HQCA
Health Quality Council of Alberta

Review of Leading Practices Related to the Administration of Medications, Including Chemotherapy Medications, through IV Pumps in Ambulatory Care Settings

Introduction

In summer 2006, a 43-year-old woman who was being treated for cancer received an overdose of chemotherapy medication. The chemotherapy medication was initiated in the outpatient clinic of a cancer centre. The drug was administered via an ambulatory IV infusion pump for use by the patient following discharge home. The pump was inadvertently programmed to deliver the chemotherapy medication over four hours rather than four days (96 hours) as intended. The patient returned to the outpatient clinic setting as soon as she discovered that the chemotherapy medication bag on the pump was empty. The patient was initially treated as an out-patient at a cancer centre and then admitted for in-patient care at the centre. The patient was transferred to a tertiary care centre ICU when her condition continued to deteriorate. The patient subsequently developed multi-organ failure and died 22 days after receiving the overdose.

Scope and Purpose

The Health Quality Council of Alberta (HQCA) is a provincial health board whose mandate includes conducting quality and safety inquiries. Although initiated in response to a specific adverse event, the focus of the HQCA review was to identify learnings and make related recommendations that have system-wide applicability. The purpose of this HQCA review is to foster system-wide quality and safety improvement through the adoption and maintenance of the recommended leading practices that have emerged from the review. The recommended leading practices require the development and implementation of supporting detailed policies and procedures applicable to patient care centres using intravenous (IV) pumps for the administration of medications, including chemotherapy medications, in home and other ambulatory care settings.

Review Process

The HQCA's recommendations were developed through a process that included interviews with clinicians and administrators from the facility involved in the incident; a review of documents related to the incident including the root cause analysis conducted by ISMP Canada; a review of relevant quality and safety literature; and consultation with selected experts in the areas of patient safety, medication safety, oncology and toxicology. The incident was reviewed, and the recommendations were developed, from a system-wide quality improvement perspective in terms of the six dimensions of quality in the *Alberta Quality Matrix for Health:* Acceptability; Accessibility; Appropriateness; Effectiveness; Efficiency and Safety.[1]

During the course of the HQCA review, it was found that many of the recommended practices were in place at the affected organization at the time of the incident and others are in the process of being implemented or are under active review. The HQCA believes that the affected organization has learned from the incident and will continue to strengthen its existing policies, processes and practices and introduce new ones based on this review, the organization's own internal review and the root cause analysis conducted by ISMP Canada.

Leading Practices

Within the framework of the *Alberta Quality Matrix for Health*, the HQCA recommends the following leading practices. The HQCA believes that these leading practices should be strongly considered for implementation throughout Alberta's health care system.

Acceptability

To enhance the acceptability of patient care associated with the administration of medications, including chemotherapy medications, through IV pumps in ambulatory care settings:

1. ***Implement an Effective Disclosure Policy*** that ensures if and when harm to patients occurs, such harm is disclosed to patients and families in a timely, full and complete manner consistent with the provincial framework for *Disclosure of Harm to Patients and Families* dated July 2006.[2] The intent is to ensure that the initial disclosure meeting with the patient and family occurs, at most, within one to two days following the discovery of harm and that subsequent disclosure meetings take place as more information is learned by the health care

team. Key elements of the initial disclosure meeting with the patient and family include:

- An explicit statement that harm occurred.
- A factual description of what is known about the event resulting in harm.
- Resulting consequences of the harm including both short- and long-term effects.
- Corrective actions that were and will be taken.
- An expression of remorse and empathy to the patient and family.
- An appropriate apology.
- A brief overview of the investigative process that will follow.
- An offer for future meetings.
- Allowance of time for clarification and questions by the patient and family.

2. ***Engage Patients in Their Own Medication Safety*** wherever feasible.[3] The intent is to include patients in their own medication safety in a partnership with applicable medical, nursing and pharmacy personnel. Some key components of this leading practice require that patients, along with their relatives or caregivers, are provided with the following:
   - The name and type of chemotherapy drug(s) prescribed, expected side effects and information on what to do if unexpected serious side effects occur.
   - Information on how the drugs will be administered, how long it will take for the drug to infuse, the risks associated with the IV pump, and, if appropriate, the ways in which patients can help monitor the safe use of such pumps including the rate of flow.
3. ***Ensure Acceptable and Timely Palliative and End-of-Life Care*** is provided for patients that have received severe chemotherapy drug overdoses for which there is no antidote or effective way to reverse drug toxicity. Disclosure of such events and harm that might be caused at the earliest possible time is vital to ensure the patient and family are fully aware of the possible consequences of the overdose and can make timely and informed decisions regarding palliative and end-of-life care.[4]

Accessibility

To enhance the accessibility of patient care associated with the administration of medications, including chemotherapy medications, through IV pumps in ambulatory care settings:

4. ***Provide 24/7 Help Line Support*** to patients receiving home IV infusions. The intent is to enable patients to quickly access help to address any questions or concerns they may have with their infusion pumps or other aspects of their out-patient care.

Appropriateness

To enhance the appropriateness of patient care associated with the administration of medications, including chemotherapy medications, through IV pumps in ambulatory care settings:

5. ***Ensure All Patient Health Records Are Complete*** including full assessments and care plans. The intent is to facilitate communication among clinicians and to maintain continuity of patient care.[5]
6. ***Improve Patient Transfer Protocols*** between treatment centres and tertiary acute care facilities to ensure timely and direct communication between care teams regarding patients that have experienced life-threatening overdoses.[6] Documented information regarding transferred patients should include a detailed consultative note outlining the patient's medical problem, the intended and actual treatment administered, the potential for short-term toxic effects and specific monitoring and therapeutic measures required.

Effectiveness

To enhance the effectiveness of patient care associated with the administration of medications, including chemotherapy medications, through IV pumps in ambulatory care settings:

7. ***Develop and Implement Toxicity Dose Range Protocols*** to enable physicians and nurses to identify acceptable and unacceptable toxicity dose ranges for the administration of chemotherapy drugs to patients within specific treatment protocols.[7] The intent is to encourage cancer centres to work together to develop appropriate dose range protocols where none currently exist with the aim of ensuring that physicians and nurses can readily identify instances when chemotherapy medications in clinically toxic dose ranges are inadvertently administered.

8. ***Develop and Implement Overdose Treatment Protocols.*** Develop and implement treatment protocols for cases of inadvertent overdoses of chemotherapy drugs. The intent is to encourage cancer centres to work together to develop appropriate overdose treatment protocols where none currently exist with the aim of ensuring that clinicians can effectively and efficiently respond to, and treat, overdoses of chemotherapy drugs according to referenced peer reviewed protocols.

9. ***Implement a Protocol to Report Overdoses to Senior Administrators.*** The intent is to ensure senior administrators are quickly alerted when severe drug overdoses occur, enabling them to immediately take appropriate supportive action regarding patient care and safety.

Efficiency

To enhance the efficiency of patient care associated with the administration of medications, including chemotherapy medications, through IV pumps in ambulatory care settings:

10. ***Develop and Implement an Incident Review Triage Process*** to ensure timely medical review of incidents with a high potential to cause patient harm regardless of the severity rating of the incident.[8] The triage process should include guidelines regarding the type and degree of variance that should trigger notification of oncologists, nurses and pharmacists.

11. ***Make Drug Toxicity and Antidote Information Readily Available.*** Ensure that drug toxicity and antidote information from both internal and external sources is readily available and effectively used by clinicians using chemotherapy drugs. Use external sources of information such as the Alberta-based Poison and Drug Information Services (PADIS) in addition to information available through the organization's internal pharmacy.[9]

12. ***Implement an Effective Informing Protocol*** that ensures that information and learnings from adverse events are shared in a timely manner with external stakeholders including medication safety and poison control organizations provincially and nationally.[10]

Safety

To enhance the safety of patient care associated with the administration of medications, including chemotherapy medications, through IV pumps in ambulatory care settings:

13. ***Review the Ambulatory Care IV Pump Selection Process and Criteria.***[11] Ensure the process and criteria used to select and standardize IV pumps for use by patients in ambulatory care settings addresses all patient safety considerations including elimination of free flow, maximum flow rates, upper and lower dosage limits and alarms to indicate occlusion or depleted infusion. Include in the review all stakeholders that have applicable clinical, technical and contractual expertise. The intent is to standardize IV pumps used in ambulatory care settings and to ensure the patient safety risks associated with the selection and use of IV pumps used in ambulatory care settings are appropriately taken into account.

14. ***Perform Independent Multiple Checks When Programming IV Pumps.***[12] Provide health care personnel responsible for programming IV pumps with written directions for programming the pumps that include independent double checked calculations prepared by pharmacy. The checking procedure should involve the following five steps:

- The first pharmacist performs dose calculations and includes them in the administration directions.
- A second pharmacist performs dose calculations, without seeing those performed by the first pharmacist, to check the first pharmacist's calculations and confirm the written administration directions. The intent is to avoid having the second pharmacist's calculations biased by knowledge of the first pharmacist's calculations.
- The pump is then programmed by pharmacy or a nurse member of a dedicated pump programming team using the confirmed written administration directions.
- A nurse or a pharmacist, who has not programmed the pump, reads back the pump readings to another member of the programming team.

- A nurse or a pharmacist compares the output to determine if it matches the original order. If the output matches the original order, the chemotherapy drug is administered through the programmed IV pump.

15. ***Use Dedicated IV Pump Programming Teams*** responsible for programming all IV pumps for use by patients receiving medication infusions in outpatient settings.[13] The intent is to standardize safety procedures and maintain a specific team having the specialized skills and knowledge required.

16. ***Use IV Pumps with Built-In Safeguards.*** Use IV pumps with built-in safeguards including elastomeric and programmable pumps and when feasible pumps utilizing 'smart' technology. IV smart pumps for use in ambulatory care settings are not currently available. When they do become available, the use of smart pump technology should be encouraged to augment current medication safety practices by the addition of such safety features as dose alerts, dosing and flow rate limits and other programming safeguards, including operator feedback to allow detection of pump programming errors.[14] The intent is to provide clinical personnel responsible for IV medication administration in ambulatory care settings with the safest pump technology available to augment current medication safety practices.

17. ***Check Actual Pump Rate of Flow against Physician Order Prior to Patient Discharge.*** If it is not feasible to use IV pumps in ambulatory care settings that have the full range of safety features found on 'smart pumps', then two final safety checks should be performed to ensure that the actual rate of drug administered through the IV pump matches the rate required in the original physician order. First, perform an independent double check to ensure the pump is programmed correctly according to the original physician order. Second, monitor the patient and the actual rate of infusion for an appropriate period of time to ensure that actual rate of flow matches the reading on the pump (_mL/h). For example, if the rate of infusion is 5mL/h and the total volume to be infused is 250mL, after one hour the volume remaining to be infused should read 245 mL.

These leading practices are not intended as standards or absolute requirements and are not intended to substitute for sound clinical judgment related to the specific needs of patients. The HQCA cannot guarantee any specific outcomes through the use of the leading practice information in this document nor are these leading practices Alberta Health and Wellness policy.

Selected References

1. The guide to the *Alberta Quality Matrix for Health* can be accessed at www.hqca.ca or upon request.
2. The *Disclosure of Harm to Patients and Families* provincial framework can be accessed at www.hqca.ca
3. With respect to the engagement of patients in their own medication safety, see for example:
   - Miranda DJ et al. "Speaking Plainly: Communicating the Patient's Role in Health Care Safety". In *Advances in Patient Safety: From Research to Implementation*. Vol. 4, Programs, Tools and Practices. Rockville, MD: Agency for Healthcare Research and Quality; 2005. Available at www.ahrq.gov/qual/advances
   - Joint Commission on Accreditation of Healthcare Organization's 'Speak Up' Campaign. *Things You Can Do to Prevent Medication Mistakes* and other patient safety guides. Available at: www.jointcommission.org/PatietySafety/SpeakUp
   - The Massachusetts Coalition for the Prevention of Medical Errors. *Your Role in Safe Medication Use: A Guide for Patients and Families*. Available at www.macoalition.org/documents/ConsumerGuide.pdf
   - Hibbard JH, Peters E, Slovic P, and Tusler M. "Can Patients Be Part of the Solution? Views on Their Role in Preventing Medical Errors". *Medical Care Research and Review* 2005; 62(5): 601-616.
4. With respect to palliative and end-of-life care, see for example:
   - Back AL, Arnold RM, Baile WF, Tulsky JA, Fryer-Edwards K. "Approaching Difficult Communication Tasks in Oncology". CA *A Cancer Journal for Clinicians* 2005; 55(3): 164-177.
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5. With respect to patient records, see for example:
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- Arora, V, Johnson, J. "A Model for Building a Standardized Hand-off Protocol". *Journal on Quality and Patient Safety*. 2006; 32(11): 646 -655.
- "Strategies to Improve Hand-off Communication". *Joint Commission Perspectives on Patient Safety*, July 2005, Volume 5, Issue 7. Joint Commission on Accreditation of Healthcare Organizations.
- "Strategies for Enhancing Physician-to-Physician and Staff-to-Physician Communication". *Joint Commission Perspectives on Patient Safety*, July 2005, Volume 4, Issue 11. Joint Commission on Accreditation of Healthcare Organizations.

6. With respect to patient transfer documentation, see for example:
   - Ligtenberg JJM et al. "Quality of Interhospital Transport of Critically Ill Patients: a Prospective Audit". *Critical Care* 2005; 9: R446-451.
   - Bomba DT, Prakash R. "A Description of Handover Processes in an Australian Public Hospital". *Australian Health Review* 2005; 29(1): 68-79.
   - Paterson ES et al. "Handoff Strategies in Settings with High Consequences for Failure: Lessons for Health Care Operations". *International Journal for Quality in Health Care*. 2004; 16(2): 125-132.
   - Heikkinen A et al. "Coordination of Care: The Patient's Journey". *Partnership of Stratis Health*, the Minnesota Department of Health and the Minnesota Association of Area Agencies on Aging. 2005 Final Report.
7. With respect to chemotherapy error prevention and toxicity dose range protocols, see for example:
   - "Reduce the risk of errors with high risk medication and administered to high risk patient populations or at vulnerable periods or transfer through the healthcare system. Guideline for maximum adult dose limits of parenteral chemotherapy". *Pathways for Medication Safety*. American Hospital Association, Health Research and Education Trust, Institute for Safe Medication Practices, 2002, 1.2.5, 1.F1.
   - Harris TJ, Northfelt DW. "Chemotherapy Error: Practical Approaches to Increasing Patient Safety". *Journal of Patient Safety* 2005; 1(4): 215-219.
8. With respect to incident review processes, see for example:
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   - American Society of Health-System Pharmacists. *ASHP Guidelines on Preventing Medication Errors with Antineoplastic Agents*, 2002: 138-154. Available at www.ashp.org
9. With respect to poison and drug information services, see for example:
   - The Poison and Drug Information Service (PADIS) in Alberta can be accessed at 1-800-332-1414.
   - In BC, the Drug and Poison Information Services can be accessed at 1-800-567-8911.
   - The Saskatchewan Drug Information Service (SDIS) can be accessed at 1-800-667-3425.
10. With respect to informing protocols, see for example:
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12. With respect to independent double checks, see for example:
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14. With respect to smart IV pump technology as well as the need for standardization before the use of smart pump technology, see for example:
    - *Reduce Adverse Drug Events Involving Intravenous Medications*, Institute of Healthcare Improvement, www.ihi.org/IHI/Topics/Patient Safety/MedicationSystems/ Changes/ IndividualChanges/ImplementSmart InfusionPumps.htm
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