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Feature - Wireless Devices and Electromagnetic Interference in Hospitals, Urban Myth?

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With the increasing pervasiveness of cell phones and wireless local area networks, and the current push to wirelessly connect handheld computers with local and wide area wireless networks, the topic of these devices possibly interfering with medical equipment seems like a timely one.

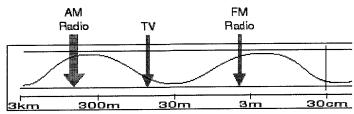
There has been a great deal of misinformation and hearsay associated with reports about cell phones, wireless local area networks (WLAN), and wide area networks (WAN) in hospitals. Most hospitals have bans on the use of cellular phones inside their facilities, despite the absence of any comprehensive scientific information supporting the impression that cell phones are dangerous in hospital.

Perhaps we should take a step back and revisit our premed physics lessons to understand more clearly exactly what we are talking about here. Those of you who don't care to remember those days, and those of you for whom this discussion is not needed, will please excuse me.

Radio frequency waves, that which are used to carry the intelligence of cell phone calls, television, and radio broadcasts is energy transmitted through space. This energy is comprised of the alternating waves of electric and magnetic fields, hence the term electromagnetic energy, or EM for short. Electromagnetic energy manifests itself only when it is interacts with matter. EM energy can only interact with certain types of matter. The types of matter with which EM energy can interact are dependent upon the frequency of the EM waves. Light is a brand of EM energy with wavelengths about a half-micron. Visible light sits close to the middle of the EM spectrum as far as wavelengths are concerned, with x-rays and gamma rays at the short end, and radio waves at the long end of the spectrum. X-rays and gamma rays have wavelengths so short that they can squeeze into atoms to ionize and disrupt them. Microwaves, with wavelength in the millimeter or so range, can heat watercontaining materials by causing the water molecules to vibrate. Radio waves, of the meter or so length, are used to



for public communications broadcasts. Very long wavelength EM energy is used by the Navy to communicate with submarines under hundreds of feet of seawater and half way around the globe.



Radio Wave Region of the Electromagnetic Spectrum

When EM radiation in the broadcast range comes in contact with a metallic object, a current is caused to flow in that object. The current will adopt the frequency of the EM wave that strikes it. If the metallic object is the antenna of a radio of cell phone, attached to circuitry appropriate to decode the signal, you have communications. However, any metallic object be caused to generate a current if struck by EM waves. The amount of current is dependent upon the strength of the EM field, and the exact geometry of the metallic object. Communications antennae are "tuned" to the exact frequencies with which they operate to maximize this effect.

EM radiation is all around us. Television, radio, cellular, and other broadcasting equipment bathe us all in a pool of EM waves. It is very difficult to exclude this EM pollution. That is why radio telescopes (as well as light telescopes for similar reasons) are built many miles from any source of transmission. Hospitals are not exempt from this exposure.

For years, the FDA and FCC have known that EM radiation from various sources could interfere with delicate medical equipment. Requirements for shielding this equipment have long been part of the FDA's requirements to market such gear. It has been only lately that the source of transmission for EM radiation could have been in such close proximity to the medical equipment itself. Having a cellular or walkytalky device within feet of a piece of sensitive medical equipment is very different than being twenty miles from a radio tower. As with all EM radiation, the strength of the field decreases with the square of the distance from its source. That is to say that the field strength at one meter from a transmitter is four times as strong as the strength only another meter away. This situation put EM shielding of medical equipment to a new test.

Early on in the life of cellular phones, analog systems operated with fairly substantial outputs. There were reports of interference with electric wheelchair circuits, cardiac pacemakers, and anesthesia equipment. Of course, telemetry equipment was particularly susceptible. It was then that a fear of cellular phones in hospital was borne. Apparently, as

at least one source states it, a sign company propagated the rumor of an FCC ban on cell phones in hospitals for the purpose of selling its signs. It appears to have worked, and the ban on cell phones in hospitals has grown to become one of the "urban myths" of our society. But, there is no such ban.

Next, a bit about jurisdiction:

The FCC has authority over all forms of equipment that is capable to transmit electromagnetic (EM) energy. The FDA has authority over all forms of medical equipment (both disposable and durable), medications, and associated delivery systems or devices.

The FDA has never, and is prohibited from doing so by its charter, banned any communications equipment. They have however, placed pre-market requirements on medical equipment (i.e., shielding requirements).

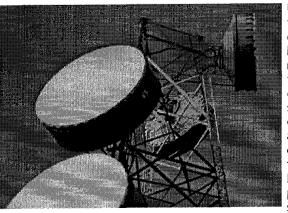
The FCC has never banned transmitters (of any type) from hospitals; providing that the equipment falls into FCC radiation flux level compliance.

There have been numerous discussions, meetings, publications, and suggestions regarding the use of portable communications equipment in the vicinity of medical equipment over the past 5 or so years. Most of these dealt with the early problems reported in electric wheelchairs, pacemakers, and anesthesia machines; which, due to inadequate shielding, malfunctioned briefly while exposed to EM interference (EMI).

In England, then NHS (National Health Service) issued report DB9702, Electromagnetic Compatibility of Medical Devices with Mobile Communications. In that 1997 report, only 4% of handheld transmitters (all types) cause any interference at a distance of one meter (3 feet). Based on that report, the agency recommended excluding those devices from "sensitive" areas (OR, ICU, telemetry units). Also, the study stated that, "The type of radio handset made a large difference to the likelihood of interference. At a distance of 1m; 41% of medical devices suffered interference from emergency services handsets, 35% suffered interference from security/porters handsets but only 4% from cellphones. No significant levels of interference were detected from cordless handsets/local area networks or cellular base stations." The report has not been updated.

Participants at the recent Health Canada medical devices roundtable reached several conclusions. They agreed that a total ban of radio-frequency transmitters in hospitals was not justified, and suggested susceptible equipment should be removed if the source of EMI cannot be controlled. They also recommended rational management of wireless telecommunication devices used in hospitals. (Janice Hamilton, "Electromagnetic interference can cause hospital

devices to malfunction, McGill group warns;" Canadian Medica Association Journal 1996; 154: 373-375).



Understand that a ban cell phones hospital ca not elimina the EMI constantly surrounding everything an urban centers, an fearing a backlash of public scrutiny ab

the issue; Cellular Telecommunications Industry Association, in conjunction with the FDA and FCC, and funded by a grant from Abbott, ran a series of studies (conducted by the University of Oklahoma); to determine what could be done about this problem. The studies concluded that better pre-market testing and more stringent shielding requirements are the answer to preventing EMI from causing medical equipment malfunction. The latest data indicate that concern, especially with newer P and spread-spectrum technologies, is overstated. Problems occurred with low frequency (0.6%), only with a small portion devices used today, and only at very close distances (6") from devices.

Medical devices in use today in our modern hospitals (this may not be true for some third world nations) have long since been upgraded to shield themselves from EMI that exists in the typic urban environment. Proof that this is the case can be found in the fact that many hospitals have lifted their cell phone bans, and some have even installed local area cellular networks for by their medical and nursing staffs.

Wireless is here to stay. We must abandon our false assumptio We need some well thought out scientific studies to debunk or prove the medical equipment EMI story. If wireless devices do interfere with delicate equipment in hospitals, then more stringent shielding requirements need to be adopted.

The following are some references:

Newest PCS phones don't interfere with medical equipment (portion follows)

As most TV sit-dram addicts know, things happen fast in hospit emergency rooms. Since a few seconds can make the differenc between life and death, decisions must be made "on the fly," a clear, fast communication is a must. But communicating with keeping track of staff and patients in an "ER" the size of Hennepin County Medical Center's 53,000-square-foot facility i no simple matter. With a number of "team centers" situated

throughout the department, "you can't just look down the hall and yell to somebody to help you," said Jan Duroche, assistant nurse manager in the department. Fortunately, HCMC greatly alleviated that concern last year when it joined the growing ranks of Twin Cities hospitals installing in-house cellular phone systems -- augmented by laptop computers and PCs -- to improve staff communication and enhance patient service.

Published in the 6 September 1994 FDA Medical Bulletin.

Therefore, FDA recommends that clinicians and other device users do the following:

- Be aware that EMI can cause steady, momentary, or intermittent disruption of the performance of medical devices.
- Follow the recommendations of the device manufacturer for avoiding EMI.
- Purchase equipment that conforms to EMC standards.
- Consider preventing known sources of interference (e.g., cellular phones, hand-held transceivers) from coming too close to patient monitors and other sensitive electronic medical devices.
- When an EMI problem is suspected, contact the device manufacturer for assistance. Local clinical engineers may also be able to assist in identifying and correcting the problem.
- Report device problems to FDA's MedWatch Program and note if the problem is believed to be linked to interference from a recognizable source of EM energy in the vicinity.

In perhaps the most complete report yet published by a US regulatory agency, the FDA explains in, "Medical Devices and EMI: the FDA Perspective," that it has worked, and will continue to work with various other agencies and industry groups to ensure that medical equipment is properly shielded against the constant barrage of EM energy they are subject to. There is no mention of a ban, or consideration for a ban, on EM sources (that comply with FCC criteria) in hospitals. Deputy Director of Science and Regulatory Policy for the US DHS, Phillip Phillips, reiterated this view in his memorandum dated 6/13/95.

The following are additional FDA references regarding EMI and medical equipment. Most date from 1994 and 1995:

Radiowaves May Interfere with Control of Powered Wheelchairs and Motorized Scooters. Food and Drug Administration (September 20, 1994). 4 pages.

Update on Cellular Phone Interference with Cardiac Pacemakers. Food and Drug Administration (November 1, 1995). 2 pages.

Williams, R.D. Keeping Medical Devices Safe from Electromagnetic Interference. FDA Consumer, Vol. 29, No.4 (May 1995), pp. 12-16.

Witters, D.M. Medical Devices and EMI: The FDA Perspective. ITEM Update (ISBN 1040-4716, 1995), pp. 22-32.

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