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

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Session overview

Overall goal ... evidence informed - policy

• Introduce the partners
  – Eastern Health
  – CADTH
  – CCHL & NL Chapter

• Provide the background leading to the Report & Webinar

• Rapid Response Report
  – Review of the literature
  – Present findings

• Discuss policy implications coming out of findings
Setting the context ...

• Seed for the initiative - call from practitioner

• Manager was following policy

• Policy (2009) was overdue to be reviewed
  – Used a risk aversion approach

“Chance favors a prepared mind” (Louis Pasteur)
Seizing an opportunity ...

- Meeting with Canadian Agency for Drugs and Technologies in Health (CADTH)

- **Request for Rapid Response**
  - Use of wireless devices and patient monitoring equipment
  - Systematic review
  - Collaboratively identified research questions

- Rapid Response report completed **January 2014**
  - Recognized there would be interest beyond Eastern Health
Extending our Partnership ... 

• Set up webinar with CCHL & NL Chapter

• Excited to share findings & engage in discussion with participants
Reviewing the Evidence

A report from
CADTH’s Rapid Response Service
OUTLINE

• Introduction
  o Areas of benefit
    ➢ Utility to Health care professionals
    ➢ Utility to patients and visitors
  o Potential Challenges

• Research questions

• Methods used

• Results
  o Study selection
  o Summary of Characteristic of included studies
  o Critical appraisal

  o Summary of findings and authors conclusions

• Summary of critical appraisal

• Responses to research questions

• Limitations

• Conclusions and Take-home Message

• Acknowledgments

• Questions
INTRODUCTION

• Wireless devices are here to stay

• They have immense potential applicability
  ➢ Professional
  ➢ Personal

• They can expose us to risk if carelessly handled

• Having a policy is a laudable means to beneficial tapping of advantages with minimized risk
UTILITY TO HEALTH CARE PROFESSIONALS

• Ability to consult with other care providers

• Look up details from a library of resources

• Access an electronic health record or other computerized system

• Easy access to patient data
UTILITY TO PATIENTS AND VISITORS TO OUR FACILITIES

- Ability to connect and relate to activity/life outside healthcare facility, share information with friends,

- Attend to urgent/important issues like manage important e-mails and appointments while waiting, and

- Refocus and calm down in anxious moments by listening to music and watching movies
POTENTIAL CHALLENGES

• Different devices share/overlap similar frequency bands and interfere with each other’s function (EMI) leading to

• Altered normal operation of equipment and also the clinical signs recorded

• Malfunction in medical equipment could expose patients to unacceptable risk of harm

• Clinicians prone to make wrong diagnoses leading to wrong treatment.
POTENTIAL CHALLENGES

- Threat to security breaches
- Patient safety
- Inappropriate disclosure of protected health information
- Software viruses and malware intended to create weaknesses in efficient functioning
- Distractions and reduced time needed for optimal patient care
Accessed February 15, 2014
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?
METHODS

• Literature search by CADTH Information Specialist

• Selection of relevant study using a predetermined protocol based on PICO

• Data abstraction and data synthesis

• Critical appraisal
  o Methodological validity and assessment, and
  o grading the strength of the evidence
RESULTS

Selection of included studies

100 citations identified from electronic literature search and screened

86 citations excluded

14 potentially relevant articles retrieved for scrutiny (full text, if available)

2 potentially relevant reports retrieved from other sources (grey literature, hand search)

16 potentially relevant reports

12 reports excluded:
- irrelevant medical equipment (6)
- irrelevant intervention (1)
- other (review articles, editorials) (5)

4 reports included in review
## CHARACTERISTICS OF INCLUDED STUDIES

<table>
<thead>
<tr>
<th>First Author, Publication year, Country</th>
<th>Study Design</th>
<th>Medical Equipment</th>
<th>Wireless technology</th>
<th>Comparator</th>
<th>Outcome Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carranza, 2011, Spain</td>
<td>Systematic review</td>
<td>Defibrillators; ventilators; brain stimulators; pumps; ophthalmic equipment and pacemakers</td>
<td>Mobile phones and cell phone-like devices operating on various technologies including but not limited to GSM, CDMA, WLAN, TACS, TDMA, GPRS; and UMTS.</td>
<td>None</td>
<td>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</td>
</tr>
<tr>
<td>Baranchuk, 2009, Canada</td>
<td>Non-Randomized study</td>
<td>ECG machines: MAC 5000; MAC 1200; and ELI 100</td>
<td>Wireless communication devices operating on GSM, CDMA, and WLAN technologies; analogue phone; and alpha-numeric pager.</td>
<td>None</td>
<td>Electromagnetic interference with interpretation of electrocardiographs (ECGs)</td>
</tr>
</tbody>
</table>

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.
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<td>Calcagnini, 2011 Italy</td>
<td>Non-Randomized study</td>
<td>Infusion pumps; defibrillators, monitors; lung ventilators; anesthesia machines; and external pacemakers</td>
<td>WiFi signals emitted by mobile terminals</td>
<td>None</td>
<td>Levels of electromagnetic interference with various medical equipment</td>
</tr>
<tr>
<td>Kapa, 2011 USA</td>
<td>Non-Randomized study</td>
<td>Cardiac monitors, ECG machines, intravenous pumps, electrophysiology ablation devices, fluoroscopy, echocardiographic machines, and laboratory analysis devices.</td>
<td>Wireless auto-identification device</td>
<td>None</td>
<td>Electromagnetic interference with various medical equipment</td>
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## SUMMARY OF CRITICAL APPRAISAL OF INCLUDED STUDIES

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<th>Limitations</th>
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| Carranza, 2011     | - Ten-year literature search in English, Spanish and French.  
                   - 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.  
                   - GSM and CDMA Cellular phones, older analog phones and alpha-numeric pager.  
                   - Performed test in isolated room to exclude confounders  
                   - complete agreement between two blinded investigators concerning cases of EMI detected | - Grades of individual studies in not provided to clarify which studies scored “low” and which scored “high”.  
                   - heterogeneity made evaluation difficult  
                   - “partially coverage of the subject matter by most of the”  
                   - small sample size |
| Baranchuk, 2009    | - Study protocol was limited to ringing phase of mobile phones only.  
                   - Only ECG machines were tested in the study.  
                   - Reproducibility of findings is uncertain in an actual healthcare environment. |

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| Calcagnini, 2011  | • Equipment was configured with routine clinical parameters using simulator/device tester.  
                   • 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.  
                   • 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. | • Findings are subject to changes due to several variables including antenna type and orientation with respect to the medical devices, reflection and absorption of RF energy by people and objects in the test area.  
                   • A narrow spectrum of RFID device and of medical equipment.  
                   • It is unclear whether medical equipment not included in the study would experience similar EMI as identified. |

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**MAIN STUDY FINDINGS AND AUTHORS’ CONCLUSIONS**

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<th>Authors’ Conclusions</th>
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<td>Carranza, 2011</td>
<td>• Several wireless devices caused EMI induced malfunction at different levels of severity in medical equipment. e.g., 1. apnea monitors; 2. ventilators; 3. pumps; 4. vital sign monitor, EEG analyzers and ultrasound devices.</td>
<td>“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.”{16610} pg. 540</td>
</tr>
<tr>
<td>Baranchuk, 2009</td>
<td>• Incidence of EMI was low (2%), comprising only artifact in the ECG recording.</td>
<td>“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”{16614} pgs. 591-592</td>
</tr>
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# MAIN STUDY FINDINGS AND AUTHORS’ CONCLUSIONS, CONT.

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| Calcagnini, 2011               | • 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. | “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.”[16611] pg. 500 |
| Kapa, 2011                     | • 25% 98 out of 32) tested devices encountered EMI at some time during testing.  
• Only one device experienced EMI at a distance greater than 3 ft but less than 5 ft feet away.  
• All EMI incidents occurred when auto identifier was activated. No interference was seen with the tags even when they were connected to the devices; and |

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 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.”
RESPONSE TO RESEARCH QUESTION #1

- A systematic review of 47 studies conducted between 1999 and 2011 found EMI in several medical equipment caused by different kinds of wireless devices.

- The incidence of clinically important interference was reported in 1.2% of 510 tests performed.

- A study found that WiFi signals from wireless devices induced various levels of EMI in medical equipment but posed no significant risk to life supporting medical devices, and

- Incidence with potential for clinical consequences to the patient was low (2 out of 45).
Another study found that 25% (8 out of 32) tested medical devices encountered EMI induced by auto-identifier.

Two of them (involving two 12-lead ECG machines) were described as hazardous.

Five equipment (including the ECG machines, an anesthesia monitor, two echocardiogram/ultrasound machines) experienced significant EMI.

A defibrillator, in addition to the equipment mentioned previously, encountered light interferences.

A third study found wireless phones on top of a MAC 5000 ECG machine induced EMI resulting in artifacts on ECG records which led to incorrect diagnosis in 18% of cases.

* An older model ECG machine was not affected (likely because of design)
RESPONSE TO RESEARCH QUESTION #2

• In the systematic review, distances at which EMI due the wireless devices were observed ranged from 2cm to 400cm.

• An ultrasonic device showed the widest variability in distance for EMI from wireless source, and

• EMI from equipment using TETRA technology had the longest reach.

• A trend in the sensitivity of medical equipment to induce EMI by the wireless devices was not apparent.
In the study involving WiFi terminals, EMIs occurred in a pump and a defibrillator operated at less than 5 cm away.

EMI due to the auto identifier occurred at distances less than 3ft, except in a single case involving a 12-lead ECG machines light EMI occurred at a distance greater 3ft but less at 5 feet.

In another study, mobile phones in direct contact with an ECG machine induced EMI.
RESPONSE TO RESEARCH QUESTION #3

• Our literature search for this report did not find any evidenced-based guidelines for wireless device use in health care settings.
LIMITATIONS

• Studies were appraised with adaptations of sections of SIGN 50 instrument considered by one researcher to be relevant.

• Validity of finding in medical equipment not included in the various tests is uncertain.

• Steady proliferation of more “advanced” wireless devices and the ongoing advancement in medical equipment technology implies that future immunity or susceptibility to EMI is indeterminate at the present time.
CONCLUSIONS AND TAKE HOME

• Clinically significant wireless induced EMI in medical equipment is rare and occurs at very short distances (mostly less than 3ft) between wireless devices and medical equipment.

• Medical equipment may be significantly protected from EMI induced by wireless devices if its designated radio frequency spectrum is not shared by commonly used wireless devices.

• Potential for EMI in medical equipment due to wireless devices increases with increased transmitter powers, lower frequencies, and shorter distances between devices.
CONCLUSIONS AND TAKE HOME

• Healthcare administrators can work with experts to select equipment that are less predisposed to EMI induced by commonly used wireless devices.

• Developing equipment inventories (detailing their RF) can be a useful reference to advise new device acquisitions, and shape policy on safe use of wireless devices.

• Wireless device use in highly instrumented areas could be regulated to protect sensitive equipment from exposure to hazardous EMI.
ACKNOWLEDGEMENT

• Chris Kamel and the Rapid Response Team of CADTH that worked on project RC0513

• Dr. Mollie Butler

• Amy O’Brian

• Sheila for liaising between resource persons for these presentation, and

• Audience members

Thank you!
FOR FURTHER INFORMATION

To learn more...

• CADTH – www.cadth.ca
• Eastern Health - http://www.easternhealth.ca/

To discuss RHA policy...

• Contact Dr. Mollie Butler at Mollie.Butler@easternhealth.nl.ca
PARTICIPANT QUESTIONS

• What policy implications come to mind as you listened to the findings of the systematic review?

• How might the findings support your organization’s wireless device policy development?