 1900	Cell phones (mobile phones)
2.45 GHz	2450	Microwave physiotherapy diathermy and microwave ovens
20 GHz	20,000	Automatic doors

Adapted from L. Grant,[21] and reprinted with permission from the author.
TETRA, Terrestrial Trunked Radio System.

and generally produce field strengths of less than 1 V/m in hospitals. By contrast, the field from a mobile radiating only 2 W can be tens of volts per metre at distances of less than a metre. Walkie-talkies and ambulance radios radiate higher power than mobiles, and cordless telephones radiate less.[22]

Recommendations for device classes

The following recommendations for wireless devices, which could be used as a basis for new hospital policy, are based on studies with limited numbers of products. These can provide a baseline that may be adaptable to similar systems. A summary of recommendations for different wireless communication systems is shown in Table 2. Included in the table is a column showing indicative interference levels from a study assessing EMI at one metre separation from 178 medical devices.[23] Emergency service radios posed the highest risk, followed by mobile phones, while wireless LAN systems showed no significant EMI at 1 metre.

Emergency service radios

As stated in the previous section, the IEC standard specifies that medical devices should be designed to resist electrical interference as follows: (1) life-support devices: 10 V/m and (2) Other medical devices: 3 V/m. These values provide convenient benchmarks for assessing risks. Fields up to 3 V/m are often encountered as background levels in healthcare facilities, and are unlikely to cause many interference problems, and therefore unlikely to cause serious problems. Fields between 3 and 10 V/m are typical of most of the measurements made inside ambulances and represent moderate risk levels.[20] Data on the safety of radios used with respect to monitoring or treatment equipment in ambulances has been collected by the U.K. Department of Health.[20] Reviews of these data conclude that the use of portable handsets and cellular telephones inside ambulances should be restricted, special precautions are needed if a patient with an external pacemaker is being transported, and warning notices, staff training, and relocating

TABLE 2. INTERFERENCE RECOMMENDATIONS FOR WIRELESS COMMUNICATION SYSTEMS

Risk of interference	*Type of communication system*	*Indicative % of medical devices suffering EMI at 1 meter*	*Recommendation*
High	Emergency service ratios (ambulance/police/fire)	41%	Use in hospitals only in an emergency, never for routine communication.
	Private business radios, e.g., porters' and maintenance staff radios (two-way radios).	35%	Minimise risks by changing to alternative lower risk technologies Recommended separation: 6–8 m
Medium	Cellphones (mobile phones) TETRA (Terrestrial Trunked Radio System) Laptop computers, palmtops and gaming devices fitted with GPRS and/or 3G HIPERLAN (HIgh PERrformance Radio Local Area Networks)	4%	A total ban on these systems is not required and is impossible to enforce effectively. Should be switched off near critical care or life support medical equipment. Should be used only in designated areas. Authorised health and social care staff and external service personnel should always comply with local rules regarding use. Recommended separation: 1800/1900 MHz & CDMA phones—0.5 m, 850/900 MHz phones—2 m
Low	Cordless telephones (including DECT) and computer ratio network systems except HIPERLAN and GPRS e.g. WiFi systems and Bluetooth®, UWB	No significant EMI	These systems are very unlikely to cause interference under most circumstances and need not be restricted. Recommended separation: 1 m

Source: Medicines and Healthcare Products Regulatory Agency (MHRA), U.K. Department of Health,[23,24] reprinted with permission.

parking bays are possible actions if risks of interference prove unacceptable.

Table 3 lists the distances from the transmitting aerials for the various types of radio covered here at which the benchmark field strength levels of 3 and 10 V/m are exceeded. Fields closer to the transmitting aerials than the distances listed in the table will exceed the benchmark values. It is recommended that if there is an urgent need to use two-way radios in the vicinity of medical equipment, a separation of 6–8 meters should be observed.[27]

Mobile phones

There are many reports in the literature on EMI and mobile/cellular telephone use.[13,25] A recent review of mobile phone interference concludes at least 4% of medical devices in hospitals could experience EMI when a mobile phone is within 2 m.[26] Mobile phones operating at frequencies around 1800 MHz appear to cause less EMI than when operating at lower frequencies around 900 MHz and need to be closer to medical equipment to affect it. However, in those countries where multiband mobile telephones operate at both high and low frequencies, it is impossible to be sure which frequency is in use at one time. It is recommended that a 2-meter separation rule be retained for mobile phones until such time as lower frequency (850 and 900 MHz) phones are no longer used.[27] The risk to medical devices from the use of new digital Terrestrial Trunked Radio (TETRA) System handsets is comparable to that from cellular phones.[28]

Radio local area networks (WiFi, Bluetooth)

Wireless networks for data transmission use a variety of radio frequencies. Table 4 shows some common wireless network protocols and the corresponding radio frequencies.

Electromagnetic waves transmitted from mobile telephones cause interference with medical electronic equipment, and thus prudence would seem necessary when introducing radio wave communication devices in hospitals. The effect of wireless communication on medical electronic equipment and vice versa, the effect of electronic equipment on wireless communication, has been studied.[30–33]

Hanada et al.[30] reported zero malfunctions when testing 2.4 GHz WLAN against nine pieces of operating medical electronic equipment. However an update of their studies in 2004 using a signal generator to generate higher power (approximately 3 W) 2.4 GHz signals, resulted in the observation of EMI in 3 pieces of equipment (2 models of syringe pumps and 1 ventilator) out of 10, with EMI observed at a maximum separation distance of 40 cm.[31]

Tan[32] tested the susceptibility of 65 devices to both a telemetry system (466 MHz/4 mW), and WLAN (2.42 GHz/100 mW). There was no effect with the 466-MHz telemetry system, but two hand-held Doppler units emitted high-pitched beating sounds when placed within 10 cm of the LAN system (LAN data transmission was acceptable).

Wallin[33] tested 2.4 GHz Bluetooth in a laboratory, operating room and an intensive care unit. Forty-four electronic medical products were tested for durations of up to 4 hours with no reported EMI problems. Advantages of Bluetooth transmission over WLAN have been reported in that transmitters consume much less power (1 mW compared to approximately 100 mW), and that the modules are smaller and less expensive.

Considering the above studies along with the data shown in Table 2 (no significant EMI at

Table 3. Critical Distances from Transmitting Aerial for Benchmark Field Strengths

Source	*Distance for 3 V/m*	*Distance for 10 V/m*
Ambulance vehicle radio	6 m	2 m
Portable handset	2 m	0.5 m
Fire appliance vehicle radio	6 m	2 m
Motorcycle radio	6 m	2 m
Helicopter ambulance	7 m	2 m
Mobile data terminal	1.5 m	0.5 m

Source: Medicines and Healthcare Products Regulatory Agency (MHRA), U.K. Department of Health,[20] reprinted with permission.

Table 4. Frequency Ranges for Wireless Networks

Wireless network	*Frequency range*
802.11 (WiFi)	
802.11b, 802.11g, 802.11n	2.4 to 2.483 GHz
802.11a	5.180 GHz to 5.805 GHz
802.15.1 (Bluetooth)	2.45 GHz
802.15.4 (ZigBee)	868 MHz, 915 MHz, 2.4 GHz
802.16 (WiMAX)	10 GHz to 66 GHz
802.16a	2 GHz to 11 GHz
Ultra-wideband (UWB)	
UWB Imaging systems	Below 960 MHz & 3.1 to 10.6 GHz
UWB Communication & measurement	3.1 to 10.6 GHz
UWB vehicle radar	24 GHz
GPS	1.2276 and 1.57542 GHz

Adapted from: Linux Unwired[29] and www.wikipedia.com

1 m for 178 tested devices), adopting a 1-meter separation approach for wireless LAN systems would seem reasonable practice.

Interference with multiple emitters

Concern is often expressed over using wireless technology because of perceived interference problems associated with the use of multiple emitters within the same spectrum. For example, deploying a WiFi IEEE 802.11b LAN and a Bluetooth LAN that both operate within the 2.4-GHz band will result in some level of interference.[2] However, collocation of Bluetooth and 802.11b systems can be successful. The IEEE has formed the 802.15 Coexistence Group to identify guidelines for limiting interference.

Simulations performed by this group show that by placing the devices 15 to 20 cm apart will enable full operability. It is acknowledged that distance is a critical factor for simultaneous Bluetooth and WLAN traffic.[34]

RADIATION EXPOSURE TO WIRELESS SIGNALS

The above discussions have concerned the risks of EMI on patient safety, and for completeness it is worth mentioning the effect of wireless signals on the body. When considering possible hazards from exposure to wireless transmitters, several considerations must be taken into account.[35] The first consideration is frequency because exposure guidelines vary with frequency. A second consideration is the power output of the transmitter, and its distance from the body. Hand-held units (either cellular telephones or other communications handsets) operate at comparatively low power levels but are used very close to the body. Mobile units (such as ambulance vehicle radios and portable handsets) operate at higher power levels, but their transmitting antennas are located some distance from their users.

A person's exposure to RF energy can be measured in several ways. For assessing exposure from transmitters located near the body, the most useful quantity is the specific absorption rate (SAR). SAR is a measure of the power absorbed in the body (either in a localized region of tissue or averaged over the whole body), expressed in units of watts per kilogram of tissue. Where the transmitter is located away from the body it is permissible to use derived limits, which are easier to measure (e.g., W/m^2). A number of organizations have established limits for human exposure to RF fields, limiting the SAR in the body to safe levels. There is no evidence, from laboratory or epidemiology studies, that exposure to RF energy at levels below recommended limits has any health significance for humans.[35]

MANUFACTURER OBLIGATIONS

The above guidelines for the use of wireless communications in hospitals are targeted at policy developers, but there are also obligations for device manufacturers in not compromising health and safety. Wireless devices should be designed and produced in a way that ensures that the device will not compromise the clinical condition or safety of a patient, or the safety and health of the user or any other person, when the device is used on a patient. Also any risks associated with the use of the device should be acceptable risks when weighed against the intended benefit to the patient and compatible with a high level of protection of health and safety.

Obligations of device manufacturers include:

1. Identifying hazards and associated risks arising from the use of the device for its intended purpose, and foreseeable misuse of the device;
2. Eliminating, or reducing, these risks as far as possible by adopting a policy of inherently safe design and construction;
3. If appropriate, ensuring that adequate protection measures are taken, including alarms if necessary, in relation to any risks that cannot be eliminated; and
4. Informing users of any residual risks that may arise due to any shortcomings of the protection measures adopted.[36]

The IEEE COMAR recommends that medical device manufacturers should design and test products to ensure conformance with current EMI standards so that their devices are not excessively sensitive to EMI.[13] This will require that the products be shielded in electrically conductive, or conductor-coated enclosures that incorporate feed through filters and other techniques to increase electromagnetic compatibility. Even when medical devices conform to existing standards, manufacturers should warn both medical professionals and patients of situations in which EMI failure may occur. The warning should include information that describes how to recognize the symptoms of EMI, how to deal with EMI problems, and how to report incidents.

A standardized EMI test method has been developed to enable engineers in clinical environments to estimate the susceptibility of medical devices to specific radiofrequency transmitters in a setting comparable to that of actual use.[37] This method should be used to identify potentially problematic situations in hospitals where transmitters are repeatedly used in close proximity to critical medical devices.

CONCLUSION

Proper application of wireless technology has the potential to increase productivity, decrease costs, and generally improve the quality of healthcare. Uncertainty and concern with regard to EMI have acted as major obstacles to the full deployment of wireless technology in many facilities. However observation of the following separation distances should not cause significant EMI to medical equipment:

- Two-way radios/walkie talkies (security/maintenance personnel)—6–8 m;
- GSM1800 and CDMA phones—0.5 m, GSM900 phones—2 m; and
- Wireless LANS/Bluetooth—1 m.

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