

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

**DATE:** 18 August, 2016

**CONTEXT AND POLICY ISSUES**

Wireless communication devices such as smartphones allow health care professionals to collect data and communicate more efficiently and to facilitate clinical decision making to improve care delivery.<sup>1</sup> Patients and hospital visitors use wireless devices to communicate with their relatives and friends, and to engage in other activities that can improve their quality of life.<sup>2-4</sup>

However, wireless communication devices emit electromagnetic radiation which can interfere with the proper functioning of electrical medical devices in healthcare settings. Electromagnetic interference (EMI) can induce susceptible medical devices to malfunction resulting in complete stoppages, inaccurate measurements, or disruptions on monitors.<sup>2</sup> Thus the effect of EMI on medical devices could potentially affect diagnosis leading to improper treatment, and increase the risk of sub-optimal and/or adverse outcomes for patients receiving care through automated medical equipment.<sup>2</sup>

The International Electrotechnical Commission (IEC) has provided technical standards (EN60601-1-2) to increase the level of immunity and improve the electromagnetic compatibility (EMC) of non-critical care and critical care medical equipment.<sup>5</sup> EMC refers to a status in which two or more instruments operate normally without receiving EMI mutually when one or all of them emit electromagnetic fields.<sup>4</sup> In 2013, the United States Food and Drug Administration (FDA) issued a guidance document to assist industry and FDA staff in identifying and appropriately addressing specific considerations related to the incorporation and integration of radio frequency wireless technology in medical devices. The document considered the selection of wireless technology, quality of service, coexistence, security, and EMC, which can have an effect on the safe and effective use of medical devices.<sup>6</sup>

In addition to the contributions of standards and guidance such as those issued by the IEC and FDA to increase the EMC of medical devices, the rapid advancement in the technology for wireless communication devices has mitigated their potential to induce EMI in medical devices.<sup>2,3</sup> For instance, the electric field output intensity was in the order of 2.0 W and 0.8 W for the analogue and second-generation (2G) mobile phones, respectively; but has decreased to

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0.25 W in third-generation (3G) cellular phones.<sup>3</sup> Therefore, 3G phones are less likely to induce EMI than 2G or analogue phones.<sup>2,3</sup>

With the changing electromagnetic environment, there has been the need to review dated restrictions on the use of mobile phone and other wireless devices in hospitals towards providing a reasonable assurance of safety and effectiveness for medical devices, without denying healthcare providers and patients the benefit of using wireless devices to improve care delivery, convenience, and patients' quality of life. In 2014, CADTH produced a Rapid Response report on the safe use of wireless devices in healthcare setting.<sup>7</sup> A summary of the findings of that report is provided in Appendix 6. This review aims to summarize additional evidence and guidelines since the previous report was produced to support policy on the safe use of wireless devices in healthcare delivery settings.

## **RESEARCH QUESTIONS**

1. What is the evidence that wireless devices interfere with medical equipment in any healthcare delivery setting?
2. What is the evidence for the safe use of wireless devices when in the vicinity of medical 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**

One systematic review<sup>2</sup> and one guideline<sup>4</sup> reported that although rare, wireless communication devices can cause electromagnetic interference (EMI) which can affect the functioning of a wide variety of medical electrical equipment. The guideline<sup>4</sup> recommends a separation distance of one meter between wireless communication devices and medical electrical equipment to prevent interruptions caused by EMI. However, hospitals can set a lower separation distance if they confirmed safety based on their own test results, manufacturer instructions for specific medical equipment, and other sources. To maintain a favorable electromagnetic compatibility environment (EMC), hospitals were advised to assign an EMC manager to work in collaboration with other departments to address EMC issues. The guideline<sup>4</sup> recommends against the use of mobile handsets in areas such as operation rooms, intensive care units (ICUs), laboratories, treatment rooms, etc., which normally have sensitive medical equipment; and against placing a wireless communication device on a medical electrical equipment as it may greatly interfere with the operation of the equipment.

## **METHODS**

### **Literature Search Methods**

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. To address research questions one and two, no filters were applied to limit the retrieval by study type. To address research question three, methodological filters were applied to limit

retrieval to health technology assessments, systematic reviews, meta-analyses, and evidence-based guidelines. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2013, and July 20, 2016.

Rapid Response reports are organized so that the evidence for each research question is presented separately.

### Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

<b>Table 1: Selection Criteria</b>	
<b>Population</b>	Patients in any health care delivery setting (hospital, intensive care unit, long-term care, outpatient clinics, other clinics, etc.)
<b>Intervention</b>	Wireless and mobile devices (cell phones, smart phones, iPads, tablets, laptops, computers with wireless capabilities, two-way radios, voice-over-internet-protocol, call bells, wireless internet)
<b>Comparator</b>	<ul style="list-style-type: none"> <li>• No wireless/mobile device use,</li> <li>• Ban on the use,</li> <li>• No active comparator</li> </ul>
<b>Outcomes</b>	<ul style="list-style-type: none"> <li>• Patient Safety</li> <li>• Interference or lack of interference with equipment (including range at which interference occurs)</li> <li>• Guidelines and recommendations regarding the use of wireless and mobile devices</li> </ul>
<b>Study Designs</b>	Health technology assessments, Systematic Reviews and/or /Meta-Analyses, Randomized Controlled Trials, Non-Randomized Studies, Evidence-based guidelines.

### Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, a case report, or were published prior to 2013.

### Critical Appraisal of Individual Studies

The included systematic review<sup>2</sup> was critically appraised using the AMSTAR checklist<sup>8</sup>, and the evidence-based guideline<sup>4</sup> was assessed using the AGREE II instrument.<sup>9</sup> Summary scores were not calculated; rather, a review of the strengths and limitations of the systematic review<sup>2</sup> and the evidence-based guideline<sup>4</sup> were described narratively. The strengths and limitations of the individual reports are summarized in Appendix 3.

## SUMMARY OF EVIDENCE

### Quantity of Research Available

A total of 585 citations were identified in the literature search. Following the screening of titles and abstracts, 579 citations were excluded and six potentially relevant reports from the electronic search were retrieved for full-text review. Seven potentially relevant publications were retrieved from the grey literature search. Of these 13 potentially relevant articles, 11 publications were excluded for various reasons, while two publications met the inclusion criteria and were included in this report. Appendix 1 describes the PRISMA flowchart of the study selection.

Additional references of potential interest are provided in Appendix 5.

### Summary of Study Characteristics

#### *Study Design*

One systematic review<sup>2</sup> and one evidence-based guideline<sup>4</sup> were included in this review. The systematic review<sup>2</sup> was authored by Mariappan et al., and was published in 2016. It included 23 primary studies published from 2000 to 2016. The guideline<sup>4</sup> was developed by the Electromagnetic Compatibility Conference Japan (ECCJ) and was published in 2014. Sources of evidence for its recommendations included an experiment using actual equipment, which was conducted to support the development of the guideline, Japanese industrial standards for electromagnetic compatibility of medical electrical equipment (JIS T 0601-1-2:2012), and the international standards.<sup>5,10</sup>

#### *Country of Origin*

The systematic review was authored by investigators from Egypt, India, and the United Kingdom, and the guideline was developed in Japan, under the sponsorship of the Electromagnetic Compatibility Conference Japan.

#### *Patient Population*

Patient characteristics were not provided by either the systematic review<sup>2</sup> or the guideline.<sup>4</sup> Both were focused on interactions between wireless communication devices and medical electrical equipment. The systematic review<sup>2</sup> included primary studies that assessed EMI in automatic external defibrillators (AEDs), cardiopulmonary/cardiovascular devices, infusion pumps, ventilators, and what the authors described as critical care devices or multiple devices. Although primary studies with implantable devices were included, this report focuses on externally situated devices at healthcare locations. The medical equipment of particular concern in the guideline<sup>4</sup> included general-purpose infusion pumps, syringe pumps, blood purifiers, external pacemakers, artificial ventilators, balloon pump driving apparatuses for auxiliary circulation, percutaneous cardiopulmonary driving apparatuses, auxiliary heart driving apparatuses, and closed circuit stationary infant incubators.<sup>4</sup>

#### *Interventions and Comparators*

Mariappan et al.,<sup>2</sup> investigated mobile phone induced EMI in medical equipment, reporting outcomes mainly for 2G and 3G phones. They included a study which analyzed the EMI

between medical equipment and personal handy-phone system (PHS) handsets, and a case study which assessed EMI effect of 4G Long Term Evolution (LTE) phone on implantable cardioverters.<sup>2</sup> No details were given about the experiments conducted to guide the development of the guideline.<sup>4</sup> Therefore, the specific generation(s) of mobile phones and types of wireless devices that were tested is uncertain, although they did not include analogue and 2G phones which had been abolished in Japan.<sup>3</sup>

### *Outcomes*

The outcome of interest in both the systematic review<sup>2</sup> and the guideline<sup>4</sup> was EMI between wireless communication devices and medical electrical equipment. While Mariappan et al.<sup>2</sup> reported occurrence of cellular phone-induced EMI in various medical equipment, the guideline<sup>4</sup> recommended a proper separation distance between wireless devices and medical equipment. In addition, the guideline<sup>4</sup> has recommendations for protecting personal and medical information, continual improvement of EMC of medical equipment, and some restriction on the manner of use of mobile handsets in shared places to minimize disturbing patients.

## **Summary of Critical Appraisal**

### ***Systematic Review***

The systematic review<sup>2</sup> was based on literature search involving multiple electronic databases and grey literature sources. The literature selection was limited to articles in English language which assessed EMI between cellular phones and critical care devices as well as monitoring devices. The inclusion and exclusion criteria were not reported, and the time period within which research publications were considered was not stated. However, the included primary studies were published between years 2000 and 2016. The method of study selection and dispute resolution was not reported, and the methodological quality of the included studies was not assessed. A list of included studies was provided with characteristics, but a list of excluded studies was not given. The authors declared no conflict of interest.

In general, the reporting of outcomes was not adequately done. For example, the occurrence of EMIs between cellular phones and medical equipment were reported without specifying the nature of the interference and/or the separation distance between the devices. Further, despite the reported EMIs in the primary studies, the conclusions of the systematic review<sup>2</sup> was dismissive of the importance of the interferences in the functioning of medical devices, citing rapidly improving technologies for both cellular phones and medical equipment, as well as a lack of statistical data on the frequency of adverse events across the healthcare system. Therefore, the conclusions were not reflective of the included primary studies. Overall, the quality of the systematic review<sup>2</sup> was poor.

### ***Evidence-based Guidelines***

The guideline<sup>4</sup> was developed to replace an older version which encouraged a ban on all use of mobile phones in hospitals, except in areas specially designated by the hospital.<sup>3,4</sup> Thus, the targeted users were hospitals. According to the authors, the change was necessary in view of the drastic changes in pertinent circumstances, such as the widespread use of mobile phones in daily life, the eradication of 2G mobile-phone services, and the improvement in EMC of medical electrical equipment.<sup>4</sup> In addition, the use of wireless devices was expected to improve efficiencies in healthcare delivery, increase conveniences, and augment patients' quality of life.<sup>4</sup>



The guideline<sup>4</sup> was developed by an expert committee of stakeholders, consisting of academic experts, staff from the Ministries of Internal Affairs and Communication; Ministry of Health; Labor and Welfare, a mobile phone business operator; a medical device manufacturer, and a hospital administrator.<sup>3</sup>

The recommendations of the guideline<sup>4</sup> are specific and unambiguous, with a clearly defined separation distance between wireless communication and medical devices, as well as area-specific recommendations. Measures to promote applicability of the guideline<sup>4</sup> include recommendation to assigning individuals to manage EMC environment, collection of information, considerations for procurement of wireless and medical devices, and implementation; among others.

However, it is unknown whether the guideline<sup>4</sup> was externally reviewed by experts prior to its publication. Further, a procedure for updating the guidelines was not provided and there was no information about the competing interests of the members of the expert committee which developed the guideline.

A potential limitation of the guideline is that the targeted users are hospitals in Japan required to use medical equipment which is compliant with Japanese standards. In addition, wireless communication devices considered for the development of the guideline<sup>4</sup> were those which met the requirements of the wireless access standards in Japan. These standards may not be the same as those in Canada. Therefore, the generalizability of the recommendations of the guideline<sup>4</sup> in the Canadian context is unknown.

## 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 summarized in Appendix 4.

*What is the evidence that wireless devices interfere with medical equipment in any healthcare delivery setting?*

### *Automated External Defibrillators (AED)*

One systematic review<sup>2</sup> reported inconsistent results about interference in AEDs during operations of cellular phones, with one primary study reporting no interferences at all regardless of the mode of operation of the phones, while another primary study observed interference in AEDs during the ringing phase of a cell phone. There was no information about the type of phones (2G, 3G, LTE etc.) and the nature of the interference. The distance between the phones and the AED were not reported for either study.

### *Cardiopulmonary/cardiovascular equipment*

One systematic review<sup>2</sup> reported that a primary study observed EMI in 21.2% (108 out of 510) of tests involving six cellular phones and 16 medical equipment, resulting in malfunctions and abnormalities in cardiopulmonary devices. However, there was no information about the type of phones. The systematic review<sup>2</sup> also reported that a primary case study found that a 3G phone in a turned off, turned on, or calling mode did not interfere with the operation of cardiovascular

equipment. The distance between the phones and the medical devices were not reported for either outcome.

#### *Critical care and monitoring devices*

One systematic review<sup>2</sup> reported EMI in the form of annoying flicker, distortion or spikes in the traces on screen, drift in the baseline, a buzz in speaker or halts in the operation of devices in the failsafe mode occurred between cellular phones and critical care equipment used in the ICU such as pulse oximeter, a blood pressure monitor, a patient monitor, a humidifier, a defibrillator, and infusion pumps. The distance between the phones and the medical devices was not reported. The systematic review<sup>2</sup> also reported that a primary study found nine critical care devices which were susceptible to EMI from 2G cellular phones compared to one device which was susceptible to 3G cellular phones. The nature of the interference and the separation distances were not reported.

One systematic review<sup>2</sup> reported that a primary study observed EMI in four and three critical care equipment caused by 2G and 3G phones, respectively. The maximum distance at which the interferences were observed was 1.5 meters for both 2G and 3G cellular phones. However, the minimum distance at which interferences were observed was 0.5 meters for 2G and 0.35 meters for 3G cellular phones.<sup>2</sup> The medical equipment tested were ECG monitors, intensive care monitors, ultrasound equipment, X-ray equipment and dialysis equipment. The ultrasound equipment was the most susceptible to EMI from the phones and was affected by both 2G and 3G cellular phones at a greater distance. It was reported that proximity of both 2G and 3G cellular phones affected the acquisition of ECG signals, however, proximity was not defined. The nature of the interference was not reported for any of the other equipment.

One systematic review<sup>2</sup> reported a primary study that found 3G cellular phones including LTE phones induced EMI in 6.3% (2 out of 32) critical care medical devices used in the ICU. It was reported that the emitted peak power from the mobile phone and the separation distance between the mobile phone and the medical equipment were the significant factors to induce EMI in the medical device. However, the specific distances, peak power and the nature of interference were not reported. Another primary study of the systemic review<sup>2</sup> observed that all the tested monitoring devices which had long leads such as ECG recorders, pulse oximeters, and treadmills were sensitive to EMI from both 2G and 3G cellular phones during their ringing and conversation phases, while the other devices were insensitive to the EMI from the tested phones.

#### *Infusion pumps*

One systematic review<sup>2</sup> reported that one of its primary studies which tested the EMI between a syringe pump, a mechanical ventilator, and a bedside monitor used in the ICU observed that only one infusion pump was affected by the GSM phone in talk mode while the other devices were unaffected by GSM and CDMA phones regardless of their modes. Another primary study of the systematic review<sup>2</sup> found that 29.4% of infusion pumps malfunctioned as a result of EMI from GSM phones. Types of the malfunctions which occurred were complete shutdowns of the pumps and stoppages of flow of the fluid, with and without alarms. The separation distance between the phones and the medical devices was not reported for either of the primary studies.

### *Ventilators*

One systematic review<sup>2</sup> reported that EMI due to GSM phones was observed in one ventilator each in three of its primary studies. The EMI rates were 7.1% (1 out of 14), 20% (1 out of 5), and 14% (1 out of 7). Another primary study of the systematic review<sup>2</sup> observed a minor abnormal response in the baby ventilator whenever it was placed between a 3G phone handset and its base station. The separation distance between the phones and the medical devices was not reported for any of the primary studies.

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

One systematic review<sup>2</sup> concluded that in general, a cell phone must be “very close” to a medical device to interfere with its function. However, the separation distances at which EMI occurred between cell phones and medical devices were not adequately reported in this systematic review<sup>2</sup>. Therefore, the definition of “very close” is uncertain.

One guideline<sup>4</sup> reported that in an experiment conducted to support the development of its recommendations, the maximum separation distance for EMI from wireless devices to affect medical practice was 18 centimeters (cm); noting that certain nuisances such as abnormal noise from speakers and blurring on the display could occur without interfering with the purpose of medical care. The authors added that the experiment was not exhaustive and was limited to the medical electrical equipment they considered to be susceptible to EMI.

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

### *Setting separation distance*

One guideline<sup>4</sup> recommended a separation distance of about one meter between mobile handsets and medical equipment to prevent EMI. According to the authors, although their experiments found that the maximum separation distance for EMI from wireless devices to affect medical practice was 18 cm; by reference to international standards (IEC 60601-1-2)<sup>7</sup>, a one-meter separation distance was recommended considering the need to make provision for older medical equipment that may not meet newer standards, the necessity to make the distance of separation easy-to-understand for hospital users, and the fact that their experiment was not exhaustive. Therefore, the guideline provided that if a hospital confirmed safety based on their own test results, instruction manuals for a specific medical equipment, or other credible sources, a lower separation distance may be set.

The guideline<sup>4</sup> recommended against putting mobile handsets on medical electrical equipment since that greatly interferes with the operation of the equipment. In addition, the guideline<sup>4</sup> recommended against the use of mobile handsets in areas such as operation rooms, ICUs, laboratories, treatment rooms, etc., which normally have sensitive medical equipment. Some general recommendations and area-specific recommendations for the use of wireless devices in healthcare settings have been summarized in Tables 6 and 7, respectively, in Appendix 4.



### *Protecting personal and medical information*

One guideline<sup>4</sup> recommended that hospitals set specific rules to protect and prevent leakage of personal and medical information in view of the recording capabilities of mobile handsets, including the ability to take pictures and make videos.

### *Improving the EMC environment*

One guideline<sup>4</sup> recommended that hospitals designate someone (EMC manager) to be in charge of efforts to achieve a favorable EMC environment. The person with this responsibility will work with other relevant departments to establish rules for using mobile handsets, and improve the management system EMC in the facility.

## **Limitations**

A major limitation of this review was that the literature search did not find any study of high methodological rigor that met the inclusion criteria. As a result, only one poor quality systematic review<sup>2</sup> and one guideline<sup>4</sup> from Japan were included in this report.

The systematic review<sup>2</sup> did not assess the methodological quality of its included primary studies. Further, the EMI outcomes were inadequately reported because specifics were not provided about the nature of interferences induced in the functioning of medical devices, and/or the separation distances at which the interferences occurred were not reported. There were instances where the separation distances were described in unscientific generic terms, such as “proximity” and “very close” which have no quantitative meaning. In addition, the findings of the systematic review<sup>2</sup> were separately reported for each individual primary study without any pooling or synthesis of results. Thus, the benefit of effect estimates from multiple studies, which is usually associated with systematic reviews, is lacking in this case. Moreover, the conclusions of the systematic review were not reflective of the findings of the included primary studies.<sup>2</sup>

The guideline<sup>4</sup> was meant to be used by hospitals in Japan which are required to use medical equipment that is compliant with Japanese standards. Further, the wireless communication devices which were considered for the development of the guideline<sup>4</sup> were required to meet wireless access standards in Japan, which could be different from Canadian standards. Therefore, the generalizability of the recommendations of the guideline<sup>4</sup> in the Canadian context is unknown.

## **CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING**

One poor quality systematic review<sup>2</sup> reported that cellular phones induced EMI in various medical devices including AEDs, cardiovascular and cardiopulmonary equipment, critical care and monitoring devices, infusion pumps and ventilators. In general, the nature of the interferences and the separation distances at which they occurred were inadequately reported. One guideline<sup>4</sup> reported that an experiment to support its development found that the maximum separation distance for EMI from wireless devices to affect medical practice was 18 cm; although EMI could result in nuisances such as abnormal noise from speakers and blurring on the display at longer distances of separation without interfering with the purpose of medical care. However, by reference to the recommended separation distance used in international standards (IEC 60601-1-2),<sup>11</sup> and in consideration of older hospital equipment with lower EMC and the fact that the equipment tested in the experiment was not exhaustive, a general

separation distance on one meter was recommended between wireless communication devices and medical electrical equipment to prevent EMI. However, hospitals were allowed to set a lower separation distance if they confirmed safety based on their own test results, manufacturer instructions for specific medical equipment, and other credible sources. To maintain a favorable EMC, the guideline<sup>4</sup> recommended that hospitals assign an EMC manager to work in collaboration with other departments to address EMC issues. The guideline<sup>4</sup> recommends against the use of mobile handsets in areas such as operation rooms, ICUs, laboratories, treatment rooms, etc., which normally have sensitive medical equipment; and against placing a wireless communication device on a medical electrical equipment as it may greatly interfere with the operation of the equipment.

The overarching conclusions of both the systematic review<sup>2</sup> and the guideline<sup>4</sup> is that the use of mobile phones and other wireless communication devices in hospitals is expected to offer a significant benefit to improve the efficiency of medical care and the convenience and quality of life for patients. Therefore, it is critical to move away from excessive restrictions of mobile devices use and to adopt a proactive approach to promote the use of such devices while ensuring safety and security of personal and medical information.

**PREPARED BY:**

Canadian Agency for Drugs and Technologies in Health

Tel: 1-866-898-8439

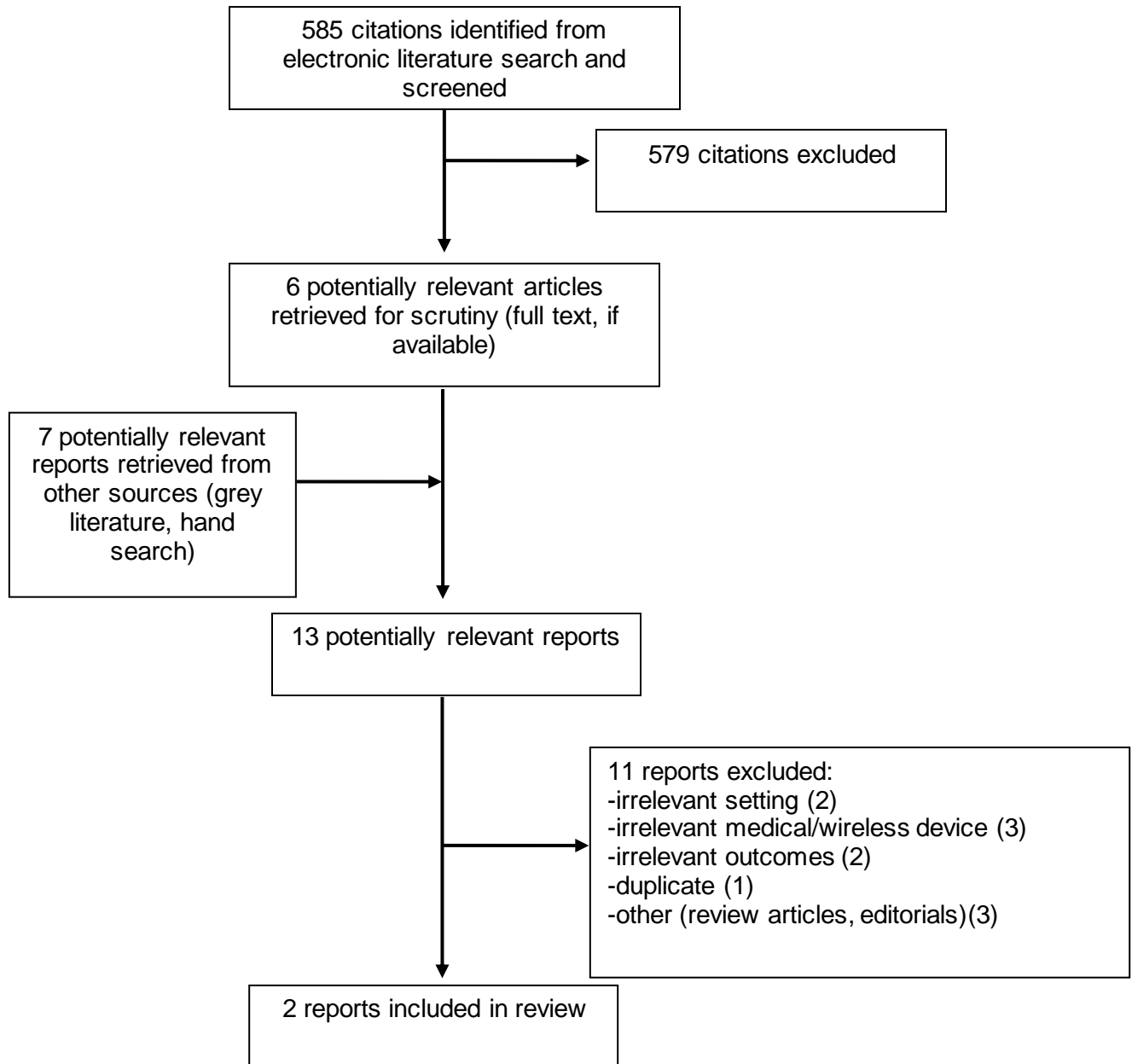
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**APPENDIX 1: Selection of Included Studies**





**APPENDIX 2: Characteristics of Included Publications**

**Table A1: Characteristics of Included Systematic Reviews and Meta-Analyses**

Country	Types and numbers of primary studies included	Medical Equipment	Wireless technology	Comparator	Outcome Measure
Mariappan, 2016 <sup>12</sup>					
India, Egypt, The United Kingdom	A total of 23 studies made up of 16 Ad hoc test, three bench test, and four case studies	A variety of medical devices including AED, cardiopulmonary devices, cardiovascular devices, critical care devices EAL, infusion pumps, ventilators, and a neonatal ventilator	2G, 3G, 4G LTE cellular phones, as well as two-way radio and PHS system. The devices used different wireless transmissions modalities including CDMA, GSM, GPRS, TDMA, UMTS, WCDMA, and Wi-Fi	N/A	EMI in medical devices from the 2G/3G/4G cellular phones

Ad hoc test refers to studies in which the evaluation had been performed on-site where the equipment was located to assess the actual EMI outcome in that environment.

AED = Automatic external defibrillators; CDMA = Code Division Multiple Access; EAL = Electronic Apex Locator; EMI = electromagnetic interference; GSM = Global System for Cellular Communication; GPRS = Global Packet Radio Service; PHS = personal handy-phone system; TDMA = Time Division Multiple Access; UMTS = Universal Cellular Telecommunication System; WCDMA = Wide Code Division Multiple Access

**Table A2: Characteristics of Included Guidelines**

Objectives			Methodology			
Intended users/ Target population	Intervention and Practice Considered	Major Outcomes Considered	Evidence collection, Selection and Synthesis	Evidence Quality and Strength	Recommendations development and Evaluation	Guideline Validation
The Electromagnetic Compatibility Conference Japan (EMCC), 2014 <sup>4</sup>						
Hospitals, including medical clinics with less than 20 hospital beds. Patients and hospital visitors (hospital users), and hospital staff	Guidelines for the secure and safe use of mobile phones and other wireless communication devices in hospitals	<ul style="list-style-type: none"> <li>Establish a proper separation distance between mobile wireless devices and medical equipment.</li> <li>Restrict aspects of phone and wireless device use such as sounds made during phone calls, of ringtones, of incoming mail tones, of operation, and of watching TV that may be source of disturbance to other patients</li> <li>Protect personal and medical information, and improve structure for EMC</li> </ul>	Sources of evidence included an experiment to establish a “general suggestion of a proper separation distance” <sup>a</sup> between mobile wireless devices and medical equipment; a Japanese standards for electromagnetic compatibility of medical electrical equipment (JIS T 0601-1-2:2012); and the wireless access system for current mobile phones in Japan, with reference to recommendations in the international standards for the electromagnetic compatibility of medical electrical equipment.	Not reported.	<ul style="list-style-type: none"> <li>To prevent EMI ensure that there is a distance separating the mobile wireless device and medical equipment.</li> <li>Based on international standards for the electromagnetic compatibility of medical electrical equipment, a separation distance of one meter between a wireless device and medical equipment was suggested to prevent EMI.</li> <li>Hospitals may set a lower separation distance for a medical equipment if safety has been confirmed based on their own test results.</li> <li>Avoid putting mobile handset on medical electronic equipment as the handset may greatly interfere with the operation of the medical equipment</li> </ul>	The guideline was formulated through reviews by experts, medical associations, wireless service providers, and relevant ministries and agencies.

EMC = electromagnetic compatibility; EMI = electromagnetic

**APPENDIX 3: Critical Appraisal of Included Publications**

<b>Table A3: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR<sup>o</sup></b>	
<b>Strengths</b>	<b>Limitations</b>
Mariappan, 2016 <sup>12</sup>	
<ul style="list-style-type: none"> <li>• The objective of the study was clearly stated</li> <li>• A comprehensive literature search in multiple databases and grey sources was conducted for relevant studies</li> <li>• Characteristics of the included studies were provided</li> <li>• The authors declared no conflict of interest</li> </ul>	<ul style="list-style-type: none"> <li>• The scientific quality of the included primary studies was not reported.</li> <li>• The separation distances at which EMI occurred between cell phones and medical devices were not adequately reported. Therefore, the definitions of proximity and “very close” as used in this systematic review are uncertain.</li> <li>• The findings were separately reported for the individual primary studies without pooling or synthesis of results. Thus, the benefit of effect estimates from multiple studies, which is usually associated with systematic reviews, is lacking in this case</li> <li>• There does not seem to be a proper link between the findings of the included primary studies and the overall conclusions of the systematic review. Thus, the conclusions must be interpreted with caution because they are not well supported by the outcomes of the included primary studies.</li> </ul>

<b>Table A4: Strengths and Limitations of Guidelines using AGREE II<sup>9</sup></b>	
<b>Strengths</b>	<b>Limitations</b>
The Electromagnetic Compatibility Conference Japan (EMCC), , 2014 <sup>4</sup>	
<ul style="list-style-type: none"> <li>• The overall objectives of the guidelines and well the targeted users whom the guideline was meant to apply were clearly described.</li> <li>• The guidelines development included relevant stakeholders, such as academic experts, staff from the Ministries of Internal Affairs and Communication; Ministry of Health; Labor and Welfare, a mobile phone business operator; a medical device manufacturer, and a hospital administrator.</li> <li>• The recommendations of the guidelines were specific and unambiguous.</li> <li>• Measures to promote applicability of the guidelines including recommendation to assigning individuals to manage EMC environment, collection of information, considerations for procurement of wireless and medical devices, and implementation; were provided.</li> </ul>	<ul style="list-style-type: none"> <li>• There were no details provided about the experiment conducted to support the development of the guidelines. However, the investigators stated that it was not exhaustive and was limited to medical electrical equipment considered by the investigators to be susceptible to EMI.</li> <li>• It is unknown whether the guidelines were reviewed by external experts prior to its publication.</li> <li>• Procedure for updating the guidelines was not provided and there was no information about the competing interests of the members of the expert committee which developed the guidelines.</li> <li>• Although the guidelines were developed with reference to international standards, the targeted users are hospitals in Japan required to use medical equipment which is compliant with Japanese standards. Also, wireless communication devices which were considered in the development of the guidelines were required to meet wireless access standards in Japan, which may be different from that of Canada. Therefore, the generalizability of the recommendations of the guidelines in the Canadian context is unknown.</li> </ul>

**APPENDIX 4: Main Study Findings and Author’s Conclusions**

Table A5 Summary of Findings of Included Studies	
Main Study Findings	Author’s Conclusions
Mariappan, 2016 <sup>12</sup>	
<p><i>Automated External Defibrillators</i></p> <ul style="list-style-type: none"> <li>One primary study reported no interferences with AED regardless of the mode of operation of mobile phones while another primary study observed interference in AED during the ringing phase of the cell phone. Thus there was inconsistency concerning EMI in AEDs caused by cellular phones. The kinds of cellular phones (2G, 3G, etc.) used in the tests and the distance between the phones and the AED were not reported in for either study.</li> </ul> <p><i>Cardiopulmonary/cardiovascular equipment</i></p> <ul style="list-style-type: none"> <li>In one primary study, tests involving six cellular phones and 16 cardiopulmonary equipment detected 21.2% (108 out of 510 tests) of EMIs. The kinds of cellular phones (2G, 3G, etc.) used in the tests and the distance of separation were not reported</li> <li>Another primary case study found that in a turned off, turned on, or calling mode, a 3G phone did not interfere with the operation of cardiovascular equipment. The distance between the phones and the medical devices was not reported.</li> </ul> <p><i>Critical care and monitoring devices</i></p> <ul style="list-style-type: none"> <li>One primary study reported that 2G and 3G cellular phones caused EMI in a pulse oximeter, a blood pressure monitor, a patient monitor, a humidifier, a defibrillator, and infusion pumps used in the ICU. Observed interferences were in the form of annoying flicker, distortion or spikes on traces on screen, drift in the baseline, buzzing noises, or halts in the operation of devices in failsafe mode. The distance between the phones and the medical devices was not reported for either outcome.</li> <li>Another primary study reported that nine critical care devices were susceptible to EMI from 2G cellular phones compared to one device which was susceptible to 3G cellular phone. The actual devices, the separation distance and the nature of the interference were not reported.</li> <li>A primary study reported that in tests involving 2G and 3G cellular phones and ECG monitor, intensive care monitor, ultrasound equipment, X-ray equipment and dialysis equipment, 2G cellular phones caused EMIs in four critical</li> </ul>	<p>The conclusions of the authors of this systematic review may be summarized as follows:</p> <ul style="list-style-type: none"> <li>In general, a cell phone must be “very close” to a medical device to interfere with its function.</li> <li>With the rapid advancement and changes in both medical equipment and cell phone technology, findings of older studies may not be relevant</li> <li>Given the high prevalence of phones and low prevalence of injury, there doesn’t seem to be much reason for concern</li> <li>It is not clear if any observed interference has an actual clinical effect on the patient (e.g. real harms)</li> <li>Overall, EMI events induced in medical devices by cellular phones are rare and require close proximity between devices, and there is no reliable data on actual safety.</li> </ul>

**Table A5 Summary of Findings of Included Studies**

Main Study Findings	Author's Conclusions
<p>care equipment compared to three EMIs caused by 3 G phones. The maximum distance at which the interferences were observed for both 2G and the 3G cellular phone was 1.5 meters. However, the minimum distance at which interference occurred was 0.5 meters for 2G cellular phones and 0.35 meters for 3G cellular phones. The nature of the interference was not adequately reported.</p> <ul style="list-style-type: none"> <li>• A primary study found that 3G cellular phones including LTE phone induced EMI in 6.3% (2 of 32) critical care medical devices used in the ICU. The specific equipment, the nature of interference, and the separation distances were not reported.</li> <li>• Another primary study observed that all the tested monitoring devices which had long leads such as ECG recorders, pulse oximeters, and treadmills were sensitive to EMI from both 2G and 3G cellular phones during their ringing and conversation phases. The nature of interferences and the separation distances were not reported.</li> </ul> <p><i>Infusion pumps</i></p> <ul style="list-style-type: none"> <li>• One primary study reported that a GSM phone in talk mode caused EMI in while one infusion pump without affecting other devices, while CDMA phones did not induce EMI in any medical device, regardless of its operational mode. The devices tested were a syringe pump, a mechanical ventilator, and a bedside monitor used in the ICU devices. The nature of interference and the separation distances were not reported.</li> <li>• Another primary study found that 29.4% of infusion pumps malfunctioned as a result of EMI from GSM phones. The malfunctions were complete shutdowns of the pumps, and the stoppage of the flow of the fluid, with and without alarms. The distance between the phones and the medical devices at which the EMIs occurred was not reported.</li> </ul> <p><i>Ventilators</i></p> <ul style="list-style-type: none"> <li>• Each of three primary studies which tested for EMI in 14, five, and seven ventilators, respectively, reported that GSM phones caused interference a ventilator (i.e. EMI rates of 7.1%, 20%, and 14%,</li> <li>• Another primary study observed a minor abnormal response in a baby ventilator</li> </ul>	



<b>Table A5 Summary of Findings of Included Studies</b>	
<b>Main Study Findings</b>	<b>Author's Conclusions</b>
whenever it was placed between a 3G phone and its base station. The nature of interference and the separation distances were not reported.	
<b>Guidelines for use, 2014<sup>4</sup></b>	
<ul style="list-style-type: none"> <li>• An experiment conducted to support the development of the guidelines found that the maximum separation distance for EMI from wireless devices to affect medical practice was 18 cm.</li> <li>• Nuisances such as abnormal noise from speakers and blurring on the display could occur at longer distances of separation without interfering with the purpose of medical care.</li> </ul>	<ul style="list-style-type: none"> <li>• The use of mobile phones and other wireless communication devices in hospitals is expected to offer a significant benefit to improve the efficiency of medical care and the convenience and quality of life for patients. Therefore, it is critical to adopt a proactive approach to promote the use of such devices while ensuring safety.</li> </ul>

AED = automated external defibrillators

<b>Table A6 Summary of some Recommendations for EMC/EMI Management in Healthcare Facilities</b>	
Guideline for use, 2014 <sup>4</sup>	
<b>Subject</b>	<b>Details</b>
<b>Deployment of EMC Managers</b>	<ul style="list-style-type: none"> <li>• It is preferable to assign someone to work on EMC in hospitals on an ongoing basis, to work with relevant departments to support the utilization of wireless communication devices, while prevention of EMI with medical electrical equipment.</li> <li>• A structure of communication should be built among EMC managers and the staff in charge of procuring and managing medical and wireless communication equipment.</li> <li>• EMC managers are expected to collect the latest information, such as EMC of wireless communication devices and medical equipment, from the manufactures of such devices, relevant ministries and agencies and other sources to facilitate improvements in the EMC environment</li> </ul>
<b>Evaluating and improving the electromagnetic environment</b>	<ul style="list-style-type: none"> <li>• It is advisable for hospitals to take the necessary measure to improve poor signal quality because in general, the better the radio wave reception, the less the output of radio waves from mobile handsets which can cause EMI in medical devices.</li> <li>• EMC managers are expected to collect the latest information, such as EMC of wireless communication devices and medical equipment, from the manufactures of such devices, relevant ministries and agencies and other sources, in an effort to improve the EMC environment</li> </ul>
<b>Procuring, implementing, operating and managing medical electrical equipment and wireless communication devices in a favorable EMV environment</b>	<ul style="list-style-type: none"> <li>• When hospitals plan to introduce some medical or wireless communication equipment for the first time, they should obtain sufficient information from the manufacturers and other sources and establish the required separation distance (through testing, if necessary) to maintain and improve a favorable EMC environment.</li> </ul>
<b>Keeping hospital users informed and educating hospital staff</b>	<ul style="list-style-type: none"> <li>• Rules for using mobile handsets should be communicated through signs posted on the walls, handouts, floor maps, etc. Hospital staff should be educated about the necessity of a favorable EMC environment in the facility.</li> </ul>

Source: Guidelines for use of mobile phones and other devices in hospital – For secure, safe use of wireless communication devices in hospitals<sup>4</sup>

<b>Table A7 Area-specific Recommendations for Mobile Handset Use</b>			
<b>Areas</b>	<b>Calls</b>	<b>E-mail, Web, and other applications</b>	<b>Area-specific precautions</b>
<b>Cafeterias, waiting rooms, corridors, elevators, halls etc.</b>	Allowed	Allowed	<ul style="list-style-type: none"> <li>• Mobile handsets in use should be separated from medical devices by at least the specified separation distance</li> <li>• Restrict use as necessary if mobile handsets are in the vicinity of restricted areas.</li> <li>• Texting while walking is dangerous and should be avoided</li> </ul>
<b>Patient rooms etc.</b>	Partially allowed	Allowed	<ul style="list-style-type: none"> <li>• Mobile handsets in use should be separated from medical devices by at least the specified separation distance</li> <li>• Restriction of calls in multiple occupancy rooms may be necessary from consideration of public manners perspective.</li> </ul>
<b>Consultation rooms</b>	Not allowed	Partially allowed (no need to switch off)	<ul style="list-style-type: none"> <li>• Provided that mobile devices are be separated from medical devices by at least the specified separation distance, there is no need to turn off handsets.</li> <li>• Consideration, such as avoiding use to prevent disturbance to a medical examinations, or to other patients, is necessary.</li> </ul>
<b>Operation rooms, ICUs, laboratories, treatment rooms, etc.</b>	Not allowed	Not allowed	<ul style="list-style-type: none"> <li>• Mobile handset should not be used and should be turned off, or they should be switched to the mode that does not emit radio waves</li> </ul>
<b>Space for mobile phones, etc.</b>	Allowed	Allowed	

Source: Guidelines for use of mobile phones and other devices in hospital – For secure, safe use of wireless communication devices in hospitals<sup>4</sup>

## APPENDIX 5: Additional References of Potential Interest

1. *An article on the already included guideline*

Hanada E, Kano T. Reformation of the Japanese Guidelines for cellular phone use in hospitals. (Presented at 2015 IEEE International Symposium on Electromagnetic Compatibility (EMC); 2015 16-22 Aug; Dresden, Germany.)

2. *A qualitative review of how clinicians in various departments of hospitals use smartphone in their work. – The outcomes are not relevant for this review*

Thomairy NA, Mummaneni M, Alsalamah S, Moussa N, Coustasse A. Use of Smartphones in Hospitals. *Health Care Manag (Frederick)*. 2015 Oct;34(4):297-307.

3. *A case report without sufficient information for critical appraisal*

Chung S, Yi J, Park SW. Electromagnetic interference of wireless local area network on electrocardiogram monitoring system: a case report. *Korean Circ J [Internet]*. 2013 Mar [cited 2016 Aug 17];43(3):187-8. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3629245>

## APPENDIX 6: Summary of the Previous CADTH Rapid Response (RR) Report<sup>7</sup>

The previous CADTH rapid response (RR) report reviewed the safety and guidelines of wireless device use and patient monitoring equipment in healthcare delivery settings. One systematic review authored in Spain and three non-randomized controlled studies; one each from Italy, the United States of America (USA), and Canada, were included in the review. The systematic review included study studies that dealt with patients admitted to healthcare. The study from Italy tested devices in a room at the intensive care department in a hospital, while the study from the USA tested equipment in the operating room, post-anesthesia unit, and cardiac electrophysiology laboratory. The study from Canada was done in an isolated room without metallic objects or operating electrical devices to avoid interference from other sources.

The included studies tested for interferences in the operation of medical devices caused by a variety of wireless communication devices and technologies including different kinds of mobile phones, Bluetooth-enabled devices, wireless local area network (WLAN), WiFi signals, in-hospital cordless phones using WLAN; and an alpha-numeric pager. The general outcome of interest in all the included studies was EMI with patients monitoring/care equipment.

The key findings of the review were as follows:

1. 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.
2. The likelihood of EMI in medical equipment due to wireless devices increases with increased transmitter powers, lower frequencies, and shorter distances between devices.
3. 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.
4. Policies to regulate wireless device used in highly instrumented areas in a healthcare environment could protect sensitive equipment from exposure to hazardous EMI.

The report concluded that despite the reportedly low incidence of clinically significant interference with medical equipment, in view of the potential for disruptions with hazardous consequences, 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.