



TITLE: Wireless Device Use and Patient Monitoring Equipment in Any Healthcare Delivery Setting: A Review of Safety and Guidelines

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CONTEXT AND POLICY ISSUES

Wireless technologies are now accepted and widely used in both professional and personal capacities because of lower deployment costs and their ability to provide greater mobility, instant access to data, and increased efficiencies.¹ Clinicians benefit from wireless devices by being able to consult with other care providers, to quickly look up details from a library of resources, to access an electronic health record or other computerized system, or to view patient data. Wireless communication devices provide patients and visitors to healthcare facilities the ability to connect and continue participating in important relational aspects of their lives during the visit. Such conveniences make their stay a more positive experience.² However, there are downsides to the use of wireless devices in the healthcare environment that may pose potential threat to security breaches and patient safety.

The use of wireless devices such as smartphones or other mobile devices with cell-phone-like capabilities including tablet computers can compromise network security increasing the likelihood of inappropriate disclosure of protected health information. In addition, mobile computing devices increase the vulnerability of software to viruses and malware intended to create weaknesses in efficient functioning that can lead to mishandling of important updates, and to stealing patient data. Electromagnetic fields (EMF) and radio signals emanating from wireless devices generate electromagnetic fields which can disrupt the operations of other electronic devices.

The phenomenon where one piece of electrical equipment may interfere with the function of another piece of electrical equipment through transmitted signals is termed “electromagnetic interference” (EMI).³ Electromagnetic interference can alter both the normal operation of equipment and also the clinical signs recorded. Therefore, disruptions due to EMI could induce malfunction in medical equipment to various degrees, some with the potential to expose patients to unacceptable risk of harm. Additionally, equipment malfunction due to EMI could leave clinicians prone to make wrong diagnoses leading to wrong treatment. Additionally, time may be used attending to such malfunction which may distract from time needed for optimal patient

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care.³ Though there have been reported incidences, including ventilator malfunctions and over delivery of medication from infusion pumps, which indicate that serious health consequences could result from EMI-induced malfunction in medical equipment, some reports indicate that the number of clinically significant incidents of EMI from mobile devices is low.⁴ A survey conducted in 2013 reported an 8% (5 out of 63) incidence of EMI in medical devices, including non-serious incidences such as display monitor interference caused by a cell phone, which ceased when the phone was turned off.²

Considering the widespread use of wireless devices, including some for medical purposes, and their popularity among health care providers as well as patients and visitors to hospitals due to advantages previously discussed, this report aims to provide current evidence on the safe use of wireless devices in healthcare environments bearing in mind the possibilities of interference with equipment function which may compromise patient safety.

RESEARCH QUESTIONS

1. What is the evidence that wireless devices interfere with patient monitoring equipment in any healthcare delivery setting?
2. What is the evidence for the safe use of wireless devices when in the vicinity of patient monitoring equipment in any healthcare delivery setting?
3. What are the evidenced-based guidelines for the use of wireless devices in any healthcare delivery setting?

KEY FINDINGS

Interference occurs when devices operate in a shared radio spectrum which is congested. Medical equipment with designated frequencies within the radio spectrum not shared by commonly used wireless devices may be significantly protected from EMI induced by wireless devices. The likelihood of EMI in medical equipment due to wireless devices increases with increased transmitter powers, lower frequencies, and shorter distances between devices. Clinically significant interference in the functioning of medical equipment induced by wireless devices is rare and occurs at very short distances (mostly less than 3ft) between wireless devices and medical equipment. Policies to regulate wireless device used in highly instrumented areas in a healthcare environment could protect sensitive equipment from exposure to hazardous EMI.

METHODS

Literature Search Strategy

A focused search (with main concepts appearing in title, abstract or major subject heading) was conducted on key resources including PubMed, The Cochrane Library (2013, Issue 12), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2009 and December 5, 2013.

Selection Criteria and Methods

One researcher screened retrieved citations and abstracts to select titles for full-text article review. Full-text publications deemed to meet the selection criteria outlined in

Table 1 were included this review.

Table 1: Selection Criteria

Population	Patients in any health delivery setting (includes hospitals, long-term care facilities, clinics, etc.)
Intervention	Wireless devices (cell phones, smart phones, iPads, tablets, laptops, computers on wheels, walkie-talkies, Voice Over Internet Protocol [VOIP – which would require wireless internet throughout facility], call bells, wireless internet)
Comparator	None
Outcomes	Patient safety Interference with monitoring/patient care equipment Lack of interference Guidelines and recommendations
Study Designs	Health Technology Assessments (HTA)/ Systematic review (SR)/Meta-analysis (MA); Randomized controlled trials (RCTs); Non-randomized studies; and Guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria in

Table 1. Thus, studies confined to devices monitoring patient conditions outside a healthcare setting (e.g. implantable pacemakers, equipment in ambulance) were excluded. Other excluded studies were those published prior to 2009, duplicate publications of a study already selected, studies already included in at least one of the selected HTAs or systematic reviews, and articles in any language other than English.

Critical Appraisal of Individual Studies

The studies included in this report focused on the potential interference of wireless devices with medical equipment. By design, they do not have defined population groups or comparators. Therefore, evaluating them using the usual PICO (Patient or Population Intervention Comparison Outcome) approach is not feasible. For this reason, appraisal of studies was done with adaptations of sections of the SIGN 50 instruments^{5,6} that address reporting, external validity and propensity to bias considered appropriate by the appraiser. Appendix 3 provides summary of critical appraisal of the included studies.

SUMMARY OF EVIDENCE

Quantity of Research Available

One hundred citations and abstracts were identified through the search; of which 14 potentially relevant articles were selected for further evaluation. Two potentially significant articles were

added from grey literature. After examining the full-text articles, 12 articles were excluded because they were irrelevant to this report with regards to type of medical equipment (implantable or operated outside a healthcare setting), interventions, or outcomes. The remaining four articles used to prepare this report comprised one systematic review⁷ and three non-randomized controlled (prospective) studies.^{3,8,9} The PRISMA flow diagram in **Appendix 1** gives an overview of the study selection process.

Summary of Study Characteristics

Characteristics of included studies have been provided in Appendix 2.

Country of origin

The systematic review⁷ is from Spain and one each of the non-randomized controlled studies is from Italy,⁸ the United States of America,³ and Canada.⁹

Study setting

The systematic review⁷ did not provide an exact description of setting for each included study, but its first inclusion criterion was that the studies dealt with patients admitted to healthcare centers or hospitals, or taking a diagnostic test with health technology. The study from Italy⁸ tested devices in a room at the intensive care department in a hospital. In the study from the US,³ all equipment was tested in the environment (operating room, post-anesthesia unit, cardiac electrophysiology laboratory) where they were normally operated, with all other equipment not involved with testing turned off to minimize background noise. The study from Canada⁹ was done in an isolated room without metallic objects or operating electrical devices to avoid interference (absorption or reflection) from other sources.

Patient population

The systematic review⁷ did not provide details about patients in the included studies. One study⁹ tested the clinical impact of EMI induced by cellular phones on the interpretation of ECG for tachycardia, atrial flutter, ventricular paced rhythm with atrial fibrillation, and normal sinus rhythm. The study involved 93 participants (mean age of 34 ± 9 years) comprising 38 (41%) males and 53 (57%) females and 2 who did not declare their gender. No other patient characteristics were reported. Another study⁸ evaluated EMI effects on a variety of medical equipment including but not limited to defibrillators, lung ventilators, anesthetic machines and external pacemakers, using patient simulators/device testers specific for each device class, instead of actual patients. In a third study,³ some equipment (echocardiography, ultrasound, 12-lead electrocardiogram, or cardiac monitors) were connected to live subject while others such as infusion pumps were not. Patient information was not provided.

Interventions and comparators

Various forms of wireless devices were interventions of interest for this report. The systematic review⁷ used studies that tested a wide range of mobile devices including ultra-high frequency (UHF) radios, different kinds of mobile phones, and Bluetooth-enabled devices among others. The devices were operated on a broad range of transmission technologies including but not limited to code division multiple access (CDMA), general packet radio service (GPRS), global system for mobile communication (GSM), Terrestrial Trunked Radio (TETRA), universal mobile

telecommunications system (UMTS), wireless local area network (WLAN) and analog. One study⁹ tested cellular phones which used different transmission technologies (CDMA, GSM, UMTS, and analog); in-hospital cordless phones using WLAN; and an alpha-numeric pager. A second study⁸ aimed to determine the extent of interference with intensive care and operating equipment due to WiFi signals emitted by mobile terminals. A third study³ evaluated potential EMI of low frequency magnetic field-based auto-identification devices. This is a relatively newer form of auto identification device that uses low magnetic field output (ranging from 8 to 800 mgauss) instead of radio frequency (RF). None of the studies had comparators.

Outcome measure

All the studies had electromagnetic interference (EMI) with patients monitoring/care equipment as a general outcome of interest. Specific outcomes of interest for the systematic review⁷ were patient security and possible harmful effects, immunity and interferences on medical devices, as well as clinical effectiveness of the devices and transmission problems due to EMI in healthcare and hospital environments. One study⁸ had two types of EMI malfunction as outcomes; one with potential to impact basic patient or operator safety, and another which affects equipment performance and compromise its use for the purpose which was procured. Another study³ classified interference of interest into hazardous, significant, light, or no effect. Hazardous interference resulted in unintended change in equipment function with direct effect on patient outcomes. Examples include a total stoppage of care equipment or unexpected alteration in the parameters from initial settings. Substantial interference refers to a situation where changes in function of monitoring equipment occurred at a level requiring care givers to attend to it so frequently that it substantially distracts from patient care. An example of this is an incorrect alarm. Light interference results in deterioration of monitoring quality at a level which does not require significant level of attention and may not impact patient care. An example is display abnormality.³ For the third study,⁹ the impact on the interpretation of ECG due to artifacts produced by EMI from wireless communication devices was the specific outcome of interest.

Summary of Critical Appraisal

Further details of summary of critical appraisal of individual studies are provided in **Appendix 3**.

Systematic Review

The systematic review⁷ was based on extensive literature search involving multiple electronic databases, manual searches in journals and grey literature sources and covering a 10-year period in three languages; Spanish, English and French. Two investigators selected papers and extracted data according to clearly defined inclusion and exclusion criteria using consensus procedure to avoid bias. A list of included studies detailing relevant characteristics such as number of interferences, specific effects, the technologies involved and distances between equipment was provided. However, a list of excluded studies was not given, and there is no statement acknowledging sources of support or about conflict of interest. Investigators assessed the quality of the studies following the recommendations of the Spanish Healthcare Technology Evaluation Agency accessed in January 2009.⁷ To make up for the paucity of literature on the subjects of research interest, the authors of the systematic review⁷ imposed no restrictions on the quality of design of included studies. The authors reported that evaluating methodological quality of the studies was a very difficult task because of their heterogeneity; the partial coverage of the subject matter by most of the papers; and the sample size not being large enough in some cases.

Non-randomized studies

Reporting

Each of the three prospective studies used in this report clearly described the objectives, main study outcomes to be measured, medical devices and interventions of interest. Two of the studies reported using statistical analysis. One study,³ used an independent value *t*-test to determine if a significant difference was present in magnetic field strength between devices for the various classifications of observed EMI. In another study,⁹ data was analyzed with SPSS and assessed for effect on position and age using chi-square tests and an independent samples *t*-test but there is no discussion in the paper about the significance of such a treatment. None of the studies reported adverse events on patients that may have been a consequence of the applied intervention.

External validity

One study⁹ tested EMI induced by of emissions from mobile phones and pagers using different kinds of transmission technology (GSM, CDMA, and analog) on three different makes of ECG machine. The technologies embody different generations of commonly used wireless communication devices so that finding from this study is likely to be representative of potential interaction between similar devices and the types of ECG machines tested. However, the study was conducted in a room without any operational electronic equipment, so it is uncertain how reproducible the findings will be in a hospital location where other equipment may be operated simultaneously.

Another study⁸ determined the extent of electromagnetic interference in intensive care and operating room equipment caused by WiFi signals emitted by mobile terminals, in an environment similar to actual operating settings of the equipment. The devices were connected to specific simulators/testers to ensure proper functioning and to monitor the device performance when exposed to the WiFi signal. The simulation makes it likely that findings are generalizable to equipment including ventilators, infusion and enteral pumps as well as anesthetic machines, which are widely found in many intensive care and operating room settings.

A third study³ evaluated interaction between the EMF induced by a wireless auto-identification device and a wide range of medical equipment commonly used medical equipment such as cardiac monitors, electrocardiographic machines, intravenous pumps, and also high technology medical equipment such as electrophysiology ablation devices, fluoroscopy, echocardiographic machines. Effects on laboratory analysis devices were assessed making the scope of medical devices tested wide enough to be representative of those used in many hospital settings. However, EMI testing was performed in most cases without a patient connected, though the device turned on. In this sense it is uncertain whether the finding would be replicated when the medical equipment are operational with patients connected.

Internal validity

All the studies^{8,9,9} performed multiple runs of each test to ensure that results were not due to chance. Two of the studies^{3,8} reported that tests protocols were based on American National Standard Institute guideline-ANSI C63.18, the appraisal of which is beyond the scope of this report because of its technical nature. In one study,⁸ tests were repeated by two operators with

no inter-operator differences observed. In another study,³ two clinicians independently reviewed all the events to determine the classification of the EMI to eliminate bias. As part of the protocol, a third clinician would be asked to adjudicate in cases of disagreement on the classification. The authors reported that the majority of devices tested were without a simulator or live subject connected, though they were switched on.³

A third study⁹ performed tests in an isolated room without any metallic objects or operating electrical devices to ensure that generated electromagnetic radiation was not absorbed or reflected by other objects and that observed EMI was not due to devices other than those being tested. However, this step also calls into question the generalizability of the study findings since medical equipment is not normally operated in such isolation in healthcare environments. Electrocardiographs were interpreted by 21 medical students, 27 registered nurses and ECG technicians, 7 industry representatives, 14 cardiology residents, 18 non-cardiology residents, and 6 attending cardiologists. All the groups, except the attending cardiologists, registered various levels of incorrect interpretation of the ECG which occurred as a result of artifacts produced by the EMI.

Funding Support

One study⁸ acknowledged partial funding support by the Italian Ministry of Health and by the S. Andrea Hospital in Rome. This support does not seem likely to influence the reported findings. Another study³ reported that a person who was involved in the collection of data, providing manuscript support for technical details, including reviewing the final manuscript to verify technical information, was an employee of the manufacturer of the tested wireless device. According to the authors, there was no funding source for the study.³

Summary of Findings

Rapid Response reports are organized so that the evidence for each research question is presented separately. Further details on individual study findings and authors' conclusions have been provided in **Appendix 4**

1. *What is the evidence that wireless devices interfere with patient monitoring equipment in any healthcare delivery setting?*

The systematic review⁷ reported findings of EMI in several medical devices caused by different kinds of wireless devices operating on a variety of transmission technologies including, Bluetooth, CDMA, GSM, TDMA, and UMTS devices. Interferences manifested in several ways including noises, screen distortions, false alarms, complete stoppages, and malfunctions in output parameters. Medical devices tested included defibrillators, ventilators, brain stimulators, pumps and ophthalmic equipment. Though interference occurred in seven (44%) of 16 devices tested, the incidence of clinically important interference was reported as 1.2% of 510 tests performed.⁷

One study⁸ evaluating EMI due to WiFi signals from wireless devices found that even though various levels of EMI were recorded, they did not pose significant risk to life supporting medical devices. Two devices (an enteral pump and an external defibrillator) out of a total of 45 were affected to such an extent that there may have been clinical consequences to the patient.⁸ Another study³ found that 8 out of 32 tested medical devices encountered EMI at some time during testing for interaction with a wireless auto-identifier. Two of the observed EMIs were

described as hazardous and involved two 12-lead ECG machines. Five significant interferences involving an anesthesia monitor, two echocardiogram/ultrasound machines, and the two 12-lead ECG machines occurred. Light interferences were reported in a defibrillator, an anesthesia monitor, the two echocardiogram/ultrasound machines, and the two 12-lead ECG machines. A third study⁹ found wireless phones operating on GSM, CDMA and analog technologies, induced EMI in a MAC 5000 ECG machine resulting in artifacts on ECG records which led to incorrect diagnosis in 18% of cases.

2. *What is the evidence for the safe use of wireless devices when in the vicinity of patient monitoring equipment in any healthcare delivery setting?*

The systematic review⁷ reported EMI in various medical equipment with distances between the equipment and the offending devices ranging from 2cm to 400cm for different episodes. The widest variation of distance (1-400cm) was recorded for interference noise induced in an ultrasonic device by a group of wireless devices using different transmission technologies (lumped together as GPRS, UMTS, and WLAN) in one of the included studies. Apart from this, the longest distances of interference seemed to be associated more often with devices using the TETRA technology. A trend in the sensitivity of medical equipment to induce EMI by the wireless devices was not apparent.

Interferences were recorded in one study⁸ when two pieces of medical equipment (an enteral pump and an external defibrillator) were operated at a very close distance (less than 5 cm) from WiFi terminals. In another study³ all observed interferences occurred within 3ft of separating distance between devices, except in a case involving a 12-lead ECG machines where EMI described as light interference occurred at a distance greater 3ft but less at 5 feet. Light interference also occurred in a fluoroscopy machine in direct contact with the wireless device, as well as an anesthesia monitor (a foot away), 2 echocardiogram/ultrasound machines (one at 2ft and the other at 3ft away), and another 12-lead ECG machines at 3ft away. In the same study, hazardous interference occurred in two 12-lead ECG machines (same mentioned above) placed a foot away from the wireless device, while significant interferences occurred in an anesthetic monitor and an echocardiogram/ultrasound machine placed in direct contact with the wireless device, and another echocardiogram/ultrasound machine and the two 12-lead ECG machines at a foot and 2ft away, respectively from the wireless source.³ A third study⁹ reported EMI in an ECG machine due to emissions from mobile phones when the phones were activated in direct contact (on top of) the machine's acquisition module.

3. *What are the evidenced-based guidelines for the use of wireless devices in any healthcare delivery setting?*

There were no evidenced-based guidelines found from the literature search conducted for this report.

Limitations

In the absence of a validated tool for appraising the types of studies included, evaluation of included studies has been done with adaptations of sections of SIGN 50 instrument considered by one researcher to be relevant. Also, for all the studies, it is unclear how identified electromagnetic interference may extend to medical equipment not included in the tests. Furthermore, there is ongoing advancement in technology employed in medical devices as well as steady proliferation of wireless devices leading to introduction of a variety of phones, tablets

and other mobile devices. It is uncertain which of these more “advanced” devices and medical equipment are immune/susceptible to, or are sources for interference without prior inspection.

The quality of the individual included studies in the systematic review⁷ is not clearly reported though the authors stated that “most of the papers included cover the subject matter only partially, and in some of the cases, the sample size was not large enough.”⁷ The authors also reported that though they assessed the quality of the included studies, restrictions were not imposed based on the quality. One is unable to tell what proportion of included studies was of high or low quality and the extent to which this impacts the applicability of the findings.

One of the studies⁸ listed changes in the radio frequency (RF) output characteristics of the RF transmitter, antenna type and orientation with respect to the medical devices, ambient RF fields, reflection and absorption of RF energy by people and objects in the test area, small changes in cable placement, and the relative positions of the RF source and the medical device as limitations that can introduce some variability in the test results. The study³ testing interference due to wireless auto-identification devices on medical equipment is limited because only one such device was used for testing.

Since the study⁹ testing EMI induced in ECG machines by cellular phone signals was performed in an isolated room without metallic objects or any operational electrical devices, findings may not represent the whole story because in a normal operating environment where several devices may be turned on simultaneously, far more complex interactions may occur between devices.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

Electromagnetic interferences were reported to occur in medical devices in all the studies used in this report. Though all radio frequency (RF) transmitting devices generate electromagnetic fields (EMF),⁴ factors that determine whether electromagnetic interference would occur include the susceptibility of the medical equipment to the EMI as a result of shared frequency, the power of the signal being transmitted from the wireless device, and the distance between the two devices. All the clinically important interferences reported occurred when distance between wireless devices and medical equipment was short, except in only one case in which interference occurred beyond 3ft. Hospitals can work with experts to select equipment that are less predisposed to EMI induced by commonly used wireless devices. They can also develop frequency/device inventories to function both as a baseline to determine what is already available in the hospital, and for use as a tool to track new device acquisitions.¹ In view of the potential for disruptions with hazardous consequences, despite the reportedly low incidence of clinically significant interference with medical equipment, it would be beneficial to fashion policies to regulate wireless device use in highly instrumented areas in healthcare environments while clinicians, patients and visitors take advantage of wireless devices to benefit profession practice and improved convenience.

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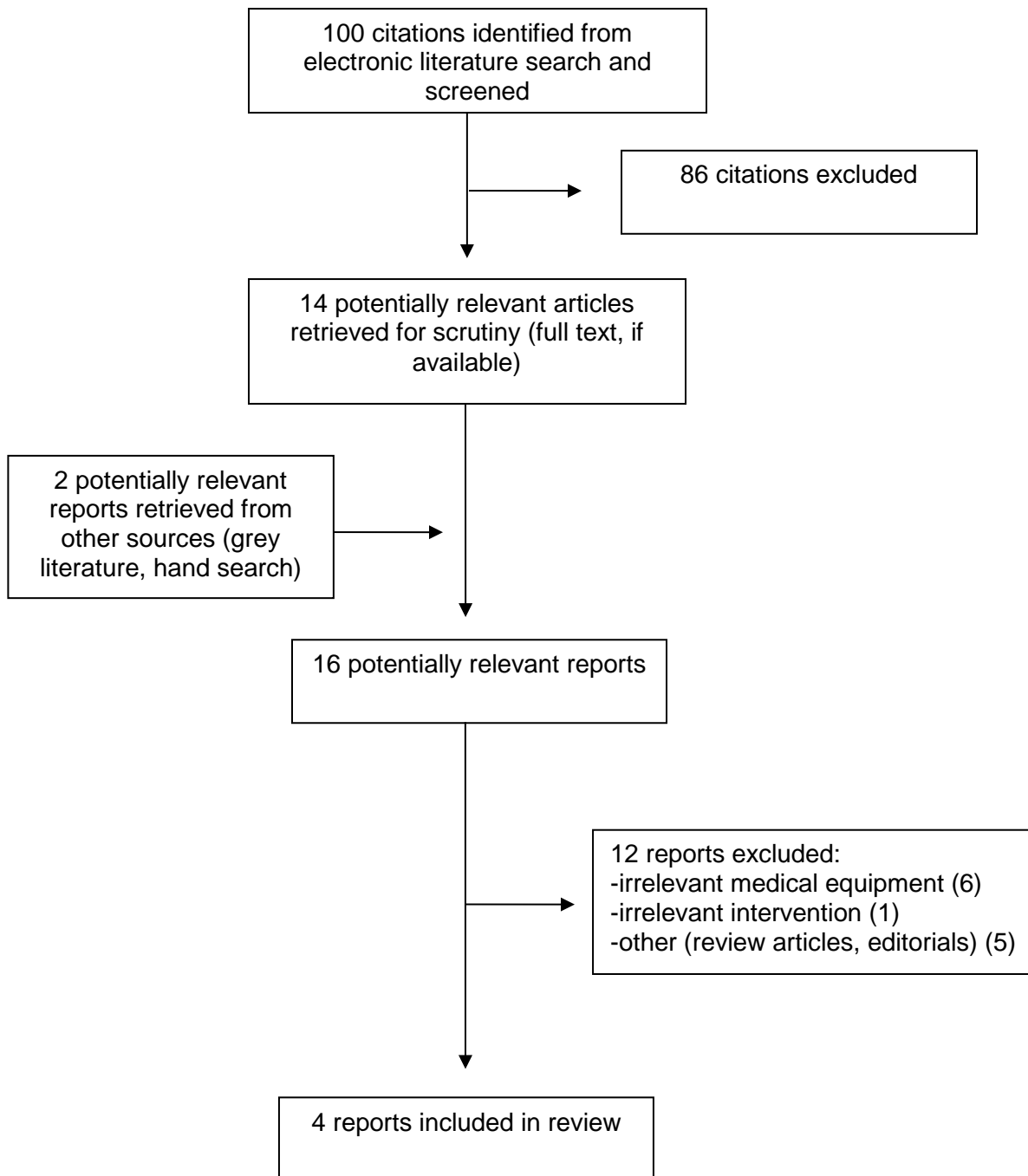
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Appendix 1: Selection of included studies



Appendix 2: Characteristics of included studies

First Author, Publication year, Country	Study Design	Medical Equipment	Wireless technology	Comparator	Outcome Measure
Carranza, ⁷ 2011 Spain	Systematic review	Defibrillators; ventilators; brain stimulators; pumps; ophthalmic equipment and pacemakers	Mobile phones and cell phone-like devices operating on various technologies including but not limited to GSM, CDMA, WLAN, TACS, TDMA, GPRS; and UMTS.	None	Patient security; harmful effects; immunity and interferences on medical devices; and effectiveness and transmission problems caused by interferences on medical devices due to radiofrequency fields
Baranchuk, ⁹ 2009 Canada	Non-Randomized study	ECG machines: MAC 5000; MAC 1200; and ELI 100	Wireless communication devices operating on GSM, CDMA, and WLAN technologies; analogue phone; and alpha-numeric pager.	None	Electromagnetic interference with interpretation of electrocardiographs (ECGs)
Calcagnini, ⁸ 2011 Italy	Non-Randomized study	Infusion pumps; defibrillators, monitors; lung ventilators; anesthesia machines; and external pacemakers	WiFi signals emitted by mobile terminals	None	Levels of electromagnetic Interference with various medical equipment
Kapa, ³ 2011 USA	Non-Randomized study	Cardiac monitors, ECG machines, intravenous pumps, electrophysiology ablation devices, fluoroscopy, echocardiographic machines, and laboratory analysis devices.	Wireless auto-identification device	None	Electromagnetic interference with various medical equipment

CDMA = Code division multiple access, ECG= electrocardiograph, GPRS = General pocket radio service, GSM = Global system for mobile communication, RF = radio frequency, RFID = radio frequency identification, TACS = Total access communication system, UMTS = Universal mobile telecommunications system. WiFi = wireless fidelity, WLAN = wireless local area network.

Appendix 3: Summary of critical appraisal of included studies

First Author, Year	Strengths	Limitations
Carranza, ⁷ 2011	<ul style="list-style-type: none"> • Systematic literature search covering a broad scope of sources, in three major languages (English, Spanish and French), and spanning a period of ten years. • Addressed several wireless technology including GSM, GPRS, UMTS, WiFi, and Bluetooth. • Study selection was done by two authors, with a third investigator in case of non-consensus. 	<ul style="list-style-type: none"> • Though it was reported that quality of included studies was assessed with specifically designed questionnaire following the recommendations of the Spanish Healthcare Evaluation Agency (January 2009), grades of individual studies in this regard is not provided to clarify which studies scored “low” and which scored “high”. • According to the authors, “most of the papers included cover the subject matter only partially, and in some of the cases, the sample size was not large enough.”⁷ pg. 536 and • The authors stated that the methodological quality of studies has been a very difficult to evaluate because of the heterogeneity of included papers.
Baranchuk, ⁹ 2009	<ul style="list-style-type: none"> • Cellular phones using currently commonly used technologies (GSM and CDMA) as well as the older analog phones and alpha-numeric pager were tested. In this sense, applicability of findings may span several generations of cellular phones, and pager that are commonly used in some hospitals. • Performing the test in an isolated environment removes possible confounders to findings allowing unusual observation to be attributed to the EMI due to emissions from the wireless devices. • There was complete agreement between two blinded investigators concerning cases of EMI detected (3) among reviewed ECGs (150). 	<ul style="list-style-type: none"> • Study protocol was limited to ringing phase of mobile phones only. Though this phase is reported to have a higher probability of inducing EMI, evaluating other operational phases such as speech and data transmission may have presented a more holistic picture. • Only ECG machines were tested in the study. Therefore, application of findings to other medical equipment liable to EMI from wireless devices is unclear. • The study was conducted in isolated room without metallic objects and no operating electrical device. Thus, it is uncertain how reproducible the finding of these studies would be in an actual healthcare environment.
Calcagnini, ⁸ 2011	<ul style="list-style-type: none"> • Each medical equipment was configured with parameters used in the clinical routine and checked for normal operation with specific patient simulator/device tester to ensure proper functioning and to monitor the device performance when exposed to the wireless 	<ul style="list-style-type: none"> • Findings of the study are subject to variability due to changes in the RF output characteristics of the RF transmitter, antenna type and orientation with respect to the medical devices, ambient RF fields, reflection and absorption of RF energy by people and objects in the test area, small

First Author, Year	Strengths	Limitations
	<p>fidelity (WiFi) signal.</p> <ul style="list-style-type: none"> • Two operators repeated the tests with various adapters and types of antennas to increase robustness in the case of negative tests, as well as the recommended distances in case of EMI. • All the devices tested met European Union (EU) safety requirements by complying with the relevant international standards. 	<p>changes in cable placement, and the relative positions of the RF source and the medical device.</p>
Kapa, ³ 2011	<ul style="list-style-type: none"> • Two clinicians independently reviewed all the events to determine the classification of the EMI and in cases of disagreement on the classification, a third clinician adjudicated. 	<ul style="list-style-type: none"> • Did not test how the presence of multiple RFID tags or operation of multiple different pieces of medical equipment may affect EMI. • Only one set of chips for the wireless device was tested so it is not clear if finding of this study extend to other low-frequency or magnetic-field based devices. • It is unclear whether medical equipment not included in the study would experience similar EMI as identified.

CDMA = Code division multiple access, ECG= electrocardiograph, GPRS = General pocket radio service, GSM = Global system for mobile communication, RF = radio frequency, RFID = radio frequency identification, TACS = Total access communication system, UMTS = Universal mobile telecommunications system. WiFi = wireless fidelity, WLAN = wireless local area network.

Appendix 4: Main study findings and authors' conclusions

First Author, Publication Year	Main Study Findings	Authors' Conclusions
<p>Carranza,⁷ 2011</p>	<ul style="list-style-type: none"> • A wireless arterial blood pressure biomedical sensor with Bluetooth wireless transmission of signals did not interfere with biomedical devices used in the operating room or vice versa. (the actual devices were not specified) • Several wireless technologies including , Bluetooth, CDMA, GSM,TDMA, and UMTS devices induced EMI in medical equipment in hospital including the following <ol style="list-style-type: none"> 1. Serious interferences occurred in three of four apnea monitors tested; 2. Multitude interferences with ventilators; including minor cases such as bad screen readings, and more serious occurrences such as increasing the frequency or stopping the equipment were reported to be caused by; 3. Several cases of interferences with pumps, most of which caused the pumps to stop; and 4. Vital sign monitoring, EEG analyzers and ultrasound devices were reported to exhibit minor effects such as noise due to EMI 	<p>“From the studies collected, it can be concluded that several cases of serious interferences in medical instruments have been reported. Measures of electromagnetic fields in healthcare environments have been reported, concluding that special protective measures should be taken against electromagnetic interferences by incoming radio waves.”⁷ pg. 540</p>
<p>Baranchuk,⁹ 2009</p>	<ul style="list-style-type: none"> • MAC 5000 ECG machine with an external acquisition module was vulnerable to radio frequency (RF) emissions from all tested cellular phones when placed in close proximity (on top of) to the external acquisition module. The other ECG machines (Mac 1200, and ELI 100) were immune to the RF emission produced by the phones. • At distances of 2m, 1m, 0.5m. and 0.25m; no EMI was detected and normal ECGs recordings were obtained. • The effects of emissions from CDMA cellular phone were qualitatively more pronounced than those of GSM or analog cellular phones. • Incidence of EMI was low (2%), 	<p>“Communication devices (mobile phones) produce EMI on ECG machines. This occurs when cellular phones are activated in direct contact to the acquisition module. EMI is not well recognized during ECG interpretation and is frequently misdiagnosed as other serious conditions. This misinterpretation may result in preventable medical error”⁹ pgs. 591-592</p>

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	<p>comprising only artifact in the ECG recording.</p> <ul style="list-style-type: none"> • Presence of artifact impaired proper interpretation of ECG in 50 (18%) out of a total of 279 cases among all healthcare professionals and industry representatives involved in the study, except the attending cardiologists. 	
<p>Calcagnini,⁸ 2011</p>	<ul style="list-style-type: none"> • According to the authors, the main finding of this study is that WiFi terminals operating at 2.45 GHz, 100 mW, do not pose significant risks of EMI to life-supporting medical devices. • Three cases of EMI malfunctions; involving one enteral pump, one external defibrillator, and one monitor, were detected out of 45 devices tested. • The maximum distance at which EMI affected the basic safety of the devices was 3 cm; the maximum distance at which EMI affected the performance of the devices was 5 cm. • Malfunction with potential to impact the basic patient safety were stoppage of infusion by enteral pump provoked by a WiFi adapters were operated in contact with or up to 2cm from the device; and the induction of a defibrillator to lose synchronization with the QRS complexes and deliver the shock with random timing, which was provoked by a WiFi adapter at 3cm. • Function was restored to defibrillator when WiFi signal was removed, but the pump blockade persisted even after switching of the WiFi signal. Normal operation with the programmed parameters was restored by turning the pump off and then on. • Malfunction involved a monitor emitting sound when adapters were operated within 5 cm. 	<p>"These tests show that WiFi adapters operating at 2.45 GHz, 100 mW, do not pose a significant risk of EMI to life-supporting medical devices, providing that they are not operated in close proximity (less than 10 cm) to the medical devices."⁸ pg. 500</p>
<p>Kapa,³ 2011</p>	<ul style="list-style-type: none"> • Out of 32 devices tested, 8 (25%) encountered EMI at some time during testing. • Signal fidelity was maintained without any loss at antenna distances up to 17 feet away 	<p>Magnetic field-based auto-identification technology using a low-frequency may provide an alternative to higher frequency RFID-based technologies in healthcare settings. "However, the potential for light to</p>

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	<p>from the tag, and all EMI was distance-dependent without any interference seen at distances beyond 4 feet.</p> <ul style="list-style-type: none"> • Of the EMI seen, 2 experienced hazardous interference (defined as unintended change in equipment function with direct effect on patient outcome), 3 experienced significant interference (influence on monitoring with significant level of attention needed causing substantial distraction from patient care), and 3 experienced light interference (influence on monitoring without significant level of attention needed). • Only one device experienced interference at a distance greater than 3 feet away, however, no EMI was noted for this device at 5 feet. • All EMI incidents occurred with the magnetic field emitted by the antenna/laser of the auto identifier when activated. No interference was seen with the tags even when they were connected to the devices; and EMI did not occur when auto-identifier antenna/laser was "off." 	<p>hazardous EMI at close distances to the patient or medical equipment raises the importance of implementing these technologies with consideration for EMI in mind. The fact that interference occurred at magnetic field strengths that would normally be considered quite low (~400–500 mgauss) raises the issue that with any novel technology, device-specific care must be taken in understanding how the novel technology may interact with the function of existing devices.”³ pg. 248-249</p>

CDMA = Code division multiple access, ECG= electrocardiograph, GPRS = General pocket radio service, GSM = Global system for mobile communication, RF = radio frequency, RFID = radio frequency identification, TACS = Total access communication system, UMTS = Universal mobile telecommunications system. WiFi = wireless fidelity, WLAN = wireless local area network.