Guidelines for Optimizing Safe Implementation and Use of Smart Infusion Pumps

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INTRODUCTION

Smart Pump Technology

Almost 20 years ago, the introduction of **SMART INFUSION PUMPS** with **DOSE ERROR-REDUCTION SYSTEMS (DERS)** and associated drug libraries launched an era of dramatic improvements in intravenous (IV) infusion safety.[1-7] **SMART INFUSION PUMPS** have allowed for a greater level of control, accuracy, and precision with drug delivery, and are designed to provide users with decision support for programmed doses and infusion rates in order to identify errors before medications or fluids are infused. Facility-customized **DERS** warn healthcare providers about potential prescribing, calculation, and programming errors by generating alerts intended to prevent infusions from being programmed outside facility-established limits. These limits can be either **HARD LIMITS** (which cannot be bypassed and prevent users from starting the infusion as programmed) or **SOFT LIMITS** (which provide a warning that an entered parameter is outside of the anticipated range but will still allow users to start the infusion as programmed once the alert has been acknowledged).[3,8] **SMART PUMP** drug libraries can be tailored to reflect organizational practices and are typically subdivided into **CARE AREAS/PROFILES** configured for different patient populations, specific care areas, or based on patient weight.[3,9]

Adoption of Smart Infusion Pumps

SMART INFUSION PUMPS are now used in more than 80% of US hospitals and are widely regarded as a standard of care to reduce infusion-related medication errors.[8,10] They are among the most ubiquitous devices in healthcare.[11] Their use includes administration of **CONTINUOUS INFUSIONS**, **BOLUS DOSE** and **LOADING DOSE INFUSIONS**, **INTERMITTENT INFUSIONS**, patient-controlled analgesia (PCA) and epidural infusions. **SMART PUMP** technology can also provide a great deal of data that is useful in improving safe practices, including compliance with using the drug library, alert types and frequency, action taken in response to an alert (e.g., reprogramming), and the frequency of overridden **SOFT LIMITS**.[4,6] The data can also help when investigating pump-related errors and assist in identifying risky practices such as unnecessary nurse dilution of IV medications.[12] Wireless connectivity of **SMART PUMPS** has been a significant technological advance, allowing the potential for hundreds of pumps to connect to a single server within a health system in order to facilitate the uploading of software revisions and the downloading of infusion data.[1,3]

Limitations of Smart Pump Technology

In their nearly two decades on the market, the widespread implementation of **SMART INFUSION PUMPS** has helped to: standardize infusion practices and drug concentrations, dose/ **DOSE-RATE** nomenclature, and dosing limits for IV medications and fluids; prevent potentially fatal under- and over-dosing while documenting "good catches"; and provide a wealth of infusion data that can be used to improve patient safety.[1,13] Without diminishing their significant role in advancing infusion safety, in most healthcare organizations, **SMART INFUSION PUMPS** still operate in isolation, unable to interact with other technologies available to maximize safety. For example, most **SMART PUMPS** are not linked to available

barcode medication administration (BCMA) systems and are not assigned to a specific patient. They do not directly communicate with the computerized prescriber order entry (CPOE) system or electronic health record (EHR), so **AUTO-PROGRAMMING** of the pump from the prescriber's order and **AUTO-DOCUMENTATION** of the IV therapy in the EHR cannot occur. Thus, **SMART INFUSION PUMPS** cannot prevent wrong patient errors, incorrect **DERS** library selections (as well as infusion line mix-ups), and they are not designed to overcome frequent alert overrides or poor compliance with engaging the **DERS** library.[1,3] Presently, most **SMART INFUSION PUMPS** cannot record the reason for each override and are unable to communicate alerts and the status of infusions in real time to another appropriate healthcare provider who can act on the information.[1] While **SMART PUMPS** are capable of producing useful information beyond basic compliance reports, many **SMART PUMP** users are not collecting or analyzing the data in meaningful ways to make improvements.[4,9,10,14]

Integrated Technology Systems

The wireless connectivity of **SMART PUMPS**, barcode scanning, radio-frequency identification (RFID) capabilities, and an industry-wide impetus to implement CPOE and EHRs have laid the foundation for integration among these technologies that can elevate **SMART INFUSION PUMPS** to a new level of intelligence.[15] National surveys show that the vast majority of hospitals have implemented or budgeted for **SMART PUMPS**, EHRs, CPOE, and BCMA.[10,16] In many hospitals, these technologies coexist but operate as "islands," without realizing their full potential.[1,2,7] The ultimate goal is to connect and monitor these technologies to provide real-time clinical decision support, **AUTO-PROGRAMMING** and **AUTO-DOCUMENTATION**, ongoing clinical surveillance, and an alert system that automatically flags any critical situation that requires immediate attention and communicates the information to the most appropriate healthcare provider, adding a new dimension to IV infusion therapy safety.[1,15] Standardization of drug names and dose/dosing units across the formulary, CPOE, automated dispensing cabinets (ADCs), BCMA, and the EHR is critical,[3] as well as the assessment and planning that occurs in order to mobilize and prepare for sufficient resource allocation, as part of the integration success.[18]

SMART PUMP-EHR INTEROPERABILITY enables the prescriber's ordered infusion parameters that have been reviewed by the pharmacist to pre-populate the **SMART INFUSION PUMP** screen (which must be confirmed by the user prior to starting the infusion) and automatically documents infusion data in the EHR.[1,15] Successful implementation can effectively reduce a variety of error types that still can occur with **SMART PUMPS** such as issues involving pump programming, wrong drug concentration, wrong rate, wrong drug, and patient weight, as well as to reduce manual data entry steps.[19]

INTEROPERABILITY between **SMART INFUSION PUMPS** and the EHR is a huge step forward for patient safety, and at the same time, is complicated and costly requiring long-term organizational commitment.[15,19] Among the key requirements for **SMART INFUSION PUMP INTEROPERABILITY** are a robust and reliable wireless infrastructure, electronic medication orders that include necessary infusion parameters, high BCMA compliance, and **SMART INFUSION PUMPS** capable of bi-directional communication with the EHR.[15,19,20] While very little information is available concerning the financial impact of **SMART INFUSION PUMP INTEROPERABILITY**, a recent study demonstrated a positive relationship concerning improved charge capture and billing compliance.[20]

SMART INFUSION PUMP INTEROPERABILITY represents the next milestone in infusion safety[19] and one day will likely be the standard for how IV medications and fluids are administered. That day is not so far off, as early adopters of **SMART PUMP INTEROPERABILITY** have created momentum and are forging the way through the myriad of challenges facing healthcare providers. These innovators are providing evidence regarding the positive link between integration and key improvements in safety, nursing and pharmacy productivity, clinical decision making, patient monitoring, alarm and alert notification, and a reduction in variation and waste.[1,17]

The experiences of early adopters of **SMART PUMP INTEROPERABILITY** can serve as a tipping point for more widespread adoption of even more intelligent infusion systems.[21] Organizations sharing their messages about "closed-loop" success can help others optimize use of their existing systems and prepare for the integration of technologies, paying particular attention to ensuring the adequacy of a wireless network, enabling all available **SMART PUMP** safety features, managing **DERS** libraries aggressively to reflect best practices, managing alerts and alarms, analyzing data on alerts and compliance, and other key strategies.[15,19]

Note: BOLDED TERMS IN SMALL CAPITAL FONT are listed in the Definitions section of the document.

MEDICATION ERRORS ASSOCIATED WITH SMART INFUSION PUMP USE

Technology has vastly improved the safety of infusion administration over the past five decades, from administration by gravity to automated infusion pumps that offered better control of the rate and consistency in delivery to **SMART INFUSION PUMPS** with **DERS**.[1,17] At the same time, infusion devices have been involved in more adverse incidents reported to the US Food and Drug Administration (FDA) than any other medical technology.[19] **SMART INFUSION PUMPS** with **DERS** have exposed an alarming and once hidden vulnerability to IV infusion errors and helped to uncover a high degree of variation in infusion practices among and even within healthcare organizations.[1,2,7] Despite their ability to detect and warn healthcare providers about errors, often organizations have not maximized **SMART INFUSION PUMP** functionality to its full potential, and serious IV errors have persisted. These errors have often occurred due to a failure to engage the **DERS** and the ease with which healthcare providers may select the wrong drug library entry or override serious alerts.[1,3]

Even when organizations optimize the use of **SMART INFUSION PUMP** technology, safety gaps still exist.[1,12,18,22,23] Most of these gaps stem from the **SMART PUMP** operating in isolation of other electronic systems, requiring manual programming and documentation by the end user.[1,19] Because current **SMART INFUSION PUMP** programming depends heavily on human action, and it is inevitable that humans will make mistakes, opportunities for error still exist.

Programming Errors

For the **DERS** limits to function effectively, the drug library must be engaged and the correct **CARE AREA/PROFILE**, medication/fluid, and concentration must be manually selected by the user.[23] The device, unaware of the patient's prescribed therapy, also relies on the user to properly input infusion information into the corresponding pump fields and to ensure the infusion is administered to the correct patient.[1] Data support that errors in pump programming are a significant contributor to medication errors involving use of infusion devices.[24]

DOSE-RATE and Infusion-Rate Mix-Ups

Confusing the medication **DOSE-RATE** with the infusion rate is a relatively frequent pump programming error type that is often unreported.[12,25] This type of wrong-field programming error in which the intended infusion rate is entered in the **DOSE-RATE** field can result in the patient receiving too much or too little solution and poses significant risk of patient harm. These mistakes can be related to differences in the names that these infusion parameters are given and the sequence in which they are listed in the medication administration record (MAR) versus the **SMART PUMP** screen.[25]

Custom Concentrations/Wildcards[26]

Programing a custom concentration, also known as a wildcard, entails selecting a drug from the library but then manually entering the concentration (e.g., xx mg/xx mL). Serious errors have occurred when **PRACTITIONERS** have unnecessarily selected a custom concentration option, and then entered the wrong concentration, even though a standard

concentration option for the drug was available in the pump library. Some of the errors appear to be mental mix-ups in which the "dose per hour" was paired with the total infusion volume (e.g., heparin 800 units/hour from a 25,000 units/250 mL bag was inadvertently entered as a concentration of 800 units/250 mL). Mix-ups have also occurred in which the "per mL" concentration was paired with the total infusion volume (e.g., a 0.2 mg/mL concentration of milrinone in a 20 mg/100 mL bag was entered as a 0.2 mg/100 mL concentration). Sometimes, the way the concentration is expressed on the label also contributes to concentration mistakes.

Custom concentration options that do not employ a hard-minimum concentration limit have led to harmful errors. This is mostly due to the counterintuitive, inverse relationship between concentration and volume. More concentrated drugs require less volume to deliver a specific dose while less concentrated drugs require more volume. When using custom concentrations, the concentration must be programmed into the pump so that it can calculate the volume needed to deliver the prescribed dose. If the programmed concentration is lower than the actual concentration in the infusion bag or syringe, the pump will deliver an overdose. If the programmed concentration is higher than the actual concentration in the bag or syringe, the pump will deliver an underdose.

Other examples of programming errors include those related to:

Dosing nomenclature[23]

- Programming errors due to non-standard nomenclature of the dose/dosing units (e.g., weight-based versus non-weight-based dosing) and **DOSE-RATE** (e.g., mg/kg/min versus mg/kg/hr)
- Calculation errors due to unit of measure inconsistency between the drug library and the EHR (e.g., a **BOLUS DOSE** ordered in milligrams, but the **SMART INFUSION PUMP** requires mg/kg)

Multiple medication infusion concentrations[12,27]

- Selection errors when choosing among multiple listed concentrations in the drug library for the same medication

Secondary Infusion Errors

In their landmark study, Cassano-Piché and colleagues determined that multiple issues exist with secondary medication administration that could result in patient harm.[27] A particularly significant risk identified was the potential for incorrect **HEAD HEIGHT DIFFERENTIAL** between the **PRIMARY** and **SECONDARY INFUSIONS**. **SECONDARY INFUSION** is the administration of an IV medication or fluid through the **PRIMARY INFUSION** line using a secondary tubing set that is attached at the upper injection port of the primary set.[28] During administration of the **SECONDARY INFUSION**, the **PRIMARY INFUSION** is designed to temporarily pause and then automatically resume upon completion of the **SECONDARY INFUSION**. Most infusion pumps currently on the market require users to manually lower the primary medication or fluid bag/bottle below the secondary container.

This is necessary to increase the secondary bag pressure differential enough to prevent the flow of the **PRIMARY INFUSION** until the **SECONDARY INFUSION** has completed.[27,30] Insufficient **HEAD HEIGHT DIFFERENTIAL** between the **PRIMARY** and **SECONDARY INFUSION** containers may result in both infusions running concomitantly at unpredictable rates or possibly the secondary not infusing at all.[27] Other serious errors reported in the literature[27] as well as to the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program (MERP) involving manual **SECONDARY INFUSION** include:

- **SECONDARY INFUSION** of a **HIGH-ALERT MEDICATION** infused too quickly even when the **SMART INFUSION PUMP** was programmed correctly
- Secondary medication container completely infused although the volume to be infused (VTBI) was set at a volume less than the total container volume
- **SECONDARY INFUSION** delayed or omitted due to the user forgetting to open the roller clamp

The manual set up of **SECONDARY INFUSIONS** can be implemented safely, but this method provides more opportunities for human error, and is highly reliant on the individual **PRACTITIONER'S** training and ability to remember to follow the manufacturer's instructions. Although successful **SMART PUMP INTEROPERABILITY** with the EHR has the potential to avert a large majority of infusion-related events (e.g., wrong concentration, wrong weight, wrong rate, wrong drug, wrong units, wrong dose), it is not capable of intercepting **SECONDARY INFUSION** set-up errors.[19]

Other Error Types

Additional error types associated with **SMART INFUSION PUMP** use include:

- Infusion line or channel mix-ups when simultaneously administering multiple infusions due to visual and physical complexity[12,27]
- Administration of discontinued infusions because of a delay in stopping the infusion or not removing the associated container from the **SMART INFUSION PUMP**[1,27]
- Inconsistent rate delivery by syringe pumps used to administer infusions at low rates (less than 5 mL/hour [especially less than 0.5 mL/hour])[31]
  - See an FDA Safety Communication (http://wayback.archive-it.org/7993/20171115052211/, https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm518049.htm) for recommendations to help reduce the potential for serious adverse events caused by the absence of flow continuity.
- Dose inaccuracy due to variability in the management of infusion container **OVERFILL**[32]
- Bolus dosing errors due to variability in **BOLUS DOSE INFUSION** preparation and the complexity associated with **BOLUS DOSE INFUSION** programming in the pump[27]

This guidance document outlines safe practice recommendations, including the use of bi-directional **INTEROPERABILITY** of **SMART PUMP** technology with the EHR, to mitigate many of the risks discussed above.

DEVELOPING CONSENSUS GUIDELINE STATEMENTS

In 2009, ISMP published its original **SMART PUMP** guidelines titled *Proceedings from the ISMP Summit on the Use of Smart Infusion Pumps: Guidelines for Safe Implementation and Use.* These safe practices were the outcome of a two-day summit of expert stakeholders and focused on implementation of **SMART PUMP** technology, use of the drug library, and clinical practices.

To address the numerous and varied errors associated with **SMART PUMP** use reported to ISMP MERP and published in the literature since the publication of this resource, ISMP initiated plans in 2017 to hold its second National Smart Infusion Pump Summit. In preparation, ISMP performed a thorough review of the literature, analyzed **SMART PUMP**-related errors reported to ISMP MERP, and conducted three ISMP practitioner surveys.[12,26,33] Error data and ISMP survey responses provided important information regarding the successes, safety concerns, and barriers with the optimization of **SMART INFUSION PUMPS**. Barriers included significant limitations of pump capabilities, alarm fatigue, persistent deficiencies related to library use and updates, availability of pumps, programming workflow, associated risks with **SECONDARY INFUSIONS**, and pump data analysis.

ISMP obtained an educational grant from Baxter, B. Braun, BD, ICU Medical, and Ivenix to support its second summit which was held in suburban Philadelphia in May 2018. The purpose of the summit was to develop an updated and expanded compendium of expert- and evidence-based best practices to maximize the intended safety benefits of this important technology and better position organizations for **INTEROPERABILITY** of **SMART INFUSION PUMPS** with the EHR.

The summit, entitled *Optimizing the Safe Implementation and Use of Smart Infusion Pumps,* was guided by the following objectives:

1. Gain consensus among key interdisciplinary stakeholders on the common risks associated with **SMART INFUSION PUMP** use
2. Identify corresponding error-reduction strategies to address:
   - Infrastructure
   - Drug Library
   - Continuous Quality Improvement (CQI) Data
   - Clinical Workflow
3. Develop key safe practices to promote organizational readiness for bi-directional **SMART INFUSION PUMP INTEROPERABILITY** with the EHR

As with the first summit, the importance of involving end users was recognized which led to the identification of organizations that had successfully implemented **SMART INFUSION PUMP** technology. Representatives from these organizations, as well as **SMART INFUSION PUMP** vendors, professional and regulatory organizations (Association for the Advancement of Medical Instrumentation [AAMI],

American Organization for Nursing Leadership [AONL], Anesthesia Patient Safety Foundation [APSF], Bainbridge Health, ECRI Institute, US Food and Drug Administration [FDA], Institute for Healthcare Improvement/National Patient Safety Foundation [IHI/NPSF], Infusion Nurses Society [INS], Pennsylvania Patient Safety Authority, Regenstrief National Center for Medical Device Informatics [REMEDI], and The Joint Commission [TJC]), and ISMP staff were invited to attend the second national summit. Representatives included pharmacists, nurses, physicians, and biomedical engineers.

A framework of recommended safe practices for **SMART PUMP** use was established by ISMP staff, and then a pre-summit survey of participants was conducted to identify early consensus on these practices, as well as top safety challenges for discussion. Breakout sessions focused on the expected use of **SMART PUMPS** and their role in perioperative, procedural, and ambulatory settings; benefits of defaulting directly to programming in **DERS**; avoiding errors with the administration of **SECONDARY INFUSIONS**; **CARE AREA/PROFILE** designations; CQI metrics; clinical workflows; **INDEPENDENT DOUBLE CHECKS** for selected **HIGH-ALERT MEDICATION** infusions; and **SMART PUMP INTEROPERABILITY** with the EHR. Combining the pre-summit work in addition to the summit discussions, participants reached consensus on a variety of safe practices. These draft guidelines were subsequently posted on ISMP's website for public comment. Recommendations from the public were reviewed and the final guidelines for *Optimizing Safe Implementation and Use of Smart Infusion Pumps* were developed, which are presented in the statements that follow.

Evidence-based research was used, as available, to support the development of the guidance statements; however, as with many patient medication safety-related issues, controlled clinical trials have rarely, if ever, been done for a specific safe practice, nor would they be ethical in many cases. As such, this guidance document relies on the synthesis of the best evidence available at the time of publication, including clinical articles and other published literature, along with expert consensus.

SUMMARY OF THE ISMP SMART INFUSION PUMP SURVEY FINDINGS

ISMP conducted three surveys[12,26,33] between 2017 and 2018 to assess use of **SMART INFUSION PUMPS** with **DERS** in the United States, revealing unique perspectives of over 1,000 nurses, pharmacists, and other healthcare professionals. Ninety-seven percent of respondents reported consistently using **SMART INFUSION PUMPS** in various units (e.g., adult, neonatal, and pediatric critical care; medical/surgical; pediatric; oncology; post-anesthesia care; labor and delivery; ambulatory infusion; emergency department). While most respondents reported widespread use of **SMART INFUSION PUMPS**, many shared safety concerns and barriers to optimizing their use. Over 700 comments expressed barriers related to significant limitations in **SMART INFUSION PUMP** capabilities, alarm fatigue, deficiencies related to library use and updates, pump availability, programming workflow, **SECONDARY INFUSIONS**, and data analysis.

Infrastructure

Three percent of respondents reported using **SMART INFUSION PUMPS** for other types of infusions such as continuously nebulized medications and enteral feedings. Thirty-one percent of respondents caring for neonatal and pediatric patients reported using the same **SMART INFUSION PUMP** to administer both parenteral infusions and enteral feedings. This may be due to lack of available FDA-cleared devices within the institution for purposes other than parenteral and/or epidural infusions. Ninety percent of respondents from larger hospitals with 100 beds or more reported having wireless transfer of data to and from **SMART INFUSION PUMPS**, mostly for drug library updates (97%), data analysis (70%), and location tracking (33%). Dozens of respondents reported insufficient **SMART INFUSION PUMPS** when the census was high and issues with wireless connectivity and **INTEROPERABILITY**.

Respondents also shared limitations of the **SMART INFUSION PUMPS**, themselves, such as not being able to self-prime, having to power down the pump in order to change the **CARE AREA/PROFILE** when transferring patients to a different care area, malfunctions, and hard-to-read screens.

Drug Library

Designing, maintaining, and using the drug library to prevent errors are foundational tasks; however, these were the most frequently reported challenges. Eighty-nine percent of survey respondents reported designing the drug library based upon the patient **CARE AREA/PROFILE**, while 6% differentiate by age group (i.e., adult, pediatric, neonatal). There were also reports of difficulty in reaching consensus among prescribers regarding which medications to include in the drug library and what the standard concentrations and dosing methods should be. Respondents also revealed the impact of drug shortages on maintaining the drug library.

Half of respondents who manage the drug library reported 1 to 3 library modifications and updates during the past year; less than 5% reported no updates during the past year. Up to 45% of nurses reported programming IV fluids without the use of the library as a basic infusion more than 50% of the time due to barriers including IV fluids not being listed in the drug library (45%), perceived

lengthy process for programming IV fluids through the drug library (19%), and lack of a hospital policy establishing expectations to use the drug library for IV fluids (10%).

Only 79% of frontline nurses use the drug library for IV medications more than 90% of the time. For compliance rates lower than 90%, most nurses reported barriers such as medications or concentrations not being listed in the drug library or needing to use basic infusion mode in an emergency.

Continuous Quality Improvement (CQI) Data

Data analysis can reveal barriers to optimizing and maximizing **SMART INFUSION PUMP** use. In the third survey[33], 96% of respondents reported that they believe reviewing data is essential to quality improvement; however, only about half reported that their organization provides dedicated staff (56%) and dedicated time (48%) for reviewing data. Most organizations that analyze **SMART INFUSION PUMP** data focus on drug library and **DERS** compliance, as well as alert frequency. More than a quarter (26%) of respondents do not believe they have the skills, tools, or time for meaningful data analysis. Many respondents also reported the available data was not linked to individual patients, **PRACTITIONERS**, units, or facilities. Respondents reported that data on basic infusions may be unavailable or not shared. Seventy-four percent of respondents are unable to identify risky practices associated with **SMART INFUSION PUMP** usage, such as unnecessary nurse dilution of products, which results in a nonstandard concentration. Respondents (83%) who analyze **SMART INFUSION PUMP** data reported that most of what is being learned is being used to update or change the drug library. Only 16% of respondents reported that data analytics has led to educational programs, and only 13% had made updates or changes in policies, procedures, and practices. Forty-seven percent of all respondents reported participating in external data analytics.

Clinical Workflow

Respondents shared error types that they have encountered despite the use of **SMART INFUSION PUMPS**. The most common types of errors reported involved **SECONDARY INFUSIONS**, including delayed or omitted **SECONDARY INFUSIONS** caused by a closed roller clamp, or **SECONDARY INFUSIONS** that were administered at the wrong rate. Even with technology, human error was still reported: programming errors due to **DOSE-RATE** confusion, decimal points, and drug selection; IV line or channel mix-ups; tubing misconnections; wrong drug; and wrong patient.

PRACTITIONERS also reported frustrations with a time-consuming and complex programming process, including difficulties finding the correct drug when scrolling through a large list of generic names and overly sensitive and false alarms.

Bi-directional Interoperability

Fifteen percent of respondents have implemented bi-directional **INTEROPERABILITY** between **SMART INFUSION PUMPS** and the EHR, facilitating **SMART INFUSION PUMP** programming and EHR documentation. Thirteen percent of survey respondents reported their facility was planning implementation within the next 12 months.

SCOPE

These guidelines are designed to encompass practices associated with the safe use of **SMART INFUSION PUMPS** for the administration of medication infusions and/or IV fluids in inpatient and/or outpatient settings, including epidural and patient-controlled analgesia (PCA) infusions. These guidelines, however, **do not** specifically address:

Treatment/Device

» Continuously nebulized medications

» Dialysis therapy and continuous renal replacement therapy (CRRT)

» Elastomeric devices

» Extracorporeal membrane oxygenation (ECMO) infusion device

» Intraventricular infusions

» Irrigation infusions

» Investigational drugs

» Magnetic resonance imaging (MRI) infusions and infusion devices for MRI

» Warmed or cold fluids (resuscitation)

Situation/Topic

» Alarm management

» Cybersecurity of **SMART INFUSION PUMPS**

» Security of opioid infusions

» The use of **SMART INFUSION PUMPS** during trauma resuscitation

GUIDELINES FOR OPTIMIZING SAFE IMPLEMENTATION AND USE OF SMART INFUSION PUMPS

1. Infrastructure

1.1 Establish that the use of **SMART INFUSION PUMP** technology (i.e., **DERS**) is expected practice throughout the organization, including in ambulatory settings such as perioperative/procedural/radiology areas, the emergency department, and infusion centers for the administration of *medication* infusions including but not limited to:

- **CONTINUOUS INFUSIONS**
- **INTERMITTENT** and **SECONDARY INFUSIONS**
- Intravenous (IV) **BOLUS DOSE** and **LOADING DOSE INFUSIONS**
- Patient-controlled analgesia (PCA) infusions
- Epidural and nerve block infusions

1.2 Establish that the use of **SMART INFUSION PUMP** technology (i.e., **DERS**) is expected practice throughout the organization, including in ambulatory settings such as perioperative/procedural/radiology areas, the emergency department, and infusion centers for the administration of all *IV fluid* infusions (e.g., continuous and **BOLUS DOSE INFUSIONS**).*

*An exception may exist where **GRAVITY INFUSIONS** continue to have clinical applicability (i.e., to administer a fluid infusion at a rate greater than the pump allows).

1.3 Utilize **SMART INFUSION PUMPS** that default directly to programming in **DERS** and which make it obvious when operating outside **DERS**.

1.4 Establish organizational expectations for use of **DERS** with the goal to maximize **PRACTITIONER** compliance to 95% or greater for the administration of *medication* infusions (including epidural and nerve block infusions).

1.5 Establish organizational expectations for use of **DERS** with the goal to maximize **PRACTITIONER** compliance to 95% or greater for the administration of *IV fluid* infusions.

1.6 Monitor **SMART INFUSION PUMP** compliance rates (target goal of 95% or greater), and address barriers leading to infusions being programmed outside **DERS**.

Discussion: **SMART INFUSION PUMPS** with **DERS** allow organizations to create a tailored library of medications with dosing guidelines by establishing standard concentrations, dosing limits, and alerts (e.g., **CLINICAL ALERTS**, **SOFT LIMITS**, **HARD LIMITS**). **SMART PUMPS** with enabled **DERS** can detect dosing and programming errors that may harm patients. Failing to employ available **DERS** as intended and to heed important **CLINICAL ALERTS** are common contributors to preventable infusion errors with **SMART INFUSION PUMPS**. Healthcare clinicians should not view the dose-checking feature of **SMART PUMPS** as an option that can be turned on or off. Nor should the alerts that arise from the system be bypassed without serious consideration. Bypassing **DERS** remains a key risk point in the use of this technology, and as such, organizations should establish a **DERS** compliance

rate of 95% or greater and monitor compliance to maximize intended safety benefits. Any barriers to programming through the drug library should be identified and resolved.

In conjunction with monitoring compliance reports, managers should perform periodic bedside assessments of **DERS** compliance to validate that the medication or fluid being infused matches the appropriate **DERS** selection. For example, **SMART INFUSION PUMPS** that have an "IV Fluid, No Drug" library entry, could allow users to select this choice to administer a medication infusion and still be considered compliant with using **DERS**.

1.7 Identify particular medications to be administered only as uninterrupted/**PRIMARY INFUSIONS** and specifically configure these in the drug library.

1.8 Use an **AUTOMATED SECONDARY IV INFUSION MANAGEMENT SYSTEM** that is not dependent on **HEAD HEIGHT DIFFERENTIAL** and can assure secondary flow. In the absence of this technology, at a minimum, implement safe practice 1.7.

1.9 Purchase/lease only **SMART INFUSION PUMPS** capable of wireless drug library updates, data transmission, and bi-directional communication with the EHR.

1.10 Require comprehensive, reliable wireless connectivity throughout the organization where **SMART INFUSION PUMPS** will be in use to:

- Update drug libraries
- Obtain **SMART INFUSION PUMP** reports and data
- Support bi-directional communication with the EHR

1.11 Utilize tracking technology to locate and manage **SMART INFUSION PUMPS** within the organization.

1.12 Define the committee(s) or department(s) with oversight of **SMART INFUSION PUMP** system software, drug library revision requests, process decisions, protocol development, and pump acquisition and maintenance.

1.13 Allocate resources for ongoing maintenance of **SMART INFUSION PUMP**-related electronic databases/systems to ensure standardization of infusion parameters and timely system updates to address drug shortages, new drugs added to the formulary, and development of new drug protocols.

1.14 Conduct a risk assessment prior to acquiring new **SMART INFUSION PUMPS**. Involve frontline users of these devices during the evaluation stage to uncover potential failure modes and usability issues.

1.15 Develop policies and procedures to address the use of **SMART INFUSION PUMPS** that accompany patients upon transfer between clinical units as well as external healthcare facilities.

1.16 Develop policies and procedures, as necessary, for the short-term rental or borrowing of **SMART INFUSION PUMPS** from outside facilities or vendors to supplement capacity. Before distribution for use, ensure that the rental/borrowed pumps:

- Are inspected by the organization's biomedical engineering department (or contracted service)
- Have cached data deleted

– Are programmed with the organization's current drug library
– Are connected to the appropriate wireless configuration

Discussion: **SMART INFUSION PUMP** software can capture extensive details about how **SMART INFUSION PUMPS** are being used and the alerts that have been generated. As such, when receiving rental or borrowed pumps from outside facilities or vendors, it is very important to ensure there is a process for removing any cached data and uploading the organization's current drug library prior to distribution to patient **CARE AREAS/ PROFILES**. If the cached data is not removed, then the pump quality improvement (QI) data will include data from the current rental/borrowing site and from previous facilities that temporarily used these pumps making data difficult to interpret. This could lead to a facility changing clinical practices or drug libraries based on usage patterns that are not reflective of their organization. It is also important to have a process to delete pump QI data when returning rental/borrowed pumps as it may include protected health information (PHI) if **PRACTITIONERS** enter medical record numbers or other patient identification when programming the **SMART INFUSION PUMPS**.

1.17 Develop policies and associated processes to address the cleaning (e.g., frequency, product[s], and methods recommended by the manufacturer), storage, distribution, and maintenance of **SMART INFUSION PUMPS**.

1.18 Implement policies and procedures for ensuring that **SMART INFUSION PUMPS** suspected of malfunction are removed from use. Before being released for patient care, the affected **SMART INFUSION PUMPS** should be calibrated and tested by biomedical engineering (or contracted service).

1.19 Implement standardized training and competency assessments for the use of **SMART INFUSION PUMPS** (including large-volume, PCA, epidural, and syringe infusion devices) across the healthcare organization and validate user competence, including traveling/agency staff, at the time of hire/orientation and on an ongoing basis.

1.20 Report adverse events, close calls, and hazardous conditions associated with the use of **SMART INFUSION PUMPS** (including large-volume, PCA, epidural, and syringe infusion devices) within the healthcare organization and to external safety organizations such as ISMP for shared learning.

1.21 Provide **PRACTITIONERS** who use **SMART INFUSION PUMPS** (including large-volume, PCA, epidural, and syringe infusion devices) with ongoing information about associated risks and errors that have occurred in the organization and/or have been reported by external organizations, as well as the strategies required to minimize these risks and errors.

2. Drug Library

2.1 Establish an interdisciplinary team (which may include, but is not limited to, a pharmacist, nurse, clinical/biomedical engineer, data analyst, medication safety representative, information systems personnel, and prescriber) to develop and test the drug library, as well as to update the library at least quarterly.[34] Consider maintaining a log of such changes in a centralized location.

2.2 Implement a standardized process for communicating drug library content changes to end users.

2.3 Standardize **SMART INFUSION PUMP** libraries across affiliated facilities within a health system unless services are not available (e.g., neonatal intensive care unit).

Discussion: Drug library standardization is also essential for successful implementation of **SMART INFUSION PUMP INTEROPERABILITY** with the EHR. See section on Bi-directional **SMART INFUSION PUMP INTEROPERABILITY** with the EHR for more information.

2.4 Implement a systematic process for reviewing drug library content that includes recent literature, evolving practice changes, facility-specific requests, formulary changes, and CQI data.

2.5 Develop and operationalize a formal change control process for the drug library to ensure requested changes are evaluated, tested, and uploaded in a coordinated and timely manner. Ensure that drug library updates are in alignment with the EHR.

2.6 Prior to go-live and for subsequent drug library modifications:

- Require an **INDEPENDENT DOUBLE CHECK** of every drug entry (e.g., drug name, dosing units, concentration, dose limits, and associated **CLINICAL ALERTS**) to verify accurate data entry.
- Review configuration and infusion running displays on the pump screen for each drug entry.

Discussion: Building the drug library requires significant manual input of information. As such, organizations should take steps to prevent transcription errors during crucial points of the drug library build and subsequent modifications. An **INDEPENDENT DOUBLE CHECK** should be performed for the entry or modification of each drug-specific element such as the standardized drug name (see statement 2.8) and applicable **TALL MAN LETTERING**, dosing units, concentration, dose limits, and associated **CLINICAL ALERTS**. After such additions or modifications are made, a review of how this information appears on the **SMART INFUSION PUMP** display screens (after a medication has been selected and while the medication or fluid is infusing) should be performed. This is an important step to identify any potential errors that may be attributed to the way information is displayed; the end user should be able to interpret and utilize the drug information and **CLINICAL ALERTS** as intended. Frontline users should participate in the review of **SMART INFUSION PUMP** displays as they will bring a unique perspective when determining the most effective way to present this information.

2.7 Establish **CARE AREAS/PROFILES** that are tailored to specific patient populations, acuity, and/or patient weight.

Discussion: **CARE AREAS/PROFILES** can be customized within the drug library to meet the drug therapy needs of different patient populations within an organization, as well as to provide significant safety benefits through the provision of IV medication concentrations and associated **SOFT** and **HARD LIMITS** that are specific to that **CARE AREA/PROFILE**.[35] These

CARE AREAS/PROFILES can be organized in the drug library based on patient acuity, location, and/or weight such as adult, pediatric, and neonatal intensive care units; medical/surgical units; emergency departments; and ambulatory infusion centers.

2.8 Standardize the nomenclature of the drug name (including the application of **TALL MAN LETTERING**), dose/dosing units (e.g., weight-based versus non-weight-based dosing; mcg/kg versus mg/kg), and **DOSE-RATE** (e.g., mg/kg/min versus mg/kg/hr) in the drug library to the fullest degree possible. Ensure that this nomenclature is consistent with the EHR, pharmacy infusion labels, and pharmacy IV workflow systems.

2.9 Limit the use of volumetric flow rate programing to fluids and medications for which it is not feasible to program in dose/dosing units, such as products prescribed as mL/kg/hr or mL/hr (e.g., IV immune globulin [IVIG], combination products such as a fenta**NYL** and bupivacaine epidural infusion).

2.10 Standardize and limit the number of drug concentrations for **CONTINUOUS** and **INTERMITTENT INFUSIONS** in the drug library and ensure they are consistent within the EHR and pharmacy IV workflow systems.

2.11 Use commercially prepared, premixed IV solutions, whenever they are available from the manufacturer and are clinically appropriate, as the basis for standardizing concentrations within the drug library.

2.12 Develop standard definitions for terms used in IV medication administration (e.g., **BOLUS DOSE** and **LOADING DOSE INFUSIONS**, **CONTINUOUS INFUSION**, **IV PIGGYBACK**, **INTERMITTENT INFUSION**, **IV PUSH**, "keep vein open [KVO]," and **SECONDARY INFUSION**).

2.13 Actively utilize **DERS** (upper and lower, **SOFT** and **HARD LIMITS**) for the following:

- Medication doses
- Medication concentrations
- Infusion rates
- **INTERMITTENT INFUSION** time duration
- **BOLUS DOSE** and **LOADING DOSE INFUSIONS** (e.g., dose, duration, rate, bolus interval)
- Patient weight

Specifically target the implementation of upper and lower **HARD LIMITS** for medication doses, concentrations, infusion rates, and **BOLUS DOSE** and **LOADING DOSE INFUSIONS**.

2.14 Restrict/limit the ability to manually program continuous medication infusion concentrations (i.e., using wildcard/custom concentrations). See section on Medication Errors Associated with **SMART INFUSION PUMP** Use for more information.

2.15 Standardize the management of infusion container **OVERFILL**, programming the volume to be infused (VTBI), and priming and **FLUSHING** parameters (for **INTERMITTENT INFUSIONS**) for preparation, drug library build, and **SMART INFUSION PUMP** programming. Provide the total volume (e.g., bag volume + manufacturer's **OVERFILL** + drug additive volume) on the product label for pharmacy dispensed single dose **INTERMITTENT INFUSIONS**.

2.16 Develop and incorporate **CLINICAL ALERTS** into the drug library that provide **PRACTITIONERS** with information that should be acknowledged during programming of the infusion (e.g., "infusion requires central line").

3. Continuous Quality Improvement (CQI) Data

3.1 Provide dedicated time and resources for regular review and analysis of **SMART INFUSION PUMP** data, at least on a quarterly basis.

3.2 Use internal and external information about adverse events, close calls, and hazardous conditions associated with the use of **SMART INFUSION PUMPS** for CQI.

3.3 Establish organizational baseline and target values for the following CQI metrics and regularly monitor these to assess drug library compliance and identify barriers to use:

- Facility compliance rate with **DERS**
- Compliance rate with **DERS** by **CARE AREA/PROFILE**
- Compliance rate with **DERS** by medication and fluid
- Total number of alerts by alert type (e.g., **SOFT** or **HARD LIMIT**, upper or lower limit)
- Total number of alerts by infusion parameter (e.g., dose, **DOSE-RATE**, concentration, duration, rate)
- Total number of alerts by medication and fluid
- Percent of overridden alerts (number of overridden alerts/total number of actions taken in response to an alert)
- Number and percent of canceled/abandoned infusions
- Percent of alerts resulting in reprogramming (e.g., good catches)
- Percent of pumps with the current version of the drug library (i.e., saturation)
- Frequency and duration of operational alarms, identifying top alarms by type and **CARE AREA/PROFILE** that may require organizational intervention

3.4 To further improve infusion safety with the use of **SMART INFUSION PUMP** technology, consider the use of the following more advanced CQI metrics:

- Rate of alerts (total alerts/total number of **DERS** infusions)
- Rate of alerts by medication and fluid
- Rate of overridden alerts by medication and fluid
- Medications that have a low frequency of use, but high rate of alerts
- Percent of medication and fluid infusions available in the drug library (total number of medication and fluid infusions available in the library/total number of orderable medication and fluid infusions in the EHR)
- Percent of medications programmed outside of preset concentrations (i.e., using wildcard/custom concentrations) to identify unapproved concentrations and risky practices such as bedside dilution and **PRACTITIONER** preparation of solutions
- Alerts due to concentration settings that are programmed below the minimum concentration limits
- Percent of infusions administered via **GRAVITY** (See discussion on next page)
- Rate of alerted infusions subsequently programmed as basic infusions (See discussion on next page)

Discussion: These metrics are more difficult to obtain and represent stretch goals for organizations seeking to further understand and improve **SMART INFUSION PUMP** use.

Percent of infusions administered via GRAVITY

This metric can be useful for an organization to monitor since **GRAVITY INFUSIONS** are not currently captured by **SMART INFUSION PUMP** software. To obtain an estimate of the infusions being administered by **GRAVITY**:[36]

1. Calculate the number of medication and fluid infusions expected to be administered via **SMART INFUSION PUMPS** from the organization's EHR data ("total administered infusions"). The accuracy of this information is the most critical component of the calculation. Errors in determining this number can result in widely variable estimations of the infusions being administered by gravity.
2. Add together the number of **DERS** infusions and basic infusions in the **SMART PUMP** analytics software to calculate "total pump infusions."
3. Subtract "total pump infusions" from "total administered infusions."
4. The difference provides a close approximation of the number of **GRAVITY INFUSIONS**.

Rate of alerted infusions subsequently programmed as basic infusions

There is tremendous value to this metric as it can be very useful in driving compliance with **DERS**. While it is possible to link a **DERS** infusion for which the user received an alert and then reprogrammed the infusion outside the drug library with the subsequent basic infusion entry, this type of report is challenging to build. An organization will not likely be able to create this report on their own and will typically need advanced data support from a third-party expert.

3.5 Address any trends identified through data analysis. Use this information as appropriate to:

- Improve compliance with the use of **DERS**
- Update the drug library
- Align the drug library with the EHR
- Address nuisance alerts
- Update/change related policy or procedure
- Modify clinical workflow
- Identify opportunities for additional education

4. Clinical Workflow

4.1 Before starting an infusion, ensure the administration set is installed in the pump according to the manufacturer's instructions, as inappropriate administration set installation can impact medication flow (e.g., **FREE-FLOW**).

4.2 When starting selected facility-defined **HIGH-ALERT MEDICATION** infusions and at additional facility-defined steps (e.g., change of shift/handoffs, change in the rate/dose of infusion, change in bag/bottle/syringe) require that a double check be performed and documented to verify the following before starting the infusion:

1. Patient
2. Patient weight used for weight-based medications
3. Drug/solution
4. Drug concentration
5. **DOSE-RATE** of **CONTINUOUS INFUSIONS**, dose and rate of **INTERMITTENT INFUSIONS**
6. Channel selection
7. Line attachment

For items 1-6, use available technology (preferred method) to perform and document the double check or use a second **PRACTITIONER** to perform and document an **INDEPENDENT DOUBLE CHECK**. For item 7, use a second **PRACTITIONER** to perform and document an **INDEPENDENT DOUBLE CHECK**.

Exception: Frequent rate changes when titrating medications (e.g., vasopressors) to effect.

Discussion: Manual **INDEPENDENT DOUBLE CHECK**s of certain **HIGH-ALERT MEDICATIONS** have been widely promoted in healthcare to help detect potentially harmful errors before they reach patients.[37,38] ISMP believes that the selective and proper use of manual **INDEPENDENT DOUBLE CHECKS** can play an important role in medication safety. Numerous studies have demonstrated the ability of **INDEPENDENT DOUBLE CHECKS** to detect up to 95% of errors.[39-43] Based on this understanding, an error rate of 10% (1 in 10) can be reduced to 0.5% (1 in 200) by introducing an **INDEPENDENT DOUBLE CHECK** process.[44] Automated double checks using technology, such as BCMA and **AUTO-PROGRAMMING** of infusion parameters from the EHR system to the **SMART INFUSION PUMP**, likely yield even better results in intercepting errors.

An **INDEPENDENT DOUBLE CHECK** requires two people to *separately* check the targeted components of the work process, without knowing the results of their colleague.[44] For example, when starting a **CONTINUOUS INFUSION** of a selected facility-defined **HIGH-ALERT MEDICATION**, the first **PRACTITIONER** programming the **SMART INFUSION PUMP** would verify the patient, patient weight (for weight-based infusions), medication, concentration, and **DOSE-RATE** against the MAR and then validate the channel selection and line attachment. A second **PRACTITIONER** would subsequently verify the same components using the MAR and then check the channel selection and line attachment before the infusion is started. If an organization has implemented **SMART INFUSION PUMP INTEROPERABILITY** with the EHR, the first **PRACTITIONER** would scan the patient, the **HIGH-ALERT MEDICATION** infusion, and **SMART INFUSION PUMP** channel to pre-populate the **SMART INFUSION PUMP** screen

with the pharmacist-verified infusion parameters. The first **PRACTITIONER** would verify the patient, patient weight (for weight-based infusions), medication, concentration, **DOSE-RATE**, and channel selection before starting the infusion. Also, a second **PRACTITIONER** would still be needed to perform an **INDEPENDENT DOUBLE CHECK** of the line attachment since current technology cannot provide an automated double check of this component.

4.3 When transferring patients to a different clinical unit, ensure the drug library **CARE AREA/ PROFILE** is appropriate for the receiving unit.

4.4 When infusions are started, reconnected, or changed (i.e., new bag/bottle/syringe), trace the tubing by hand from the solution container, to the pump, and then to the patient for verification of the proper pump/channel and route of administration.

4.5 Differentiate infusion pumps used to administer medications and fluids via different routes of administration (e.g., IV, enteral, epidural) to reduce the risk of wrong route errors.

- Utilize only devices that have been cleared by the FDA for the delivery of enteral nutrition solutions.
- To differentiate from IV infusions, use separate FDA-cleared pumps that are designated for epidural infusions.
- Only use multi-channel infusion pumps for a single patient for the simultaneous delivery of therapies by the same route (e.g., IV and epidural infusions are not infused on the same individual pump).
- Utilize International Organization for Standardization (ISO) route-specific connectors (e.g., neuraxial [when available], enteral).

4.6 If administering an IV **BOLUS DOSE** or **LOADING DOSE INFUSION** from a continuous medication infusion, only use a **SMART INFUSION PUMP** that allows programming of the **BOLUS DOSE INFUSION** (or **LOADING DOSE INFUSION**) and **CONTINUOUS INFUSION** with separate **HARD LIMITS** for each and then automatically switches to the **CONTINUOUS INFUSION** rate once the **BOLUS DOSE** or **LOADING DOSE INFUSION** has been delivered.

4.7 Immediately discard all continuous IV medications and epidural infusions (e.g., **CONTINUOUS INFUSIONS** of magnesium, neuromuscular blocking agents, and opioids) after discontinuation (i.e., do not leave hanging on an IV pole or at the bedside).

5. Bi-directional Smart Infusion Pump Interoperability with the EHR

5.1 Implement bi-directional (i.e., **AUTO-PROGRAMMING** and **AUTO-DOCUMENTATION**) **SMART INFUSION PUMP INTEROPERABILITY** with the EHR.

5.2 Establish a multidisciplinary project team to guide the planning and implementation of **SMART INFUSION PUMP INTEROPERABILITY** with the EHR that includes all key stakeholders such as:

- Nursing
- Pharmacy
- Medical staff
- Senior leadership
- Finance
- Information technology services
- Biomedical engineering
- Risk management
- EHR/BCMA vendor
- **SMART INFUSION PUMP** vendor
- Medication safety **PRACTITIONER**
- Clinical educator

Ensure representation includes subject-matter experts, administrative decision-makers, and frontline **PRACTITIONERS**, representing each patient care area where the technology will be utilized. Identify a member of senior leadership as a champion of the project.

5.3 Clearly define the scope of the project including necessary financial and labor resources as well as the patient care areas that are to be included and excluded.

5.4 Establish organizational expectations for the use of **AUTO-PROGRAMMING** with the goal to maximize **PRACTITIONER** compliance to 95% or greater for the administration of *medication* infusions contained within the drug library.

5.5 Establish organizational expectations for the use of **AUTO-PROGRAMMING** with the goal to maximize **PRACTITIONER** compliance to 95% or greater for the administration of *IV fluid* infusions contained within the drug library.

5.6 Prior to implementation, perform a detailed assessment of the wireless infrastructure, to ensure robust and reliable wireless coverage in all patient care areas where infusion pumps are used. Upgrade the wireless network if gaps in coverage are identified.

5.7 Perform a risk assessment of current workflows, identify variable practice patterns, and create standard work for the administration of medication and fluid infusions, including:

- **PRIMARY INFUSIONS**
- **SECONDARY INFUSIONS**
- **GRAVITY INFUSIONS**
- Titrated infusions
- **BOLUS DOSE** and **LOADING DOSE INFUSIONS**
- Use of "carrier" infusions or "medication lines"
- Intermittent line **FLUSHES**
- Priming
- Emergency situations
- Small volume, low flow syringe infusions

5.8 Maximize the use of BCMA by analyzing data related to scanning compliance of medications/fluids and patients.

5.9 Align medication names, concentrations, dosing units, and dosing limits in medication-related policies/procedures/protocols and throughout organizational electronic databases/systems.

5.10 Ensure that all dosing configurations (e.g., total dose, weight-based dose, body surface area [BSA]-based dose) for each medication infusion are built to flow from the EHR to the **SMART INFUSION PUMPS** correctly.

5.11 Perform testing of all infusion orders in a test environment or with a test patient prior to go-live as well as, at a minimum, comprehensive testing of all infusion order types with any EHR software update. In addition, perform testing of modifications to the drug library prior to activating the update.

Discussion: Some organizations have found that this testing is most successful when frontline nurses are engaged as the primary testers.

5.12 Ensure **SMART INFUSION PUMP** drug library parameters match protocols and order sentences for titratable medications. The titratable order sentence should include the following:

- Starting dose/**DOSE-RATE**
- Minimum and maximum dose
- Increments by which to adjust the dose and specific time interval for assessment/adjustment
- Measurable clinical parameters to determine dosage adjustment

5.13 Evaluate and modify EHR and pump tolerance settings (e.g., **SYSTEM ROUNDING LOGIC**) as clinically appropriate to avoid nuisance alerts between the EHR and **SMART INFUSION PUMP**.

5.14 Ensure all **SMART INFUSION PUMPS**/channels are correctly identified with a unique barcode label that is permanent, accessible, readable, and cleanable.

Discussion: To support **SMART INFUSION PUMP INTEROPERABILITY**, **SMART INFUSION PUMPS**/channels (including rental or borrowed pumps) need to have a scannable barcode that matches a record in the EHR. Correct installation of the barcode label on each **SMART INFUSION PUMP** and pump channel is a vitally important step.[18] Mix-ups between **SMART PUMPS**/channels while setting up or programming an infusion have been reported.[45,46] A 2017 ISMP newsletter highlighted an error in which a single pump channel barcode was associated with more than one pump leading to the electronic documentation of insulin at two different rates of infusion (3 mL per hour and 60 mL per hour). In the absence of a built-in pump/channel barcode, perform an **INDEPENDENT DOUBLE CHECK** to verify the pump serial number and EHR record when affixing barcodes to **SMART INFUSION PUMPS**/ channels.[46]

5.15 Develop workflows for the transfer of patients between areas with **INTEROPERABILITY** and without **INTEROPERABILITY**.

5.16 Define procedures for **SMART INFUSION PUMP** dissociation between use on separate patients to avoid incorrect data association.

5.17 Develop downtime procedures to guide workflow (e.g., the use of manual **SMART INFUSION PUMP** programming [without **INTEROPERABILITY**], monitoring the replacement of **CONTINUOUS INFUSIONS**) in situations when the system has gone down.

5.18 Develop a **SMART INFUSION PUMP INTEROPERABILITY** response plan for any unscheduled wireless network downtime and newly discovered gaps in wireless coverage.

5.19 Establish a standard approach for initial and ongoing staff training and competency assessment for use of **INTEROPERABILITY** workflow. Ensure the education provided to staff simulates the new workflow as closely as possible and emphasizes the intended safety benefits.

5.20 Monitor and share data available from both the EHR and **SMART INFUSION PUMPS** with key organizational stakeholders to ensure improvements in **INTEROPERABILITY** performance. Consider the following CQI metrics to assess **SMART INFUSION PUMP INTEROPERABILITY**:

- Compliance with **INTEROPERABILITY** (e.g., by **CARE AREA/PROFILE**, medication/fluid, user) (See discussion below)
- Total number of alerts by medication/fluid, **CARE AREA/PROFILE**
- **AUTO-DOCUMENTATION** mismatch with EHR order (See discussion below)
- Percent of failed **AUTO-PROGRAMMING** attempts
- Rate of auto-programmed infusions (total number of auto-programmed infusions/total number of administered infusions)

Discussion:

Compliance with INTEROPERABILITY

How this metric is calculated likely differs depending on an organization's specific EHR and pump vendors. For compliance with **INTEROPERABILITY** at the organizational level, aim to determine the number of in-scope infusions where **AUTO-PROGRAMMING** was initiated and completed divided by the number of all in-scope infusions.

AUTO-DOCUMENTATION mismatch with EHR order

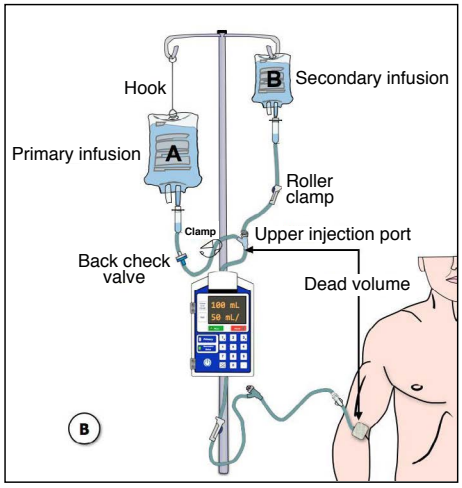
This metric can be useful to understand the degree to which users are manually changing infusion parameters that have been sent to the pump. It is calculated by determining the percent of infusions which have successfully auto-populated on the pump screen, but one or more parameters (e.g., VTBI, rate, dose) were modified before the infusions were started and thus the information sent back to the EHR from the pump does not match the original order.

DEFINITIONS

Term	Definition
AUTO-DOCUMENTATION (also known as auto-charting or infusion documentation)	Sending infusion information (such as intake data, **DOSE-RATE** of **CONTINUOUS INFUSIONS**, dose changes, rate changes, and IV start and stop times) automatically to the EHR system for manual **PRACTITIONER** confirmation to enable accurate recording of this information in the patient's record after the infusion has started. (Adapted from: ECRI Institute, 2018)[47]
AUTOMATED SECONDARY IV INFUSION MANAGEMENT SYSTEM	A **SMART INFUSION PUMP** capable of automatic infusion delivery of two different medications or fluids (e.g., plain IV fluid and an intermittent IV antibiotic) through the same tubing. This mode ensures that the entire **INTERMITTENT INFUSION** volume is infused, without the need to adjust the **HEAD HEIGHT** of the **PRIMARY** and **SECONDARY INFUSION** containers. This mode also detects if the secondary line is clamped.
AUTO-PROGRAMMING	Automatic programming of infusion parameters from the EHR system to the **SMART INFUSION PUMP** (which are then verified, and the infusion is started manually by a **PRACTITIONER**) after use of the BCMA system to associate the patient, medication/fluid container (e.g., bag, bottle, syringe), and pump channel. (Adapted from: ECRI Institute, 2018)[47]
BOLUS DOSE INFUSION	A discrete dose of medication or fluid given in a set volume at the desired infusion rate or for a specified time duration prior to (see **LOADING DOSE INFUSION**) or during a **CONTINUOUS INFUSION**.
CARE AREA/PROFILE	Method of grouping medication and fluid infusions that may have different **SOFT** and **HARD LIMITS**, patient weight parameters, as well as different pump alarm thresholds (e.g., air-in-line alarm threshold), and are typically associated with a specific nursing unit, location, or patient population. Examples include critical care, medical/surgical, pediatrics. (Adapted from: Hoh & Krueger, in collaboration with ISMP, 2017)[34]
CLINICAL ALERTS	Information about a specific medication or IV fluid that is displayed on the **SMART INFUSION PUMP** screen when the medication/fluid is selected from the library and which typically requires clinician acknowledgement to proceed. This information is configured by the facility.
CONTINUOUS INFUSION	A medication or fluid that is prescribed with a **DOSE-RATE** (e.g., 10 mg/kg/min) or infusion rate (e.g., mL/hour). The infusion continues until therapy is no longer required or when the solution container is depleted. Dose or rate programming changes may occur during the infusion. (Adapted from: Hoh & Krueger, in collaboration with ISMP, 2017)[34]

Term	Definition
DOSE ERROR-REDUCTION SYSTEMS (DERS)	Refers to the integral computer software in **SMART INFUSION PUMPS** intended to aid in prevention of infusion programming-related errors and warn users of potential over- or under-delivery of a medication or fluid by checking programmed doses/rates against facility-configurable preset limits specific to a medication/fluid, and to a clinical application (e.g., epidural administration) and/or location (e.g., neonatal intensive care unit, medical/surgical unit).
DOSE-RATE	Amount of medication (in non-volumetric units) in a **CONTINUOUS INFUSION** administered per unit of time (e.g., 10 mg/kg/min)
FLUSH/FLUSHING	A term used to describe the administration of a compatible IV fluid through an IV line so that the existing contents of the line are administered into the patient's bloodstream. This is a method to ensure residual IV fluid or medication in the dead volume has been administered to the patient or cleared from the IV line. Methods of delivery can be manual (e.g., **IV PUSH**) or by infusion pump. (Adapted from: Pinkney, S. et al., 2014)[45] The Infusion Nurses Society (INS) defines **FLUSH/FLUSHING** as the act of moving fluids, medications, blood, and blood products out of the vascular access device into the bloodstream: used to assess and maintain patency and prevent precipitation due to solution/medication incompatibility.[4]
FREE-FLOW	This is a condition where uncontrolled flow of medication or fluid occurs through an infusion set.
GRAVITY INFUSION	Medication or fluid administered without an infusion device or **DERS** that relies on the force of gravity to infuse and that is manually controlled (e.g., with a roller clamp).
HARD LIMIT (within drug library)	A medication or fluid-specific forcing function that ensures that an infusion cannot be given outside facility-established medication or fluid-specific parameters (e.g., concentration, **DOSE-RATE** of **CONTINUOUS INFUSIONS**, dose of **INTERMITTENT INFUSIONS**, duration of **INTERMITTENT INFUSIONS**). These upper (maximum) and lower (minimum) limits are set in the drug library and cannot be overridden.
HEAD HEIGHT DIFFERENTIAL	With most infusion pumps, the primary medication or fluid bag/bottle needs to be lowered using a hanger provided with the secondary administration set to create a distance between the bottom of the **SECONDARY INFUSION** container and the top of the fluid level in the primary container. (Adapted from: ECRI Institute, 2016)[28] See **SECONDARY INFUSION** for related graphic.

Term	Definition
HIGH-ALERT MEDICATIONS	Drugs that bear a heightened risk of causing significant patient harm when used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. See *ISMP's List of High-Alert Medications in Acute Care Settings* at: https://www.ismp.org/recommendations/high-alert-medications-acute-list.
INDEPENDENT DOUBLE CHECK	A procedure in which two individuals, preferably two licensed **PRACTITIONERS**, separately check each component of the work process. An example would be one person calculating a medication dose for a specific patient and a second individual independently performing the same calculation (not just verifying the calculation) and matching the results.
INTERMITTENT INFUSION	A medication or fluid infusion that is delivered over a specified time at prescribed intervals. (Adapted from: Hoh & Krueger, in collaboration with ISMP, 2017)[34]
INTEROPERABILITY	See **SMART INFUSION PUMP INTEROPERABILITY**
IV PIGGYBACK	See **SECONDARY INFUSION**
IV PUSH	Direct manual administration of a medication using a syringe, usually under pressure, connected to an IV access device; this may include a manually administered IV bolus dose in an emergency.
LOADING DOSE INFUSION	The initial dose of a medication given by infusion that is intended to rapidly achieve a therapeutic level prior to initiating the **CONTINUOUS INFUSION** or scheduled maintenance dose infusion.
OVERFILL	The excess volume in a container of an injectable product, exceeding the content indicated in the labeling. The excess volume is intended to be sufficient to permit withdrawal and administration of the labeled volumes. (Adapted from: FDA, 2015)[49]
PRACTITIONER	A licensed healthcare professional who is authorized within the institution to prescribe, dispense, or administer medications, such as a physician, physician assistant, nurse anesthetist, nurse practitioner, nurse, pharmacist, or respiratory therapist.
PRIMARY INFUSION	Infusions (e.g., continuous or intermittent medications, IV fluids) that are delivered through the primary administration set.[34]

Term	Definition
SECONDARY INFUSION	The infusion of a second IV medication or fluid through a patient's **PRIMARY INFUSION** line using a secondary set at the upper injection port of the primary administration set. (Adapted from: ECRI Institute, 2016)[28] 
SMART INFUSION PUMP/ SMART PUMP	An infusion pump with integral computer software (see **DERS**) that is, at a minimum, capable of: 1) maintaining a drug library of standard medication concentrations, which when enabled, is used to support dose calculations and alert the user to incorrect orders, calculation errors, or programming errors, that would result in significant over- and under-delivery of a medication or fluid; and 2) capturing administrative infusion data in a systematic, objective manner to support improvement in safe medication administration. If the programmed dose is outside the preset limits, the pump alerts clinicians and can either require confirmation before beginning delivery (**SOFT LIMIT**) or not allow delivery at all (**HARD LIMIT**).
SMART INFUSION PUMP INTEROPERABILITY (also referred to as smart infusion pump integration)	Refers to technologies that enable the creation of an electronic connection between an infusion pump channel and an EHR system. This connection allows the pump channel, the patient, and the medication order to be associated with one another. (Adapted from: ECRI Institute, 2018)[47]
SOFT LIMIT (within drug library)	A medication or fluid-specific limit that can be overridden by a **PRACTITIONER**. These upper (maximum) and lower (minimum) limits advise the user that the specified infusion is about to be infused outside facility-established parameters (e.g., common dosage range).
SYSTEM ROUNDING LOGIC	An algorithm or a method used to standardize rounding parameters to avoid unnecessary nuisance alerts during **SMART INFUSION PUMP AUTO-PROGRAMMING**.

Term	Definition
TALL MAN LETTERING	Refers to a method of differentiating the appearance of similar drug names known to be confused with one another by using bolded, uppercase letters to draw attention to a small group of unique letter characters that are different in each of the drug names. A list of look-alike drug names with recommended tall man letters can be found at: https://www.ismp.org/recommendations/tall-man-letters-list.

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ABOUT ISMP

The Institute for Safe Medication Practices (ISMP) is the only 501c (3) nonprofit organization devoted entirely to preventing medication errors. During its more than 25-year history, ISMP has helped make a difference in the lives of millions of patients and the healthcare professionals who care for them.

ISMP is known and respected as the gold standard for medication safety information. It also has served as a vital force for progress. ISMP's advocacy work alone has resulted in numerous necessary changes in clinical practice, public policy, and drug labeling and packaging.

Among its many initiatives, ISMP runs the only national voluntary practitioner medication error reporting program, publishes newsletters with real-time error information read and trusted throughout the global healthcare community, and offers a wide range of unique educational programs, tools, and guidelines.

In 2020, ISMP formally affiliated with ECRI Institute to create one of the largest healthcare quality and safety entities in the world. The affiliation will allow both organizations to work more closely together for the benefit of providers, patient advocates, governments, and most importantly, patients.

As an independent watchdog organization, ISMP receives no advertising revenue and depends entirely on charitable donations, educational grants, newsletter subscriptions, and volunteer efforts to pursue its life-saving work. For more information or to donate to protect patients worldwide from harmful medication errors, visit ISMP online at www.ismp.org.

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