Cancer Care Ontario

Use of Continuous Infusion Pumps During Radiation Treatment

Recommendation Report

A special project developed by the Radiation Treatment Program, Nursing and Psychosocial Oncology Program, and Systemic Treatment Program of Cancer Care Ontario for circulation to Regional Cancer Programs.

Report Date: March 2012
Update: January 2017

ISSUE

Radiation/electromagnetic interference (EMI) may adversely affect the operation of electronic infusion pumps during the delivery of radiation treatment and compromise patient care. It is important to provide recommendations for clinical practice regarding this issue.

ISSUE SUMMARY

Cancer treatment is highly complex, requires collaboration among a variety of health care professionals and utilizes a number of sophisticated treatment methods and devices. With this increasing trend toward multimodality treatment and concurrent chemoradiation therapy protocols, there is likely to be an increased incidence of patients undergoing radiation treatment while simultaneously receiving continuous infusion chemotherapy. However, there is limited published information regarding the effects of radiation on ambulatory chemotherapy infusion pumps as well as what should be done to reduce the risks to patients.

The purpose of this document is to heighten awareness of this issue within the clinical community, provide considerations for minimizing possible negative effects on patient care, avoid potential corruption of the memory chip and potential infusion errors, and encourage the monitoring of infusion devices after exposure to radiation/EMI. The recommendations included in this report are intended to serve as suggested points of consideration in the development of institution-specific policies and procedures. Please note that this document may also have relevance to electronic infusion pumps used to deliver non-chemotherapy agents, such as insulin, analgesics and other agents though they are not specifically addressed in this document.

RECOMMENDATIONS FOR CLINICAL PRACTICE

The following considerations for clinical practice are derived from a limited evidentiary base and have been supplemented with consensus of the working group. The working group recommends that the following considerations be taken into account in the development of institution-specific policies and procedures.

1. Each cancer centre should develop institution-specific policies and procedures that outline the steps necessary for the reduction of radiation to infusion pumps, as well as what safety tests should be performed on the pumps in case of exposure and who to contact if

there are questions or concerns. The development of said policies and procedures should be a multi-professional endeavour and collaboration among the nursing, radiation, chemotherapy and biomedical engineering departments is strongly encouraged.

2. If practical, radiation treatment personnel should be responsible for identifying patients that have infusion pumps at the time of treatment and communicating such information with the other individuals involved in the patients' care.
3. If practical, patients receiving infusional treatments should be disconnected from electronic infusion pumps prior to receiving radiation therapy and reconnected once radiation treatment is completed for each session. While a patient is receiving radiation therapy the electronic infusion pump should be kept outside the treatment room. If the patient cannot be disconnected from the electronic infusion pump for medical reasons, low-energy radiation should be employed (i.e. <8MV x-rays) to avoid the risk of exposing the pump to neutrons, and the pump should be placed out of the direct radiation beam and as far away as possible.
4. Given that Registered nurses have the clinical competencies related to intravenous line management (either peripheral or central), any infusion pump should be managed by said personnel; such as for disconnecting, or reconnecting pumps as required.
5. If there is a need for decision to provide a bolus dose of medication prior to radiation treatment, such as pain medication, a physician order is required; and only a Registered nurse who is managing that patient should deliver the bolus dose.
6. If practical, Elastomeric Pumps, which are not known to be affected by radiation/EMI since they do not contain electronic parts, should be used.
7. All infusion pumps exposed to radiation/EMI anywhere inside the treatment room should be assessed by a Registered nurse to ensure proper functioning after each treatment is completed. If a pump passes its 'self-test', it should be tagged to indicate the exposure date so that it can be monitored for a period of time which has been predetermined by the institution. If a pump does not pass its 'self-test' or displays an error code, the Registered nurse, should ensure that the patient receives a replacement pump and send the defective pump to the Biomedical Engineering department for assessment and if necessary, repair. The Biomedical Engineering department should consider develop instructional sheets on how to perform pump self-checks and what steps to take to make sure that the pump is working safely.
8. In the case that a patient receives radiation treatment at an institution other than the one that originally connected the infusion pump, radiation treatment personnel should ensure that the original institution is aware that the infusion pump has been exposed to radiation. In the event that an infusion pump is found to be defective before the patient leaves the radiation treatment unit, radiation treatment personnel should notify the original institution of the malfunction.

METHODS

Questions raised through Cancer Care Ontario (CCO) clinical discussion forums suggest variability in practice and a lack of consensus around an appropriate approach across the province. The scope of this document is to address patient safety issues and to provide advice on reducing the risks related to the effect of radiation/EMI on infusion pumps.

The published literature was systematically searched using MEDLINE (1996-2008) and EMBASE (1980-2008) databases. The complete search strategies are included in Appendix 1. Articles pertaining to pacemakers and defibrillators were excluded since they were to be addressed in a separate document. Articles in a language other than English were also excluded, because resources were not available for their translation. Reference lists were searched for relevant articles and authors were contacted to further inquire about potential studies. In an effort to keep the document current and to update the evidence base the MEDLINE and EMBASE databases were searched in 2008-2012, 2012-2014 and 2014-2016 (See Appendix 2, 3 and 4 for search strategies). No additional studies were identified in the 2008-2012 and 2014-2016

searches, however the 2012-2014 search identified 2 articles that were deemed suitable for inclusion (the language limitation was removed from the latter search).

An environmental scan of unpublished documents from websites of various radiation organizations was carried out and the search terms were also entered in a general Google™ search. The environmental scan utilized combinations of the following search terms: electromagnetic interference, EMI, linear accelerators, electronic pump, electronic infusion pump, infusion treatments, infusion pump, ambulatory chemotherapy, ambulatory chemotherapy infusion pump, radiation therapy, radiation and RT. The websites of the following organizations were searched for the effects of radiation/EMI on infusion pumps (Table 1). This search was also updated in 2012, 2014 and 2016, however no new information was identified.

Table 1. Environmental scan of web sites for the effects of radiation on infusion pumps.

Organizations
Australian Radiation Protection and Nuclear Safety Agency
American Society for Therapeutic Radiology and Oncology (ASTRO)
American Society of Clinical Oncology (ASCO)
American Association of Physicists in Medicine (AAPM)
American College of Radiation Oncology (ACRO)
Canadian Association of Radiation Oncology (CARO)
Health Canada
U.S. Food and Drug Administration (FDA)
Medicines and Healthcare products Regulatory Agency (MHRA)
Association for the Advancement of Medical Instrumentation (AAMI),
ECRI Institute
Healthcare Products Regulatory Agency (HPRA)

The compiled evidence was reviewed by a multidisciplinary working group, which included representation from nursing and psychosocial oncology, radiation oncology, radiation therapy, medical physics, pharmacy and medical oncology. The group met through in-person meetings and used e-mail as the main vehicle of communication. Differences were resolved through consensus and the use of evidence that informs this document.

A draft copy of this recommendation report was reviewed by a multidisciplinary external review panel which included representation from nursing, radiation oncology, radiation therapy, medical oncology, and medical physics (See Appendix 4 for more information on this process).

RESULTS

The systematic search of the literature identified 152 citations; following title and abstract screening, three articles were deemed relevant for inclusion. Two additional articles were identified from the reference lists, however after full text review one was excluded since it was not related to radiation oncology. Of the four included articles two were case reports (1, 2), one was an expert consensus report (3) and one was a hazard report (4). Three manufacturer device alerts were identified in the environmental scan (5-7). An additional article was suggested by a member of the external review panel and considered relevant for inclusion (8).

In 1999 Lacerna *et al.* (1) examined the effects of megavoltage radiation exposure on two new ambulatory infusion pumps. The first pump received gradually increasing doses of radiation and its complete malfunction was attributed to exposure from a single dose of 20 Gy. The cumulative dose for the first pump was 38 Gy. Based on these results, the second pump received 20 Gy of radiation in one setting followed by 2 Gy per dose until complete malfunction at a total cumulative dose of 42 Gy. Additionally, in the second pump the flow rate of chemotherapy was temporarily decreased by 25% prior to malfunction without the pump exhibiting any abnormalities. These findings suggest that cumulative radiation exposure is a key factor in semiconductor damage and the authors caution that even after the pump is removed from direct radiation it can accumulate enough radiation for complete failure to occur during the treatment of

fewer than 20 patients. The authors point out that completely disconnecting the pump and removing it from the radiation field (i.e. keeping the pump outside the treatment room) would eliminate the risk of radiation damage; however this may not be practical for routine purposes.

More recently Wu and Wang (2) reported a single case description of a radiation induced malfunction of an implanted programmable intrathecal pump. The intrathecal pump was located directly over the patient's sarcoma therefore shielding during the course of radiotherapy was not feasible without incurring the risk of tumour under-dosing. Due to the patient's condition relocation of the pump was not possible; instead the pump was turned off prior to the start of treatment. The patient received a total dose of 50.4 Gy (daily dose of 1.8 Gy) using tomotherapy and 6 MV photons. The intrathecal pump began to alarm, with a constant soft beeping, after 20 treatments (the estimated cumulative dose was in the range of 28.5 to 36 Gy). The alarm could not be stopped and lasted for four days, ceasing spontaneously and without intervention. The patient was closely monitored during this time and successfully completed the remaining course of treatment. Technical analysis of the pump indicated that the battery was completely depleted and that the electronic circuit was damaged which may have caused the alarm to sound. Wu and Wang call for additional studies on the radiation dose-damage relationship and highlight the importance of direct communication between the radiation oncologist and the pain management specialist prior to the start of treatment. The report offers the following recommendations to minimize the likelihood of pump malfunction:

1) *Adequate shielding.* Shielding requirements for the pump need careful consideration since they may vary based on the radiation technique used (megavoltage, electron or orthovoltage). For instance, lead shielding may not be sufficient when using megavoltage radiotherapy due to its powerful tissue penetration.
2) *Radiation exposure minimization.* Measurements of the radiation dose to the pump should be performed for accurate dose estimation on the first day of treatment.
3) *Relocation.* If situated directly in the radiation field, pump relocation should be considered. Additionally, the radiation source should be moved as far as possible from the pump.
4) *Switching the pump off during the course of treatment.* The pump medication can be replaced with normal saline and the patient can be started on equivalent does of oral medications before radiation treatment.
5) In a multidisciplinary expert consensus report on the use of intrathecal therapy for cancer pain management Stearns *et al*. (3) suggest that placing the pump near the radiation field may result in decreased battery life of the implant system while complete battery drain or electric failure may occur if the pump is placed directly in the field. The authors recommend moving the radiation source, shielding with lead, and relocation to minimizing exposure. Additionally, they suggest that pump placement location should be planned in advance to avoid future radiation fields.

In 2001, the Health Devices periodical published a hazard report (4) discussing multiple incidents of Baxter Colleague infusion pumps malfunctioning during the course of radiotherapy using linear accelerators. In each case, the alarms sounded and the pump stopped working during the course of treatment. The pumps had to be turned off and re-set to silence the alarm. The number of incidents or the treatment dose is not specified in the report. The cause of pump failure was not determined, however it is speculated that the malfunction can be attributed to EMI from the linear accelerators. The report cautions that effects of EMI on medical devices are unpredictable, and the potential to cause an infusion pump to increase its infusion rate cannot be ignored. Testing the device's ability to resist EMI from a linear accelerator is suggested. The report states that facilities intending to use electronic devices in the proximity of a linear accelerator should adhere to the following recommendations:

For any type of electronic device:

1. Alert radiation therapy personnel to the possibility that any electronic device might fail during treatment.

2. Do not operate any electronic device during radiotherapy treatment before testing the compatibility of the device with the linear accelerator.
3. Do not use any device during radiotherapy that is adversely affected by EMI from the linear accelerator. Note: that the device can still be in the room and attached to the patient, but must be switched off.
4. When any device fails during radiotherapy, test it thoroughly before returning it to service.

For infusion pumps in particular:

1. Alert any patient requiring the use of an infusion pump during radiotherapy about the possibility of the pump's alarming during treatment.
2. Review the necessity of using an infusion pump during a radiotherapy treatment session. If a pump is necessary, try the following solutions:
    a. Attempt to position the pump so it is unaffected by EMI. The position should be identified through initial compatibility testing performed without a patient being connected.
    b. Try enclosing the pump in suitably designed electromagnetic shielding and/or filters.

The three documents located in the environmental scan (5-7) were device alerts from manufacturers, directly related to the malfunction described in the Hazard Report (4) above. In 2006 and again in 2007 Baxter Corporation issued communications providing additional information regarding the use of Colleague Volumetric Infusion pumps in linear accelerator radiation suites. These safety alert letters stated that Baxter had evaluated the malfunction, and attributes it to the corruption of the memory chip due to radiation exposure, and will be implementing changes that will significantly reduce the likelihood of this malfunction. The nature of the changes was not indicated. The communication also stated that since the potential for corruption cannot be entirely eliminated Baxter had altered the operator's manual to recommend against the use of the pump in linear accelerator suites. In 2010 the FDA ordered a recall of all Baxter Colleague Volumetric Infusion Pumps due to the company's longstanding failure to correct the numerous problems with the pumps (7).

As cited in Wilkinson *et al*. (8), Baumann *et al*. reported on the potential for thermal neutrons to cause soft errors (an error in a signal or datum which is wrong) in integrated circuits by way of interacting with the isotope boron-10, which is found in the lower intermetal dielectric layers of electronics' integrated circuits. Building upon this work, Wilkinson *et al*. examined the potential for soft errors in electronics operating in the vicinity of linear accelerators since high-energy radiotherapy creates an undesirable flux of neutrons. The authors positioned 10 static random-access memory (SRAM) devices known to be sensitive to thermal-neutron-induced soft errors approximately 50 cm from the isocenter of the linear accelerator's beam. Each device was alternately exposed in the following conditions: 1) without shielding; 2) with shielding from EMI; 3) with shielding from thermal neutrons; and 4) while held outside the treatment room as a control. A total of four soft errors were detected, three from the unshielded devices and one from an EMI-shielded device. It was noted that no errors were detected when the devices were shielded from thermal neutrons or held outside the treatment room. During the exposures, a larger capacity SRAM device was positioned 50 cm off axis and continuously monitored. During 10 minutes of exposure a total of 89 errors were recorded on this device. The authors also examined 14 electronic devices that might be typically found near linear accelerators and determined that all of the devices contained boron-10. Their findings suggest that many integrated circuits used in electronics typically found in radiotherapy settings contain boron-10 compounds and that a radiotherapy linear accelerator causes a high rate of soft errors in electronics which contain this compound.

2012-2014 Update Results

The 2012-2014 update of the literature identified 55 citations; following title and abstract screening, 4 articles were deemed relevant for inclusion, following full text review 2 articles were included in this report. One of the articles (9) was translated from French to English.

Abrous-Anane *et al.* (9) recently published a case report on a patient with an implanted infusion pump who received radiation therapy for cervical cancer. The 54 year old patient had a Baclofen (Lioresal ®) pump surgically implanted under the abdomen and received exclusive treatment with radiation therapy. A theoretical dose constraint threshold was set at 0.5 Gy by the pump manufacturer. Dosimetry testing was then performed to determine the optimal form of treatment. Using tomotherapy the pump received an average dose between 10 Gy (if it was considered as an organ at risk) and 12.5 Gy. When the dose was delivered using three-dimensional conformal radiation therapy (3D-CRT), it was reduced to 1.16 Gy, which was still slightly higher than the recommended threshold. Based on these findings, and a lack of data in the literature, the patient received 3D-CRT (8 and 18 MV). Precautions were taken to exclude the pump from radiation beams, hospitalize the patient during treatment, monitor the patient daily for over or under dosing and to have the manufacturer monitor the pump on a biweekly basis. No pump malfunction incidents were reported during the treatment or during the patient's follow up visits.

In addition, Abrous-Anane *et al.* (9) performed a series of tests on 5 identical pumps. The pumps were placed in a water tank and exposed to direct beams of 18 MV with doses ranging from 2 to 40 Gy. The first pump received radiation doses which increased by 2 Gy, the doses increased by 4 Gy in next 2 pumps and by 16 Gy in the last 3 pumps. The pumps tolerated the doses without any malfunctions.

Festa *et al.* (10) reported the results of a test performed on an infusion pump device which was exposed to an electromagnetic field radiated by a radiofrequency identification (RFID) reader. The authors concluded that the pump continued to function without sounding an alarm despite being placed as close as 15 cm from an antenna or close to 2 antennas.

While these 2 studies add to the body of evidence on the use of continuous infusion pumps during radiation treatment, their findings do not impact the original conclusions made in this report. Therefore no changes were made to the recommendations.

2014-2016 Update Results

The 2014-2016 update of the literature identified 3607 citations. Following a narrowing of the search strategy, 50 citations were located and deemed relevant. Following the title and abstract screening, 5 articles were reviewed in further detail and assessed for inclusion into the report. Following in-depth review, the 5 articles were not deemed to be relevant for inclusion.

DISCUSSION

The recommendations put forth in the documents summarized in the previous section are similar to the opinions of the working group. However some discussion arose around the recommendation to switch patients from the pump to oral treatment, presented by Wu and Wang (2). Under many circumstances this recommendation is not practical or easy to carry out, particularly when the patient is receiving one or two doses. Additionally switching patients to oral treatment would not be feasible for analgesics and other medications with a narrow therapeutic index. In many cases, intravenous chemotherapy cannot be substituted by oral doses.

The group also pointed out that the recommendation found in the hazard report, suggesting to simply switch off the device is not a sufficient precaution and would not limit the potential damage to the pump.

It is CCO's intention to disseminate this report to the Regional Cancer Programs and advisory committees within the province and to make the document available to Ontario healthcare providers and the general public on the CCO website.This report will be reviewed every two years to determine whether the information is still accurate and relevant to current practice and revised accordingly.

For general inquiries regarding this report, please contact: RTP@cancercare.on.ca

ACKNOWLEDGEMENTS

This report was developed with the assistance of Kate Bak, BA, MSc; Sarah Costa, BA, MSc; Carina Simniceanu, BSc, MA; Lisa Durkin, BA, MHSc; Eric Gutierrez MRT(T), CMD, BSc; Esther Green BScN, MSc(T); Sherrie Hertz, BScPhm; Leonard Kaizer, MD, FRCPC; Elizabeth Murray BA, MPPA; Elizabeth Lockhart, BHSc, MSc; Michael Sharpe, PhD; Stephen Breen, PhD; Raquel Shaw-Moxam, BSc, MSc; Maureen Trudeau, BSc, MA, MD; Padraig Warde, MB, MRCPI, FRCPC; and Anthony Whitton, BSc, MBBS, FRCPC.

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APPENDIX 1. Literature search strategy

Database: Ovid MEDLINE(R) <1996 to September Week 2 2008>[1]

1. Ambulatory chemotherapy infusion pump:.mp. (1)
2. Ambulatory chemotherapy:.mp. (37)
3. Infusion pump:.mp. (3834)
4. Infusion treatment:.mp. (156)
5. Electronic infusion pump:.mp. (3)
6. Electronic pump:.mp. (20)
7. or/1-6 (4027)
8. Electromagnetic Interference:.mp. (277)
9. EMI:.mp. (90476)
10. or/8-9 (90666)
11. radiat:.mp. (117802)
12. linear accelerator:.mp. (1549)
13. or/11-12 (118376)
14. 10 and 13 (5314)
15. limit 14 to english language (4896)
16. cardiac pacemaker:.mp. (720)
17. 15 not 16 (4890)
18. 7 and 13 (46)
19. limit 18 to english language (40)
20. from 19 keep 1-40 (40)

Database: EMBASE <1980 to 2008 Week 38>[2]

1. Ambulatory chemotherapy infusion pump:.mp. (1)
2. Ambulatory chemotherapy:.mp. (40)
3. Infusion pump:.mp. (3564)
4. Infusion treatment:.mp. (288)
5. Electronic infusion pump:.mp. (3)
6. Electronic pump:.mp. (24)
7. or/1-6 (3892)
8. Electromagnetic Interference:.mp. (344)
9. EMI:.mp. (133271)
10. or/8-9 (133507)
11. radiat:.mp. (244071)
12. linear accelerator:.mp. (3430)
13. or/11-12 (244877)
14. 10 and 13 (11717)
15. limit 14 to english language (10992)
16. cardiac pacemaker:.mp. (1364)
17. 15 not 16 (10977)
18. 7 and 13 (60)
19. limit 18 to english language (58)
20. from 19 keep 1-40 (40)
21. from 20 keep 1-40 (40)

[1] A literature search was performed again in 2010 and 2011 using the identical search strategy. No new articles were found.
[2] A literature search was performed again in 2010 and 2011 using the identical search strategy. No new articles were found.

APPENDIX 2. 2008-2012 Update - Literature search strategy

MEDLINE <1946 to March Week 1 2012>,

1. ambulatory chemotherapy infusion pump:.mp. (1)
2. ambulatory chemotherapy:.mp. (99)
3. ambulatory chemo$:.mp. (102)
4. infusion pump:.mp. (8802)
5. infusion treatment:.mp. (407)
6. infusion treat$:.mp. (431)
7. electronic infusion pump:.mp. (5)
8. electronic pump:.mp. (31)
9. or/1-8 (9326)
10. electromagnetic interference:.mp. (543)
11. EMI:.mp. (214547)
12. or/10-11 (214915)
13. radiat$:.mp. (343499)
14. irradiat$:.mp. (171566)
15. linear accelerat$:.mp. (4204)
16. or/13-15 (440912)
17. 12 or 16 (640073)
18. 9 and 17 (221)
19. limit 18 to english language (188)
20. cardiac pacemaker:.mp. (2602)
21. 19 not 20 (187)
22. limit 21 to yr="2008 -Current" (30)

EMBASE <1947 to 2012 Week 11>

1. Ambulatory chemotherapy infusion pump:.mp. (1)
2. ambulatory chemotherapy:.mp. (169)
3. ambulatory chemo$:.mp. (174)
4. infusion pump:.mp. (6877)
5. infusion treatment:.mp. (553)
6. infusion treat$:.mp. (585)
7. electronic infusion pump:.mp. (6)
8. electronic pump:.mp. (42)
9. or/1-8 (7641)
10. electromagnetic interference:.mp. (659)
11. EMI:.mp. (250721)
12. or/10-11 (251171)
13. radiat$:.mp. (597555)
14. irradiat$:.mp. (258485)
15. linear accelerat$:.mp. (7447)
16. or/13-15 (711415)
17. 12 or 16 (935103)
18. 9 and 17 (196)
19. limit 18 to english language (171)
20. cardiac pacemaker:.mp. (3739)
21. 19 not 20 (169)
22. limit 21 to yr="2008 -Current" (42)

APPENDIX 3. 2012-2014 Update – Literature search strategy

MEDLINE(R) <1946 to March Week 4 2014>

1. ambulatory chemotherapy infusion pump:.mp. (1)
2. ambulatory chemotherapy.mp. (105)
3. ambulatory chemo$.mp. (108)
4. infusion pump.mp. (1756)
5. infusion pump/ (4679)
6. infusion treat$:.mp. (444)
7. electronic infusion pump:.mp. (6)
8. electronic pump:.mp. (29)
9. *chemotherapy/ (21696)
10. or/1-9 (28141)
11. electromagnetic interference:.mp. (535)
12. EMI:.mp. (219028)
13. or/11-12 (219396)
14. radiat$:.mp. (357263)
15. irradiat$:.mp. (173585)
16. radiotherapy:.mp. (171095)
17. *radiation/ (3058)
18. linear accelerat$:.mp. (4478)
19. photon$:.mp. (86826)
20. or/11-19 (782019)
21. 13 or 20 (782019)
22. 10 and 21 (595)
23. cardiac pacemaker:.mp. (2675)
24. 22 not 23 (595)
25. limit 24 to yr="2012 -Current" (28)

EMBASE <1980 to 2014 Week 14>

1. ambulatory chemotherapy infusion pump:.mp. (1)
2. ambulatory chemotherapy.mp. (160)
3. ambulatory chemo$.mp. (162)
4. infusion pump.mp. (6879)
5. infusion pump/ (5773)
6. infusion treat$:.mp. (549)
7. electronic infusion pump:.mp. (11)
8. electronic pump:.mp. (51)
9. *chemotherapy/ (17015)
10. or/1-9 (24585)
11. electromagnetic interference:.mp. (829)
12. EMI:.mp. (286274)
13. or/11-12 (286841)
14. radiat$:.mp. (591745)
15. irradiat$:.mp. (215569)
16. radiotherapy:.mp. (270389)
17. *radiation/ (8795)
18. linear accelerat$:.mp. (8044)
19. photon$:.mp. (91552)
20. or/14-19 (882105)
21. 13 or 20 (1083764)
22. 10 and 21 (2821)
23. cardiac pacemaker:.mp. (3093)
24. 22 not 23 (2819)
25. limit 24 to yr="2012 -Current" (792)
26. Conference Abstract.pt. (1375889)
27. 25 not 26 (36)

Appendix 4. 2014-2016 Update – Literature search strategy

MEDLINE(R) < 1946 to October Week 2 2016 >

1. ambulatory chemotherapy infusion pump:.mp (1)
2. ambulatory chemotherapy.mp. (120)
3. ambulatory chemo$.mp. (123)
4. infusion pump.mp. (1867)
5. infusion pump/ (5032)
6. infusion treat$:.mp. (478)
7. electronic infusion pump:.mp. (8)
8. electronic pump:.mp. (33)
9. *chemotherapy/ (22676)
10. or/1-9 (29577)
11. electromagnetic interference:.mp. (621)
12. EMI:.mp. (260908)
13. or/11-12 (261324)
14. radiat$:.mp. (406618)
15. irradiat$:.mp. (194692)
16. radiotherapy:.mp. (196320)
17. *radiation/ (7500)
18. linear accelerat$:.mp. (5004)
19. photon$:.mp. (99492)
20. or/14-19 (695017)
21. 13 or 20 (900763)
22. 10 and 21 (635)
23. cardiac pacemaker:.mp. (2866)
24. 22 not 23 (635)
25. limit 24 to yr="2014 -Current" (28)
26. limit 25 to english language (26)

Embase < 1974 to 2016 October 24 >

1. ambulatory chemotherapy infusion pump:.mp. (1)
2. ambulatory chemotherapy.mp. (195)
3. ambulatory chemo$.mp. (196)
4. infusion pump.mp. (8512)
5. infusion pump/ (7312)
6. infusion treat$:.mp. (680)
7. electronic infusion pump:.mp. (14)
8. electronic pump:.mp. (64)
9. *chemotherapy/ (67060)
10. or/1-9 (76324)
11. electromagnetic interference:.mp. (1026)
12. EMI:.mp. (373269)
13. or/11-12 (373943)
14. radiat$:.mp. (761990)
15. irradiat$:.mp. (270284)
16. radiotherapy:.mp. (461432)
17. *radiation/ (30259)
18. linear accelerat$:.mp. (11744)
19. photon$:.mp. (117162)
20. or/14-19 (1183841)
21. 13 or 20 (1443276)
22. 10 and 21 (16308)
23. cardiac pacemaker:.mp. (3977)
24. 22 not 23 (16306)
25. limit 24 to yr="2014 -Current" (4822)
26. limit 25 to english language (4572)
27. Conference Abstract.pt. (2360081)
28. 26 and 27 (3607)
29. limit 28 to (english language and yr="2014 -Current") (3607)

30. or/1-8 (9404)
31. 30 and 21(335)
32. 31 not 23 (333)
33. 32 not 27 (286)
34. limit 33 to (english language and yr="2014 -Current") (35)

APPENDIX 5. RECOMMENDATION DEVELOPMENT PROCESS

Internal Review by the Multidisciplinary Working Group
Prior to the submission of this recommendation report for external review, the report was reviewed by a multidisciplinary working group, which included representation from nursing and psychosocial oncology, radiation oncology, radiation therapy, medical physics, pharmacy and medical oncology. The group met through in-person meetings and used e-mail as the main vehicle of communication.

External Review by Ontario Health Professionals
Following the review and approval of the recommendation report by the multidisciplinary working group at CCO, the report was circulated to a multidisciplinary external review panel which included representation from nursing, radiation oncology, radiation therapy, medical oncology, and medical physics.

Methods
Members of the working group at CCO were asked to suggest individuals from their respective disciplines who, in their opinions, would be suitable to review the report. The recommendation report was emailed to 18 health professionals from the disciplines of radiation treatment, systemic treatment, nursing, and medical physics in Ontario. Individuals were asked to provide feedback regarding the content and recommendations contained in the report. Follow-up reminders were sent three weeks and four weeks after the initial request for participation was sent.

Results
Nine responses were received from the 18 individuals that were approached to participate in the external review process (50% response rate). All responses were received via email and comments were provided either in the body of the email messages or incorporated using the 'track changes' function in the Microsoft Word document which was circulated with the initial request. Two of the respondents indicated that they each had shared the document with colleagues. One respondent indicated sharing the report with two additional colleagues and the other noted sharing the report with three additional colleagues. In each case, the feedback submitted was based on a combination of their reviews as well as those of their colleagues. In total, the recommendation report was reviewed by 14 health professionals external to CCO.

Summary of Written Comments
Of the 14 external reviewers, four approved the report as it was provided to them and 10 provided comments and suggested revisions. The main points contained in the written comments are summarized below:

Issue

- One respondent noted that there are many other sources of EMI in a health care setting. Therefore it should be specifically stated that the document pertains only to situations involving radiation therapy.

Issue Summary

- One respondent noted the importance of noting that recommendations contained in the report are applicable to infusion pumps which provide analgesics and other non-chemotherapy agents.

Results

- In reference to the 'multiple incidents of Baxter Colleague infusion pumps malfunctioning during the course of radiotherapy using linear accelerators', it was noted that it would be useful to provide the actual number of incidents and time period over which the incidents were reported.
- A summary table listing potential pump problems (e.g. battery depletion, corruption of memory chip, etc.) by type of pump and type of radiation was suggested. The inclusion of information detailing which types of pumps are used in Ontario and for what indications the pumps are used for was suggested.

Discussion

- One respondent noted a concern regarding the delivery of narcotics being decreased if the pump is not shielded and that should the pump be turned off, a bolus should be given at the time of both pump disconnection and reconnection.

Recommendations for Clinical Practice

- The potential for error arising from the disconnection of infusion pumps was noted.
- For situations when a patient cannot be disconnected from the electronic infusion pump, a recommendation regarding the quality of radiation used was suggested. For example, does the published evidence or expert opinion suggest a preference for lower versus higher x-ray energies? Should x-ray and electron radiation be considered equivalent in these recommendations?
- One respondent noted that it may be useful to indicate if there is any perceived utility in an estimate of the dose received by the device, or if any threshold doses should be considered.
- One respondent queried whether there is evidence to support that Elastomeric Pumps are <u>not</u> affected by radiation or whether there no evidence to indicate that they are affected by radiation.
- It was suggested that the report indicate that the disconnection and reconnection of an infusion pump must be performed by an appropriately skilled 'health care professional' rather than a 'registered nurse'.
- It was noted that the report should specify that a nurse instead of a 'health care professional' should assess the infusion pump. Some health care professionals may not have the specialized knowledge required to assess whether a pump is working correctly.
- Testing of pumps exposed to radiation by 'biomed teams' was suggested.

The following additional recommendations were suggested:

- To address which member of the health care team should be responsible for identifying that a patient has an infusion pump as well as communicating the information to other individuals involved in the patient's care.
- To provide guidance on communicating with other hospitals or health care institutions that initially connected the infusion pumps. It was suggested that guidance be provided regarding the recommended communication in the event that pumps are exposed to radiation and/or found to be defective.
- To recommend that any instances of infusion pump malfunction be reported to a central CCO body. This would allow for the accumulation of data regarding malfunction probabilities of these devices. It was noted that such data would aid best-care practices within cancer centres as well as educate manufacturers regarding realistic device limitations.

Additional Evidence

- An additional publication (Wilkinson *et al*., 2005) was identified and suggested for review.

Additional Comments

- A formal assessment of the types of infusion pumps most commonly used in Ontario was suggested.

Modifications to the Report

After reviewing and discussing the feedback received from external reviewers, the working group made the following changes to the report:

Issue

- The issue statement was reworded to specifically state that the document pertains to a health care setting involving the delivery of radiation treatment.

Issue Summary

- No changes were made as the report already noted that the document 'may also have relevance to electronic infusion pumps used to delivery non-chemotherapy agents as well, such as insulin, analgesics and other agents though they are not specifically addressed in this document'.

Results

- In reference to the 'multiple incidents of Baxter Colleague infusion pumps malfunctioning during the course of radiotherapy using linear accelerators', further information regarding the actual number of incidents and the time period over which the incidents was not included such information was not available.
- A summary table listing potential pump problems (e.g. battery depletion, corruption of memory chip, etc.) by type of pump and type of radiation was deemed to be outside of the scope of this report and affiliated working group.
- Information detailing which types of pumps are used in Ontario and for what indications the pumps are used for was deemed to be outside of the scope of this report and affiliated working group.
- A summary of the additional publication (Wilkinson *et al*., 2005) identified by an external reviewer was included.

Discussion

- The concern regarding the delivery of narcotics being decreased if the pump is not shielded and the suggestion that if the pump is turned off a bolus should be given at the time of both pump disconnection and reconnection were addressed in the Recommendation #4 in 'Recommendations for Clinical Practice' section.

Recommendations for Clinical Practice

- A recommendation regarding the quality of radiation to be used in the event that a patient cannot be disconnected from the electronic infusion pump was included.
- An estimate of the dose received by an infusion pump during radiation treatment and threshold doses to be considered were deemed to be outside of the scope of this report and affiliated working group.
- Recommendations regarding the disconnection and reconnection of an infusion pump and the assessment of a pump to ensure proper functioning were revised to recommend that these functions be performed by a Registered nurse (or equivalent).
- Testing of pumps exposed to radiation by 'biomed teams' was not included in the recommendations due to concerns from the working group that it may not be feasible, or necessary, to have all pumps exposed to radiation assessed by Biomedical Engineering personnel without causing undue disruption in patient care. However, Recommendation #6 does suggest that pumps found to be defective should be sent to the Biomedical Engineering department for assessment and if necessary, repair.

- An additional recommendation was added to indicate that a member of the radiation treatment team should be responsible for identifying that a patient has an infusion pump as well as communicating the information to other individuals involved in the patient's care.
- An additional recommendation was added to provide guidance on communicating with other hospitals or health care institutions that initially connected the infusion pumps.
- The development of a process to facilitate the reporting of any instances of infusion pump malfunction to a central CCO body was deemed to be outside of the scope of this report and affiliated working group.

Additional Evidence

- The additional publication (Wilkinson *et al*., 2005) identified by an external reviewer was considered to be relevant and included in the report.

Additional Comments

- A formal assessment of the types of infusion pumps most commonly used in Ontario was deemed to be outside of the scope of this report and affiliated working group.