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Implementation of smart infusion pump interoperability in the ED

Problem: Interoperability between smart infusion pumps and the electronic health record (EHR) allows information to be shared seamlessly between the two systems. With this level of bidirectional (e.g., auto-programming and auto-documentation) interoperability, infusion parameters are wirelessly transmitted from the EHR to prepopulate settings on the smart infusion pump, and infusion data are wirelessly sent back to the EHR, where it is documented. To start an infusion, the nurse first scans the barcode on a patient's identification (ID) band, the medication/infusion bag, and the pump or associated pump channel. Infusion parameters are transmitted from the EHR to the pump for the nurse to verify and accept, eliminating manual programming steps. Also, programming information is transmitted back to the EHR, validated by the nurse, and recorded electronically, creating a closed-loop system.

As described in the ISMP ***Guidelines for Optimizing Safe Implementation and Use of Smart Infusion Pumps*** (www.ismp.org/node/972), successful implementation of interoperability can effectively reduce the potential for a variety of pump programming related errors such as wrong drug, wrong drug concentration, wrong rate, and wrong patient weight. For this reason, the ISMP ***Targeted Medication Safety Best Practices for Hospitals***, *Best Practice #8* (www.ismp.org/node/160), calls for the implementation of smart infusion pump interoperability with the EHR and organizational expectations (e.g., compliance goals) for the use of the bidirectional modality for all medication and hydration infusions.

Although interoperability is a huge step forward for patient safety and many hospitals have implemented it, challenges exist that have limited its use outside inpatient units, including in the emergency department (ED). Reported barriers include the practice of nurses infusing certain medications without an infusion pump (e.g., antibiotics) and the need for practitioners to administer bolus fluids at a rate that some pumps cannot accommodate.

Practitioners from the University of Virginia Health Medical Center (UVA Health) discussed their experience implementing interoperability in the ED during a May 2024 Medication Safety Officers Society (MSOS) member briefing. UVA Health is a 659-bed academic medical center with a 70-bed, Level 1 Trauma ED with approximately 75,000 ED visits per year. In the ED, the organization provides pharmacist coverage 24 hours a day, 7 days a week. UVA Health implemented interoperability for inpatient units in 2017. At the time, the hospital excluded the ED due to the barriers noted earlier. However, in 2022, a pump programming error occurred in their ED, highlighting the importance of expanding the use of interoperability there. The organization reevaluated the feasibility of implementing interoperability in the ED and moved forward with implementation as follows.

Project Oversight

Successful execution of interoperability requires interdisciplinary input and expertise. To ensure a thorough and thoughtful structure, UVA Health created two implementation teams: an executive steering committee and a working project team. The steering committee met every other week and the project team met weekly for the duration of the project. The steering committee served as the decision-making body, provided strategic directions, and removed barriers to ensure

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SAFETY briefs

ExactaMix disposable inlets may contain particulates. On August 20, 2024, Baxter issued an Urgent Medical Device Correction (www.ismp.org/ext/1416) due to reports of particulate matter in their automated compounding device (disposable) inlets used with the **ExactaMix** and **ExactaMix Pro** compounders. Automated compounding devices are commonly used for parenteral nutrition (PN) preparation, but may also be used to compound other complex sterile preparations. The impacted disposable inlets (product codes: H938173, H938174, H938175, H938176) include tubing with different attached (capped) components on each end (**Figure 1**). Users have observed particulate matter before use within the primary packaging inlet components, including within the sterile fluid path tubing. Particulate matter may end up in the final admixture if the priming cycle during compounder setup does not remove it. If practitioners do not notice the particular matter and they infuse the product, patient harm may occur if an in-line filter is not used. To date, Baxter has not received any reports of patient harm related to this issue.

Figure 1. An example of a Baxter disposable inlet that may contain particulate matter.

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the goals and timelines were met. The committee included a project manager, the chief of nursing, pharmacy, information and technology, quality, and operations, as well as ED nursing leadership, and the director of clinical engineering. The project team was tasked with evaluating and designing workflows, identifying and overcoming barriers (with the support of the steering committee), developing a training and education plan, and building go-live strategies. This team included the steering committee project manager, the lead ED clinical pharmacist, the nursing interoperability subject matter expert (SME), and representatives from ED nursing leadership, pharmacy leadership, clinical engineering, informaticists, medication-use strategy pharmacists, and ED physicians, along with an infusion pump vendor representative for support.

Workflow Design and Build

The project team began by reviewing data, lessons learned, and experiences that had been documented during the inpatient interoperability implementation. They revisited a previously completed failure mode and effects analysis (FMEA) and identified significant gaps in training during the inpatient rollout, resulting in poor compliance after the initial go-live date. As the team prepared for interoperability in the ED, the FMEA served as the blueprint for implementation. Also, the project team evaluated the ED nursing workflow to determine if the general interoperability principles used for inpatient units could apply to nurses in the ED. The team identified that the layout of the ED rooms mimicked inpatient rooms for interoperability purposes, as each room had an infusion pump and an adjacent computer.

One barrier that the team identified and acted upon was that the barcode scanners were stored away from the computers. Poor ergonomics led to difficulty for nurses accessing and redocking the scanner, resulting in the lack of use and loss of battery power for continued use. Barcode scanning is a crucial step in interoperability. To address this, the team identified optimal placement to support best ergonomic position, and mounted scanners on the walls near computers. The team also invited ED nurses and leadership to inpatient intensive care units (ICUs) to allow the nurses to observe interoperability in practice and how it can be beneficial in timely situations for critically ill patients. This also provided the ED nurses with opportunities to identify differences in workflow, such as the EHR software modules that prescribers use to order medications in the ED.

The team then collaborated with ED clinical pharmacists and nursing staff to identify additional practices that may differ from inpatient units that could be incompatible with the interoperability process in the ED. Three primary concerns were raised. The first issue was the lack of the ability to order a rapid (e.g., faster than 999 mL/hour) intravenous (IV) fluid bolus infusion administered either via gravity or with a pressure bag without impacting interoperability compliance numbers, as that would exceed the smart infusion pump's maximum rate. The solution to this was to build a new ED-specific bolus fluid order for these clinical needs and have the orders be out of scope for interoperability. Prescribers, pharmacy, and nursing collaborated to build and test these orders in their respective workflows.

The second issue involved intermittent infusions. The general practice in the ED was to administer intermittent infusions, such as antibiotics, without using a pump or as a primary infusion. To facilitate ED nurses using the pump to administer intermittent infusions, the team developed and provided education and hands-on training on how to set up secondary infusions using the pump. In addition, they added an alert in the EHR when a prescriber ordered an intermittent infusion for an ED patient to prompt the order of a carrier fluid (e.g., a small bag of compatible fluid that is used as a primary infusion to allow administration of the intermittent infusion via a secondary administration set). The team worked with the hospital supply chain to ensure the ED maintained a sufficient inventory of appropriately sized carrier fluid bags to accommodate the increasing need for secondary infusions. They also evaluated supplies, such as tubing, to ensure they were available in all ED medication preparation locations.

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Organizations that use the ExactaMix or ExactaMix Pro compounder should inspect all inlets before use, including the inlet primary packaging, tubing, connectors, and spikes. If staff see particulate matter, do not use the inlet and sequester it to return to Baxter. Ensure inlets are primed before use according to the instructions in the compounder operator's manual. After compounding, visually inspect the compounded product for precipitates and particulates. Baxter recommends using a minimum of a 1.2 micron in-line filter during product administration for all products made on the compounder. The American Society for Parenteral and Enteral Nutrition (ASPEN) recommends all PN admixtures be filtered using a 1.2-micron filter (www.ismp.org/ext/1417), and it is particularly important now to prevent patient harm. While organizations may already be using 1.2 micron in-line filters for PN administration, they should consider what other items are prepared by ExactaMix at their institution and determine if the use of a 1.2 micron in-line filter is appropriate, or if they should stop using ExactaMix for the preparation of these non-PN compounds. Baxter is in the process of replacing the affected product codes (refer to Appendix A in the letter for affected lot numbers). According to the company, customers who do not observe particulate matter may continue to use the inlets as outlined in the 'Actions to be Taken by Customers' section of the letter. If issues are identified, notify the US Food and Drug Administration (FDA) and ISMP, in addition to sequestering the product and informing Baxter via email at: corporate_product_complaints_round_lake@baxter.com.

Oral agent packaged in a vial similar to an injectable. A practitioner reported concerns with the packaging of Medexus Pharma's **GLEOLAN** (aminolevulinic acid), a diagnostic agent used for visualization of malignant tissue during surgery in patients with glioma. Although the medication is for oral use and the carton and vial contain the statement "For Oral Use Only," this may be overlooked by practitioners as the red font on a black background may be difficult to read and the packaging resembles vials used for parenteral injection (**Figure 1**, page 3).

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Finally, considering the new practice of administering intermittent infusions via the pump, the ED nursing team was concerned about the limited number of infusion pump channels available. While UVA Health did purchase additional channels, one specific concern was the potential for a delay in antibiotic administration to septic patients if nurses had to search to locate another infusion pump channel. To alleviate this, the clinical team developed ED-specific orders for first-dose beta-lactam antibiotics that could be administered via IV push. These orders were restricted to the first dose of antibiotic administered in the ED.

Communication and Change Management

While the build was in progress, the project team routinely met with nurses, prescribers, and pharmacists in the ED to discuss the rollout. This helped the team maintain consistent messaging and avoid abrupt changes without significant communication and feedback from end users. The team also set up a simulation area in the ED to allow nurses to test interoperability. In addition to introducing the nurses to the new workflow, the simulations allowed the team to identify which steps were most troublesome or unclear to the end users. The consistent presence and visibility of key members of the team cultivated a positive relationship with the ED staff, which contributed to a successful go-live implementation.

The EHR changes the team built to accommodate interoperability in the ED were implemented incrementally using just-in-time teaching methods. This allowed team members to immediately apply the content learned. This was a strategic recommendation, as one of the major weaknesses the team identified from the inpatient implementation was that training was completed too far in advance of the initial go-live date. Incorporating incremental changes allowed the nursing staff to focus on each step of interoperability rather than multiple changes at once.

Education

The team collaborated with an ED clinical pharmacist and ED nursing educator to develop simulation scenarios. The simulations were intended to mimic the ways users could interact with the interoperability systems and incorporated commonly used medications prescribed for ED adult and pediatric patients. Simulations included common errors and barriers that nurses may encounter with corresponding recommendations to address them. Incorporating the scenarios into the interoperability test domain of the EHR and smart infusion pump for simulation was resource-intensive, requiring significant support and prioritization from the executive steering committee.

Once the team built scenarios, the nursing SME for interoperability educated one primary trainer, along with select ICU nurses with interoperability experience (e.g., train-the-trainer program) to ensure consistency in content and style of training. ED leadership ensured all users were allotted time to complete their training, and nursing leadership worked proactively to encourage training sign-up. The team was able to achieve a near 100% training rate in the 3 weeks immediately prior to the go-live date.

Prior to simulation training, all users completed a computer-based learning (CBL) activity to preview the process. After completing the CBL, users attended an assigned 2-hour training block. The team designed the training simulation to mirror true practice as closely as possible. The simulations included orders in the EHR environment used in the ED, along with fluids and tubing to administer to a simulated arm. This level of simulation allowed the trainees to encounter various error messages and problems to allow troubleshooting.

Go-Live Strategies

The project team proactively planned for support and monitoring for go-live. For the first week,

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The prescribing information (www.ismp.org/ext/1378) recommends that a health-care provider reconstitute the oral Gleolan powder prior to administration to provide the appropriate dose according to the patient's body weight:

Completely remove the white cap and aluminum crimp seal from each vial. Remove and retain the rubber stopper from the vial. Using an appropriate volumetric measuring device, measure 50 mL of drinking water and add to each vial containing 1,500 mg of Gleolan. The resulting reconstituted solution is 30 mg/mL. If required, replace the stopper and store the reconstituted solution for up to 24 hours at room temperature prior to administration.

Prior to administration, transfer the entire contents of the prepared vial(s) into an appropriate dosing container (e.g., oral medicine bottle); ensure the entire contents of the vials are transferred. After transfer, discard the empty vial(s). Using a disposable volumetric syringe, remove the administration volume of reconstituted Gleolan solution from the dosing container and transfer it to a separate oral dosing container. Discard unneeded volume of Gleolan solution. Administer orally 3 hours (range 2 to 4 hours) prior to induction of anesthesia.

Figure 1. Gleolan for oral solution is provided in a vial that resembles those used for parenteral injection.

We warned about this concern in our December 13, 2018 article, *Is oral imaging agent at risk for IV use?* Since the product looks like a parenteral medication vial, a

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the pump vendor and several key members of the project team were stationed in the ED for 24/7 support. Because of the relationships developed in the months leading up to interoperability, the ED nurses were comfortable coming to the team with questions and need for assistance. To identify potential problems in near-real time, the team designed a scorecard that showed scanning compliance percentage (e.g., patient ID band, medication, pump/channel), what types of errors were occurring, and which specific infusions were not administered with interoperability. For the first two weeks, ED leadership and the project team reviewed this scorecard and followed up on each infusion to understand the barriers to using interoperability. With time, the scorecard was reviewed weekly by ED leadership, and then monthly. Members of the team continue to evaluate compliance data and collaborate with ED leadership to identify any barriers.

Results

On the first day of using interoperability, the department achieved an 81% compliance rate (n=97/119). The vendor's goal for the go-live date was 80%, although the vendor did note that hospitals do not often achieve this on the first day. Not only was the ED team able to achieve this goal on day one, but they have maintained and increased their compliance rates. Since the go-live date, compliance rates have consistently been similar to hospital-wide averages at nearly 90%.

Safe Practice Recommendations: ISMP encourages organizations to engage leadership in evaluating the feasibility of implementing interoperability in the ED. Consider the following recommendations:

Complete an FMEA. Prior to implementing interoperability in the ED, a team such as the medication safety committee should complete an FMEA to identify and address potential issues and barriers. If your organization has already implemented interoperability in other areas (e.g., inpatient units), gather feedback from end users, incorporate lessons learned from errors and close calls (i.e., good catches), and address any issues/barriers. Determine differences in ED workflow and environment (e.g., ED medication-specific nuances, location of equipment) that need to be addressed from the system standpoint.

Designate resources. Plan for and provide support for ED staff before, during, and after go-live. Routinely meet with nurses, prescribers, and pharmacists in the ED to discuss the rollout, enhance communication, and gather feedback.

Use simulation. Before implementing interoperability in the ED, use simulation to evaluate the systems in a test environment. Work directly with software vendors to understand potential problems that have been reported and recommendations to prevent them. Simulate the workflow to test what does and does not work, gain crucial feedback from end users, and identify any potential safety gaps. Consider holding "a day in the life" to run real-life simulations to see how interoperability works in your ED settings with a diverse group of end users and compare to vendors' testing environments. Ask end users to identify vulnerabilities and discuss concerns with the team so they can address any issues before implementation.

Educate practitioners. Prior to implementation and during new hire orientation and annual competency assessments, educate practitioners about the proper use of interoperability. Ensure end users understand the steps required (e.g., after scanning make sure to review the order populated in the EHR), and the risk of patient harm if they bypass interoperability.

Promote a culture of safety and learning. Routinely meet with end users in the ED to discuss the rollout and foster increased communication and feedback. Be curious, regularly ask staff about safety issues, and exhibit appreciative listening. For additional information, see our July 11, 2024 newsletter article, *Cultivate discussions in a psychologically safe workplace—Part I*.

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practitioner may prepare and withdraw the dose using a parenteral syringe and needle and then inadvertently administer it intravenously (IV).

We have reached out to the US Food and Drug Administration (FDA) and Medexus Pharma to recommend the manufacturer package the product in a container that practitioners would associate with an oral product (e.g., oral liquid bottle), rather than something that looks like a vial that contains an injectable medication. Per the manufacturer, alternative container closure systems are not possible because the Gleolan manufacturing process relies on lyophilization to achieve the finished dosage form. Since oral Gleolan is a freeze-dried product, they told us that due to stability reasons, it is not possible to use a screw cap or other alternative primary packaging. If the package cannot be changed, we recommend the manufacturer improve the warning statement on the label or even use a cap with a printed warning to alert users that this is for oral use only.

The topic of inadvertent administration of an oral medication via the IV route was discussed in our March 21, 2024 article, *Implement strategies to prevent persistent medication errors and hazards: 2024*. Using parenteral syringes—syringes with luer connectors that mistakenly can be attached to needleless IV systems—allows for improper administration of oral/enteral liquid medications via the IV route, which is a significant patient safety risk. The unintended administration of oral liquid medications via the IV route can result in serious patient harm, including infection and/or pulmonary emboli, and even death. Sadly, we continue to receive reports in which patients were inadvertently given an oral liquid medication IV.

If your organization purchases this product, ensure staff are aware of the correct preparation and administration instructions. Doses should be prepared and dispensed from the pharmacy in an ENFit/oral syringe to prevent the use of a parenteral syringe and administering the drug via the wrong route.

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Analyze and respond to data. Nurse managers and pharmacy leaders must have a system to monitor compliance and gather feedback from end users to ensure the use of interoperability is maximized. Develop and share interoperability compliance goals, and regularly evaluate if system changes are needed. Investigate instances where interoperability was bypassed to understand barriers, correct system issues, and/or coach staff as needed.

Learn from errors. Review internally reported interoperability-related errors as well as published external events. Encourage staff to report close calls and errors that have reached the patient. Share impactful stories and recognize staff for good catches, including those caught through the use of interoperability. Inform staff that the changes were a result of reporting to foster ongoing reporting.

Next Steps

UVA Health's interoperability experience was successful in part due to thoughtful planning with simulations and education to prepare staff. As with any system implementation, a proactive plan to demonstrate compliance and implement quality improvements is advised. At UVA Health, this is accomplished internally by monthly reviews of interoperability compliance. Data and errors are evaluated and shared with staff to gather feedback, facilitate learning, and enhance workflow and systems.

Conclusion

UVA Health has made an upfront investment to enhance safety by operationalizing interoperability in the ED. The medication safety team feels this structure and level of reliability has made a difference for their medical center, practitioners, and patients. We encourage organizations to learn from this model when implementing interoperability in their ED.

We thank Amy Johnston, MSN, RN, AGCNS-BC, CNRN, Principal Lead for Nursing Medication Safety Programs, and Kara Thornton, PharmD, MEd, CCRP, Medication Quality, Performance Improvement and Safety Pharmacist, at UVA Health for sharing a systematic review of their ED interoperability implementation, as well as helping to write this article. Email ISMP (ismpinfo@ismp.org) with questions.

Special Announcements

Register for ISMP symposium on injection safety

Going to the *Illinois Council of Health-System Pharmacists Annual Meeting*? Register to attend ISMP's breakfast symposium on applying best practices for injection safety on **September 14, 2024** (continuing education credit available)! To save your space and to learn more about risks associated with the preparation and administration of intravenous (IV) medications and implementing ready-to-use products, visit: www.ismp.org/ext/1415.

MSB releases white paper on look-alike labels

One of the most frequent issues with injectable products reported to ISMP involves look-alike medication labels. ISMP's subsidiary, Med Safety Board (MSB), has issued a white paper calling for pharmaceutical manufacturers to ensure injectable medication labels are well-differentiated to minimize mix-ups and prevent patient harm. The white paper includes key labeling attributes that manufacturers should consider when designing labels and healthcare organizations should consider when purchasing or adding products to their formulary. For a copy of the white paper, visit: www.ismp.org/ext/1418.

ASHP USP Chapter <797> activities

The American Society of Health-System Pharmacists (ASHP) is offering six **FREE** on-demand activities including webinars, *Frontline Conversation* sessions, and podcasts centered around the revised USP Chapter <797> requirements in different healthcare settings. Continuing education credit is available with the webinars for pharmacists and technicians. For more information and to participate in the activities, visit: www.ismp.org/ext/1405.

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