Patient Safety Alert

File Number: 16/17- 05 February 7, 2017

CORRECT LABELLING AND USE OF IRRIGATION SOLUTIONS

Irrigation solutions are topical preparations used intra-operatively during procedures such as laparoscopic surgery, transurethral resection of the prostate, micro-vascular and orthopedic surgeries. Topical irrigation with a heparinized solution may be used to cleanse a wound and prevent thrombosis. Heparin is an anti-coagulant which is considered a high-alert medication. Unintended <u>intravenous</u> administration of heparinized irrigation solution can increase a patient's risk of bleeding.

RECOMMENDATIONS

The Ministry of Health recommends that regional health authorities and health care organizations:

- Have safety and risk prevention guidelines for medication management in the operating room based on accepted standards of practice, and ensure that staff are familiar with these guidelines.
- Have standard protocols to manage the effects of high-alert medications such as heparin. Specific operational recommendations include:
 - Apply a distinct "For Irrigation Only" auxiliary label to all bags and bottles to be used for irrigation.
 - Designate a space for staff to prepare medications without distractions. Ensure that all required supplies (including labels) are readily available.
 - Segregate the storage of all bags and bottles intended for irrigation from those intended for intravenous administration. Use commercially available products whenever possible.
 - Designate irrigation specific equipment (e.g., poles, tubing, connections and basins) for use with solutions intended for irrigation.
 - Connect irrigation mixtures to the designated tubing while on the sterile field (i.e., do not hang on the pole without any tubing attached) whenever possible.
- Disseminate the Institute for Safe Medication Practices and ISMP Canada safety bulletins (see Supporting Documents) to relevant staff to support development and adoption of safe practices.

Supporting Documents:

- 1. Accidental Intravenous Infusion of Heparinized Irrigation in the OR Institute for Safe Medication Practices December 1, 2016 http://www.ismp.org/Newsletters/acutecare/showarticle.aspx?id=1154
- 2. Accidental Intravenous Infusion of a Heparinized Irrigation in the Operating Room Institute for Safe Medication Practices Canada Volume 16 Issue 6 August 30, 2016
- 3. The Trouble with Irrigations Saskatoon Health Region Patient Safety Discussion Document September 2015

Background of the Critical Incident

Two similar incidents occurred involving the intravenous infusion of heparinized lactated Ringer's solution which was intended for irrigation.

In the first incident, a bag labeled as 1000 mL lactated Ringer's solution was infused into a pediatric patient during surgery. Care providers were unaware that the lactated Ringer's solution contained 50,000 units of heparin (the medication had been added but the bag was not labeled to indicate this addition). A plan for reversal with protamine guided by heparin concentration was done. The patient was closely monitored post-operatively and remained clinically stable.

In the second incident, a circulating nurse in the operating room used grey tape to label a 1000 mL bag of lactated Ringer's solution to which 50,000 units of heparin had been added. The heparinized solution intended for irrigation was inadvertently infused by the intravenous route. When the patient was transferred from the operating room, staff in the post-anesthesia care unit recognized the error immediately and administered protamine. The patient was monitored carefully and recovered without sequelae.

Analysis

In the first incident, the irrigation was prepared prior to the start of the case in an effort to be efficient. Pre-mixing medications and storing for future use (even when labeled properly) exposes the patient and care providers to inadvertent mistakes in administration.

In addition, the lactated Ringer's solution was not labeled indicating the addition of 50,000 units of Heparin. Due to congestion in the workspace, the nurse was not able to access and apply the red "Medication Added" auxiliary labels that should be used in this situation. No other warning labels were affixed to the intravenous solution solution.

In the second incident, the independent double-check did not involve visualization of the "medication added" label on the intravenous bag.

Patient safety alerts may be issued by the Ministry of Health following the review of at least one critical incident reported to the Ministry. A critical incident is defined as a serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health service provided by, or a program operated by, a regional health authority, Saskatchewan Cancer Agency or health care organization.

The purpose of a patient safety alert is to recommend actions that will improve the safety of patients who may be cared for under similar circumstances. Recommendations are intended to support the development of best practices and to act as a framework for improvement and can be adapted to fit the needs of the health service organization. When possible, policies or initiatives that have been developed by RHAs or the Saskatchewan Cancer Agency will be shared, to encourage adoption of similar policies or actions.



December 1, 2016 Volume 21 Issue 24

Acute Care 🤬 ISMP Medication Safety Alert

Educating the Healthcare Community About Safe Medication Practices

Accidental IV infusion of heparinized irrigation in the OR



PROBLEM: Accidental intravenous (IV) administration of a solution intended for bladder or wound irrigation is a repetitive error that has been the topic of numerous events published in this newsletter. These events typically involved confusion between unlabeled solutions on the sterile field, mix-ups between irrigation and parenteral solution bags, or mix-ups between irrigation and venous access lines during

connection or reconnection of the solutions. These errors have happened both inside and outside the operating room (OR).

ISMP's sister organization, ISMP Canada, recently published two similar events involving the inadvertent IV infusion of heparinized lactated ringer's solution intended for intraoperative irrigation.¹These cases are being shared with US healthcare practitioners to raise awareness of the prevalence of this type of wrong-route error and the harm that can result.

(Medication Incidents Reported in Canada

A circulating nurse in the OR added 50,000 units of heparin to a 1,000 mL bag of lactated ringer's solution in anticipation of this solution being needed for intraoperative irrigation. The OR scrub nurse confirmed that the right drug, right dose, and right solution were used during preparation. Due to congestion in the workspace, the nurse was unable to access a red "Medication Added" auxiliary label, which was typically applied in this situation, and so, the bag was never labeled as containing heparin. This bag, labeled as containing only lactated ringer's solution, was then stored on an IV pole outside the sterile field in the OR.

When the patient required fluid replacement during surgery, the mislabeled bag of heparinized lactated ringer's solution on the pole was retrieved by a different OR circulating nurse and given to the anesthesia provider who administered it IV. When the heparinized irrigation solution was requested by the surgery team, staff discovered it was missing and recognized the error. The patient was treated with protamine intraoperatively and recovered without complication.



In the second event, a circulating nurse in the OR used a small piece of gray tape to label a 1,000 mL bag of lactated ringer's solution to which 50,000 units of heparin had been added (Figure 1). The low contrast between the gray background and writing on the tape made it hard to read. The poorly visible.

Figure 1. Gray tape label on bag of lactated ringer's (from Canada) with added heparin is

heparinized solution intended for irrigation was thought to be a plain bag of lactated ringer's solution and was subsequently infused via the IV route. When the patient was transferred from the OR, staff in the post-anesthesia care unit (PACU) recognized the error immediately and administered protamine as ordered. The patient was monitored carefully and recovered without sequelae.

continued on page 2-Irrigation >

SAFETY briefs

Betaine anhydrous vs. betaine hydrochloride. A patient with Philadelphia chromosome-positive acute lymphocytic leukemia had been on dasatinib (SPRYCEL) as part of his treatment regimen. Dasatinib requires gastric acidity for ideal absorption, and acid suppressors are generally contraindicated. Due to persistent significant gastritis, this patient eventually required the addition of a proton pump inhibitor. In such cases, patients may benefit from adding oral betaine hydrochloride, available as a nutritional supplement, to minimize impaired absorption of dasatinib. Betaine hydrochloride has been shown to transiently re-acidify gastric pH in patients with drug-induced hypochlorhydria (www.ncbi.nlm.nih.gov/ pubmed/25274610). At the hospital where this patient was being treated, the pharmacy had the US Food and Drug Administration (FDA)-approved prescription product betaine on the formulary (CYSTADANE). This is the anhydrous form and not the same as betaine hydrochloride. Cystadane (betaine anhydrous) is indicated for the treatment of homocystinuria. Although the physician correctly prescribed betaine hydrochloride for the patient, the pharmacy mistakenly discontinued on page 2-SAFETY briefs >

Interested in an ISMP Fellowship?

If you are interested in one of the ISMP or FDA/ISMP Safe Medication Management Fellowships and will be attending the ASHP Midvear Clinical Meeting next week, we would love to meet you at our booth (# 808) in the Exhibit Hall from 11 a.m. to 3 p.m. on Monday and Tuesday, and from 11 a.m. to 2 p.m. on Wednesday. We will have a brochure available about our programs, and you will have an opportunity to meet with a current fellow or staff. More detailed information about the fellowships will appear in the December 15, 2016 newsletter.

Supporting Document 1 -- PSA 16/17-05

> Irrigation—continued from page 1

Background

Ideal irrigation solutions are not always available in ready-to-use packaging designed for irrigation. During surgical procedures, a sterile IV solution may be used as is or may be mixed with an additive for wound irrigation to remove debris.² The use of IV bags and tubing creates a hazardous situation that can result in accidental IV infusion of the irrigation solution. The packaging of IV and irrigation solutions, both with and without additives, looks very similar, and the current compatibility of access ports intended for differing routes of administration makes misconnections possible. Other contributing factors that can lead to mix-ups include: unlabeled or poorly labeled solutions; overreliance on the expected location of solutions on poles or the sterile field; a failure to read labels; repetitive task designs that foster automatic behavior with little conscious attention; a changeable, chaotic workspace; and workflow problems.

The use of heparin in irrigation solutions can help prevent thrombosis,³ but unintended IV administration of the heparinized irrigation solution can increase the surgical patient's risk of bleeding. Unintended IV administration of plain hypotonic sterile water-based irrigation solutions, or those containing additives other than heparin (e.g., Dakin's solution⁴ [diluted sodium hypochlorite]) have also resulted in patient harm. Thus, the potential for this type of error is a serious concern.

SAFE PRACTICE RECOMMENDATIONS: Several opportunities for reducing the risk of errors and/or mitigating the potential for patient harm were identified through analysis of the incidents described above.

Pharmacy preparation. Whenever possible, have the pharmacy prepare, label, and supply commonly used irrigation mixtures to the OR.

Use lowest standard concentration. Use the lowest effective concentration of heparin in irrigation solutions, and standardize the strength and base solution so pharmacy can prepare the irrigation mixtures or they can be purchased commercially, if available.

Consider sodium chloride 0.9% for heparinized irrigations. Sodium chloride 0.9% is available in pour bottles and is known to be stable when mixed with heparin. If heparinized irrigation solutions are required, consider mixing the heparin with sodium chloride 0.9% instead of lactated ringer's solution. Lactated ringer's solution may necessitate the use of an IV bag, which risks confusion as an IV solution.

Differentiate irrigation solution containers. Purchase or prepare sterile solutions for irrigation in pour bottles or other route-specific packaging. Also, utilize fluid bags of a different size for solutions intended for irrigation (e.g., 2 L or 3 L bags). The container shape or bag volume can provide a visual cue to differentiate the route of administration.

Store safely. Segregate products intended for fluid replacement from those intended for irrigation by storing them in different areas of the OR or in different sections of the warming cabinet. Prominently label these areas "IV Use Only" or "Irrigation Use Only."

Label immediately. Label all irrigation solutions immediately when an additive is mixed into the solution. Ensure that the name and amount of any medication added to the irrigation solution is clearly visible on the labeled solution. Ensure that all required supplies (including labels) are readily available in the areas where medications or solutions are prepared.

continued on page 3-Irrigation >

SAFETY briefs cont'd from page 1 pensed betaine anhydrous, which has no therapeutic benefit for the intended purpose.

People may consider the specific salt of a drug unimportant. In the case of betaine, the salt is significant. But betaine anhydrous information sources don't highlight any distinction between that product and betaine hydrochloride. The hospital has since built a distinct entry in their electronic drug dictionary for betaine HYDROCHLORIDE (with uppercase, bold lettering) and added alerts about distinct indications for this versus the anhydrous formulation. They are also sending a proposal to Lexicomp, the drug information resource they use, asking the vendor to distinguish between the two forms in the monographs. It would be helpful if all drug information publishers would include a note about this difference in the betaine anhydrous (Cystadane) monograph.

Minibag volume confusion. If you are using B. Braun partial-fill containers of 50 mL of sodium chloride 0.9% in 100 mL minibags, be aware that confusion has been reported where the 50 mL minibag cartons were stored by mistake with the 100 mL minibag cartons. This led to mix-ups in which the wrong volume minibag was used when filling emergency kits and automated dispensing cabinets. The hospital noted that the way "50/100 mL" appears on the box led to the



Figure 1. The "50/100 mL" notation misled staff, and the 50 mL-fill minibags were stored with 100 mL-fill minibags.

confusion (**Figure 1**). We've passed this information along to B. Braun. But for now, if you have these minibags, you may want to mark the outer carton to clarify that these 100 mL minibags only contain 50 mL.

Supporting Document 1 -- PSA 16/17-05 ISMP: Acute Care ISMP Medication Safety Alert

> Irrigation—continued from page 2

Affix auxiliary warning. Affix a unique, prominent auxiliary label (Figure 2) reading "FOR IRRIGATION ONLY," to any irrigation solution (including plain irrigation solutions without additives), whether commercially available or mixed by pharmacy or by OR personnel.

Use irrigation tubing, if available. When preparing or dispensing solutions intended to be used for irrigation, attach irrigation-specific connectors and tubing, if available, rather than IV connections and tubing, to prevent inadvertent IV administration.

Figure 2. Example of a brightly Designate "irrigation" poles. Use only designated colored auxiliary label indicating "irrigation" poles if irrigation fluids must be hung for decanting. A mixture intended for irrigation is usually de-

canted into a sterile basin on the sterile field; the solution, pole, and the basin on the sterile field must all be labeled.

Communicate during transitions. Incorporate verbal communication tools such as a transition of care report when a patient is transferred from the OR to PACU and/or for staff relief during a case. In one of the incidents described here, the procedure for transfer of care from the OR to the PACU included reconciliation and verification of all medications and fluids. This process worked as intended, the error was detected upon transfer, and the appropriate intervention was implemented promptly.

Establish protocols for reversal. Establish standard protocols to manage the adverse effects of high-alert medications such as heparin. In both cases mentioned above, the facilities had a protocol to manage heparin overdose/toxicity by the administration of the reversal agent, protamine.

ISMP thanks ISMP Canada for allowing the reprint of this article, with minor edits for the US audience, which appeared in the August 30, 2016, ISMP Canada Bulletin.¹

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ISMP Symposia at the 2016 ASHP Midyear **Clinical Meeting**

Below is a list of ISMP symposia that will be conducted at the 51st annual ASHP Midyear Clinical Meeting in December. Register online for any or all of the ISMP symposia at: www.ProCE.com/ISMP2016.

Planning for a Seamless Transition for Infusion Pump Integration with the EHR Sunday, December 4, 2016

9:00 a.m.-11:00 a.m.



FOR IRRIGATION ONLY

MEDICATION ADDED

DRUG

AMOUNT

"FOR IRRIGATION ONLY."

This symposium will provide vou with information on how to prepare your organization for auto-programming of IV in-

fusions and optimization of closed-loop technologies. An overview of the implementation process in two different electronic health record (EHR) systems will be provided.

From the Front Line: Improving Sterile Compounding Safety

Monday, December 5, 2016 11:30 a.m.-1:00 p.m.



This symposium will highlight the experience of one pharmacy director who was challenged to respond to a fatal

compounding error and led his team through a time of uncertainty and transformational change. Other experts will explore the use of technology to verify sterile products and highlight changes in the updated ISMP guidelines for sterile compounding.

Error Prevention in Chemotherapy: Building Safer **Medication Use Systems**

Tuesday, December 6, 2016 11:30 a.m.-1:00 p.m.



This symposium will explore current issues related to medication safety in oncology and practical recommendations to

reduce the risk of harmful errors. Leading national experts will provide information on often unrecognized safety challenges with chemotherapy, and discuss actual cases where serious errors have occurred.













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CMIRPS SCOPIM Canadian Medication Incident Reporting and Prevention System Système canadien de déclaration et de prévention des incidents médicamenteux

ISMP Canada Safety Bulletin

Volume 16 • Issue 6 • August 30, 2016

Accidental Intravenous Infusion of a Heparinized Irrigation in the Operating Room

- Apply a distinct "For Irrigation Only" auxiliary label to all bags and bottles to be used for irrigation.
- Designate a space for staff to prepare medications without distractions. Ensure that all required supplies (including labels) are readily available.
- Segregate the storage of all bags and bottles intended for irrigation from those intended for intravenous administration. Use commercially available products whenever possible.
- Designate irrigation specific equipment (e.g., poles, tubing, connections and basins) for use with solutions intended for irrigation.
- Connect irrigation mixtures to the designated tubing while on the sterile field (i.e., do not hang on the pole without any tubing attached) whenever possible.

ISMP Canada received 2 reports describing similar incidents involving the inadvertent intravenous (IV) infusion of a heparinized* lactated Ringer's solution intended for irrigation. These cases are shared to alert practitioners about this potential hazard and to raise awareness among healthcare providers of the prevalence of this type of wrong-route incident and the harm that can result. Strategies are proposed to optimize the safety of procedures for the preparation, storage, and intraoperative use of irrigation fluids, especially those containing the high-alert medication heparin.¹

Medication Incidents

A circulating nurse in an operating room (OR) added 50,000 units of heparin to a 1000 mL bag of lactated Ringer's solution, in anticipation of this solution being needed for intraoperative irrigation. Due to congestion in the workspace, the nurse was not able to access and apply the red "Medication Added" auxiliary labels that were usually used in this situation. The OR scrub nurse confirmed that the right drug, right dose, and right solution were used during preparation. The bag was then stored on an IV pole outside the sterile field, in the operating room. When the patient required fluid replacement during surgery, the unlabeled bag of heparinized lactated Ringer's on the pole was retrieved and given to the anesthesia provider who infused it IV. Then, when the heparinized irrigation solution was requested by the surgery team, staff discovered it missing and recognized the error. The patient was treated with protamine intraoperatively and recovered without complication.

In the second event, a circulating nurse in the OR used grey tape to label a 1000 mL bag of lactated Ringers to which 50,000 units of heparin had been added (see Figure 1). The heparinized solution

* A heparinized IV solution is one to which the anticoagulant heparin has been added.

ISMP Canada Safety Bulletin – www.ismp-canada.org/ISMPCSafetyBulletins.htm

Figure 1. Grey tape label on a bag containing heparin intended for irrigation.



intended for irrigation was inadvertently infused by the IV route. When the patient was transferred from the OR, staff in the post-anesthesia care unit (PACU) recognized the error immediately and administered protamine. The patient was monitored carefully and recovered without sequelae.

Background

During surgical procedures, a sterile preparation such as an IV solution may be used for wound irrigation, because ideal irrigation solutions are not always available in packaging designed for irrigation. The risk of a substitution error is increased whenever a solution intended for injection is used for irrigation, because the packaging for many of these solutions, both with and without additives, looks very similar.

Heparin is a widely used anticoagulant and is considered a high-alert medication.¹ Topical irrigation with a heparinized sterile solution achieves 2 important objectives during surgery: cleansing of the wound to remove debris³ and prevention of thrombosis.⁴ Unintended IV administration of heparin can increase a patient's risk of bleeding. The drug protamine reverses the anticoagulant effects of heparin and can be administered to minimize patient harm should an error be detected or adverse effects develop.

Various factors contribute to a risk of inadvertent IV administration of a product intended for another route (e.g., irrigation,⁵ epidural,^{2,6} subcutaneous,⁷ enteral⁸⁻¹⁰). The potential for this type of error is a grave concern; a literature scan and review of patient safety alerts confirmed the prevalence of wrong-route incidents and the need for system improvements to prevent patient harm.¹¹

Recommendations

Several opportunities for reducing the risk of error recurrence and/or mitigating the potential for harm were identified through analysis of the incident described above. The reporting facilities have already incorporated several changes to their procedures.

Acute Care Facilities

- Establish standard protocols to manage the adverse effects of high-alert medications such as heparin. In both cases, the facilities had a protocol to manage heparin overdose/toxicity by the administration of the reversal agent, protamine.
- Incorporate verbal communication tools such as a transition of care report when a patient is transferred from the OR to PACU and/or for staff relief during a case.
- Develop safety and risk prevention strategies for medication management in the OR based on accepted standards of practice such as those developed by the Operating Room Nurses Association of Canada.¹² Provide training to familiarize staff with these guidelines and their rationale.
- Share examples of effective error detection and reduction strategies with practitioners in the affected patient care area and throughout the organization to demonstrate their value. In one of the incidents described here, the procedure for

transfer of care (from the OR to the PACU) included reconciliation and verification of medications and fluids. This process worked as intended, the error was detected upon transfer, and the appropriate intervention was implemented promptly.

Personnel Responsible for Scheduling and Room Set-Up in the OR

- Schedule time for the OR to be prepared before elective surgery, to support obtaining and setting up necessary supplies and equipment. Adequate time and focused attention are needed if these preparatory tasks are to be carried out safely.
- Designate a space for staff to prepare medications without distractions. Ensure that all required supplies (including labels) are readily available.
- Segregate products intended for fluid replacement from those intended for irrigation by storing them in different areas of the OR or in different sections of the warming cabinet. Label these areas (e.g., "IV Use Only" or "Irrigation Use Only").
- Use designated equipment for irrigation solutions; clearly label or otherwise identify this equipment.

Personnel Responsible for Medications and Solutions in the OR

- Purchase or prepare sterile solutions intended for irrigation in pour bottles or other route-specific packaging.
- Standardize the strengths of high-alert medication mixtures for irrigation so that commercially available premixed solutions can be used.
- Utilize fluid bags of a different size for solutions intended for irrigation (e.g., 3 L or 250 mL bags). The bag volume can provide a visual cue to differentiate the route of administration. One reporting facility now uses bags containing 5000 units of heparin in 250 mL of 0.9% sodium chloride.
- Assess the feasibility of the hospital pharmacy preparing and supplying commonly used irrigation mixtures to the OR.
- Affix a unique, prominent auxiliary label² (see Figure 2), reading "FOR IRRIGATION ONLY", to any extemporaneously prepared irrigation solution, whether mixed by pharmacy or by OR

Figure 2. Brightly-coloured auxiliary label indicating "FOR IRRIGATION ONLY".



personnel. Ensure that the name and amount of medication added are clearly visible on the labelled solution.

- When preparing or dispensing solutions intended to be used for irrigation, attach irrigation-specific connectors and tubing, if available, rather than IV connections and tubing, to prevent inadvertent IV administration. A mixture intended for irrigation is usually decanted into a sterile basin in the sterile field; use only designated "irrigation" poles if irrigation fluid must be hung for decanting. The pole and the basin must be labelled.
- Conduct an independent double check whenever a high-alert medication is added to an irrigation solution. Review independent check processes to ensure that they include verification of the route of administration and application of the appropriate label(s).
- Connect irrigation mixtures to the designated tubing while on the sterile field (i.e., do not hang on the pole without any tubing attached) whenever possible.

Conclusion

This bulletin highlights the potential for inadvertent IV administration of solutions intended for irrigation and proposes strategies to reduce the occurrence of this type of error. Interventions to reduce this risk include visual differentiation and segregated storage of bags to be used for different purposes, use of

irrigation tubing for bags intended for this route of administration, and additional prominent labelling. Whenever possible, connect irrigation mixtures to the designated tubing while on the sterile field (i.e., do not hang on the pole without any tubing attached). Additional measures, such as preparing irrigation solutions in the pharmacy, using commercially available products, dedicating separate space for medication preparation in the OR, designating equipment and supplies for irrigation purposes, robust double-check processes for high-alert medications, and reconciliation of medications at each transfer of care, further support patient safety. Hospital practitioners are encouraged to consider these factors when designing and improving their medication use systems.

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ISMP Canada Safety Bulletin - Volume 16 • Issue 6 • August 30, 2016



Canadian Medication Incident Système canadien de déclaration et de Reporting and Prevention System

The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.



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Issue 1 September 2015

On the edge Triggering Safety Discussions

THE TROUBLE WITH IRRIGATIONS.....

Irrigation solutions are topical preparations used intra-operatively during procedures such as laparoscopic surgery, transurethral resection of the prostate, micro-vascular and orthopedic surgeries. Irrigation is commonly used for washing out debris or unwanted fluids, preventing thrombosis or controlling intraoperative bleeding. When a topical irrigation is accidentally infused the result can be catastrophic. Three near miss events have occurred in the health region over the last few months.

During an eight hour surgery a bag of 1000 mL Lactated Ringers containing 50,000 units of Heparin intended for irrigation was accidentally infused into a patient. Although the right drug, dose and solution were double checked, affixing a "medication added" label to the bag was forgotten. The bag was hung on a shared IV pole ready for when it was needed. When the surgeon called for the irrigation solution, it was nowhere to be found. It was guickly realized that the heparinized solution had been inadvertently infused earlier in the surgery, all the while believing it to be Lactated Ringers. The patient recovered following treatment with a reversal agent. In addition to risk of increased bleeding the patient also had an epidural catheter in situ posing an additional threat to patient safety.

Three months later under very similar circumstances a bag of 1000 mL Lactated Ringers containing 50,000 units of Heparin was prepared in anticipation of the surgeon's need for topical irrigation. Again the double check confirmed the right drug, dose and solution however the added medication was written on grey tape rather than on a highly visible red "medication added" label. Although the irrigation solution was never required by the surgeon, it was mistakenly selected and administered as an infusion. The error was discovered in the post anesthesia care unit. A reversal agent was administered and the patient recovered.

In another irrigation-related incident, sterile water was used instead of the intended glycine. In this case two procedure-specific case carts were mixed up. Both the sterile water and glycine are prepackaged in 3 L irrigation bags. Because the Team believed they were accessing the correct case cart, and therefore the correct irrigation solution, they did not verify the irrigation solution prior to delivery. Although the risk of a potentially life-threatening complication existed, the patient suffered no harm.

Safety Discussion

1. The least amount of drug possible.....

The delivery of some topical irrigation has recently changed in the operating room. Previously two providers within the sterile field were required to manually irrigate the surgical site; one operating an irrigation syringe and the other manipulating the continuous flush device. Now, one person can deliver the irrigation with the help of a pressurized IV bag hanging on an IV pole off of the sterile field.

The ready availability of 1000 mL Lactated Ringers IV solution in the operating room environment facilitated this change in practice. Simply adding Heparin 50,000 units into this volume created the required 50 units per mL concentration. On post-incident review, only a very small amount of irrigation solution was actually required for the surgeries. A volume reduction from 1000 mL to 250 mL more closely matched the irrigation need and further mitigated the scale of an inadvertent medication error.



Lactated Ringers 1000 mL compared to 250 mL

2. Proper labelling and visualization.....

Proper labelling involves the documentation of critical safety information on various products including IV bags, specimen containers and syringes. Improper labelling is one of the top reported safety concerns in the Health Region. In the two heparin incidents, red "medication added" labels were not affixed to the IV bags. In the third example the selection of the wrong, commercially labelled irrigation bag was not recognized. Switching attention amongst multiple priorities and distractions played a big role in all the cases. Interestingly the double check was performed confirming the right drug, the right dose and the right solution however on all occasions visualizing the label on the solution was not done. If proper labelling was applied and/or read the likelihood of the error reaching the patient would have been reduced.





IV bag with grey label

IV bag with proper label



Highly visible green label specific to irrigation for future consideration

3. Preparing the irrigation just in time....

Efficiency in the workplace is highly encouraged and rewarded. Unfortunately there are times when efficiency can invite unintended danger. The irrigations involved in the examples noted above were prepared well ahead of the time they would be needed. They were then hung on IV poles. Appreciating that IV bags on IV poles are normally infused, the mere availability of the prepared bags increased the chances that the IV bags intended for irrigations would be used as infusions.

What care providers need to know:

- 1) Prepare or select the least amount of drug whenever possible.
- 2) Prepare the irrigation solution just before or at the time it is needed.
- Immediately complete and affix a 'medication added' label to the product, no delay or exceptions.
- Add auxiliary labelling to clarify "For Topical Use Only" and/or "High Alert" when appropriate.

From reporting to learning



The three events discussed in this paper are specific to the operating room; however the lessons learned apply throughout our system. As health care providers we create and re-create safety through practice. The systems and environment under which we practice are filled with time pressures, distractions, competing priorities and our own human (cognitive) vulnerabilities. Over time, practice evolves to cope with these many hazards and pressures. The described events are not reflective of careless providers rather the products of unsafe systems. Telling front-line providers to be more careful next time will not make the system safer. It will become safer when all levels of the organization work together to design processes and systems that support providers in creating safety through everyday practice.

The purpose of this paper is to encourage safety discussions amongst healthcare providers. We invite you to join the discussion by emailing your safety thoughts and comments to:

aemsadmin@saskatoonhealthregion.ca.

Ongoing discussions will be posted on: Patient Safety Infonet Site

Patient Safety Office - April 1- July 31, 2015

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