

Health Quality Ontario Qualité des services de santé Ontario

Multiple Intravenous Infusions Phases 2a and 2b: OHTAC Recommendation

Ontario Health Technology Advisory Committee

May 2014

Multiple Intravenous Infusions Phases 2a and 2b: OHTAC Recommendation. May 2014; pp. 1–16

Suggested Citation

This report should be cited as follows:

Ontario Health Technology Advisory Committee (OHTAC). Multiple intravenous infusions phases 2a and 2b: OHTAC recommendation [Internet]. Toronto: Queen's Printer for Ontario; 2014 May. 16 p. Available from: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/ontario-health-technology-assessment-series/MIVI-phase2a.

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Conflict of Interest Statement

All authors in the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

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Health Quality Ontario (HQO) is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with advisory panels, clinical experts, developers of health technologies, scientific collaborators, and field evaluation partners to provide evidence about the effectiveness and cost-effectiveness of health interventions in Ontario.

To conduct its systematic reviews of health interventions, the Evidence Development and Standards branch examines the available scientific literature, making every effort to consider all relevant national and international research. If there is insufficient evidence on the safety, effectiveness, and/or cost-effectiveness of a health intervention, HQO may request that its scientific collaborators conduct economic evaluations and field evaluations related to the reviews. Field evaluation partners are research institutes focused on multicentred clinical trials and economic evaluation, as well as institutes engaged in evaluating the safety and usability of health technologies.

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The Ontario Health Technology Advisory Committee (OHTAC) is a standing advisory subcommittee of the Board of Directors of Health Quality Ontario. Based on the evidence provided by Evidence Development and Standards and its partners, OHTAC makes recommendations about the uptake, diffusion, distribution, or removal of health interventions within the provincial health system. When making its recommendations, OHTAC applies a unique decision-determinants framework that takes into account overall clinical benefit, value for money, societal and ethical considerations, and the economic and organizational feasibility of the health care intervention in Ontario.

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When sufficient data are available, OHTAC tracks the ongoing use of select interventions it has previously reviewed, compiling data by time period and region. The results are published in the Ontario Health Technology Maps Project Report.

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Background

The Ontario Health Technology Advisory Committee commissioned HumanEra (formerly the Health Technology Safety Research Team), with support from Health Quality Ontario and in collaboration with the Institute for Safe Medication Practices Canada, to generate evidence-based recommendations to reduce the hazards associated with administering multiple IV infusions to a single patient.

A challenge to studying the risks associated with multiple IV infusions is that they are not confined to a single controlled element (e.g., an isolated technology issue); instead, a detailed understanding of many system elements (e.g., clinical tasks and processes, infusion pump technology, hospital policies and procedures, individual practices, nursing training) is required. As such, HumanEra aimed to identify and help mitigate the risks associated with multiple IV infusions while accounting for the complex interactions between system elements. Different but complementary human factors methods and tools were used to achieve this objective, and the following multi-phase project was designed:

- Phase 1: Environmental Scan
 - Phase 1a: Situation Scan
 - Phase 1b: Practice and Training Scan
- Phase 2: Risk Prevalence and Mitigation
 - Phase 2a: Ontario Survey
 - Phase 2b: Laboratory Study
- Phase 3: Knowledge Translation

Phase 2a

In Phase 2a, HumanEra conducted an Ontario-wide survey (1) to answer the following research questions:

- 1. What is the potential prevalence of practices recommended in the Phase 1b report?
- 2. What is the potential prevalence of practices identified in the Phase 1b report that may mitigate or contribute to patient safety issues?
- 3. What tools, processes, or policies do clinical units in Ontario currently use to implement practices that may mitigate or contribute to patient safety issues?

Phase 2b

In Phase 2b, HumanEra conducted a laboratory study (2) to answer the following research questions:

- 1. What errors are associated with administering and managing multiple IV infusions—in particular errors regarding the following:
 - setting up and programming multiple primary continuous IV infusions
 - identifying IV infusions
 - managing dead volume
 - setting up secondary intermittent IV infusions
 - administering an IV pump bolus

- 2. To what extent do practice-, technology-, and education-oriented interventions mitigate these errors?
- 3. What are nurses' perceptions regarding the safety of practice-, technology-, and educationoriented interventions, and would they use those interventions in their clinical practice?

Note: Throughout the Multiple Intravenous Infusions reports, the study team generally refers to nurses, because they are the primary group responsible for administering IV infusions in the clinical environments that are in the study scope. However, we recognize that other health care professionals may be involved in the administration of multiple IV infusions (e.g., physicians).

Conclusions

Phase 2a

Previous work has shown that the administration of multiple IV infusions to a single patient is a complex task with many potential associated patient safety risks. The Ontario survey revealed variability in IV infusion practice across the province and potential opportunities to improve safety. Specific practices and/or technology related to secondary infusions, IV tubing labelling, patient transfers, dead volume management, and IV bolus administration were highlighted as requiring attention.

Many respondents indicated an awareness of previously identified risks (e.g., restricting the serial connections of 3-way stopcocks, minimizing coadministration of infusions with central venous pressure lines). In these cases, the majority of respondents appeared to take the necessary precautions (e.g., the majority of respondents did appear to use a back check valve when secondary infusions were administered).

Phase 2b

The laboratory study showed that errors occur during common tasks associated with administering and managing multiple IV infusions. However, improvements to best practices, infusion system technologies, and education can help reduce many of these risks by addressing a gradual misalignment of practices, technology, and education. In the short term, supporting clinicians via targeted education, standard best practices, and bedside clinical decision support can improve the identification and completion of some task requirements. In the longer term, innovation is needed to minimize the routine and person-dependent tasks that are currently required to administer multiple IV infusions. Still, given the complexity of this practice, even with improved technology the safe administration of multiple IV infusions will likely always require user vigilance.

Addressing the issues and implementing the recommendations identified in this study will require the sustained commitment and alignment of all stakeholders. However, with collective action based on evidence, improvements to the administration and management of multiple IV infusions—and thus patient safety—are obtainable and must be a priority.

Recommended Interventions

The study findings showed that many of the risks associated with managing multiple IV infusions were due to a lack of standardization in clinical practice, IV infusion system design, and education. The following 12 recommended interventions demonstrate the need for standardization at these 3 levels.

Setting Up and Programming Multiple Primary Continuous IV Infusions

Standardized Practice

- 1. Reduce the potential for errors or interruptions to infusion therapy when setting up multiple IV infusions at 1 time (e.g., during line changes, patient transfers) by:
 - standardizing the type, format, placement, and content of date labels applied to infusions to ensure consistent communication so that line changes are not performed more frequently than recommended by professional associations or hospital policies
 - standardizing medication concentrations (where possible), infusion pumps/channels, and IV components between units, and having pumps/channels follow patients to help minimize the need to re-establish infusions after patient transfers

Identifying an IV Infusion

Standardized Practice

- 2. The setup of multiple IV infusions should facilitate accurate and timely identification and tracing. Suggested tactics include:
 - augmenting and standardizing visual communication of infusion details (e.g., contents) along the infusion pathway; consider the following strategies in consultation with front-line staff:
 - Label primary IV tubing with the name of the infusate, near the infusion pump and near the injection port closest to the patient.
 - When multiple IV access ports are being used, indicate (near the infusion pump) the patient access port to which an infusion is connected.
 - distinguishing the "plain IV line" (e.g., the maintenance or fluid replacement line) for emergency use by using a label that is visually prominent and different from all other labels used in the bedside environment

Standardized Design

3. The design of infusion systems should facilitate accurate and timely identification and tracing. Suggested tactics include:

- mapping the IV container to the corresponding IV pump/channel
- separating IV infusions and minimizing tangles
- using gowns with snaps, ties, or Velcro on the shoulders and sleeves to remove line-tracing obstructions

Managing Dead Volume

Standardized Practice

- 4. When multiple IV infusions must be connected to a single patient access port, practices should include consideration of dead volume to minimize unrecognized residual medications and transitional issues (e.g., time lag before a desired change is reflected at the patient's bloodstream and unintended dose rate changes of connected infusions), particularly the following:
 - During infusion setup, the amount of dead volume should be minimized by:
 - connecting IV infusions as close as possible to the patient access port
 - using a single multiport/multi-lead connector when more than 2 IV infusions must be connected (e.g., do not use multiple 3-way stopcocks in series or chain IV infusion tubing together using lower IV injection ports); multiport/multi-lead connectors should not be chained together
 - When a change is made to an IV infusion that is connected to other IV medications, minimize the dead volume impact by:
 - grouping compatible medications by therapeutic class whenever possible (e.g., sedatives on 1 access port; vasopressors on another) to avoid unwanted clinical effects
 - avoiding the connection of a continuous IV medication infusion to the access port used to monitor central venous pressure (CVP), to prevent unintended boluses of or interruptions to continuous IV medications when a transduced CVP line is calibrated, used for measurement, or flushed
 - avoiding the use of a transducer to flush the CVP line (or CVP reading if using a manometer) when an intermittent IV medication is administered using the CVP line until the medication has cleared all IV tubing (including the access port), to prevent a bolus of the intermittent IV medication beyond its maximum allowable rate
 - administering residual intermittent medication in primary IV tubing (i.e., in dead volume after a secondary IV infusion or IV push) using the recommended rate for the intermittent

medication, both to ensure complete dose administration at the intended rate and to prevent drug incompatibilities

 using new IV tubing when initiating a new concentration of a continuous IV medication infusion to prevent infusing any of the previous concentration remaining in the tubing at the rate intended for the new concentration

Standardized Design

5. The design of IV infusion systems (including all IV components) should minimize unnecessary priming/dead volume, and by extension, unrecognized residual medications and transitional issues (e.g., time lag before a desired change is reflected at the patient's bloodstream and unintended dose rate changes of connected infusions).

Standardized Education

6. IV infusion-related education (e.g., academic, in-service, annual recertification) should teach dead volume principles and facilitate the development of skills in dead volume management to minimize errors.

Setting Up Secondary Intermittent IV Infusions

Standardized Practice

- 7. The setup of a secondary IV infusion should:
 - minimize the risk of administering primary and secondary IV infusions concurrently when the secondary IV infusion requires a large IV container (e.g., 1,000 mL) or a high flow rate (e.g., > 500 mL/h), as this may affect system fluid dynamics. Contact the infusion pump manufacturer to confirm recommended setup requirements for such secondary IV infusions (e.g., lowering the primary IV container with 2 hooks or clamping the primary IV tubing above the pump).
 - minimize the risk of drug incompatibilities by using new secondary IV tubing or ensuring that the tubing is flushed according to protocol before reusing it for different IV medications
 - minimize the impact to patients of administering the primary and secondary IV infusions at the wrong flow rate. Suggested tactics include:
 - not connecting a secondary IV infusion to a high-alert primary IV infusion
 - administering continuous high-alert IV medications as primary IV infusions only
 - ensuring that health care organizations identify the amount of overfill in IV containers and the dead volume in IV tubing/connectors, to help clinicians account for these factors and ensure complete dose administration at the intended rate when programming a secondary infusion

Standardized Design

- 8. The design of IV infusion systems should minimize the risk of secondary IV infusion setup errors (e.g., not sufficiently lowering the primary IV container below the secondary IV container, not opening the roller clamp on the secondary IV tubing), which can result in unintended concurrent flow of primary and secondary IV infusions and/or incorrect flow rates. Suggested tactics include:
 - eliminating the physical setup requirements for administering a secondary IV infusion (e.g., infusion pumps that independently control fluid flow from primary and secondary IV containers)
 - detecting setup errors and alerting users, to facilitate interception and correction (e.g., alarm when clamp on secondary IV tubing is left closed)

Standardized Education

- 9. Education (e.g., academic, in-service, annual recertification) on secondary IV infusions should address current gaps in training and include:
 - underlying IV infusion principles
 - setup risks (e.g., IV container height errors, primary IV tubing without a back check valve)
 - best practices (e.g., view the activity in infusion drip chambers to verify that the secondary infusion is active and that the primary infusion is not active)

Administering IV Pump Boluses

Standardized Design

- 10. The design of IV infusion systems should minimize the risk of bolus programming errors (e.g., extended bolus administration) and errors with the resumption of the primary continuous infusion after bolus administration. Suggested tactics include:
 - administering an IV pump bolus using a smart pump bolus feature that allows the following:
 - directly copying a prescriber's ordered bolus dose in drug-specific units during pump programming (i.e., no unit conversion calculations required)
 - programming the bolus duration (e.g., minutes) instead of the bolus rate (e.g., mL/h); include, if available, the option to autopopulate the bolus duration from the drug library
 - communicating that a bolus infusion is being programmed (rather than a primary or secondary infusion) and providing clear feedback on the bolus status
 bolus soft and hard limits to be defined by clinical area
 - configuring and updating smart pump drug libraries for each clinical area to support appropriate use of the IV bolus feature:
 - enabling the bolus feature for only medications that should be bolused, with clinically appropriate soft and hard dose and rate/duration limits.
 - including hard upper rate limits for continuous IV infusions of high-alert medications (when possible) to prevent the administration of an IV pump bolus by directly increasing the primary continuous IV infusion rate

Other System Issues

- 11. Organizational risk-management programs should actively monitor and track safety recalls and alerts to ensure compliance with best practices and prompt product removal or correction of materials/equipment.
- 12. Health Canada medical device licensing for high-risk devices (such as infusion systems) should require that the manufacturer submit the results of usability and safety assessments done in typical clinical scenarios, based on human factors assessment methods, and showing a high level of usability and safety. Considering the interaction between technologies, users, workflows, and use environments during the premarket design process can reduce post-market adverse events.

Decision Determinants

OHTAC has developed a decision-making framework that consists of 7 guiding principles for decisionmaking and a decision determinants tool. When making a decision, OHTAC considers 4 explicit main criteria: overall clinical benefit, consistency with expected societal and ethical values, value for money, and feasibility of adoption into the health system. For more information on the decision-making framework, please refer to the *Decision Determinants Guidance Document* available at: <u>http://www.hqontario.ca/evidence/evidence-process/evidence-review-process/decision-makingframework</u>.

Appendix 1 provides a summary of the decision determinants for this recommendation.

Based on the decision determinants criteria, OHTAC weighed in favour of standardizing practice, design, and education related to the administration of multiple IV infusions.

OHTAC Recommendations

Based on the available evidence:

- OHTAC recommends standardizing the practice, design, and education related to the administration of multiple IV infusions to mitigate associated risks. Specifically, OHTAC recommends the adoption of the 12 interventions indicated by the HumanEra field evaluations relating to the:
 - setup and programming of multiple primary continuous infusions
 - identification of an infusion
 - management of dead volume
 - setup of secondary intermittent infusions
 - administration of IV pump boluses
- OHTAC recommends that HQO and HumanEra develop an implementation strategy to facilitate the adoption of these interventions by the health system and establish key performance indicators to evaluate adherence to safe practice.

Appendices

Appendix 1: Decision Determinants

Table A1: Decision Determinants for Multiple Intravenous Infusions Phases 2a and 2b

Decision Criteria	Subcriteria	Decision Determinants Considerations
Overall clinical benefit How likely is the health technology/intervention to result in high, moderate, or low overall benefit?	Effectiveness How effective is the health technology/intervention likely to be (taking into account any variability)?	 Multiple research methods were used to identify IV infusion risks in a broad range of clinical units in Ontario hospitals Identified risks and potential mitigations were further explored in an experimental lab study based in a simulated adult intensive care unit. The lab study found that interventions significantly reduced multiple IV infusion-related errors The study suggested interventions in 3 areas: clinical practice, design of IV infusion technology and equipment, and clinician education
	Safety How safe is the health technology/ intervention likely to be?	 A multidisciplinary expert panel supported the suggested interventions to improve the safety of administering multiple IV infusions
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention?	 A highly conservative estimate is that at least 2,000 patients a day require multiple IV infusions in Ontario
		 The study was not designed to establish the prevalence of errors and their impact on Ontario patients. However, there is evidence from multiple sources (peer-reviewed literature, interviews, incident databases, controlled simulation studies) that errors associated with administering multiple IV infusions do occur, resulting in patient harm (including death), and that they are not unique to any 1 clinical unit, hospital, or region; this evidence served as a call to identify and evaluate interventions to improve the safety of administering multiple IV infusions and was the focus of the study
	Need How large is the need for this health technology/intervention?	 For acutely ill patients who require multiple IV medications, there are no alternative therapies at this time. Interventions to improve safety are needed to minimize errors Many risks associated with the administration of multiple IV infusions are not ameliorated by smart infusion pump
Consistency with expected societal and ethical values ^a How likely is adoption of the health	Societal values How likely is the adoption of the health technology/intervention to be congruent with expected societal values?	 Ontarians expect effective and safe care. The consideration and implementation of interventions found to reduce risks are ethical, expected, and consistent with societal expectations

Decision Criteria	Subcriteria	Decision Determinants Considerations
technology/intervention to be congruent with societal and ethical values?	Ethical values How likely is the adoption of the health technology/intervention to be congruent with expected ethical values?	 Clinician training programs and patient safety initiatives should acknowledge and accept that humans are fallible, and that a variety of factors can predispose humans to making errors. Clinicians should be encouraged and supported in identifying near-misses and errors so that the health care system continuously learns from its mistakes and evolves to handle new risks
Value for money How efficient is the health technology likely to be?	Economic evaluation How efficient is the health technology/intervention likely to be?	 A formal economic evaluation was not conducted
Feasibility of adoption into health system How feasible is it to adopt the health technology/intervention into the Ontario health care system?	Economic feasibility How economically feasible is the health technology/intervention?	 The interventions have variable implementation timelines and costs. Health care institutions are not the only stakeholders responsible for implementing interventions Interventions addressing clinical practice and clinician education can be reviewed immediately and implemented in the short term. These interventions require human resources at each health care institution to review and select the approaches most appropriate for their needs Interventions involving the design of IV infusion technology require a long-term approach that emphasizes the need for manufacturers, clinicians, and regulatory agencies to address identified issues. When replacing IV infusion technology, health care institutions should consider the issues and interventions identified by this study as part of their procurement selection criteria
	Organizational feasibility	 It is expected that the introduction of the suggested interventions into clinical environments will reduce risks if carefully considered by clinical staff in each care area for their appropriateness and relevance to the area's unique needs Most interventions are based on data from a laboratory study simulating a single adult intensive care unit. The impact of variability in clinical units across Ontario on the feasibility of each intervention is accounted for at a high level by the review of the expert panel, and in light of direct observations made by the research team in multiple clinical environments. Longitudinal effectiveness of the interventions has not been evaluated

Abbreviations: IV, intravenous.

^aThe anticipated or assumed common ethical and societal values held in regard to the target condition, target population, and/or treatment options. Unless there is evidence from scientific sources to corroborate the true nature of the ethical and societal values, the expected values are considered.

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