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Mitigating the Risks Associated With Multiple IV Infusions: Recommendations Based on a Field Study of Twelve Ontario Hospitals

Prepared by the Health Technology Safety Research Team in Collaboration With the Institute for Safe Medication Practices Canada, on Behalf of the Ontario Health Technology Advisory Committee

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Overview

The Ontario Health Technology Advisory Committee (OHTAC) of Health Quality Ontario commissioned the Health Technology Safety Research Team (HTSRT) at the University Health Network to conduct a multi-phase study to identify and mitigate the risks associated with multiple intravenous (IV) infusions.

The initial report, *Multiple Intravenous Infusions Phase 1a: Situation Scan Summary Report*, summarizes the interim findings based on a literature review, an incident database review, and a technology scan. It can be found on HTSRT's website at:
http://www.ehealthinnovation.org/files/Multiple%20IV%20Infusions_Phase1a_SummaryReport.pdf

The next report, *Multiple Intravenous Infusions Phase 1b: Practice and Training Scan*, has been published and is available on the Health Quality Ontario website at:
http://www.hqontario.ca/en/eds/tech/pdfs/2012/multipleinfusions1b_May.pdf

This document outlines 9 patient safety recommendations that have been made based on the findings of both completed study phases, above. The recommendations are ordered as they appear in the Phase 1b report; this ordering is not intended to imply priority or recommended sequence of implementation. These recommendations relate to the administration of multiple IV infusions, and they are proposed for uptake by health care institutions in Ontario. They have been reviewed and approved by both the Multiple IV Infusions Expert Panel and OHTAC.

Note: In the Phase 1b field study, nurses in 12 clinical units were observed administering multiple IV infusions. For the sake of consistency within and among Phase 1b reports, the term nurse *is used throughout, but we recognize that other health care professionals, including physicians, respiratory therapists, and dialysis technicians, may also be involved in the administration of multiple IV infusions.*

Who Should Read This Document

The information in this field update is intended for inpatient and outpatient care areas where multiple IV infusions are administered to patients. In particular, the following care areas were studied to inform these recommendations:

- critical care units (adult and pediatric, all clinical specialties)
- outpatient chemotherapy clinics
- hospital emergency departments

Senior hospital managers, clinical managers, educators, practice leaders, and those responsible for medical equipment procurement decisions are all well positioned to enact these recommendations.

Format of the Document

This document first presents a full list of all 9 recommendations for quick reference. The recommendations and their associated rationales are then described in more detail according to the following safety-related themes:

- secondary infusions
- line identification
- line set-up and removal
- IV bolus administration

Application of the Precautionary Principle

The precautionary principle dictates that even if the cause and effect data are not fully established scientifically, precautionary measures should be taken. (1;2) The recommendations in this report are derived from direct observational and interview data. While these methods of field study yield a rich source of data, there are limitations to applying these methods—mainly that the prevalence of a particular issue cannot be established. The rationales for the recommendations in this report were based on the potential for particular types of errors (i.e., the existence of failure modes) rather than the direct observation of errors, for two reasons:

- The frequency of errors for each individual failure mode is not high enough for all to be detected in the time allotted.
- The failure modes are not identified a priori to allow for routine inspection.

Nonetheless, some errors were directly observed during the study.

The failure modes identified in the Phase 1b report have the potential to occur during tasks related to administering multiple IV infusions; these tasks are routine elements of patient care across Ontario. Although not all errors necessarily lead to patient harm, in some cases a patient may incur serious harm, and even death. The findings of the Phase 1b field study are consistent with other studies that highlight the severity of infusion errors. (3;4)

Furthermore, research highlighting the prevalence of infusion errors (5-7) correlates with the United States Food and Drug Administration (FDA) statistics (8) that, between 2005 and 2009, more than 56,000 infusion pump incidents were reported, including 710 deaths. While the failure modes associated with these incidents and those described in the literature may not include all the failure modes identified in the Phase 1b field study, the precautionary principle dictates that even if the cause and effect data are not fully established scientifically, precautionary measures should be taken.

The analysis and recommendations in this document encourage a cautious and measured approach to improving safety in IV care. While modifications to infusion systems and related work practices are suggested to improve the safety of infusions administered via a large-volume infusion pump, substitution of gravity infusions for pump-controlled, large-volume infusions is not recommended, given the many advantages provided by large-volume infusion pumps. All findings and recommendations should be implemented, with careful appraisal of the risks and benefits of doing so for each specific context.

Summary of Recommendations

Secondary Infusions

1. When initiating a secondary medication infusion (often referred to as a *piggyback* infusion), nurses should verify that the secondary infusion is active—and that the primary infusion is not active—by viewing the activity in both drip chambers. Full drip chambers should be partially emptied to restore visibility.

2. *Continuous* high-alert medications* should be administered as primary infusions. *Continuous* high-alert medications should not be administered as secondary infusions. No secondary medications should be connected to high-alert primary continuous infusions. (9)

3. Secondary infusions should be attached to primary infusion sets that have a back check valve. If infusion sets without back check valves are also available, multiple strategies should be employed to ensure that the types of tubing available are easily differentiated, and that the likelihood of a mix-up is minimized.

Line Identification

4. Hospitals should work towards the use of gowns that have snaps, ties, or Velcro on the shoulders and sleeves to facilitate line tracing and gown changes. Metal fasteners (e.g., metal snaps) should be avoided to prevent patient burns if a gown with metal fasteners goes into the magnet room of an MRI suite.

5. If an "emergency medication line" controlled by an infusion pump is set up, it is strongly suggested that the associated primary IV tubing be labelled as the emergency medication line at the injection port closest to the patient. The label should be prominent and visually distinct from all other labels in the environment.

Line Set-Up and Removal

6. When setting up multiple IV infusions at the same time (e.g., a new patient requires many ordered infusions immediately, routine line changes), infusions should be set up 1 at a time, as completely as possible, before setting up the next infusion. Set-up tasks required for each infusion vary and may include:
    - labelling (e.g., IV tubing, pump)
    - spiking and hanging the IV bag
    - connecting the IV tubing to the pump
    - programming the IV pump
    - connecting the IV tubing to the appropriate location (e.g., patient access, manifold)
    - starting the pump (unless a secondary infusion must be set up prior to starting the pump, or other infusions need to be connected to a multi-port connector before flushing)

    Minor modifications to this recommendation are required for routine line changes (see the Rationale for Recommendation 6).

*The Institute for Safe Medication Practices defines high-alert medications as "drugs that bear a heightened risk of causing significant patient harm when they are used in error." For more information visit: http://www.ismp.org/tools/highalertmedications.pdf

7. Multiple 3-way stopcocks joined together in series to connect multiple IV infusions into a single line are prone to leaks, which may often be undetectable. Hospitals should provide multi-port or multi-lead connectors, and nurses should use these connectors to join multiple IV infusions into a single line, as required.

IV Bolus Administration

8. Hospitals should develop a policy to limit the practice of manually increasing the infusion rate to administer a medication bolus of a primary continuous infusion. If a separate medication bolus cannot be prepared, and the bolus is administered using the primary continuous infusion pump/pump channel, then the nurse should program the bolus dose parameters (i.e., total amount of medication to be given over a defined duration) into the pump without changing any of the primary infusion parameters. Some examples of how to specify the bolus dose parameters include the following:
    - programming a bolus using a dedicated bolus feature in the pump (preferred, if available)
    - programming a bolus using the pump's secondary feature but without connecting a secondary IV bag (pump will draw the bolus from the primary IV bag)

9. Hospitals should ensure that their smart pump drug libraries include hard upper limits for as many high-alert medications as are appropriate for each clinical area, in order to prevent the administration of a bolus by manually increasing the primary flow rate.

Secondary Infusions

Recommendation 1

When initiating a secondary medication infusion (often referred to as a *piggyback* infusion), nurses should verify that the secondary infusion is active—and that the primary infusion is not active—by viewing the activity in both drip chambers. Full drip chambers should be partially emptied to restore visibility.

Rationale

Figure 1 depicts a typical secondary infusion set-up.

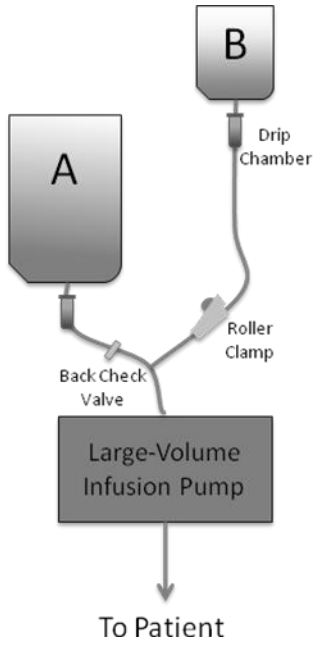

Figure 1: Primary Infusion (IV Bag A) With Secondary Infusion (IV Bag B) Attached

Several requirements must be met for a secondary infusion to infuse as intended. These requirements include, but are not limited to, the following:

- Bag B must be hung higher than bag A, so that bag B can infuse first.
- Bag B must be connected to the primary infusion tubing upstream of the infusion pump.
- The secondary infusion tubing (set) must be unclamped such that the fluid from bag B can flow.
- The primary infusion tubing must be equipped with a back check valve to prevent retrograde flow of IV medication from bag B into bag A.
- The infusion pump must be programmed correctly for both bag A and bag B.

If these set-up requirements are not met, the primary and secondary infusions can infuse at incorrect, and often indeterminate, rates without detection by the pump or notification to the user; most large-volume

infusion pumps cannot distinguish which bag is infusing at any 1 time. A visual inspection of the drip chambers will highlight secondary infusion set-up errors, likely before patient harm occurs.

A visual inspection allows nurses to detect whether the primary drip chamber is active when a secondary infusion is running. An active primary drip chamber indicates that 1 of the requirements described above has not been met, or that other unanticipated issues may be occurring. For example, at high secondary infusion flow rates, the pressure exerted by the pump can be enough to overcome the primary flow protection offered by the back check valve, causing simultaneous delivery of both the primary and secondary infusions at indeterminate rates. In this unique case, a reduction in secondary infusion flow rate may be required, if possible, or the primary infusion tubing may need to be clamped upstream of the secondary infusion port to obstruct primary fluid flow. The flow rate that overcomes the flow protection of a back check valve varies depending on the specific components (e.g., pump, administration set, IV bag) and the drug connected to the system.

An inactive secondary drip chamber also indicates a potential set-up error and should prompt nurses to investigate.

Recommendation 2

Continuous high-alert medications* should be administered as primary infusions. *Continuous* high-alert medications should not be administered as secondary infusions. No secondary medications should be connected to high-alert primary continuous infusions. (9)

Rationale

Delivering a continuous high-alert medication as a secondary infusion leads to the following concerns:

1. The infusion pump cannot differentiate between primary and secondary infusions. There is no infusion pump alarm to alert the nurse when the secondary volume to be infused (VTBI) is complete. The pump will automatically change to the primary infusion rate, and the primary infusion will begin as soon as the secondary IV bag is empty, leading to an interruption in the secondary infusion until the situation is detected and a new secondary IV bag is hung and programmed.

2. The volume in the IV tubing between the secondary port and the end of the primary tubing can be significant. When initiating a high-alert continuous medication as a secondary medication, there can be substantial delay before the medication reaches the patient. Conversely, when a medication must be discontinued, some will remain in the primary tubing and be delivered at the primary rate. Furthermore, if the secondary VTBI has been reached, the residual medication in the tubing will be delivered at the primary rate.

3. There could be an increased risk of confusion between the primary and secondary infusions, as well as a risk of infusion pump programming errors.

4. The severity of patient harm could increase if a programming error occurs.

Secondary infusions are intended for the delivery of one-time or intermittent doses of IV agents (e.g., antibiotics, electrolytes). If a continuous infusion is administered as a secondary infusion, the pump will

*The Institute for Safe Medication Practices defines high-alert medications as “drugs that bear a heightened risk of causing significant patient harm when they are used in error.” For more information visit: http://www.ismp.org/tools/highalertmedications.pdf

automatically switch to the primary infusion when the VTBI has completed, resulting in an interruption of the continuous secondary medication.

In addition, if a VTBI that is less than the secondary infusion bag volume is programmed, the pump will switch to the primary rate prematurely and administer the secondary IV agent at the primary rate. This failure mode has occurred with a continuous morphine IV infusion running as the secondary infusion and has contributed to at least 1 known patient death.

Finally, because secondary infusions are reserved for one-time or intermittent infusions, running a continuous infusion on a secondary line may confuse nurses who are participating in a patient's care but did not set up the infusions, increasing the risk of subsequent programming and set-up errors.

Recommendation 3

Secondary infusions should be attached to primary infusion sets that have a back check valve. If infusion sets without back check valves are also available, multiple strategies should be employed to ensure that the types of tubing are easily differentiated, and that the likelihood of a mix-up is minimized.

Rationale

When a secondary infusion is connected to a primary infusion set that does not have a back check valve, the secondary IV agent will back flow up the primary IV tubing, mixing with the primary IV agent. When the secondary infusion is complete and the fluid begins to flow from the primary IV bag, a mixture of the primary and secondary IV agents will be delivered at the primary rate. Figure 2 illustrates the flow path (dotted line) of a secondary IV agent (bag B) when the primary IV tubing is equipped with a back check valve (left), and when it is not so equipped (right).

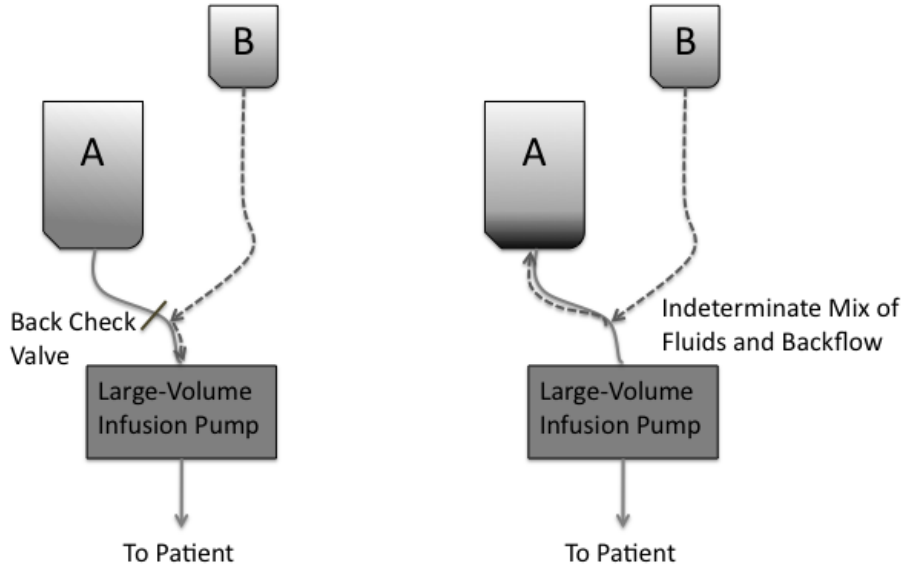

Figure 2: Secondary Infusion Set-Up With and Without a Back Check Valve

Line Identification

Recommendation 4

Hospitals should work towards the use of gowns that have snaps, ties, or Velcro on the shoulders and sleeves to facilitate line tracing and gown changes. Metal fasteners (e.g., metal snaps) should be avoided to prevent patient burns if a gown with metal fasteners goes into the magnet room of an MRI suite.

Rationale

Visual or physical obstructions that prevent nurses from following the path of an IV tube increase the risk that the nurse will mix up IV tubing paths when tracing IV lines, because the path is not continuous. Shoulder sleeves on patient gowns are a common obstruction, interfering with line tracing and line management. Sometimes, nurses must disconnect and reconnect IV tubing to perform patient care tasks such as gown changing and bathing. Unnecessary disconnections and reconnections may be associated with patient safety risks (e.g., infection control, line mix-ups). Figure 3 illustrates a gown with snaps at the shoulder and sleeves to help reduce these risks.

Metal gown fasteners (e.g., metal snaps) should be avoided to prevent a patient burn should a gown with metal fasteners go into the magnet room of an MRI suite. (10)

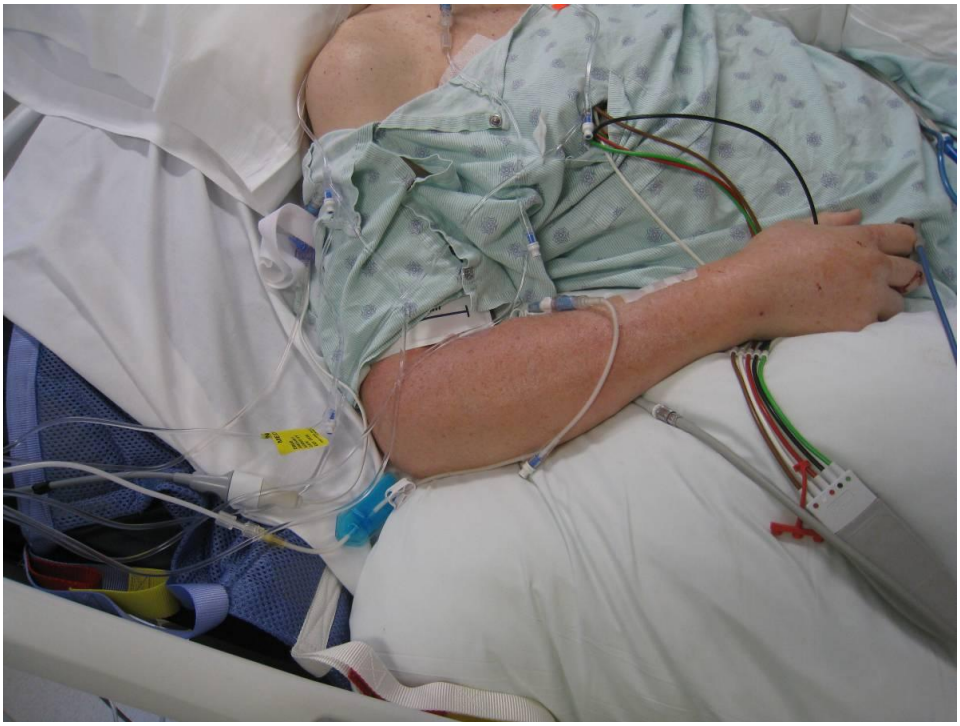

Figure 3: Lines Passing Through a Patient's Gown Sleeves

Recommendation 5

If an "emergency medication line" controlled by an infusion pump is set up, it is strongly suggested that the associated primary IV tubing be labelled as the emergency medication line at the injection port closest to the patient. The label should be prominent and visually distinct from all other labels in the environment.

Rationale

An "emergency medication line" is a continuous IV infusion of a maintenance fluid directly into a venous access device, with no other continuous IV infusions connected. A dedicated emergency medication line should infuse only fluid (i.e., not medication) continuously. Its purpose is to provide a safe means of infusing potentially potent medications without needing to consider flow rates, compatibility or dead volume issues. When medications are not being administered, the line can be used to support the patient's hydration needs.

Emergency medication lines are often established for critically ill patients, particularly those with central lines. They are particularly useful in emergency situations, because some medications need to be infused quickly, and nurses who did not set up the IV lines may be involved in administering those medications. However, due to the physical complexity of infusion set-up for critically ill patients, the emergency medication line is not always easy to identify, especially if the nurse is not familiar with the patient's specific IV set-up. By distinctly labelling the emergency medication line directly upstream of the lowest injection port (where IV push medications are injected), a nurse can easily identify the correct port to inject an emergency syringe push of medication. Injecting medication into the incorrect port could result in an unintended bolus of a potent medication and/or unwanted drug interactions. Figure 4 illustrates an emergency medication line label photographed during the field study.

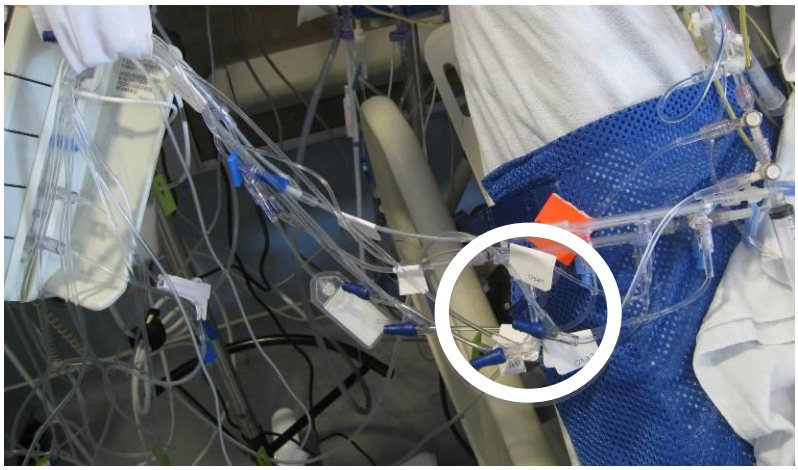

Figure 4. An Emergency Medication Line Label

Another issue is the use of emergency medication lines to deliver secondary (piggyback) infusions. If secondary medications are infused on the emergency medication line and an emergency medication is then required, nurses should consider stopping the secondary infusion due to potential compatibility issues, and flushing the dead volume of the primary tubing below the injection port prior to administering the emergency medication.

Line Set-Up and Removal

Recommendation 6

When setting up multiple IV infusions at the same time (e.g., a new patient requires many ordered infusions immediately, routine line changes), infusions should be set up 1 at a time, as completely as possible, before setting up the next infusion. Set-up tasks required for each infusion vary and may include:

- labelling (e.g., IV tubing, pump)
- spiking and hanging the IV bag
- connecting the IV tubing to the pump
- programming the IV pump
- connecting the IV tubing to the appropriate location (e.g., patient access, manifold)
- starting the pump (unless a secondary infusion must be set up prior to starting the pump, or other infusions need to be connected to a multi-port connector before flushing).

Minor modifications to this recommendation are required for routine line changes (see Rationale).

Rationale

Batch-processing infusion set-up tasks (e.g., performing the same set-up task for multiple infusions at 1 time), creates opportunities for mismatch errors (e.g., connecting the wrong IV tubing to a programmed pump, adhering the wrong label to the pump). An example of batch-processing would be hanging all the ordered IV bags onto an IV pole before loading each piece of IV tubing into the corresponding infusion pump. Mismatch errors can result in pump programming and line identification errors, causing nurses to interact with the incorrect IV tubing (e.g., injecting IV medications into the wrong port, connecting and disconnecting the wrong IV tubing).

Figure 5 shows several strands of IV tubing in close proximity, increasing the likelihood that mismatch errors will occur.

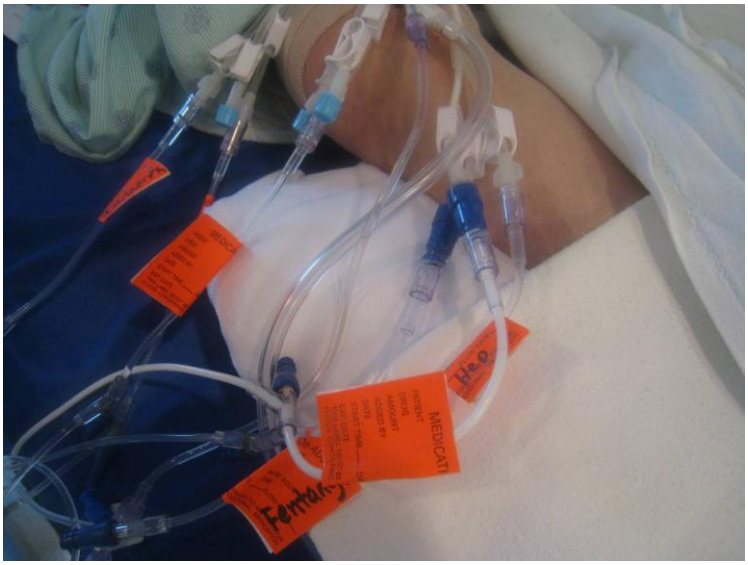

Figure 5: Multiple IV Tubes in Close Proximity

Labelling may be particularly prone to mismatch errors, because it is commonly deferred until after all other line set-up tasks are complete (it is often considered nonessential in comparison to initiating a medication). Batch-processing labelling tasks can result in placing the wrong label on the wrong IV component (e.g., placing a morphine label on the levophed tubing). If external labels are applied to infusion pumps to help identify the drug infusing on each pump/pump channel, the risk of mix-ups is heightened if the pump labels are not removed prior to the next use of the pump.

To reduce the risks associated with batch-processing IV set-up tasks, it is recommended that a nurse completely set up each IV medication and connect it to the patient before introducing the next one. When changing multiple lines as part of a routine line change, it is also recommended that a one-at-a-time process be followed for each medication line, from the IV bag to the lowest connector above the venous access catheter. If a multi-port or multi-lead connector is being used, all medications should be attached to a new connector following a one-at-a-time approach before exchanging the new connector with the old one in the manner least disruptive to medication flow, particularly if the medications are maintaining hemodynamic stability.

Recommendation 7

Multiple 3-way stopcocks joined together in series to connect multiple IV infusions into a single line are prone to leaks, which may often be undetectable. Hospitals should provide multi-port or multi-lead connectors, and nurses should use these connectors to join multiple IV infusions into a single line, as required.

Rationale

Chaining together a series of 3-way stopcocks to connect multiple infusions (Figure 6) leads to a higher risk of disconnections and leaks than using multi-port or multi-lead connectors.

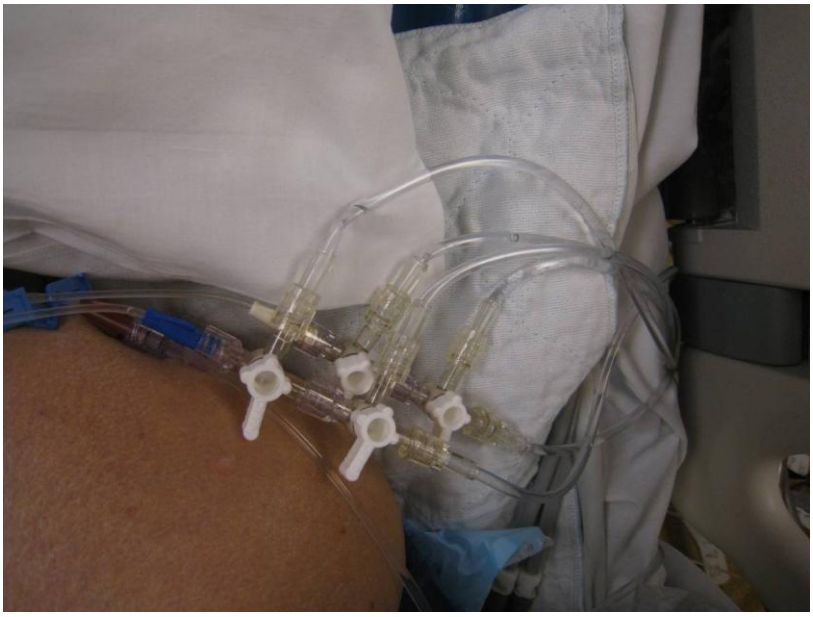

Figure 6: Example of 3-Way Stopcocks Attached in Series

The use of single connectors intended for multiple IV inputs (multi-port connectors) decreases the number of chained connections, and therefore reduces the risks of leaks and disconnections (Figure 7). In

addition, multi-port connectors concentrate the number of connections in one physical area, increasing nurses' awareness of which drugs share a single IV line, improving line identification.

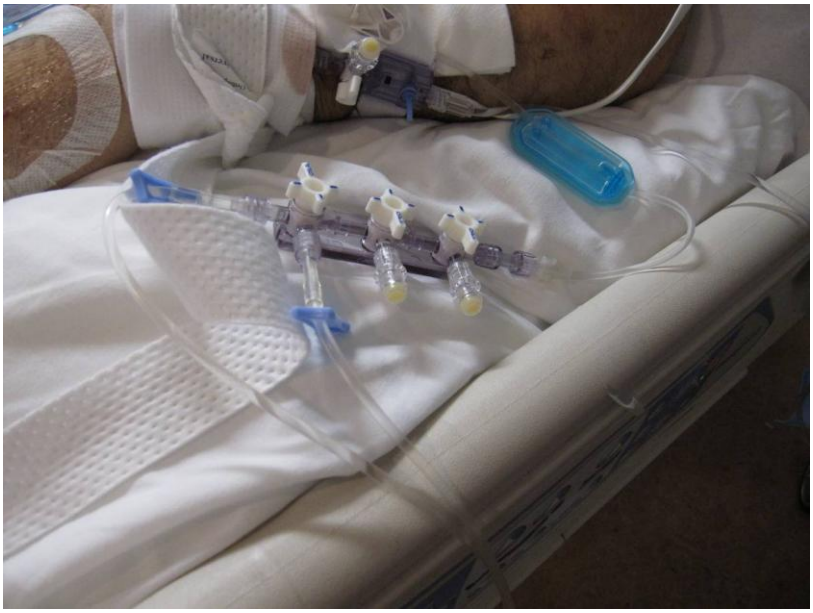

Figure 7: Example of Rigid Multi-Port Connector That Achieves the Same Functionality as Chained 3-Way Stopcocks

An additional advantage of using multi-port connectors is that they help minimize the shared volume of infusions compared to other practices (e.g., chaining continuous primary infusions together using the lowest injection port of each tubing).

This recommendation is intended to restrict the use of 3-way stopcocks to join multiple IV infusions into a single line. It is not intended to limit their use for venous and arterial pressure monitoring or other applications; however, organizations should be aware of the general risks surrounding stopcock use as presented here. There are manifolds available with integrated stopcocks that facilitate both pressure monitoring and medication administration on the same line. These are available for sale in Ontario, and are widely used. This type of connector falls within this recommendation.

IV Bolus Administration

Recommendation 8

Hospitals should develop a policy to limit the practice of manually increasing the infusion rate to administer a medication bolus of a primary continuous infusion. If a separate medication bolus cannot be prepared, and the bolus is administered using the primary continuous infusion pump/pump channel, then the nurse should program the bolus dose parameters (i.e., total amount of medication to be given over a defined duration) into the pump without changing any of the primary infusion parameters. Some examples of how to specify the bolus dose parameters include the following:

- programming a bolus using a dedicated bolus feature in the pump (preferred, if available)
- programming a bolus using the pump's secondary feature but without connecting a secondary IV bag (pump will draw the bolus from the primary IV bag)

Rationale

Increasing the primary infusion flow rate to administer an IV bolus is risky, because the bolus dose is not tightly controlled (a nurse must maintain vigilance to stop the bolus once the intended dose has been administered). If a nurse is distracted during the bolus, a large overinfusion of a highly potent medication can occur.

Both alternative methods of specifying the dose parameters listed in this recommendation represent safer administration alternatives than manually increasing the primary rate, because they encourage, at a minimum, both the bolus rate and VTBI to be specified, minimizing the opportunity of an overdose. The relative safety merits of programming a bolus infusion using a dedicated bolus feature appear to be greater than that of programming a bolus infusion using the secondary mode. A detailed comparative analysis is required of the failure modes of each approach, taking into consideration the various design approaches of the bolus feature used by each manufacturer across all products, but is beyond of the scope of this analysis.

Manually changing both the infusion rate and the VTBI on the primary continuous infusion would appropriately limit the bolus dose. However, if a nurse other than the one who initiated the bolus responds to the volume infused alarm (i.e., the end of infusion alarm), he/she could reset the pump's VTBI parameter to the remaining bag volume without changing the infusion rate back to the primary continuous rate, since he/she would not be aware that a bolus had been running previously. This would result in an over-infusion.

Recommendation 9

Hospitals should ensure that their smart pump drug libraries include hard upper limits for as many high-alert medications as are appropriate for each clinical area, in order to prevent the administration of a bolus by manually increasing the primary flow rate.

Rationale

Previous research on the efficacy of smart infusion pumps (pumps equipped with Dose Error Reduction Systems) suggests that hard limits (i.e., a software feature that prevents an infusion from being administered if the pump settings exceed the safe range for that medication) are an effective means of

preventing the administration of infusions at an unsafe flow rate, but soft limits are not. (11;12) The implementation of hard limits can help minimize the likelihood of IV boluses being delivered in the unsafe manner described in Recommendation 8.

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